AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

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ASN REPORT

on the state of nuclear safety
and radiation protection in France in |2016|

AUTORITÉ DE SÛRETÉ NUCLÉAIRE

The ASN (Nuclear Safety Authority)

presents its report on the state of nuclear safety and radiation protection in France in 2016.

This report is required by Article L. 592-31 of the Environment Code.

It was submitted to the President of the Republic, the Prime Minister and the Presidents of the Senate and the National Assembly, pursuant to the above-mentioned Article.

SUMMARY

ASN actions

Activities regulated by ASN

From left to right

Margot TIRMARCHE - Commissioner
Pierre-Franck CHEVET - Chairman
Lydie ÉVRARD - Commissioner
Sylvie CADET-MERCIER - Commissioner
Philippe CHAUMET-RIFFAUD - Commissioner

On the whole, 2016 was satisfactory despite a worrying context

Montrouge, 14th March 2017

The year was marked by the detection of a serious generic anomaly. Eighteen EDF reactors were potentially affected by excess carbon in the steel used in the manufacture of the steam generators. Specific checks were ordered by ASN on all these reactors and five of them had to be shut down early.

This is not the first time this type of generic anomaly has been found: for the French electrical system, it confirms the need to ensure that there is sufficient margin to deal with the shutdown of several reactors following the detection of a generic anomaly.

In addition, irregularities dating back to the manufacture of large reactor components have been detected in the Creusot Forge plant. Numerous design and manufacture conformity deviations were also found during the periodic safety reviews on the installations.

These findings mean that:
- In the future, for new constructions and modifications made to existing facilities, improvements are necessary in design, manufacturing and installation, as well as in the corresponding inspections. This is now a priority in the light of the major work that would be necessary to extend the operating service life of the older facilities.
- With regard to past activities, the historical manufacturing review initiated by Areva must be completed and the conformity deviations remedied during the periodic safety reviews.

This complex situation must give rise neither to denial, nor to defeatism: denial of the scale and even sometimes the reality of the problems observed; defeatism which would discourage the completion of the necessary manufacturing reviews, or undermine the motivation of those involved in safety on a day to day basis.

This situation demands that both the consequences and causes of anomalies and irregularities be identified and dealt with: this is the absolute pre-requisite for consolidating nuclear safety.

Apart from these anomalies or irregularities, the operating safety of Basic Nuclear Installations (BNI) was on the whole maintained at a high level, although particular vigilance is still required in the field of radiation protection, particularly for the medical sector, in which four level 2 incidents occurred in 2016.

This assessment of 2016, with its positive and negative points, comes at a worrying time:
- Safety and radiation protection challenges will grow over the period 2017-2020:
  - The evaluation of the continued operation of the 900 MWe reactors beyond their fourth safety review is a key issue. ASN will issue a generic opinion in 2019 on this subject after analysis of the studies yet to be produced by EDF.
  - The other main nuclear installations, in particular fuel cycle installations and research reactors, will undergo a periodic safety review during the same period. By the end of 2017, ASN will have received about fifty review files for analysis.
  - Deployment of the post-Fukushima improvements will need to be continued, more particularly with regard to the fixed equipment of the "hardened safety core" supplementing the mobile means already in place.
  - The projects or construction sites for new installations, EPR, *Cigéo, Réacteur Jules Horowitz* (RJH), ITER are behind schedule. Safety is not generally a factor, except for the Flamanville EPR vessel anomaly, which is being given special treatment.
- The main industrial firms, Areva, CEA, EDF, who hold prime responsibility for the safety of their installations, are experiencing economic or financial difficulties. Wide-reaching reorganisations are in progress. Time will be needed for them to take full effect.
- For 2017, ASN and the Institute for Radiation protection and Nuclear Safety (IRSN) obtained additional staff, although the personnel levels are still inadequate for dealing with these issues comprehensively. A situation such as this is not however sustainable and ASN is once again asking for a review of the financing of safety

regulation, to enable it to have appropriate resources tailored to its needs and those of IRSN.

This worrying context must encourage all stakeholders to exercise the greatest vigilance to ensure that safety remains a priority. For its part, ASN will be attentive to the technical and financial capacity of the industrial firms, as well as to ensuring that they maintain in-house skills that are vital for safety. It will in particular ensure that the necessary safety investments are actually made.

* * *

Towards the harmonisation of nuclear safety and radiation protection in Europe

At the European level, three Directives on nuclear safety, waste management and radiation protection were adopted or updated in recent years.

European harmonisation of safety and radiation protection remains a priority for ASN, which is actively involved in the work of ENSREG[1], WENRA[2] and HERCA[3].

In 2018, a comparative review of reactor ageing management practices will be carried out in Europe. The framework of the review was defined in 2016 and ASN will draft the French report in 2017 for subsequent inclusion in this review.

ASN is heavily committed to the harmonisation and coordination of emergency situations management in Europe. In 2017, three emergency exercises are scheduled to test cross-border coordination.

The continued operation of ageing installations is a major issue

The first of the fourth ten-yearly outage inspections will take place in 2019. It will be a challenge on the one hand for industry – which will have to conduct the studies and then carry out the necessary work and on the other for ASN and IRSN – which will have to analyse the proposals and then check the modifications actually made.

ASN intends to issue a generic opinion in 2019 on the continued operation of the 900 MWe reactors beyond forty years. This opinion will be drafted with the participation of the public. The periodic safety reviews of each 900 MWe reactor, which will lead to a public inquiry, will then be staggered until 2030. Furthermore, following the Fukushima Daiichi accident, ASN prescribed the deployment of a "hardened safety core". This comprises mobile equipment which, in the event of an accident, can be connected to the installation, along with fixed equipment. This mobile equipment has already been fully deployed in France. The fixed equipment, which requires a large number of studies and a significant production lead-time, will be deployed during the course of the next periodic safety reviews.

Installations other than power reactors cover a wide variety of activities: research, fuel cycle, waste management, production of radiopharmaceuticals and industrial irradiators, etc. These installations are mainly ageing. Several dozen of these installations will have to undergo a periodic review, often for the first time. For both ASN and IRSN, this already means a considerable increase in the workload, which will only get heavier in the coming years. An analysis approach proportionate to the safety issues is being set up to deal with this.

In any case, ASN will ensure that the safety improvements (earthquake resistance, fire protection, etc.) prescribed further to these reviews are actually carried out, despite the economic, financial and budget constraints faced by the licensees.

During the first periodic safety review of the UP3 plant on the La Hague site, which began in 2010, ASN asked Areva to examine the conformity and ageing of the evaporators used to concentrate the fission products. This led to the identification of faster than anticipated corrosion on this equipment. ASN thus set operating conditions to limit the phenomenon and specified more frequent corrosion measurements. Depending on the results of these measurements, ASN may be obliged to require shutdown of the facility. In 2016, Areva proposed the safety options for new evaporators, which could enter service in 2021.

Pressure equipment: a worrying situation

In 2005, regulations reinforced the requirements regarding verification of nuclear pressure equipment conformity. In 2015, these reinforced checks led to the detection of significant excess carbon in certain parts of the Flamanville EPR reactor vessel: ASN will issue a position statement on the serviceability of the vessel in mid-2017.

An anomaly of the same type was subsequently also identified on certain steam generators of 18 reactors in operation. Five of these reactors have been shut down early, at ASN's request, so that the necessary inspections could be carried out. Based on the results of these inspections, ASN was able to authorise restart of these reactors, subject to restrictions on their operating conditions.

Following the EPR vessel anomaly, ASN asked for a historical review of the quality of past manufacturing in the Creusot Forge plant. This has already led to the detection of major irregularities: "concealed" files showing anomalies hidden from the customer and the regulatory authority and the suspected falsification of measurement

1. *European Nuclear Safety Regulators Group.*
2. *Western European Nuclear Regulators Association.*
3. *Heads of the European Radiological protection Competent Authorities.*

or examination reports. In 2016, these irregularities already led to the shutdown of Fessenheim reactor 2 and the extension of the shutdown of Gravelines reactor 5. The review is scheduled to continue: the anomalies identified will be processed. Thought is already being given as to how to better prevent and detect this type of irregularity during manufacturing checks.

EPR, an advanced design but a difficult birth

The Flamanville EPR reactor is a "Generation III" pressurised water reactor, offering a significantly higher level of safety than the reactors currently in service. The EPR in particular offers greater protection against external hazards and increased means of mitigating the consequences of accidents with core melt.

ASN underlines the fact that EDF still needs to carry out significant work before start-up, to examine the serviceability of the nuclear pressure equipment, the vessel in particular and, more generally, to guarantee the performance of the safety systems.

The industrial contractors must learn the lessons of the difficulties encountered on the Flamanville EPR, in terms of design, manufacturing and construction.

Improved protection of the population in the event of an accident

In 2016, the Government decided to extend the scope of the Off-site Emergency Plans (PPI) triggered by the public authorities in the event of an accident from 10 to 20 km around the NPPs. This decision is consistent with the proposal from the European radiation protection and safety authorities (HERCA and WENRA) to harmonise measures to protect the populations in the event of a severe accident. Interministerial work is now required to define the practicalities of this extension.

In 2016, a new national distribution campaign for iodine tablets, supervised by ASN, was launched for the populations located within the zone around the NPPs covered by the current PPIs. This campaign was an opportunity to raise awareness of the nuclear risk among the persons concerned.

The increasing urban development around BNIs requires particular vigilance, in order to maintain the effectiveness of the population protection measures contained in the contingency plans, more specifically their evacuation. ASN is thus consulted on urban development projects around BNIs and published a guide on this subject in 2016.

Decommissioning, complex operations taking longer than expected

The decommissioning of a Basic Nuclear Installation (BNI) is a lengthy and complex operation involving risks. To date, about thirty BNIs of all types have been shut down or are undergoing decommissioning in France.

In 2016, for technical reasons, EDF stated that it intended to change its decommissioning strategy for the Gas-Cooled Reactors (GCR). This means that EDF is proposing to postpone their decommissioning by several decades. In July 2016, ASN asked EDF to optimise its industrial process in order to comply with the principle of decommissioning within a time-frame that is as short as possible, as stipulated by the Environment Code.

CEA will also be decommissioning a number of civil or defence-related BNIs. In general, ASN observes significant delays in the performance of decommissioning operations. This situation is prejudicial to safety. At the request of ASN and the Defence Nuclear Safety Regulator (ASND), CEA proposed its new decommissioning strategy at the end of 2016. It will be the subject of a joint position statement to be issued by ASN and ASND in 2018, at which time the adequacy of the human and budget resources allocated to these operations will be closely examined.

In June 2016, Areva transmitted its decommissioning strategy for the installations concerned on the La Hague and Tricastin sites, and it will be reviewed in 2017 for a position statement to be issued in 2018.

Radiotherapy and interventional imaging: two priorities for radiation protection

As part of the process to transpose the European Radiation Protection Directive, ASN will ensure that the requirements are appropriate to the potential consequences of medical activities. ASN also intends to issue resolutions on quality assurance in medical imaging, on continuing training of professionals in the field of radiation protection of persons exposed to ionising radiation for medical purposes and on the "diagnostic reference levels".

ASN maintains its inspection priorities in radiotherapy and interventional imaging. In these two fields, ASN will ensure that the preliminary risk assessment is reinforced, as a result of changes, both technological and organisational, and will focus in particular on the adequacy of the human resources allocated to these activities. In interventional imaging, optimisation of the doses received by the patients on the one hand and by the professionals on the other, in particular with regard to the lens of the eye, remains the main objective.

The growth of new imaging techniques implies greater initial and continuing radiation protection training for the entire medical profession.

Radon, measures to protect exposed individuals

For the French population, radon is the leading source of exposure to ionising radiation of natural origin: about 20% of the French population is potentially exposed to radon. After tobacco, this gas is the second risk factor for developing lung cancer.

The home is the main location for exposure to radon. *The 2016-2019 National Radon Action Plan,* published by ASN in January 2017, gives priority to raising the awareness of the public and the main players concerned by the radon risk. In addition, the law requires mandatory information of persons buying or renting property in the *départements* with a high radon risk.

Furthermore, for facilities open to the public and for the workplace, ASN assists the local authorities and employers with measurement of the radon concentration. It also takes part in the transposition of the European Radiation Protection Directive into French law, which will more particularly allow improved monitoring of annual occupational exposure.

Important decisions for waste disposal are to be made in the near future

It is intended that long-lived, high and intermediate level waste will eventually be disposed of in the *Cigéo* underground facility. Act 2016-1015 of 25th July 2016 set the reversibility conditions for such a repository which shall, on the one hand, be able to adapt to changes in energy policy (for example, disposal of spent fuels as-is) and, on the other, allow recovery of waste packages already emplaced in the repository. In 2017, ASN will rule on the safety options for this repository, taking account of the conclusions of the peer review conducted under the supervision of the International Atomic Energy Agency at the end of 2016. On these bases, a *Cigéo* creation authorisation application should be submitted in 2018.

The production of very low level radioactive waste will rise significantly with the future decommissioning of the current fleet of NPPs. In order to minimise transport traffic, might it not be wise to envisage several regional repositories rather than a single centralised facility? ASN considers that a public debate needs to be held on this subject.

As the commissioning calendar for the repositories for such waste remains uncertain, storage capacity for these wastes must be increased. More specifically with regard to spent fuels, ASN considers that the licensees must anticipate saturation of the storage capacity in the NPPs or the pools in the Areva plant in La Hague: the safety options for a new centralised pool will be examined soon.

More efficient oversight, but greater resources are still needed

The Energy Transition for Green Growth Act marked a significant step forward for safety and radiation protection. ASN's duties and powers have been extended - more particularly to include oversight of the protection of sources against malicious acts - and the role of IRSN has been reinforced. This Act also consolidated the Local Information Committees and more generally the provisions concerning the information and involvement of the citizens.

ASN and IRSN also obtained an increase in their oversight and assessment resources in the 2015-2017 three-year budget Plan. ASN restates the need for financing of its human resources that is in keeping with the unprecedented nuclear safety and radiation protection challenges.

The Nuclear Safety Authority (ASN)

ASN was created by the 13th June 2006 Nuclear Security and Transparency Act. It is an independent administrative Authority responsible for regulating civil nuclear activities in France. It also contributes towards informing the citizens.

ASN is tasked, on behalf of the State, with regulating nuclear safety and radiation protection in order to protect workers, patients, the public and the environment from the risks related to nuclear activities.

ASN aims to provide efficient, impartial, legitimate and credible nuclear regulation, recognised by the citizens and regarded internationally as a benchmark for good practice.

Competence
Independence
Rigour
Transparency

ASN

Its roles

Regulating
ASN contributes to drafting regulations, by giving the Government its opinion on draft decrees and Ministerial Orders, or by issuing statutory resolutions of a technical nature.

Authorising
ASN examines all individual authorisation applications for nuclear facilities. It can grant all licenses and authorisations, with the exception of major authorisations for Basic Nuclear Installations, such as creation and decommissioning. ASN issues the licenses provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations.

Monitoring
ASN is responsible for ensuring compliance with the rules and requirements applicable to the facilities or activities within its field of competence. Inspection is one of ASN's main means of oversight, although it also has appropriate powers of enforcement and sanction.

Informing
Primarily through its website *www.asn.fr* and its *Contrôle* magazine, ASN informs the public and the stakeholders (Local Information Committees, environmental protection associations, etc.) of its activities and the state of nuclear safety and radiation protection in France.

In emergency situations
ASN monitors the steps taken by the licensee to make the facility safe. It informs the public of the situation. ASN assists the Government. It in particular sends the competent Authorities its recommendations concerning the civil security measures to be taken.

Regulation and monitoring of diverse activities and facilities

Nuclear power plants, radioactive waste management, nuclear fuel shipments, packages of radioactive substances, medical facilities, research laboratories, industrial activities, etc. ASN oversees an extremely varied range of activities and installations. This regulation covers:
- 58 nuclear reactors producing nearly 80% of the electricity consumed in France, along with the EPR reactor currently under construction;
- all French fuel cycle facilities, from fuel enrichment to reprocessing;
- several thousand facilities or activities which use sources of ionising radiation for medical, industrial or research purposes;
- several hundred thousand shipments of radioactive substances nationwide, every year.

The support of experts

When taking certain decisions, ASN calls on the expertise of technical support bodies. This is primarily the case with the Institute for Radiation Protection and Nuclear Safety (IRSN). The ASN Chairman is a member of the IRSN Board.
ASN also requests opinions and recommendations from scientific and technical Advisory Committees of Experts.

Its organisation

The Commission

The Commission defines ASN general policy regarding nuclear safety and radiation protection. It consists of five Commissioners, including the Chairman.

Pierre-Franck CHEVET **Chairman**	Philippe CHAUMET-RIFFAUD **Commissioner**	Sylvie CADET-MERCIER **Commissioner**	Lydie ÉVRARD **Commissioner**	Margot TIRMARCHE **Commissioner**
DATE APPOINTED				
12th November 2012 for 6 years	10th December 2014 for 6 years	21st December 2016 for 6 years	10th March 2017 for 6 years	12th November 2012 for 6 years
APPOINTED BY				
President of the Republic			President of the Senate	President of the National Assembly

Impartiality

The Commissioners perform their duties in complete impartiality and receive no instructions either from the Government or from any other person or institution.

Independence

The Commissioners perform their duties on a full-time basis. Their mandate is for a six-year term. It is not renewable. The duties of a Commissioner can only be terminated in the case of impediment or resignation duly confirmed by a majority of the Commissioners. The President of the Republic may terminate the duties of a member of the Commission in the event of a serious breach of his or her obligations.

Competencies

The Commission issues resolutions and publishes opinions in ASN's *Official Bulletin*. The Commission defines ASN external relations policy both nationally and internationally. The Commission defines ASN regulatory policy. The Chairman appoints the nuclear safety inspectors, the radiation protection inspectors, the health and safety inspectors for the nuclear power plants and the staff responsible for verifying compliance with the requirements applicable to pressure vessels. The Commission decides whether to open an inquiry following an incident or accident. Every year, it presents the ASN *Report on the state of nuclear safety and radiation protection in France* to Parliament. Its Chairman reports on ASN activities to the relevant commissions of the French Parliament's National Assembly and Senate as well as to the Parliamentary Office for the Evaluation of Scientific and Technological Choices. The Commission drafts ASN internal regulations and appoints its representatives to the High Committee for Transparency and Information on Nuclear Security.

Commission figures in 2016

76 sessions

32 opinions

42 resolutions

Headquarters and the regional divisions

ASN comprises a headquarters and eleven regional divisions with competence for one or more administrative regions. This organisation enables ASN to carry out its regulation and monitoring duties over the entire country and in the overseas territories of France. The headquarters are organised thematically and are responsible at a national level for their fields of activity. The ASN regional divisions operate under the authority of the regional representatives, appointed by the ASN Chairman. They are ASN's representatives in the regions and contribute locally to ASN's public information role. The divisions carry out most of the direct inspections on nuclear facilities, radioactive substances transport operations and small-scale nuclear activities. In emergency situations, the divisions assist the Prefect of the *département**, who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility on the site.

* Administrative region headed by a Prefect.

Key figures in 2016

483 staff members

82 %
management

294 inspectors

1,793
inspections
of nuclear facilities, of shipments of radioactive substances, of the medical, industrial and research sectors, of approved organisations

18,350
inspection follow-up letters
available on *www.asn.fr*
as at 31st December 2016

395
technical opinions
sent to ASN by IRSN

25 Advisory Committee meetings

2,820
authorisations and licenses

20
press conferences

27
press releases

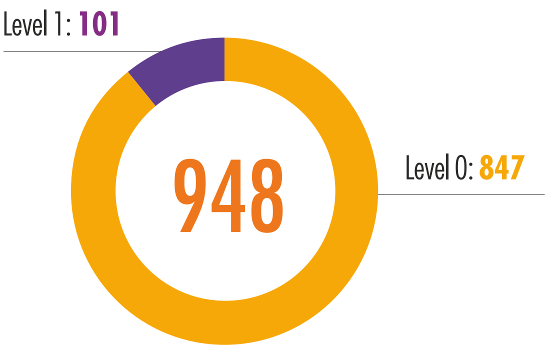
72 information notices

7 emergency exercices

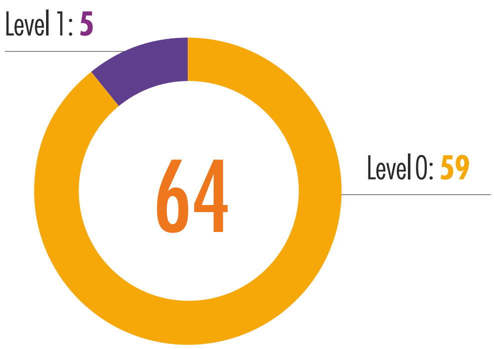
€80.79 million total budget for ASN

€85 million IRSN budget devoted to expert appraisal work on behalf of ASN

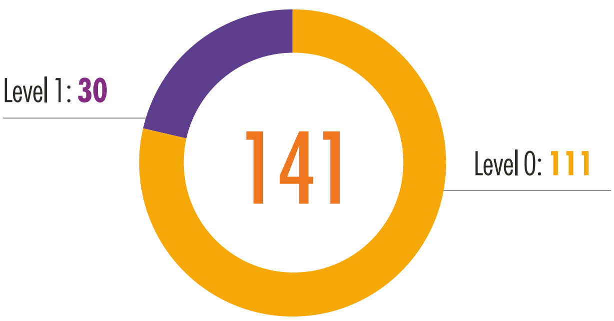
Number of significant events rated on the INES scale* in 2016



Basic Nuclear Installations



Transport of radioactive substances



Small-scale nuclear activities (medicine and industry)

* INES : *International Nuclear and Radiological Event Scale*

ASN organisation chart as at 14th March 2017

COMMISSION

Commissioners
Sylvie CADET-MERCIER
Philippe CHAUMET-RIFFAUD
Lydie ÉVRARD
Margot TIRMARCHE

Chairman
Pierre-Franck CHEVET

Head of Private Office
Laurent FELBER

GENERAL DIRECTORATE

Deputy Directors General
Julien COLLET, Alain DELMESTRE, Jean-Luc LACHAUME

Adviser
Henri LEGRAND

Director reporting to the General Director
Guillaume BOUYT

Director General
Olivier GUPTA

Head of Staff
Ambroise PASCAL

DEPARTMENTS

Nuclear power plant department
Anne-Cécile RIGAIL

Nuclear pressure equipment department
Rémy CATTEAU

Transport and sources department
Fabien FÉRON

Waste, research facilities and fuel cycle facilities department
Christophe KASSIOTIS

Ionising radiation and health department
Jean-Luc GODET

Environment and emergency department
Bénédicte GENTHON

International relations department
Frédéric JOUREAU

Communication and public information department
Alain DELMESTRE

General Secretariat
Daniel DELALANDE

Management and Appraisal Mission
Alain RIVIÈRE

11 REGIONAL DIVISIONS

Bordeaux division
Regional representative: Patrice GUYOT
Regional Head: Paul BOUGON

Caen division
Regional representative: Patrick BERG
Regional Head: Hélène HÉRON

Châlons-en-Champagne division
Regional representative: Emmanuelle GAY
Regional Head: Jean-Michel FÉRAT

Dijon division
Regional representative: Thierry VATIN
Regional Head: Marc CHAMPION

Lille division
Regional representative: Vincent MOTYKA
Regional Head: Rémy ZMYSLONY

Lyon division
Regional representative: Françoise NOARS
Regional Head: Marie THOMINES

Marseille division
Regional representative: Corinne TOURASSE
Regional Head: Laurent DEPROIT

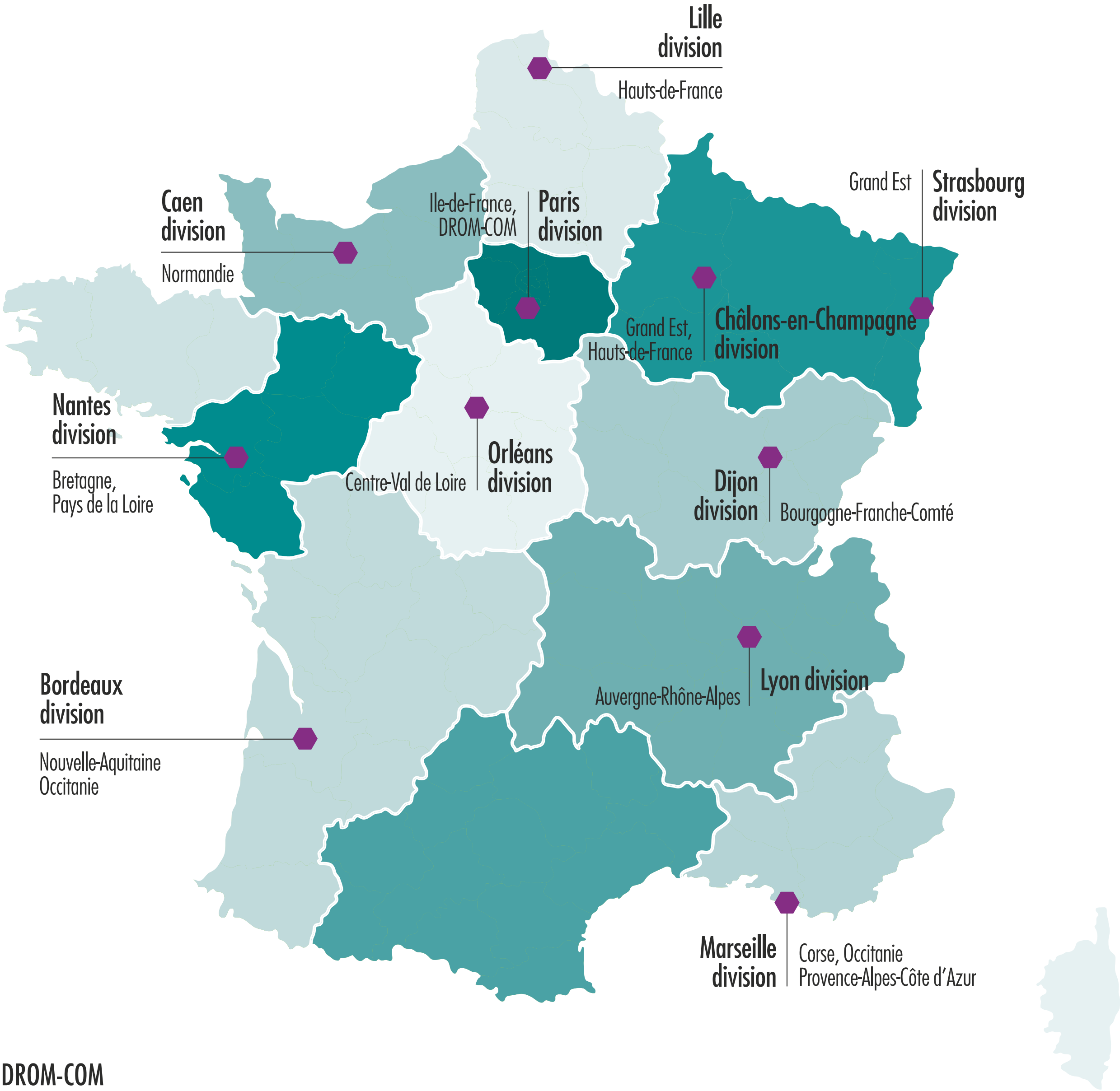
Nantes division
Regional representative: Annick BONNEVILLE
Regional Head: Pierre SIEFRIDT

Orléans division
Regional representative: Christophe CHASSANDE
Regional Head: Pierre BOQUEL

Paris division
Regional representative: Jérôme GOELLNER
Regional Head: Bastien POUBEAU

Strasbourg division
Regional representative: Emmanuelle GAY
Regional Head: Pierre BOIS

ASN in the regions



DROM-COM

Division Caen and Orléans respectively involved in the Bretagne region and Ile-de-France region for control of the only BNIs.

In a difficult context, **stringency and serenity** underpin all ASN resolutions

Olivier GUPTA - Director General

Montrouge, 14th March 2017

In the current context, with its numerous tensions and decisions with significant implications, ASN ensures that its operations enable it to issue resolutions that are balanced, robust and taken with collective responsibility.

ASN has modified its regional organisation to ensure greater legibility for all stakeholders and is enhancing its efficiency in order to focus its resources on activities with the greatest nuclear safety and radiation protection implications.

Finally, following ten years during which the regulatory framework has been considerably reinforced, ASN is conducting a review in 2017 of its responsibilities and of the future development of its oversight procedures.

The operation of ASN

In the current situation, the correct working of ASN and its technical support organisation, IRSN, is decisive.

ASN intends first of all to continue to work with rigour, based on methodical technical assessments and with reference to regulatory requirements and, more generally, to the nuclear safety and radiation protection objectives; with perseverance, seeing its investigations through to completion; with calm and serenity, without ignoring the context but at the same time without giving way to precipitation. This is what ASN did in 2016, more particularly on the most sensitive subjects such as the carbon content anomaly on certain steam generator channel heads.

ASN also aims to preserve its ability to produce collective resolutions, so that they do not rely on a single person and so that each link in the decision-making chain contributes its own competence and expertise. This method of operation is valid, including at the highest level, because the most important decisions do not rest on a single person, but on a commission, as required by law.

Finally, ASN and IRSN must continue to work smoothly at all levels, each within its own field. The joint ASN-IRSN approach in place since 2014 to assess the means needed for oversight and assessment is thus particularly welcome. With regard to day to day operations, the 2016 audit of the implementation of the convention governing relations between ASN and IRSN underlined the quality of the relationship, while identifying avenues for progress that ASN and IRSN will be implementing as of 2017.

Organisation

In 2016, ASN will have completed the majority of its review of the regional reforms. On the basis of the principles set out by the Commission, the discussions with the personnel and their representatives led to the best possible arrangement, which can be implemented in 2017. This was a major milestone. The geographical scope of competence of ASN's 11 regional divisions is now more consistent with the boundaries of the new administrative regions, leading to greater legibility for ASN's contacts in the regions.

Means and efficiency

For several years now, ASN has been working on enhancing the efficient use of its resources, to ensure oversight that is both effective and commensurate with the issues at stake. 2016 thus saw the adoption of the system of BNI classification according to the risks they present: the nature and scale of oversight measures, the degree of detail of investigations and the hierarchical level of the signature of documents concerning an installation are thus adapted to its nuclear safety and radiation protection implications. This work will continue in 2017, more specifically with the drafting of a statutory resolution to clarify the system for BNI modifications, to ensure that it is more closely tailored to the corresponding implications.

ASN has initiated a wide-ranging review of the system authorising and regulating activities in small-scale nuclear facilities. The aim is more specifically to examine how this system needs to be changed to boost its efficiency, on the basis of an approach proportionate to the risks, taking account of ongoing legislative and regulatory changes related to the transposition of the Directive on Basic Radiation Protection Standards. By means of a statutory resolution, ASN will more particularly specify the scope of application of the notification, registration and authorisation systems.

Finally, with a view to simplifying matters for those in charge of nuclear activities and making administrative processing easier, ASN opened its electronic notification portal in 2016. It is first of all operational for companies notifying transports of radioactive materials and in 2017 will be broadly expanded to include all activity files requiring notification in the small-scale nuclear sector and for notification of significant events.

Checks and inspections

The considerable reinforcement of the legislative and regulatory framework over the past ten years means that the nuclear safety and radiation protection oversight system is far better placed to deal with the current challenges.

ASN now has appropriate enforcement powers, reinforced by the Ordinance of 11th February 2016. One example of these powers is that in 2016 it succeeded in obtaining conformity of the CIS bio international facility with regard to the fire risk. ASN will continue to use these measures whenever required, with discernment and conviction.

A body of orders, resolutions and guides clarifies and stabilises the requirements so that those responsible for nuclear activities have a clearer understanding of the objectives and the acceptable means of achieving them. The procedures are also more clearly defined.

The legislative and regulatory framework promotes not only transparency but also public participation. The role of the Local Information Committees (CLI) in public information has been reinforced and ASN urged each CLI to hold meetings open to the public, as required by law. ASN contributes to the process started in 2016 and which will continue in 2017, under the supervision of the High Committee for Transparency and Information on Nuclear Safety (HCTISN), in order to clarify the public consultation procedures on the occasion of the fourth ten yearly outage inspections of the NPPs.

Finally, a formal framework for work at the European level was also finalised: in 2017, ASN will host an IRRS (Integrated Regulatory Review Service) follow-up mission, under the peer review system made mandatory in Europe. It will participate actively in preparing for a topical peer review on the management of reactor ageing.

ASN's independence and powers give it a high level of responsibility in the implementation of oversight, especially at a time of major challenges. The current situation requires that ASN take a questioning look at its responsibilities, role and position, from three perspectives:

- Despite the difficulties they are experiencing, how does ASN ensure that the licensees fully exercise their responsibility for nuclear safety and radiation protection?
- How does ASN exercise in full its role as architect of the oversight system, of which IRSN is a part? It is more particularly up to ASN, with the support of IRSN, to continue to specify oversight priorities, whether in the field or in terms of analysis of files.
- How can ASN reinforce the effectiveness of its actions in a manner commensurate with the issues and challenges? The aim is more specifically to advance oversight so that it is better able to detect fraudulent situations, while recognising that this can never be exhaustive and that the presence of ASN inspectors in the field remains a crucial aspect of the system.

ASN intends to continue to examine these subjects in 2017 within the context of preparation of its new multi-year strategic plan. The goal is to define a new direction for ASN, in a difficult context in which ASN must fully exercise the responsibilities entrusted to it by the legislator.

* * *

I wish to thank all ASN personnel for their commitment in carrying out ASN's duties in 2016. I know that I can rely on them to meet the challenges facing ASN in 2017.

Significant events in **2016**

ASN actions

Activities regulated by ASN

01 Nuclear activities: ionising radiation and health and environmental risks

Ionising radiation may be of natural origin or caused by human activities, referred to as nuclear activities.

The exposure of the population to naturally occurring ionising radiation is the result of the presence of radionuclides of terrestrial origin in the environment, radon emanations from the ground and exposure to cosmic radiation.

Nuclear activities are activities entailing a risk of exposure to ionising radiation, emanating either from an artificial source or from natural radionuclides. These nuclear activities include those conducted in Basic Nuclear Installations (BNIs) and the transport of radioactive substances, as well as in all medical, veterinary, industrial and research facilities where ionising radiation is used.

Ionising radiation is defined as radiation that is capable of producing ions – directly or indirectly – when it passes through matter. It includes X-rays, alpha, beta and gamma rays, and neutron radiation, all of which have different energies and penetration powers.

The effects of ionising radiation on living beings can be "deterministic" (health effects such as erythema, radiodermatitis, radionecrosis and cataracts, which are certain to appear when the dose of radiation received exceeds a certain threshold) or "probabilistic" (probability of occurrence of cancers in an individual, but no certainty). The protective measures against ionising radiation aim to avoid deterministic effects, but also to reduce the probability of occurrence of radiation-induced cancers, which constitute the main risk.

Understanding the risks linked to ionising radiation is based on health monitoring (cancer registers), epidemiological investigation and risk assessment via extrapolation to low doses of the risks observed at high doses. There are still however numerous uncertainties and unknowns, in particular with regard to radio-sensitivity, certain radiation-related diseases at high doses, the effects of low doses, the radiological signature of cancers and certain non-cancerous diseases.

Exposure to ionising radiation in France

The entire French population is potentially exposed to ionising radiation, but to differing degrees, depending on whether the ionising radiation is of natural origin or the result of human activities.

On average, the exposure of an individual in France was estimated by the French Institute for Radiation Protection and Nuclear Safety (IRSN) at 4.5 millisieverts (mSv) per year in 2015, varying by a factor of from 1 to 15 depending on the location, the eating habits, the medical exposures, etc.; the sources of this exposure are as follows:

- For about 2.9 mSv/year, naturally occurring radioactivity, including 0.6 mSv/year for radiation of telluric origin (excluding radon), 0.3 mSv/year for cosmic radiation, 0.6 mSv/year for internal exposure from food and tobacco, and about 1.4 mSv/year, for radon, with considerable variation related to the geological characteristics of the land (a new map of the country was produced in 2011 according to the radon exhalation potential) and to the buildings themselves; in zones defined as high-priority, periodic measurements must be taken in places open to the public and in the workplace. A national action plan for the period 2011-2015 has been implemented; its results and a new plan for the period 2016-2019 were published.
- For about 1.6 mSv/year (estimate for 2012), diagnostic radiological examinations, with a clear upwards trend (+ 23% from 2007 to 2012); particular attention must thus be paid to controlling the doses delivered to patients.
- For about 0.02 mSv/year, the other artificial sources of exposure: past airborne nuclear tests, accidents affecting facilities, releases from nuclear installations.

Nuclear activity workers undergo specific monitoring (more than 350,000 individuals in 2015); in 2015, the annual dose remained below 1 mSv (annual effective dose limit for the public) for 96% of the workforce monitored, while 20 mSv (regulation limit for nuclear workers) was exceeded for two individuals; the collective dose has fallen by about 50% since 1996 while the population monitored has grown by about 60%. For workers in activity sectors entailing technological enhancement of naturally occurring radioactive materials, the doses received in 85% of cases are less than 1 mSv/year. In a number of known industrial sectors however, it is quite probable that this value will be occasionally exceeded.

Finally, aircrews are subject to particularly close monitoring owing to their exposure to cosmic radiation at high altitude. Of the recorded doses, 83% are between 1 mSv per year and 5 mSv per year, while 17% are below 1 mSv per year.

Outlook

For occupational radiation protection, the main objectives for the coming years concern compliance with the new exposure limit for the lens of the eye (set at 20 mSv/year as of 2017), more specifically in the field of interventional practices.

2017 will also be marked by the deployment of the 2016-2019 Third National Action Plan for management of the risk related to radon.

02 Principles and stakeholders in the regulation of nuclear safety and radiation protection

Nuclear activities must be carried out in compliance with the eight fundamental principles of the Environment Charter, the Environment Code and the Public Health Code.

- the principle of nuclear licensee responsibility for the safety of its facility;
- the "polluter-pays" principle: the polluter responsible for the environmental damage bears the cost of pollution prevention and mitigation measures;
- the precautionary principle: the lack of certainty, in the light of current technical and scientific knowledge, should not delay the adoption of proportionate prevention measures;
- the participation principle: the populations must take part in drafting public decisions;
- the justification principle: a nuclear activity may only be carried out if justified by the advantages it offers by comparison with the exposure risks it can create;
- the optimisation principle: exposure to ionising radiation must be kept as low as is reasonably achievable;
- the limitation principle: the regulations set an individual's ionising radiation exposure limits as a result of a nuclear activity;
- the prevention principle: anticipation of any environmental damage through rules and actions taking account of the *"best available techniques at an economically acceptable cost"*.

The safety approach, governed more particularly by the ten fundamental principles of the International Atomic Energy Agency (IAEA), is characterised by the requirement for continuous improvement.

The nuclear activity regulators

The French nuclear safety and radiation protection oversight organisation is defined more specifically in the Environment Code. It was reinforced more recently by the 17th August 2015 Energy Transition for Green Growth Act (TECV) and the Ordinance of 10th February 2016 containing various nuclear-related provisions.

Parliament defines the applicable legislative framework and monitors its implementation, more particularly via its specialist committees or the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST) to which ASN presents its report each year on the state of nuclear safety and radiation protection in France.

On the advice of ASN, the Government defines the general regulations for nuclear safety and radiation protection. Again on the advice of ASN, it also takes major individual decisions concerning BNIs (creation authorisation, etc.). It is responsible for civil protection in an emergency.

In the current governmental organisation, the Minister for the Environment, Energy and the Sea, responsible for international climate

relations, is responsible for nuclear safety and, together with the Minister for Social Affairs and Health, for radiation protection.

In each *département*, the Prefect – as the State's representative – is responsible for population protection measures. The Prefect is also involved during various procedures to oversee local coordination and provide the Ministers or ASN with an opinion.

ASN is an independent administrative Authority. It is tasked with regulating nuclear activities and contributes to public information. It sends the Government proposals for regulatory texts and is consulted on the texts prepared by the Ministers. It clarifies the regulations through statutory resolutions. It issues certain individual authorisations and proposes others to the Government. Nuclear activities are monitored and inspected by the ASN staff and by organisations duly authorised by ASN. If noncompliance is detected, ASN may adopt enforcement measures and apply sanctions. ASN contributes to France's European and international actions within its areas of competence. Finally, it provides its assistance for management of radiological emergencies.

On technical matters, ASN relies on the expertise provided by IRSN and by the Advisory Committees of Experts. ASN also convenes pluralistic working groups enabling all the stakeholders to contribute to drafting doctrines and action plans and monitor their implementation.

ASN is also committed to the field of research, in order to identify areas requiring further investigation in order to meet the medium to long term expert assistance requirements. It has set up a Scientific Committee.

ASN is run by a Commission of five full-time, irrevocable Commissioners, nominated for a non-renewable 6-year mandate by the President of the Republic (who appoints the President and two commissioners), the President of the Senate and the President of the National Assembly.

A sanctions committee within ASN, established under the TECV Act, is responsible for the application of administrative fines in the event of any breach of the regulations.

ASN has head office departments and eleven regional divisions around the country. Its total workforce stands at 483 employees. In 2016, the ASN budget stood at €80.79 million. Moreover, about 400 IRSN staff work on providing ASN with technical support. In 2016, IRSN thus devoted €85 million to this work, equally funded by a subsidy from the State and revenue from a tax paid by the licensees of the large nuclear installations.

In total, the State's budget for transparency and the regulation of nuclear safety and radiation protection amounted to €176.54 million in 2016.

Consultative bodies

The organisation of nuclear security and transparency is also based on consultative bodies, in particular the High Committee for Transparency and Information on Nuclear Security (HCTISN), an information, consultation and debating body dealing with the risks linked to nuclear activities, the High Council for Public Health (HCSP) which contributes to the definition of multi-year public health objectives, evaluates the attainment of national public health targets and contributes to their annual monitoring, as well as the High Council for the Prevention of Technological Risks (CSPRT) tasked with giving an opinion on some draft regulatory texts. For each BNI, consultation takes place within a Local Information Committee (CLI).

Outlook

Faced with unprecedented challenges, ASN considers that a significant reinforcement of its human and financial resources and those of IRSN is essential. Despite the decisions that have gone in its favour (creation of 50 additional posts for 2015-2017), it remains preoccupied by the inadequacy of these budgetary measures.

In 2017, ASN will continue to monitor stakeholder involvement and seek to reinforce guarantees of the independence of its assessment work and the transparency of its decision-making process.

03 Regulations

The specific legal framework for radiation protection and nuclear activities is based on the international norms, standards or recommendations drawn up by various organisations, in particular the International Commission for Radiological Protection (ICRP), a non-governmental organisation, the International Atomic Energy Agency (IAEA) and the International Standard Organisation (ISO).

At a European level, under the EURATOM Treaty, various directives concern nuclear safety and radiation protection, in particular Council Directive 2013/59/Euratom setting the basic standards for health protection against the dangers arising from exposure to ionising radiation and Council Directive 2009/71/Euratom of 25th June 2009 setting a community framework for the nuclear security of nuclear installations.

At the national level, the Public Health Code defines general population protection rules (dose limits for the public, etc.) and creates a system of oversight for nuclear activities. The Environment Code sets out the rules applicable to large nuclear facilities and to radioactive waste. Other texts are more specialised, such as the Labour Code, which deals with radiation protection of workers, or the Defence Code, which contains provisions regarding defence-related nuclear activities or the prevention of malicious acts. Finally, various texts apply to certain nuclear activities but without being specific to them. This legal framework has been the subject of extensive revision for a number of years now.

The activities or situations regulated by ASN include a number of different categories presented below, along with the relevant regulations.

Small-scale nuclear activities: this category covers the many fields that use ionising radiation, including medicine (radiology, radiotherapy, nuclear medicine), human biology, research, industry and certain veterinarian, forensic or foodstuff conservation applications.

The Public Health Code, which is currently being revised, creates a system of authorisation, registration or notification for the manufacture, possession, distribution, including import and export, and utilisation of radionuclides. ASN issues licenses and authorisations, carries out registration and receives notifications. The revision of the Code, in particular the creation of registration and the inclusion of protection against malicious acts for the most dangerous radioactive sources, will be effective on 1st July 2017.

The general rules applicable to small-scale nuclear facilities are the subject of ASN statutory resolutions.

Exposure of individuals to radon: human protection is based primarily on the obligation of monitoring in geographical areas where the concentration of naturally occurring radon can be high. This monitoring is mandatory in certain premises open to the public and in the workplace. A strategy to reduce this exposure is necessary, should the measurements taken exceed the action levels laid down in the regulations. The reform in progress should lead to a reduction in the reference level for facilities open to the public (from 400 Bq/m^3 to 300 Bq/m^3).

Basic Nuclear Installations (BNIs): these are the most important nuclear facilities; they are the facilities of the nuclear electricity generating sector (nuclear power plants, main facilities of the "fuel cycle"), the large storage and disposal facilities for radioactive substances, certain research facilities and the large accelerators or irradiators. There are nearly 150 of them, spread over about 40 sites.

The legal regime for the BNIs is defined by section IX of Book V of the Environment Code and its implementing Decrees. This regime is said to be "integrated" because it aims to prevent or manage all risks and detrimental effects that a BNI is liable to create for humans and the environment, whether or not radioactive in nature. It in particular requires that the creation of a BNI be authorised by a decree issued on the advice of ASN and that ASN authorise start-up of the installation, stipulate requirements regarding its design and operation with respect to protection of the population and the environment and authorise delicensing of the installation.

In the event of final shutdown of a facility, its licensee proceeds with decommissioning in the conditions defined by a decree issued on the advice of ASN and on the basis of the licensee's file, in accordance with the principle of immediate dismantling.

ASN is working on a revision of the BNI general technical regulations: after publication of the Ministerial Order of 7th February 2012 setting the general rules applicable to BNIs, ASN thus initiated the publication of about fifteen statutory resolutions; in 2016, it adopted three resolutions and published a guide on how it consults the licensees and the public on its projects. This system is supplemented by guides, which are not legally binding and which present ASN policy; 26 guides have so far been published.

Pressure equipment specially designed for BNIs is subject to special rules updated in 2015 and 2016.

The transport of radioactive substances: the safe transport of radioactive substances is based on the "defence in depth" principle involving on the one hand the packaging and its content, which must withstand the foreseeable transport conditions, and on the other the means of transport and its reliability, plus the response measures to be deployed in the event of an incident or accident.

The regulations concerning the transport of radioactive materials are based on the IAEA recommendations integrated into the international agreements covering the various modes of dangerous goods transport. At a European level, the regulations are grouped into a single 24th September 2008 Directive, transposed into French law by an amended Order dated 29th May 2009, known as the "TMD Order".

ASN is in particular responsible for approving package models for the most dangerous shipments.

Contaminated sites and soils: the management of sites contaminated by residual radioactivity warrants specific radiation protection measures, in particular if remediation is envisaged. Depending on the current and future uses of the site, decontamination objectives must be set and the removal of the waste produced during post-operation clean-out of the contaminated premises and remediation of soil must be managed, from the site up to storage or disposal.

In 2012, ASN published its doctrine for the management of sites contaminated by radioactive substances.

The revision of the provisions of the Public Health Code will make it possible to implement institutional controls for polluted sites and soils.

Outlook

2017 will be devoted more specifically to the implementation of the wide-ranging reforms to the legislative texts adopted in 2015 and 2016. Three decrees should renew the regulatory provisions of the Environment, Public Health and Labour Codes. ASN is also expected to adopt resolutions tailoring its oversight more closely to the issues, in particular through a change in the rules applicable in the event of the modification of a BNI and the implementation of the registration of certain small-scale nuclear activities. It will continue to create general technical regulations for BNIs and define the framework applicable to the protection of radioactive sources against malicious acts.

04 Regulation of nuclear activities and exposure to ionising radiation

In France, nuclear activity licensees are responsible for the safety of their activity.

They cannot delegate this responsibility, and must ensure permanent surveillance of both this activity and the equipment used. Given the risks for humans and the environment linked to ionising radiation, the State regulates nuclear activities, a task it has entrusted to ASN.

Control and regulation of nuclear activities is a fundamental responsibility of ASN. The aim is to verify that all licensees fully assume their responsibility and comply with the requirements of the regulations relative to radiation protection and nuclear safety, in order to protect workers, patients, the public and the environment from risks associated with radioactivity.

Inspection is the key means of monitoring available to ASN. It requires one or more ASN inspectors (nuclear safety inspectors, radioactive substance transport safety inspectors, labour inspectors and radiation protection inspectors) to go to a monitored site or department, or to carriers of radioactive substances. It consists in performing spot checks on the conformity of a given situation with regulatory or technical baseline requirements. After the inspection, a follow-up letter is sent to the person responsible for the inspected site or activity and published on *www.asn.fr*.

ASN's regulatory actions are also carried out by other means such as examination of authorisation applications and analysis of significant events. The inspection is proportionate to the level of risk presented by the installation or the activity and the way in which the licensee assumes its responsibilities. ASN has a broad vision of control and regulation, encompassing material, organisational and human aspects. Its regulatory duties entail the issue of resolutions, prescriptions, inspection follow-up documents, plus administrative or criminal penalties as applicable, along with assessments of safety and radiation protection in each activity sector.

This arrangement is supplemented by systematic technical inspections in certain fields, carried out by approved organisations.

Assessment

1,793 inspections were carried out in 2016 by the ASN inspectors. These 1,793 inspections represent 1,872 days of actual inspection in the field.

ASN also continued to experiment with methods other than inspections, in order to better address activities with lesser implications.

In 2016, ASN was notified of:
- 1,048 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 948 of these events were rated on the INES scale[1] (847 events rated level 0 and 101 events rated level 1). Of these events, 12 significant events were rated as "generic events" including one at level 1 on the INES scale;
- 64 significant events concerning the transport of radioactive substances, including five events rated level 1 on the INES scale;

1. *INES : International Nuclear and Radiological Event Scale.*

- 585 significant events concerning radiation protection in small-scale nuclear activities, including 141 rated on the INES scale (of which 30 were level 1 events).

ASN was notified of no event rated level 2 or higher on the INES scale in 2016.

In 2016, following the inspections carried out, the ASN inspectors transmitted eight reports to the public prosecutors.

In 2016, ASN took nine administrative actions (formal notice, deposit of sums, etc.) against managers of nuclear activities. Moreover, for the first time, ASN took the decision to suspend a test certificate, concerning a reactor 2 steam generator at the Fessenheim NPP. This steam generator contains manufacturing anomalies that are important enough to compromise the safety demonstration used as the basis for issue of this certificate.

In an Ordinance of 10th February 2016, further to the TECV Act of 17th August 2015, measures supplemented ASN's powers of administrative sanction, making them more incremental. ASN can now impose daily fines on a BNI licensee until such time as the nonconformities observed have been remedied.

Outlook

In 2017, ASN intends to carry out about 1,800 inspections on BNIs, radioactive substances transport operations, activities employing ionising radiation, organisations and laboratories it has approved and activities involving pressure equipment. ASN will as a priority inspect the activities with potentially serious consequences, defined in consideration of the experience feedback from 2016.

Further to the irregularities found in the manufacture of certain NPP equipment items, ASN has initiated and will in 2017 be continuing a review of BNI licensee monitoring of their contractors and subcontractors, of ASN oversight and of the alert mechanisms.

ASN will continue to revise the procedures for notification of significant events, taking into account the feedback from the events notification guide in small-scale nuclear activities and the changes in regulations in the BNI sector.

It will continue with changes to its sanctions policy, implementing the provisions of the TECV Act and the Ordinance of 10th February 2016.

In the environmental field, ASN will continue its regulatory work to implement the provisions of the TECV Act. It will continue with the transposition of the European "IED", Industrial Emissions Directive, and the "Seveso 3" Directive on major accidents involving hazardous substances. ASN will also initiate a revision of the BNI Order of 7th February, more specifically to take account of recent changes to the general environmental regulations.

05 Radiological emergency and post-accident situations

Nuclear activities are carried out with the two-fold aim of preventing accidents and mitigating any consequences should they occur. Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for managing a radiological emergency situation must be planned for, tested and regularly revised.

Radiological emergency situations therefore include:
- emergency situations occurring in a BNI;
- accidents involving Radioactive Material Transports (RMT);
- emergency situations occurring in the field of small-scale nuclear activities.

Emergency situations affecting nuclear activities can also comprise non-radiological risks, such as fire, explosion or the release of toxic substances.

ASN takes part in management of these situations, for questions concerning the regulation of nuclear safety and radiation protection and, drawing on the expertise of its technical support organisation, IRSN, performs the following four main assignments:

- ensure and verify the soundness of the steps taken by the licensee;
- advise the Government and its local representatives;
- contribute to the circulation of information;
- act as Competent Authority within the framework of the international conventions.

The ASN emergency response organisation set up for an accident or incident in a BNI more specifically comprises:

- at the national level, an emergency centre in Montrouge, consisting of three Command Posts (PC):
  - a "Strategy" Command Post, consisting of the ASN Commission, which, in an emergency situation, could be called on to issue resolutions and impose prescriptions on the licensee of the installation concerned;
  - a Technical Command Post (PCT) in constant contact with its technical support organisation, IRSN, and with the ASN Commission. Its role is to adopt a stance for advising the Prefect, who acts as the director of contingency operations;
  - a Communication Command Post (PCC), located close to the Technical Command Post. The ASN Chairman or his representative acts as spokesperson, a role which is distinct from that of the head of the Technical Command Post.
- at the local level:
  - ASN representatives working with and advising the Prefect in his decisions and communications;
  - ASN inspectors present on the site affected by the accident.

Significant events

In 2016, the national emergency centre was activated for seven national exercises and, for the first time, for the purposes of an exercise on a national defence site, jointly with the Defence Nuclear Safety Regulator (ASND).

Three exercises concerned an accident scenario involving the transport of radioactive substances in *départements* in which there is no BNI. The national exercise on 20th and 21st September 2016 on the Areva site at La Hague was combined with the major governmental exercise SECNUC 2016 and involved activation of the Interministerial Crisis Committee (CIC).

In 2016, no real event led to activation of the national emergency centre.

The decision to extend the perimeter of the PPI (Off-site Emergency Plans) to 20 km around NPPs and the preparation for immediate evacuation within a radius of 5 km is consistent with the recommendations of the approach by HERCA-WENRA (Heads of European Radiation Control Authorities - Western European Nuclear Regulators' Association) published at the end of 2014 to improve harmonisation of the emergency management systems across Europe.

In October 2016, the Ministry for the Interior notified the Prefects of *départements* containing an NPP of the approach to be followed to implement the national plan for the response to a major nuclear or radiological accident. More particularly the pertinence of the activation of the PPI during the reflex phase over 2 km was again confirmed, as was the response strategy covering the entire country. The new measures to be incorporated into the PPI for the NPPs are clarified: extension from 10 to 20 km of the PPI radius and the pre-distribution of stable iodine tablets, the preparation for immediate evacuation over 5 km, the introduction of initial instructions to restrict the consumption of foodstuffs as of the emergency phase, taking account of the local context for the population protection decisions. Following its opening for public consultation, ASN Guide No.15 on the management of activities around BNIs was published in the second half of 2016.

Outlook

In accordance with the nuclear emergency duties entrusted to it by the Environment Code, ASN makes an active contribution to the review process currently being carried out by the public authorities following the Fukushima Daiichi accident, with the aim of improving the national radiological emergency organisation.

The regional implementation of the national plan for the response to a major nuclear or radiological accident will continue to be tested in 2017 during exercises, in particular in those *départements* in which there is no BNI.

Following the Government's September 2016 adoption of the principle of extending the radius of the PPI perimeter around NPPs from 10 to 20 km, the preparation of immediate evacuation over 5 km and the pre-distribution of stable iodine tablets up to 20 km, ASN will in 2017 contribute to the PPI update work carried out by the offices of the Prefects and to the new population information and iodine tablets distribution campaign for inhabitants in the zone between 10 and 20 km from the NPPs.

The nuclear safety Regulators confirmed the need for continued work internationally to improve the coordination of the respective approaches of each country in an emergency situation. In 2017, ASN will continue with the European initiatives taken with a view to harmonising actions on either side of the borders to protect populations in an emergency situation and to develop a coordinated response by the safety and radiation protection Authorities in the event of a near or remote accident, more specifically as part of the follow-up to the HERCA/WENRA approach. In 2017, ASN will organise an exercise with one or more border countries to test this approach and define joint working documents.

In 2017, in order to prepare the offices of the Prefects for the performance of public protection measures or post-accident actions, certain exercises will be followed up by a phase focusing on civil protection objectives, or workshops on the post-accident phase.

Finally, in 2017, ASN will finalise the draft of the resolution on the obligations of BNI licensees relative to the preparation for and management of emergency situations and the content of the on-site emergency plan, aiming to clarify the provisions of Title VII of the Order of 7th February 2012 setting the general rules for BNIs.

One of the priority actions for 2017 will be to make progress with setting up an on-call duty team at ASN.

06 Informing the public and the other audiences

After the Act of 13th June 2006 on Transparency and Nuclear Security (TSN), the TECV Act of 17th August 2015 reinforced the transparency provisions. It makes explicit ASN's duty to give its assessment of the state of nuclear safety and radiation protection in its annual report. The Act also comprises a range of provisions applicable to the CLIs, in particular the requirement for each CLI to hold a public meeting at least once a year.

ASN informs the general public, the media, the institutional public and professionals of its activity. It publishes its resolutions and its positions on its website. Every year, ASN presents its Report on the state of nuclear safety and radiation protection in France to Parliament.

ASN also encourages the involvement of civil society in nuclear safety and radiation protection and in particular collates observations from the stakeholders and the public on its draft decisions and resolutions on *www.asn.fr*.

In 2016, ASN coordinated the information and iodine distribution campaign for the residents living around the NPPs, in order to raise their nuclear risk culture awareness.

Significant events

ASN presented its *Report on the State of Nuclear Safety and Radiation Protection in France* to the OPECST. This report, which constitutes the reference document on the state of the activities regulated by ASN in France, is submitted each year to the President of the Republic, to the Government and to Parliament.

In 2016, ASN was called to regular hearings by Parliament on its activities, on subjects concerning nuclear safety and radiation protection.

In 2016 ASN organised twenty national and regional press conferences.

In January 2016, ASN presented its New Year's greetings to about thirty journalists from the national and international press.

On 26th May, ASN organised a press conference attended by some forty journalists to present its *Report on the state of nuclear safety and radiation protection in France*.

On 5th December, ASN held a press conference with IRSN on the situation of the steam generators made of steel containing a high carbon concentration.

The ASN regional divisions then held regional conferences to present the results of their activities for the year.

In partnership with the National Association of Local Information Committees and Commissions (Anccli) ASN organised the 28th CLI conference in Paris, in November 2016.

ASN took part in the Mayors and local authorities fair, on a joint stand with IRSN for the first time.

ASN, the Local Information Committee for the Tricastin large energy facilities and IRSN, organised a seminar on the service life extension of the French 900 MWe nuclear reactors beyond 40 years.

ASN coordinated the fifth stable iodine distribution campaign around EDF's NPPs, with the support of a pluralistic steering committee comprising representatives from the ministries responsible for national education, the interior and health, IRSN, the regional health agencies, the national orders of pharmacists, physicians and nurses, CLIs and the Anccli, the Association of representatives of communes containing NPPs and EDF.

The national levels for iodine collection from pharmacies stand at 51% for private individuals, 36% for companies and facilities open to the public (ERP) and 85% for schools. 390,000 boxes of tablets were collected from pharmacies, as opposed to 320,000 in 2009, or an increase of 22%.

The *www.asn.fr* website is the main outlet for ASN information. The content of the ASN website is available on mobile phones and tablets, but also on the main social networks.

Outlook

In 2017, ASN will continue to actively contribute to implementing steps to reinforce nuclear transparency in accordance with the requirements of the TECV Act.

ASN will expand public information about its professions and the skills of its personnel. It will for example study the creation of a "recruitment" section on its website, in order to present the full diversity of its professions and competencies and offer career prospects to people from different backgrounds.

It will reinforce transparency on the subjects under its responsibility, together with the other stakeholders. ASN will improve the conditions in which members of the public can express their opinion on the draft regulatory texts on *www.asn.fr*.

The development of the ASN-IRSN travelling exhibition, the strengthening of ties with schools and the national education authority, the creation of information initiatives for the populations situated in the PPI zones around the nuclear installations are all means of making the various audiences more aware of the culture of risk and questions concerning nuclear safety and radiation protection.

The campaign for informing and distributing iodine tablets to the populations living near the EDF nuclear power plants took place in 2016. In 2017, ASN will continue to inform the population about the nuclear risk with the extension of the PPI zones from 10 to 20 km; it will ensure correct implementation of the obligation of regular information of the persons living within the PPI zone, as set out in the TECV Act. In 2017, actions will focus on schools as well as on companies and facilities open to the public. The aim is to improve the level of iodine tablet collection by facilities open to the public and ensure close to 100% coverage by schools.

ASN will continue its interchanges with elected officials and stakeholders. After the presidential and legislative elections, it will more particularly meet the new members of Parliament to present its roles to them. It will continue its participation in the debates on nuclear safety and radiation protection.

ASN will continue to support CLI activities. For those CLIs that so wish, this support will more particularly concern their actions to involve the population in their work, such as holding meetings open to the public, as required by the TECV Act.

07 International relations

ASN is actively involved in international cooperation, enabling it to contribute to reinforcing nuclear safety and radiation protection worldwide, while consolidating its competence and its independence.

Significant events

Europe is a priority for ASN actions. Several European directives set common requirements and standards across Europe in the fields of nuclear safety and radiation protection. ASN contributes to drafting these rules, in particular through ENSREG (European Nuclear Safety Regulators Group), which assists the European Commission. ENSREG is currently overseeing the first European peer review, which will be held in 2017 and 2018 and will concern management of reactor ageing.

The European Authorities carry out numerous initiatives aimed at harmonising nuclear safety and radiation protection regulations and practices. Two associations, WENRA and HERCA, bring together the heads of the European nuclear safety and radiation protection authorities respectively. These associations strengthened their cooperation in the field of management of transboundary emergency situations. HERCA has carried out several actions to support transposition of the Euratom Directive on basic radiation protection standards.

Beyond Europe, ASN plays an active role in the work overseen by the UN's IAEA agency. IAEA defines safety standards, which are then used by its Member States to draft their own national regulations. These standards are also used as the basis for peer audit missions by the safety regulators and nuclear licensees. ASN is also involved in the peer audits of its counterparts. An ASN commissioner for example headed the first review of the new Japanese safety regulator (NRA – Nuclear Regulation Authority).

ASN also takes part in the work done by the Organisation for Economic Cooperation and Development's Nuclear Energy Agency (NEA), allowing the exchange of information, experience and practices between the national regulatory Authorities. In 2016, the NEA published a report on the lessons learned from the Fukushima Daiichi accident and green papers on defence in depth and on safety culture among the regulators. ASN also takes part in several ASN groups, one of which is devoted to inspection practices in the various Member States.

ASN plays an active role in the international MDEP (Multinational Design Evaluation Programme) initiative, the aim of which is to develop innovative approaches to pool the resources and knowledge of safety regulators tasked with evaluating and overseeing the construction of new reactors. ASN contributes in particular to the group devoted to the EPR reactor, as well as to the groups working on codes and standards, digital instrumentation and control and multinational inspection of nuclear component manufacturers.

ASN also works with many countries through bilateral agreements. ASN takes care to share its best practices and conversely to understand the methods used in other countries. Personnel exchanges are organised regularly, ranging from a few days to assignments lasting several years.

ASN is continuing with its commitment to international assistance programmes. The purpose of this assistance is to enable the countries concerned to acquire the safety and transparency culture that is essential for a national system of nuclear safety and radiation protection regulation. In 2016, ASN took part in projects for the benefit of the safety and radiation protection regulators of Algeria, China, Madagascar, Morocco, the Democratic Republic of the Congo and Vietnam.

ASN acts as the national point of contact for international conventions on nuclear safety and the safety of spent fuel and radioactive waste management. These conventions are an important tool in reinforcing nuclear safety worldwide, in particular through the three-yearly meetings at which each country submits a report on the implementation of these conventions for peer review.

ASN is the competent Authority for the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency. The purpose of these conventions is to facilitate the circulation of information and cooperation between countries in the event of a nuclear accident.

Outlook

In 2017, ASN will continue to work on developing the European approach to nuclear safety and radiation protection. It will make an active contribution to the European peer review on the management of reactor ageing.

In 2017, ASN will host the follow-up mission to the peer review carried out by IAEA in 2014, in order to assess the progress accomplished since then.

The 7th review meeting of the contracting parties to the convention on nuclear safety will be held in 2017, for which ASN will present the French report.

Finally, ASN will continue its involvement in the cooperation instruments assisting third party countries in the field of nuclear safety.

08 Regional overview of nuclear safety and radiation protection

ASN has 11 regional divisions through which it carries out its regulatory responsibilities throughout metropolitan France and in the French overseas *départements* and regional authorities.

In 2016, ASN adapted its operations to the creation of the new regions. It retains all its local establishments, which are responsible for its actions in the field. Several ASN regional divisions may thus be required to coordinate their actions within a given administrative region. As at 31st December 2016, the ASN regional divisions comprised 216 staff members, including 154 inspectors.

Under the authority of the regional representatives, the ASN regional divisions carry out field inspections on BNIs, on radioactive substances transports and on small-scale nuclear activities. They investigate most of the licensing applications submitted to ASN by the nuclear activity licensees within their regions. For these activities and within these installations, they check application of the regulations relative to nuclear safety, radiation protection, pressure equipment and Installations Classified on Environmental Protection grounds (ICPEs). They carry out labour inspection duties in the nuclear power plants.

In a radiological emergency situation, the ASN regional divisions assist the Prefect of the *département*, who is responsible for protection of the population, and oversee the steps taken by the licensee on the site to make the facility safe. To ensure preparedness for these situations, they take part in preparing the emergency plans drafted by the Prefects and in periodic exercises.

The ASN regional divisions contribute to the public information duty. They for example take part in the meetings of the Local Information Committees (CLIs) of the BNIs, and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

The purpose of this chapter is to present an assessment of nuclear safety and radiation protection in each region, in addition to ASN's overall assessment for each major activity and main licensee. It also presents the local issues and approaches particularly representative of ASN's regional actions, more specifically in terms of public information and transboundary relations.

09 Medical uses of ionising radiation

For more than a century, medicine has made use of various sources of ionising radiation, both for diagnostic purposes and for therapy. While their benefits and usefulness have long been medically proven, these techniques however contribute significantly to the population's exposure to ionising radiation.

Behind exposure to natural ionising radiation, medical exposure represents the second source of exposure for the population and the leading source of artificial exposure. Protection of the patients benefiting from medical imaging examinations or therapeutic care using ionising radiation is regulated by the Public Health Code, while that of personnel working in the corresponding facilities is regulated by the Labour Code.

In France, there are several thousand conventional or dental radiology devices, just over a thousand computed tomography facilities, more than a thousand facilities carrying out interventional radiology and fluoroscopy-guided procedures, 225 nuclear medicine units using unsealed sources for *in vivo* or *in vitro* diagnostics and for internal radiotherapy.

In addition, as at the end of 2016, 176 external radiotherapy centres equipped with 476 treatment devices, handling some 180,000 patients every year, were identified by ASN. 750 radiotherapists were identified.

Nuclear medicine comprises about 700 specialist practitioners, along with another 1,000 physicians from other specialities working together in nuclear medicine units (interns, cardiologists, endocrinologists, etc.)

In 2016, ASN issued 883 authorisations, of which 58% were for computed tomography, 22% for nuclear medicine, 15% for external radiotherapy, 4% for brachytherapy and 1% for blood product irradiators.

Significant Radiation Protection Events (ESR) in 2016

Since July 2015, the radiotherapy units have been able to carry out on-line notification of ESR on an on-line notification portal shared by the French Health Products Safety Agency (ANSM) and ASN. It will be extended to cover the entire medical sector at the beginning of 2017.

After a gradual rise over the period 2007 to 2014, the number of ESR notified to ASN dipped slightly in 2015. In 2016, 493 ESR were notified: 160 concerned radiotherapy (mainly patient positioning anomalies) or brachytherapy, 117 nuclear medicine, 116 computed tomography and 24 interventional radiology. 67% of the ESR concern patients and 10% of the ESR concern workers, primarily in nuclear medicine.

The occurrence of four ESR rated 2 on the ASN-SFRO (French Society for Radiation Oncology) scale should be noted[1]. These events are the result of errors in the target volume to be treated (1 ESR), the side to be treated (1 ESR), dose fractionation (1 ESR) and finally a dose error in brachytherapy (1 ESR).

The events notified to ASN in 2016 show that the consequences with the most significance in radiation protection terms concern:
- for the workers; nuclear medicine and interventional radiology;
- for the patients; interventional radiology during lengthy, complex procedures, radiotherapy – in particular for hypofractionated treatments – and nuclear medicine, with radiopharmaceuticals administration errors;
- for the public and the environment; nuclear medicine, with leaks from radioactive effluent pipes and containments.

The lessons learned from the significant radiation protection events notified to ASN underline the need to increase the involvement of Radiation Protection Officers (RPO) and medical physicists in the management of radiation protection, and to develop the training of the professionals using ionising radiation.

The radiation protection situation in radiotherapy

The safety of radiotherapy treatments is a priority area of regulation and oversight. ASN used to systematically inspect radiotherapy centres every two years, but since 2016 it inspects every three years. An annual frequency is however applied in certain particular cases, more specifically for centres which are at risk in terms of human resources or organisation.

Experience feedback from the events of which ASN is notified underlines the considerable potential consequences of hypofractionated treatments, which lead to a higher level of irradiation per session. In 2016, ASN focused its inspections on this type of treatment.

ASN considers that the management of the quality and safety of care is now integrated into the operation of the radiotherapy centres, even if there are disparities between them. It however observes that insufficient account is taken of risk management approaches in order to make the treatments even safer.

ASN wishes to draw attention to the need to analyse the impact on the activity of the workers of both the increase in activity (number of treatments, treatment complexity) and of changes, whether technical (use of a new technique or practice), human (shortage of radiotherapists) or organisational (grouping of units, merging or acquisition or centres, cooperation between facilities). These changes can weaken the existing safety barriers and be the cause of ESR.

With regard to brachytherapy, the departments benefit from the organisation set up for external radiotherapy, concerning both the deployment of a quality management system and the radiation protection of workers and patients. ASN considers that efforts must be made to reinforce the radiation protection training of workers if a high-level source is present and to carry out internal radiation protection technical inspections.

The radiation protection situation in nuclear medicine

ASN considers that the radiation protection of workers, patients and protection of the environment are on the whole progressing. However, with regard to worker protection, it is important that the individual job studies be completed and that continuing training be reinforced. ASN considers that patient radiation protection needs to be improved by in particular applying quality assurance procedures to the checks to be made when using automated systems.

1. *This scale is designed for communication with the public in comprehensible, explicit terms, concerning radiation protection events leading to unexpected or unforeseeable effects on patients undergoing a radiotherapy medical procedure.*

The radiation protection situation in computed tomography

ASN is continuing with its oversight of the regulation of patient radiation protection in the field of computed tomography, given the rise in the contribution of this imaging technique to the average effective dose per inhabitant.

ASN observes that application of the principles of justification and optimisation continue to differ widely from one site to another. The training of professionals needs to be improved in order to achieve better management of the doses of radiation delivered to the patients, while maintaining the medical benefits of this imaging technique.

The radiation protection situation in interventional practices

As in 2015, ASN considers that the urgent measures it has been recommending for several years to improve the radiation protection of patients and professionals in the exercise of interventional practices, particularly in operating theatres, have not been sufficiently implemented. These measures must in particular concern the training of all the professionals associated with this form of care, especially those who have not received patient radiation protection training at university level, the intervention by the medical physicist and the increase in the means allocated to the PCRs.

In the field of medical physics, the efforts made since 2007 to boost the numbers of medical physicists must be continued in order to meet the medical imaging needs.

Owing to the implications for both professionals and patients and owing to a lack of radiation protection culture among intervention personnel, in particular in the operating theatres, ASN maintained its oversight of the facilities performing fluoroscopy-guided interventions as a national priority in its inspection programme for 2017.

Outlook

In radiotherapy, ASN together with the professionals will examine the conditions for anticipating and better managing growth in activity, as well as technical, human and organisational changes and will examine risk management policies in the large health groups.

In the field of imaging, ASN will continue its work to promote the development and initial and continuing training of all professionals involved in performing the procedures, in order to improve the management of the doses delivered to the patients. The development of quality assurance in imaging and the increased involvement of medical physicists in optimising the doses delivered to the patients are also areas in which progress is required. Interventional practices, more particularly in the operating theatres, remain an inspection priority.

10 Industrial, research and veterinary uses and source security

Small-scale nuclear activities stand out through their extreme heterogeneity and the very large number of licensees concerned. Industrial and research uses of radioactive sources, that is to say from radionuclides, are mainly industrial irradiation, gammagraphy inspection of materials, checking of physical parameters such as dust levels or density, neutron activation and various detection techniques, plus trackers. Electrical devices emitting ionising radiation are used for similar purposes, as well as for veterinary diagnostic radiology.

ASN must therefore adapt its efforts to the radiation protection issues of these activities if it is to regulate them effectively. ASN is in particular attentive to overseeing the management of ionising radiation sources, monitoring their conditions of possession, utilisation and disposal and ensuring the accountability and monitoring of source manufacturers and suppliers.

Assessment

In 2016, with regard to the users, ASN examined and notified 277 new licenses, handled 971 license renewals or updates and revoked 325 licenses for users and holders of ionising radiation sources. ASN granted 139 licences and renewed

265 licenses to use X-ray generating devices and issued 324 notification acknowledgements. With regard to the suppliers, 65 licence or license renewal applications were examined. ASN also carried out 389 inspections of users and suppliers.

Industrial radiography activities are an inspection priority for ASN, with nearly 100 inspections per year. ASN finds that the way the companies address the risk varies widely. ASN is worried by the radiological zoning defects observed.

ASN's monitoring of establishments and laboratories using radioactive sources for research purposes shows a distinct improvement in radiation protection. At the same time, ASN presented the generally satisfactory results of an inspection campaign carried out in 2015 on laboratories using the "Mössbauer" spectrometry technique.

ASN's inspectors also identified good field practices in the veterinary sector, as a result of the efforts made over the past few years. ASN continued its verification of the withdrawal from service of smoke detectors using radioactive sources, lightning arresters and radioactive lightning conductors.

At the Nuclear Security Summit in Washington in April 2016, France initiated an international undertaking to support research, development and the implementation of technologies which do not use high level sealed radioactive sources. ASN and the National Nuclear Security Administration (United States) thus jointly chaired a think tank on the replacement of these sources by alternative technologies. In December 2016, ASN presented the results of the working group at the international conference on nuclear security organised by IAEA.

Unlike in previous years, no incident was rated level 2 on the INES scale in 2016. The most notable incident of 2016 concerns the deterioration of a gamma radiography device used in worksite conditions in a BNI.

Given the number of cases of abnormal radioactivity being detected in metals and consumer goods around the world, ASN considers that France needs to rapidly implement a nationwide radioactivity detection strategy. It made its position known to the authorities in charge of these checks and organised a number of discussion meetings on this subject in 2016.

In the regulatory field, 2016 was the first year of application of ASN resolution 2015-DC-0521 of 8th September 2015 concerning the registration of movements with IRSN and resolution 2015-DC-0531 of 10th November 2015 in which ASN broadened the scope of activities subject to notification.

ASN continued with transposition into French law of European Directive 2013/59/Euratom of 5th December 2013, which will in particular introduce an intermediate administrative system between notification and authorisation, a simplified authorisation known as the "registration system", tailoring the regulatory constraints more closely to the radiation protection issues.

Finally, in 2016, the legislative process necessary for creating a regulatory framework for measures by those responsible for nuclear activities to protect sources against malicious acts was completed by Ordinance 2016-128 of 10th February 2016. ASN, together with the High Defence and Security Official at the Ministry for the Environment, continued to prepare the texts necessary for the effective implementation of oversight. As ASN was designated the oversight authority for these measures regarding most radioactive sources, it also continued the steps begun to plan ahead for training of its staff and develop appropriate tools so that this new role could be taken on board rapidly and efficiently. It has virtually completed its survey work on the existing facilities. In the civil sector, this concerns about 4,000 sources distributed around some 250 facilities in France.

Outlook

As of 2017, ASN will be preparing for the entry into force of the new administrative systems applicable to nuclear activities, issuing the necessary resolutions for the nuclear activities concerned by these new systems. It will also modify the resolutions concerning the content of the authorisation application files, including elements necessary for the oversight of source security.

ASN will extend its electronic notification portal to all activities subject to notification, simplifying the process for the professionals (this arrangement is already in use for notification of transport activities).

ASN will continue to carry out its licensing and oversight duties, tailoring its efforts and the oversight procedures to the specific radiation protection implications of the particular activities.

11 Transport of radioactive substances

About 770,000 consignments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, which account for just a few per cent of the total number of dangerous goods packages transported each year. 88% of the transported packages are intended for the health, non-nuclear industries or research sectors, of which about 30% is accounted for by the medical sector alone. The nuclear industry accounts for about 12% of the annual traffic of radioactive substances.

The content of the packages varies widely: their radioactivity level varies from a few thousand becquerels for low-activity pharmaceutical packages, to trillions of becquerels for spent fuel. Their weight also varies from a few kilogrammes to about a hundred tonnes. Road transport accounts for about 90% of radioactive substances shipments, rail 3% and sea 4%. Air transport is widely used for small and urgent packages over long distances, for example, low activity radiopharmaceutical products. All of these shipments can be international.

The main participants in transport arrangements are the consignor and the carrier. ASN checks that transport safety regulations are correctly applied for radioactive and fissile substances used for civil purposes. The major risks in the transport of radioactive substances are the risks of irradiation, contamination, criticality, but also toxicity or corrosion. To prevent them, the radioactive substances in the packages must be protected in particular from fire, mechanical impact, water ingress into the packaging facilitating criticality reactions, chemical reaction between package components. Safety is thus based above all on the robustness of the package, which is the subject of rigorous regulatory requirements. Given the international nature of these shipments, the regulations are drawn up on the basis of recommendations issued under the aegis of the International Atomic Energy Agency (IAEA). Although all packages must comply with strict rules, only 3% require ASN approval. If a package is unable to meet all the regulatory prescriptions, the regulations nonetheless allow for its transport by means of a shipment under special arrangement which requires ASN approval of the proposed compensatory measures.

Assessment

With regard to authorisations, ASN issued 37 approval certificates for packages or special arrangement shipments during the course of 2016. The Areva TN company submitted an approval request for the TN G3 package model, intended for the transport of spent fuel from the EDF NPPs to the La Hague plant. ASN referred this subject to the Advisory Committee for Transports (GPT).

Since the implementation of the BNI Order, on-site transports of radioactive substances within the facilities must be covered by the licensee's baseline requirements. Even if the licensees have taken steps in the right direction on this point, ASN notes that some have yet to achieve a satisfactory result. ASN received additional data in 2016 and this is currently being examined.

ASN performs inspections at all the stages in the life of a package: from manufacture and maintenance of packaging, to package preparation, shipment and reception. Inspections also concern preparedness for emergency situations.

In 2016, ASN carried out 106 inspections in radioactive substance transport. In particular, following the identification of irregularities during the manufacture of nuclear industry equipment by the Creusot Forge plant, ASN conducted an inspection in November 2016 of the Areva TN company which produces the transport packages for which Creusot Forge is a subcontractor. The inspectors noted that Areva TN had initiated measures to detect and process potential irregularities but that these actions were unable to detect all the irregularities affecting the components of the transport packaging manufactured by Creusot Forge. ASN thus asked Areva TN to take part in the exhaustive review of the Creusot Forge files, with regard to its particular field of activity.

ASN considers that the radiation protection situation of the carriers could be improved, in particular for the carriers of radiopharmaceuticals, who are significantly more exposed than the average worker. ASN intends to publish a guide in 2017 to help carriers achieve a clearer understanding of the regulatory requirements and best practices with regard to radiation protection.

In 2015, ASN adopted a resolution, which came into force in 2016, requiring that companies transporting radioactive substances be subject to the notification obligation. Notification is submitted in electronic format on *www.asn.fr*. ASN therefore now has a clearer picture of the characteristics of the companies, enabling it to tailor its oversight resources more closely to the issues.

In the event of an accident involving transport, it should be able to minimise the consequences for the public and the environment. In addition to the national emergency exercises, ASN is looking to organise local transport emergency exercises to allow more frequent drills by the offices of the Prefect and the emergency services. Together with the Ministry of the Interior, ASN tasked IRSN with drawing up a scenario that could be easily applied in each *département*. These local emergency exercises could take place as of 2017.

In 2016, concerning the transport of radioactive substances, ASN was notified of 58 level 0 events and 5 level 1 events on the INES scale. More than half of these events concern the nuclear industry. The medical and non-nuclear sectors are the cause of relatively few transport events when compared with the corresponding traffic levels, probably owing to a lack of notification.

Outlook

In 2017, ASN intends to maintain its oversight of the manufacture and maintenance of packages requiring approval, in particular for the older packaging, and to take account of the irregularities in the manufacture of certain package components. With regard to on-site transports, ASN considers that the licensees concerned must step up their efforts so that the measures in progress can be completed.

12 EDF Nuclear Power Plants

58 Nuclear Power Plants (NPPs) operated by EDF are at the heart of the nuclear industry in France. ASN imposes stringent safety requirements on power reactors, the regulation and oversight of which mobilises nearly 200 of its staff and as many IRSN experts on a daily basis.

ASN developed an integrated approach to regulation that covers not only the design of new installations, their construction, modifications, integration of feedback, but also social, human and organisational factors, radiation protection, environmental protection, worker security and the application of labour legislation.

Significant events

Experience feedback from the Fukushima Daiichi accident

EDF deployed temporary or mobile measures to enhance protection against the main situations of total loss of the heat sink or electrical power supplies. The Nuclear Rapid Intervention Force (FARN) has been fully operational since the end of 2015. EDF has also begun to implement a large part of the final measures, more particularly the construction of buildings intended to house the high-capacity ultimate back-up diesel generator sets.

In 2016, ASN issued a position statement on the natural external hazard levels to be considered for the "hardened safety core" and asked EDF to carry out additional studies.

Examination of NPP operating life extensions

In April 2016, ASN issued a position statement on the orientations of the generic study programme to be carried out to prepare for the fourth periodic safety reviews of the nuclear reactors. ASN is currently examining the generic studies linked to this review. In 2019, Tricastin reactor 1 will be the first 900 MWe reactor to undergo its fourth ten yearly outage inspection. The fourth ten-yearly outage inspections for the 900 MWe plant series reactors will run until 2030.

In 2016, Paluel reactor 1 was the first 1,300 MWe reactor to undergo its third ten-yearly outage inspection. These third ten-yearly outage inspections for the 1,300 MWe plant series reactors will run until 2023.

In February 2015, ASN ruled on the orientations of the periodic safety review associated with the second ten-yearly in-service inspections of the 1,450 MWe reactors. It is currently examining the generic studies for this review. The second ten-yearly inspections for the 1,450 MWe plant series reactors will run from 2018 to 2022.

The Flamanville 3 EPR reactor

ASN is currently examining the commissioning authorisation application for Flamanville 3, transmitted by EDF in March 2015. In 2016, it more specifically examined the safety case studies, the safety of fuel storage and handling, the design of the safety systems and protection against the effects of internal and external hazards.

On 12th December 2015, ASN issued a position statement concerning the approach used to demonstrate the mechanical properties of the Flamanville 3 EPR vessel closure head and bottom head proposed by Areva NP. Subject to its observations and requests being taken into consideration, ASN considers that the approach proposed by Areva NP is acceptable in principle and had no objection to the initiation of the new planned programme of tests, held in 2016.

In December 2016, Areva NP sent ASN a technical file resulting from the test programme. ASN will issue a position statement on the serviceability of the vessel no later than the end of the first half of 2017.

Lessons learned from detection of the Flamanville EPR vessel anomaly

The detection of this vessel anomaly led ASN to ask Areva NP and EDF to learn all possible lessons from this event.

Following ASN's requests, EDF informed ASN at the end of 2015 that the channel heads of the steam generators fitted to 18 reactors, manufactured by Creusot Forge and Japan Casting and Forging Corporation (JCFC), were also concerned by the carbon segregation problem.

A detailed characterisation of these channel heads by EDF was carried out at ASN's request in order to consolidate the hypotheses utilised by EDF in the fracture strength calculations and to confirm that there was no risk. The need for additional checks on some of the channel heads manufactured by JCFC more particularly led ASN on 18th October 2016 to direct EDF to perform them within three months, entailing the shutdown of five reactors concerned before January 2017.

Further to the detection of several anomalies concerning the production of the Areva NP plant in Le Creusot, in particular including the carbon positive macrosegregations, ASN asked Areva NP to conduct a general review of the quality of its previous and ongoing nuclear activities in this plant.

These reviews revealed irregularities in the oversight of manufacturing, including inconsistencies, modifications or omissions in the production files, concerning manufacturing parameters or test results.

As at the end of 2016, Areva NP has identified 91 irregularities concerning EDF reactors in operation, 20 affecting equipment intended for the Flamanville EPR reactor, one affecting a steam generator intended for but not yet installed in the Gravelines NPP reactor 5 and four affecting transport packaging for radioactive substances. One of these irregularities led ASN in July 2016 to suspend the test certificate for one of the Fessenheim NPP reactor 2 steam generators.

ASN conducted its own analysis of each of the irregularities, jointly with IRSN. Regardless of their actual safety consequences, these irregularities reveal unacceptable practices and some of these irregularities may actually be cases of falsification.

The reviews initiated by Areva NP must continue and could well bring further irregularities to light. ASN is ensuring that the review process is seen through to completion, more specifically by means of inspections at Creusot Forge.

Fall of a steam generator

During the Paluel NPP reactor 2 outage (since May 2015) for its third ten-yearly outage inspection, a steam generator fell while being handled on 31st March 2016. In June 2016, pending its removal, EDF secured the fallen SG in order to prevent any movement.

ASN is examining EDF's proposals to enable the resumption of operations to remove the fallen SG and carry out replacement of the SGs. The reactor building clearance operations will make it possible to access the various equipment items present in it, so that the assessments needed to identify the damage to the installation can be carried out. ASN will monitor performance of the necessary repairs and checks to be conducted with a view to restarting the installation.

Nuclear reactors operated by EDF

ASN considers that there are differences in operational rigour between the various NPPs in 2016. Although there were fewer reactor scrams than in previous years, failure to comply with operating technical specifications is once again the cause of a non-negligible number of significant events, reflecting a lack of rigour in the preparation and execution of operations. More generally, ASN considers that EDF places insufficient emphasis on preventing operating deviations.

ASN notes that the quality of maintenance work could be improved and that the number of quality defects found remains stable. ASN observes the persistence of problems with management of activities owing to problems with the procurement of spares and with equipment repairs. ASN also regularly observes a lack of rigour in technical oversight of interventions and in monitoring of contractors.

In the light of the project to extend the service life of the NPPs in operation, the "major overhaul" programme and the lessons learned from the Fukushima Daiichi accident, ASN considers that it is important for EDF to continue the efforts started to resolve the problems mentioned and improve the effectiveness of its maintenance work.

The inspections carried out by ASN in 2016 during the reactor maintenance and refuelling outages and during reactor operating periods, revealed a number of deviations which called into question the actual availability of certain systems important for the safety of the installations, such as the electrical systems or the safeguard systems.

ASN considers that in 2016, the situation of the second barrier is worrying, further to the discovery of the segregation anomaly in the SG channel heads.

The results of the third ten-yearly outage tests on the 900 MWe reactor containments have so far shown leak rates conforming to regulation criteria (29 of 34 reactors have undergone this test), except for that of Bugey reactor 5, for which ASN is examining the repair file submitted by EDF.

The organisation in place on the sites for managing skills, qualifications and training is on the whole satisfactory. EDF is making major investments in hiring and training in order to anticipate the renewal of the skills threatened by staff retirements.

In a context of a rising volume of maintenance work, the collective dosimetry on all the reactors increased in 2016. The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion.

ASN considers that EDF's organisation for the nuisance and impact control of NPPs on the environment is satisfactory on most sites. ASN however notes that a number of the deviations found during the previous inspections remain uncorrected. Incorporating operating experience feedback remains an area for progress and ASN observes that the deviations persist in the operation and monitoring of the installations.

The ASN assessments of each NPP are detailed in chapter 8 of the report. Certain sites stand out positively:
- in the fields of nuclear safety and environmental protection: Fessenheim;
- in the field of radiation protection: Blayais, Chinon, Civaux, and Golfech.

Other sites are on the contrary underperforming with respect to at least one of these three topics:
- in the field of nuclear safety: Belleville-sur-Loire, Cruas-Meysse, Golfech and, to a lesser extent, Bugey;
- in the field of radiation protection: Cruas-Meysse, Dampierre-en-Burly;
- in the field of environmental protection: Cruas-Meysse, Gravelines.

Evaluation of the manufacture of Nuclear Pressure Equipment (ESPN)

The year 2016 was marked by the detection of irregularities which could constitute falsification and concealment of deviations, with varying degrees of scale and severity, in several ESPN manufacturing plants. This was in particular the case in the Areva NP Creusot Forge plant, where these practices had continued for several decades.

ASN considers that these irregularities reveal unacceptable practices. These practices compromise the irreproachable level of quality expected in the manufacture of equipment which is a factor in guaranteeing its in-service resistance. These irregularities more particularly concern primary system equipment, which is among the most important equipment in an NPP and for which the consequences in the event of failure are not examined in the nuclear safety case.

This experience feedback and the ASN inspections highlight significant shortcomings in the quality and nuclear safety culture on the part of some of the staff present in these plants. ASN requires that the various industrial firms, in particular the licensees who are responsible for nuclear safety, implement fundamental organisational measures to guarantee a high level of quality in the supply chains.

Outlook

2017 will see the continued examination of the generic studies for the fourth periodic safety review of the 900 MWe reactors, as well as the second periodic safety review of the 1,450 MWe reactors.

ASN will examine the initial review conclusions reports for the third ten-yearly outage inspections of the 1,300 MWe reactors, so that it can issue a position statement on the continued operation of these reactors.

In 2017, ASN will continue to examine the measures proposed by EDF as a result of the lessons learned from the Fukushima Daiichi accident. ASN will also continue to oversee the work to deploy the fixed items of the «hardened safety core» on the sites (ultimate back-up diesels, ultimate water source, local emergency centre).

Concerning the Flamanville 3 EPR reactor, 2017 will also see continued examination of the commissioning authorisation application for this reactor. ASN will also continue with the conformity assessments of the nuclear pressure equipment most important for safety. ASN will in particular issue its position on whether or not the vessel is suitable for service.

In 2017, ASN will continue the actions it started further to the generic anomaly on the SG channel heads and the irregularities brought to light in the Creusot Forge plant. It will in particular check implementation of the review of all the components manufactured in the past at Creusot Forge. ASN will also finalise its ongoing review of the necessary adaptation of oversight methods in order to combat fraudulent practices.

13 Nuclear fuel cycle installations

The fuel cycle concerns all the steps involved in the fabrication of the fuel and then its reprocessing once it has been used in nuclear reactors.

The main plants in the cycle – Areva NC Tricastin (Comurhex and TU5/W), Georges Besse II (GB II), Areva NP Romans-sur-Isère (ex-FBFC and ex-Cerca), Areva NC Mélox, La Hague and Areva NC Malvési (which is an Installation Classified on Environmental Protection grounds – ICPE) – are part of the Areva group. These plants include facilities which have BNI status.

Significant events

Tricastin uranium storage facility

Following the delicensing of part of the Pierrelatte defence BNI by decision of the Prime Minister of 20th July 2016, the BNI 178 Tricastin uranium storage facility was created. This installation groups the uranium storage facilities and the new emergency management premises. ASN registered this facility in December 2016 and will oversee its operation in 2017.

Together with the ASND, ASN ensured the continuity of nuclear safety oversight for this facility. Joint actions are carried out: an inspection and visits to the facility also took place, enabling ASN to verify the facility's baseline requirements, which must be brought into line with the BNI regulations.

Areva NC monitoring of the status of evaporator capacity

For the periodic safety review of BNI 116, ASN asked Areva in 2011 to examine the conformity and ageing of the fission products concentration evaporators in units T2 (BNI 116) and R2 (BNI 117). In 2014, Areva NC informed ASN of corrosion of these items that was on a scale greater than that considered in the design. During the course of 2015, Areva NC sent ASN the results of the *in-situ* measurement campaigns. As the maintained integrity of these items has major safety implications, the ASN Commission heard the Areva CEO on 11th February 2016. In its resolution 2016-DC-0559 of 23rd June 2016, ASN stipulated the conditions to be met by Areva NC for continued operation of the fission products concentration evaporators in the La Hague plants. ASN is particularly attentive to the development of corrosion in this equipment and may demand shutdown of the facility in the event of excessive deterioration.

In 2016, Areva NC submitted a request to ASN for its opinion regarding the safety options for the new evaporators, with a view to commissioning them in 2021.

Moreover, in 2011, Areva NC brought to light several perforations of the shell of an evaporator used to concentrate fission product solutions before vitrification in the R7 unit (BNI 117). This evaporator could not be returned to service and needs to be replaced. In 2016, the licensee submitted an authorisation application to ASN for replacement of the old evaporator and commissioning of a new one, currently being envisaged for 2018.

Assessment and outlook

Cross-disciplinary aspects

ASN will be continuing its review of several of the Areva Group's BNIs and will extend this process to new facilities at La Hague and Romans-sur-Isère in particular, but also to EDF's inter-regional fuel stores (in Chinon and Bugey). At the end of 2017, ASN shall more specifically issue a position statement on the continued operation or otherwise of the Cerca facility at Romans-sur-Isère, which is required to carry out major reinforcement work.

With regard to the current Areva group, ASN will be particularly vigilant in ensuring that the BNI licensees to be created as a result of the ongoing division process, are in full possession of the capabilities needed to meet their responsibilities. In particular, the capability of the two groups resulting from the division of Areva as it currently stands shall be credible enough to make any modifications to the installations concerned and manage any internal crises.

Fuel cycle consistency

In 2016, ASN started an examination of the new "Cycle impact" file covering the period 2016-2030 and aimed at anticipating the various emerging needs in order to manage the nuclear fuel cycle in France. ASN will in particular focus on monitoring the level of occupancy of the spent fuel underwater storage facilities (Areva and EDF). It asked EDF, as client, to examine the impact on the anticipated saturation dates for these storage facilities of the shutdown of a reactor, of a possible modification in the spent fuel reprocessing traffic, as well as the solutions envisaged for delaying this saturation. ASN considers that Areva and EDF must very rapidly define a management strategy going beyond 2030. The examination of the «Cycle impact» file submitted in 2016 is ongoing and will be jointly examined at the beginning of 2018 by the Advisory Committee of Experts for Laboratories and Plants (GPU), the Advisory Committee of Experts for Waste, the Advisory Committee of Experts for Nuclear Reactors (GPR) and the Advisory Committee of Experts for Transports (GPT).

Tricastin site

ASN will continue to monitor the reorganisation of the Tricastin platform to ensure that these major organisational changes within the group have no impact on the safety of the various BNIs on the site. It will also ask the platform licensees to complete the unification process scheduled for 2012 or ask that they guarantee their independence by abandoning the pooling of the equipment and entities that they today require.

Romans-sur-Isère site

Given the malfunctions observed in recent years, ASN will pursue its heightened surveillance of the facility in 2017 in order to ensure that nuclear safety performance of this site's licensee is improved. It will be attentive to compliance with the deadlines for performance of the work defined in the facility's safety improvement plan and the revision of its safety baseline requirements. It will also be attentive to ensuring the implementation of the improvements planned as part of the stress tests.

La Hague site

In 2017, ASN will be particularly vigilant with regard to the development of corrosion in the fission products concentration evaporators. Areva NC shall be required to consolidate its methods for inspecting this equipment and its corrosion forecasts. Areva NC has started to replace this equipment, for gradual commissioning between 2020 and 2021. ASN will examine the corresponding applications.

The work done following the stress tests performed in the wake of the Fukushima Daiichi accident should be completed in the first quarter of 2017. ASN will check correct performance and the correct functioning of the equipment installed, along with the corresponding provisions.

With regard to the forthcoming process of reprocessing changes in the La Hague facility, ASN attaches particular importance to two modifications: On the one hand, the TCP project which will allow reprocessing of several fuel assemblies that could not hitherto be treated, thus postponing saturation of the spent fuel storage pools and, on the other, the replacement of the R7 evaporator, for which the particularly corrosive solutions are currently being concentrated in other equipment in the plant and are liable to damage it.

ASN considers that efforts must be continued for the recovery and packaging of legacy waste. ASN will ensure that any changes in Areva's industrial strategy do not lead to failure to comply with the ASN prescriptions concerning the recovery and removal of waste from silo 130 and the STE2 and HAO sludge.

14 Nuclear research and miscellaneous industrial facilities

The nuclear research and miscellaneous industrial facilities are different from the BNIs involved directly in the generation of electricity (reactors and fuel cycle facilities). These BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), by other research organisations (for example the Laue-Langevin Institute (ILL), the ITER international organisation and the Ganil) or by industrial firms (for instance CIS bio international, Synergy Health and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

The safety principles applicable to these facilities are identical to those applied to power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and detrimental

effects. To improve the way in which these specific risks and detrimental effects are taken into account and in accordance with the resolution of 29th September 2015, ASN placed the installations it regulates into three categories.

Significant events and assessment

With regard to CEA, the generic subjects on which ASN focused in 2016 were:

- the periodic safety reviews, in particular concerning the integration of aspects common to the BNIs on a given site;
- the radioactive waste management system and decommissioning of CEA installations;
- safety management at CEA, checked by two specific inspections on the Cadarache and Saclay centres in 2016.

ASN underlines that the performance of these numerous reviews associated with the preparation of the final shutdown and decommissioning authorisation application files represents a major safety issue, which will require significant resources on the part of CEA, in particular with regard to changes to the regulations. ASN will also be vigilant with regard to the actual initiation of the decommissioning operations on the facilities finally shut down, in accordance with French regulations. In 2017 it will examine the updated decommissioning, post-operational clean-out and waste and materials management strategy at CEA.

ASN considers that the level of safety in the facilities operated by CEA is on the whole satisfactory, in particular the operation of its experimental reactors. However, ASN observes a drift in several CEA projects with an impact on safety and considers that CEA must reinforce its surveillance and its oversight of external contractors in a context of large-scale subcontracting.

With regard to the other nuclear installations, ASN remains concerned by the radiopharmaceutical production facility operated by CIS bio international on the Saclay site. CIS bio international is a key player on the French market for radiopharmaceutical products used for both diagnosis and therapy.

Despite the efforts made by CIS bio international to reinforce its integrated management system and human resources and despite a few improvements noted, ASN considers that these reinforcements remain insufficient to ensure that lasting, concrete results are obtained. Operating rigour, the oversight and conformity of operations, the transverse nature of the organisation, compliance with the facility's baseline requirements, with decisions and with the regulations, for implementation of modifications, must be reinforced.

Owing to the large number of undertakings made by CIS bio international following the review, but not complied with, ASN stipulated completion deadlines for them in February 2016. In 2016, ASN applied administrative enforcement measures for non-compliance with a prescription regarding the removal of radioactive materials.

Following an unannounced inspection in February 2016, ASN served CIS bio international with formal notice to comply with several requirements concerning control of the fire risk. CIS bio international complied with this formal notice.

In 2017, BNI 29 will undergo a periodic safety review, for which a conclusions report shall be submitted no later than 31st July 2018. ASN shall be attentive to CIS bio international's compliance with regulations, prescriptions and its undertakings, to improvements in operating safety and to the progress of the work underway.

Outlook

A wide variety of research and other facilities are regulated by ASN. ASN will continue to oversee the safety and radiation protection of these installations as a whole and compare practices per type of installation in order to choose the best ones and thus promote operating experience feedback. ASN will also continue to develop a proportionate approach to the risks and detrimental effects of the installations, as classified by the resolution of 29th September 2015.

CEA

ASN considers that the "major commitments" approach implemented by CEA since 2006 is on the whole satisfactory.

ASN will be particularly attentive to compliance with the deadlines for transmission of the decommissioning files for CEA's old facilities which have been or will shortly be shut down (in particular Phébus, Osiris, MCMF, Pégase, Eole-Minerve). The Rapsodie reactor is also concerned as are the following waste processing facilities: the storage area (BNI 56) in Cadarache, the effluent treatment station (BNI 37) in Cadarache, the solid radioactive waste management area (BNI 72) in Saclay. The drafting of all these decommissioning files and then performance of these decommissioning operations represents a major challenge for CEA, for which it must make preparations as early as possible. Finally, ASN will monitor the preparation work for the decommissioning of the Osiris reactor shut down in 2015.

In 2017, ASN intends to:

- continue with surveillance of the operations on the RJH reactor construction site and prepare for examination of the future commissioning authorisation application;
- begin examining the significant modification authorisation application for Masurca and examine the safety review file completed by CEA;
- complete its examination of the periodic safety review files for the LEFCA and LECA facilities and decide on the conditions for their possible continued operation.

Other licensees

ASN will continue to pay particularly close attention to ongoing projects; that is ITER and commissioning of the Ganil extension.

ASN will continue to examine the periodic safety review files for Ionisos.

ASN will finalise the examination of complete commissioning of the “hardened safety core” on the RHF operated by the ILL, several years ahead of the other licensees.

Finally, in 2017, ASN will maintain its close surveillance of the radio-pharmaceuticals production plant operated by CIS bio international, with regard to the following points:
- increased operational rigour and safety culture;
- performance of the prescribed work for continued operation of the plant following its last periodic safety review;
- post-operational clean-out work on the very-high level units shut down in the facility.

15 Safe decommissioning of Basic Nuclear Installations

The term decommissioning covers all the activities performed after shutdown of a nuclear facility, in order to attain a final condition in which all the dangerous and radioactive substances have been removed. About thirty nuclear facilities of all types are currently shut down or undergoing decommissioning in France.

Assessment

The year 2016 was marked by the transmission by CEA and Areva of the decommissioning and waste management strategy files for their facilities and by EDF’s announcement of a change in decommissioning strategy for its first-generation GCR (Gas-Cooled Reactors), with decommissioning being postponed by several decades owing to technical difficulties relating to dismantling under water. ASN asked EDF to justify this new strategy with respect to the “decommissioning within a time-frame that is as short as possible” requirement set out by law.

2016 saw the completion of the decommissioning files for four BNIs which were considered to be exhaustive enough to be submitted to a public inquiry at the beginning of 2017. This concerns the decommissioning files for Areva BNIs 93 (Eurodif) and 105 (Comurhex), EDF BNI 94 (AMI Chinon) and CEA BNI 52 (ATUE Cadarache). They received an opinion from the environmental authority in 2016. No facility was delicensed in 2016 but ASN received a delicensing application for the Active Materials Analysis Laboratory (LAMA) (BNI 61) operated by CEA in Grenoble. In 2016, one could also mention the beginning of decommissioning work on the Chooz A reactor vessel and the publication of the Decree of 2nd June 2016 requiring that CEA carry out decommissioning work on the Phenix power plant (BNI 71). The main significant event in 2016 concerned an outside contractor worker who received more than one quarter of the regulation annual effective dose limit in the plutonium technology facility (ATPu) (BNI 32) operated by CEA in Cadarache. The event was rated level 1 on the INES scale.

In October 2016, ASN carried out an in-depth inspection of Areva’s organisation and the progress of legacy waste recovery from the La Hague site, which represents a major safety issue. ASN found that even though efforts have been made to prevent certain operations falling even further behind schedule, sticking points could significantly penalise the progress of other operations. ASN also revealed that the first recovery deadline stipulated by the resolution of 9th December 2014, concerning waste in silo 130, had not been met, even though noteworthy efforts worth

were made to recover these wastes, which was not the case for other projects.

In terms of regulation, ASN issued an opinion on 28th January 2016 on the draft decree updating the procedures surrounding final shutdown and decommissioning of BNIs, by making a clearer distinction than before between final shutdown of the facility and its decommissioning. ASN considers that this Decree, signed on 28th June 2016, represents a notable step forward.

In 2016, ASN updated and published the new version of guide No. 6 concerning final shutdown, decommissioning and delicensing of BNIs and technical guide No. 14 concerning structural post-operational clean-out operations. The provisions of this guide have already been implemented on numerous installations with diverse characteristics, such as research reactors, laboratories, fuel manufacturing plant, etc. Finally, ASN also published guide No.24 on the management of contaminated soils in nuclear installations.

With regard to the financing of decommissioning and the management of the resulting waste by the licensees, ASN issued an opinion to the General Directorate for Energy and Climate on 26th May 2016 regarding the update documents for 2015 supplied by the licensees. In this opinion, it more particularly recalled the importance of regularly reassessing the hypotheses used by the licensees when defining the amounts of the provisions to be set aside.

Outlook

The main actions to be carried out by ASN in 2017 will be to monitor the decommissioning and waste management projects, in particular the recovery and packaging of CEA and Areva legacy waste, concerning which the delays observed are jeopardising the safety of the sites concerned. In particular, the strategy files from these two licensees, submitted in June and December 2016 respectively, will be the subject of an in-depth examination.

ASN will also issue a position statement on EDF's request for a change in strategy regarding the decommissioning of its first-generation gas-cooled reactors.

The periodic safety reviews of the facilities undergoing decommissioning, for which most of the conclusions files will be transmitted by the licensees in 2017, will also be the subject of close examination, appropriate to the risks and detrimental effects of these facilities.

Finally, in order to clarify the regulations on decommissioning and waste management, updated by the Ordinance of February 2016, ASN will continue to develop new guides in these fields as well as in the field of BNI contaminated sites and soils.

16 Radioactive waste and contaminated sites and soils

The term radioactive waste implies radioactive substances for which no subsequent use is planned or envisaged. These substances can come from both nuclear activities and non-nuclear activities in which the radioactivity naturally contained in substances, which are not used for their radioactive properties, has been concentrated by the processes employed.

A site contaminated by radioactive substances is any site, either abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site can constitute a hazard for health and the environment. Contamination by radioactive substances can be the result of industrial, craftwork, medical or research activities.

Significant events

A highlight of 2016 was the finalising of the 2016-2018 French National Plan for Radioactive Material and Waste Management (PNGMDR). This three-year plan presents the rules of the radioactive substances management policy nationwide, identifies new needs and determines the objectives to be achieved, more specifically in terms of studies and research to create new management solutions.

At the beginning of 2017, this Plan was transmitted to Parliament and the Decree and Order of 23rd February 2017 establish its prescriptions.

2016 was also marked by the submission of Andra's safety options file concerning the *Cigéo* deep geological disposal project currently being examined by ASN. In accordance with the request from ASN and ASND, Areva also submitted the waste management and decommissioning strategy file for its facilities. After examination, this file will be the subject of a joint opinion by the two authorities.

Finally, in 2016, ASN published a guide on defining and modifying the BNI waste zoning plan in order to make it easier to apply the regulations concerning the operational management of radioactive waste in these facilities.

Assessment and outlook

Generally speaking, ASN considers that the French radioactive waste management system, built around a specific legislative and regulatory framework, a National Plan for Radioactive Materials and Waste Management (PNGMDR) and the agency Andra for management of radioactive waste independently of the waste producers, is capable of regulating and implementing a structured and coherent national waste management policy. ASN considers that there must eventually be safe management for all waste, more specifically by means of a disposal solution.

The regulations concerning the management of radioactive waste

In 2017, ASN will finalise the resolution concerning the packaging of radioactive waste. It will draw up draft resolutions concerning radioactive waste disposal and storage installations. These draft texts will be made available for consultation by the stakeholders and the public.

Licensee waste management strategies

ASN periodically assesses the strategies put into place by the licensees to ensure that each type of waste has an appropriate solution and that the range of solutions implemented form a coherent whole. ASN in particular remains attentive to ensuring that the licensees have the necessary treatment or storage capacity for managing their radioactive waste and anticipate the construction of new facilities or renovation work on older facilities, sufficiently far in advance. In 2017, ASN will continue to closely monitor the legacy waste or spent fuel retrieval and packaging operations, focusing on those presenting the most significant safety implications.

In this respect, ASN and ASND are evaluating Areva's waste management strategy submitted in mid-2016, and that of CEA, submitted at the end of 2016. ASN and the ASND aim to issue their conclusions in 2018.

Low Level, Long-Lived Waste

With regard to Low Level, Long-Lived radioactive Waste (LLW-LL), ASN considers that progress in the creation of management solutions is essential. Analysis of the file submitted by Andra in 2015, pursuant to the PNGMDR, showed that it will be difficult to demonstrate the feasibility – in the zone investigated – of a repository for all LLW-LL type waste. In its opinion of 29th March 2016, ASN asked that in accordance with the PNGMDR, Andra submit a report by mid-2019, presenting the technical and safety options for this disposal facility and an industrial management system for LLW-LL waste established jointly with the producers of these wastes.

Depending on the results of this report, the waste producers should on the one hand create new storage capacity to avoid delaying decommissioning operations and, on the other, speed up the deployment of alternative strategies if their waste is not compatible with the Andra project.

In 2017, ASN will start revising the safety guide relative to the disposal of LLW-LL type radioactive waste.

High and Intermediate Level, Long-Lived Waste

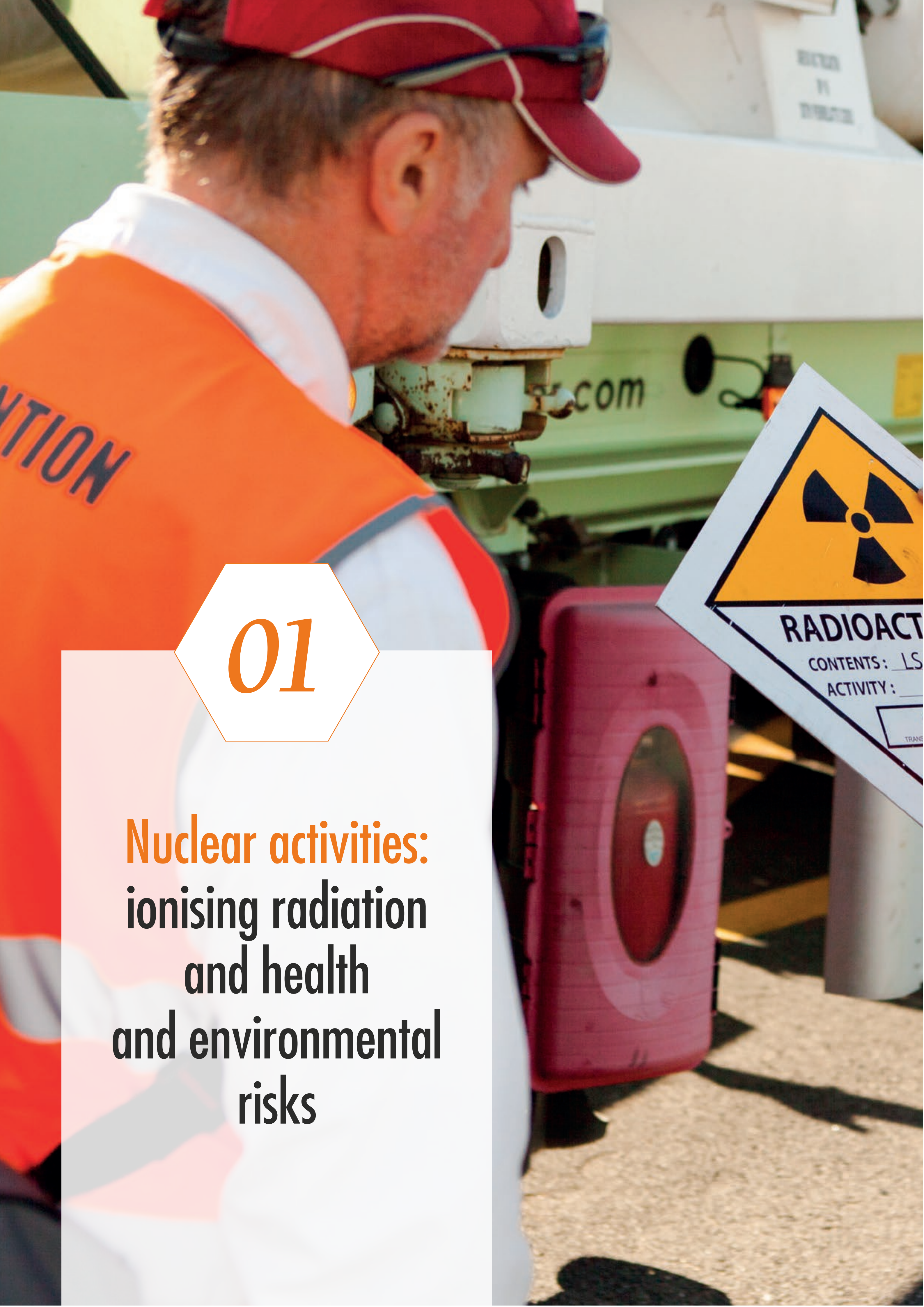
With regard to the *Cigéo* project for the disposal of High and Intermediate Level, Long-Lived Waste (HLW and ILW-LL), 2017 will see the drafting of ASN's opinion on Andra's safety options file for *Cigéo*, submitted by Andra in 2016, more specifically containing the project's safety options, the technical retrievability options, a preliminary version of the waste acceptance specifications and a project development plan. This file is the first overall safety file for the facility since 2009. In particular, it underwent an international peer review under IAEA supervision in November 2016. The ASN opinion, which will be based on a study of the safety options file by the competent advisory committees of experts and on the report from the IAEA experts, shall specify its requirements regarding the content of the *Cigéo* creation authorisation application that Andra aims to submit in mid-2018.

Management of the former uranium mining sites and polluted sites and soils

With regard to the former uranium mining sites, ASN will in 2017 attempt to address the concerns of the Regional Directorates for the Environment, Planning and Housing regarding the Areva Mines action plan for the management of mining waste rock. It will focus more specifically on the management of potentially sensitive cases, in particular with regard to the radon risk. Together with the Ministry responsible for the Environment, it will continue its work and will ensure that any action taken is completely transparent and involves the local stakeholders.

As far as the contaminated sites and soils are concerned, ASN will in 2017 continue to state its position on the projects for the rehabilitation of contaminated sites on the basis of its doctrine published in October 2012 and will work with the Ministry responsible for the Environment on the revision of the Circular of 17th November 2008 relative to the management of certain types of radioactive waste and sites with radioactive contamination. ASN will issue an opinion at the beginning of 2017 on the draft decree to transpose Directive 2013/59/Euratom, which in particular concerns the procedures for oversight and management of sites and soils contaminated by radioactive substances. It will also maintain its investment in the operational management of the Radium Diagnosis operation, the purpose of which is to detect and, as applicable, treat any radium pollution inherited from past activities. It will pursue its action in collaboration with the government departments concerned and the other stakeholders.

ASN will also continue its involvement in international work on these topics, in particular within IAEA, ENSREG, WENRA, as well as bilaterally with its counterparts.



01

Nuclear activities: ionising radiation and health and environmental risks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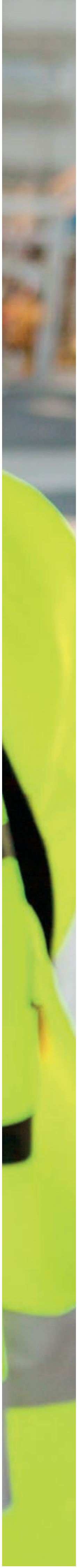


Ionising radiation may be of natural origin or caused by human activities referred to as nuclear activities. The exposure of the population to naturally occurring ionising radiation is the result of the presence of radionuclides of terrestrial origin in the environment, radon emanations from the ground and exposure to cosmic radiation.

Nuclear activities are defined in the Public Health Code as *"activities involving a risk of exposure of persons to ionising radiation associated with the utilisation of artificial sources of radiation, whether substances or devices, or natural sources of radiation, whether natural radioactive substances or materials containing natural radionuclides…"* These nuclear activities include those carried out in Basic Nuclear Installations (BNI) and during the transport of radioactive substances, as well as in the medical, veterinary, industrial and research fields.

The various principles with which the nuclear activities must comply, particularly those of nuclear safety and radiation protection, are set out in chapter 3.

In addition to the effects of ionising radiation, BNIs are similar to all industrial installations in that they are the source of non-radiological risks and detrimental effects such as the discharge of chemical substances into the environment, or noise emission.

1. State of knowledge of the hazards and risks associated with ionising radiation

Ionising radiation is defined as being capable of producing ions – directly or indirectly – when it passes through matter. It includes X-rays, alpha, beta and gamma rays, and neutron radiation, all of which are characterized by different energies and penetration powers.

1.1 Biological and health effects

Whether it consists of charged particles, for example an electron (beta radiation) or a helium nucleus (alpha radiation), or of photons (X rays or gamma rays), ionising radiation interacts with the molecules making up the cells of living matter and alters them chemically. Of the resulting damage, the most significant concerns the DNA of the cells and this damage is not fundamentally different from that caused by certain toxic chemical substances, whether exogenous or endogenous (resulting from cellular metabolism).

When not repaired by the cells themselves, this damage can lead to cell death and the appearance of harmful biological effects if tissues are no longer able to carry out their functions.

These effects, called "deterministic effects", have been known for a long time, as the first effects were observed with the discovery of X rays by W. Roentgen (in the early 1900's). They depend on the nature of the exposed tissue and are certain to appear as soon as the quantity of radiation absorbed exceeds a certain dose level. These effects include, for example, erythema, radiodermatitis, radionecrosis and cataract formation. The higher the radiation dose received by the tissue, the more serious the effects.

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular type because residual genetic anomalies can be transmitted by successive cellular divisions to new cells. A single genetic mutation is far from being sufficient to cause the transformation into a cancerous cell, but this damage due to ionising radiation may be a first step towards cancerisation.

The suspicion of a causal link between exposure to ionising radiation and the appearance of a cancer dates back to 1902 (observation of skin cancer in a case of radiodermatitis).

Subsequently, several types of cancers were observed in occupational situations, including certain types of leukemia, broncho-pulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than 60 years of a cohort of about 85,000 people irradiated at Hiroshima and Nagasaki has enabled the regular assessment of the morbidity[1] and mortality due to cancer following exposure to ionising radiation, and the description of the dose-effects relationships – which often form the basis of current regulations. Other epidemiological work

1. *Number of persons suffering from a given disease for a given time – usually one year – in a population.*

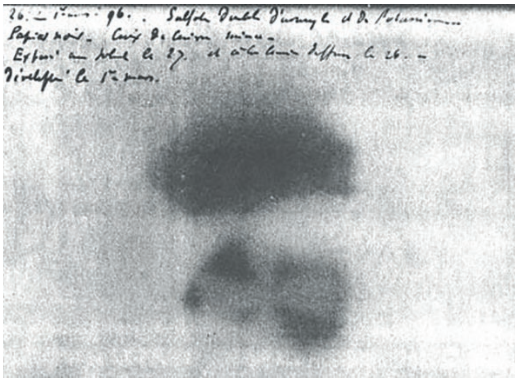


Image of the Maltese cross placed in the darkness between the uranium ore and the photographic plate, work of 26th February 1896 (photograph and annotation by Henri Becquerel).

has revealed a statistically significant rise in cancers (secondary effects) among patients treated using radiotherapy and attributable to ionising radiation. We can also mention the Chernobyl accident which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in young people exposed during their childhood. The consequences of the Fukushima Daiichi accident on the health of the neighbouring populations are not yet sufficiently known and analysed to draw epidemiological lessons from them.

The risk of radiation-induced cancer appears at different levels of exposure and is not linked to the exceeding of a threshold. It is revealed by an increase in the probability of cancer in a population of a given age and sex. These are then called probabilistic, stochastic or random effects.

The internationally established public health objectives related to radiation protection aim to prevent the appearance of deterministic effects and reduce the probabilities of cancers arising from exposure to ionising radiation, which are also known as radiation-induced (or radio-induced) cancers; the results of the studies as a whole seem to indicate that radiation-induced cancers represent the predominant health risk associated with exposure to ionising radiation.

1.2 Evaluation of risks linked to ionising radiation

The monitoring of cancers in France is based on 14 general registers in metropolitan France (covering 18 *départements* and the greater Lille urban area) and 3 registers in the overseas French *départements*. In addition to this, there are 12 specialised registers: 9 *département* registers covering 16 continental *départements*, 2 national cancer registers for children under 15 years of age concerning malignant haemopathy and solid tumours, and 1 multicentric mesothelioma register for France as a whole.

The aim of the register for a given area is to highlight differences in spatial distribution, to reveal changes over time in terms of increased or reduced incidence in the different cancer locations, or to identify clusters of cases.

This method of monitoring aims to be descriptive but is unable to highlight any causal effect between an exposure to ionising radiation and cancers, given that other environmental factors may also be suspected. Furthermore, it should be noted that the *département* registers do not necessarily cover the areas close to the nuclear installations.

Epidemiological investigation is complementary to monitoring. The purpose of epidemiological surveys is to highlight an association between a risk factor and the occurrence of a disease, between a possible cause and an effect, or at least to enable such a causal relation to be asserted with a very high degree of probability. The intrinsic difficulty in conducting these surveys or in reaching a convincing conclusion when the illness is slow to appear or when the expected number of cases is low, which is the case with low exposure levels of a few tens of millisieverts (mSv) for example, must be borne in mind. Cohorts such as that of Hiroshima and Nagasaki have clearly shown an excess of cancers, with the average exposure being about 200 mSv; studies on nuclear industry workers published in recent years suggest risks of cancer at lower doses (cumulative doses over several years).

These results support the justification of radiological protection of populations exposed to low doses of ionising radiation (nuclear industry workers, medical personnel, medical diagnostic exposure, etc.).

Low-dose risks are assessed for risk-management purposes by extrapolating the risks observed at higher doses. This calculation gives an estimate of the risks entailed by exposure to low doses of ionising radiation. For these estimates, the prudent hypothesis of a linear no-threshold relationship between exposure and the number of deaths from cancer has been adopted internationally. This hypothesis implies that there is no dose threshold below which one can assert that there is no effect. The legitimacy of these estimates and of this hypothesis nevertheless remains scientifically controversial, as very large scale studies would be necessary to further support the hypothesis.

On the basis of the scientific syntheses of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) has published the risk coefficients for death by cancer due to ionising radiation, i.e. 4.1% excess risk per Sievert (Sv) for workers and 5.5% per Sievert for the general public (see ICPR publication 103, chapter 3, point 1.1.1).

The evaluation of the risk of lung cancer due to radon[2] is based on a large number of epidemiological studies conducted directly in the home in France and on an international scale. These studies have revealed a linear relationship, even at low exposure levels (200 becquerels per cubic metre (Bq/m^3)) over a period of 20 to 30 years. The World Health Organisation (WHO) has made a synthesis of the studies and recommends maximum annual exposure levels of between 100 and 300 Bq/m^3 for the general public. ICRP publication 115 compared the risks of lung cancer observed through studies on uranium miners with those observed in the overall population and concluded that there was a very good correlation between the risks observed in these two conditions of exposure to radon. The ICRP recommendations confirm those issued by the WHO which considers that, after tobacco, radon constitutes the highest risk factor in lung cancer.

In metropolitan France, about 19 million people spread over some 9,400 municipalities are potentially exposed to high radon concentrations. According to InVS (French Health Monitoring Institute) figures from 2007, between 1,200 and 2,900 deaths from lung cancer can be attributed each year to radon exposure in the home, that is to say between 4 and 10% of deaths due to lung cancer (30,555 deaths, National Cancer Institute – INCa – 2015)[3]. A national action plan for managing radon-related risks has been implemented since 2004 on the initiative of ASN and is updated periodically (see point 3.2.2).

1.3 Scientific uncertainties and vigilance

The action taken in the fields of nuclear safety and radiation protection in order to prevent accidents and limit detrimental effects has led to a reduction in risks but not to zero risk, whether in terms of the doses received by workers or those associated with discharges and releases from BNIs. However, many uncertainties persist and require that ASN remains attentive to the results of the scientific work in progress, for example in radiobiology and radiopathology, with possible consequences for radiation protection, particularly with regard to management of risks at low doses.

One can mention, for example, several areas of uncertainty concerning radiosensitivity, the effects of low doses, the signature of mutations that could be observed in radiation-induced cancers and certain non-cancerous diseases observed in radiotherapy follow-ups.

2. *Radon is a natural radioactive gas, a daughter product of uranium and thorium, an emitter of alpha particles and is classified as a known human pulmonary carcinogen by the International Agency for Research on Cancer - IARC.*
3. *The new results concerning the risk of death by cancer other than leukemia were published in the British Medical Journal; those on the leukemia risk were published in the* Lancet.

1.3.1 Radiosensitivity

The effects of ionising radiation on personal health vary from one individual to the next. Since it was stated for the first time by Bergonié and Tribondeau in 1906, it is for example known that the same dose does not have the same effect when received by a growing child or by an adult.

The variability in individual radiosensitivity to high doses of ionising radiation has been extensively documented by radiotherapists and radiobiologists. High levels of radiosensitivity have been observed in persons suffering from genetic diseases affecting the repair of DNA and cellular signalling; in these individuals they can lead to "radiological burns".

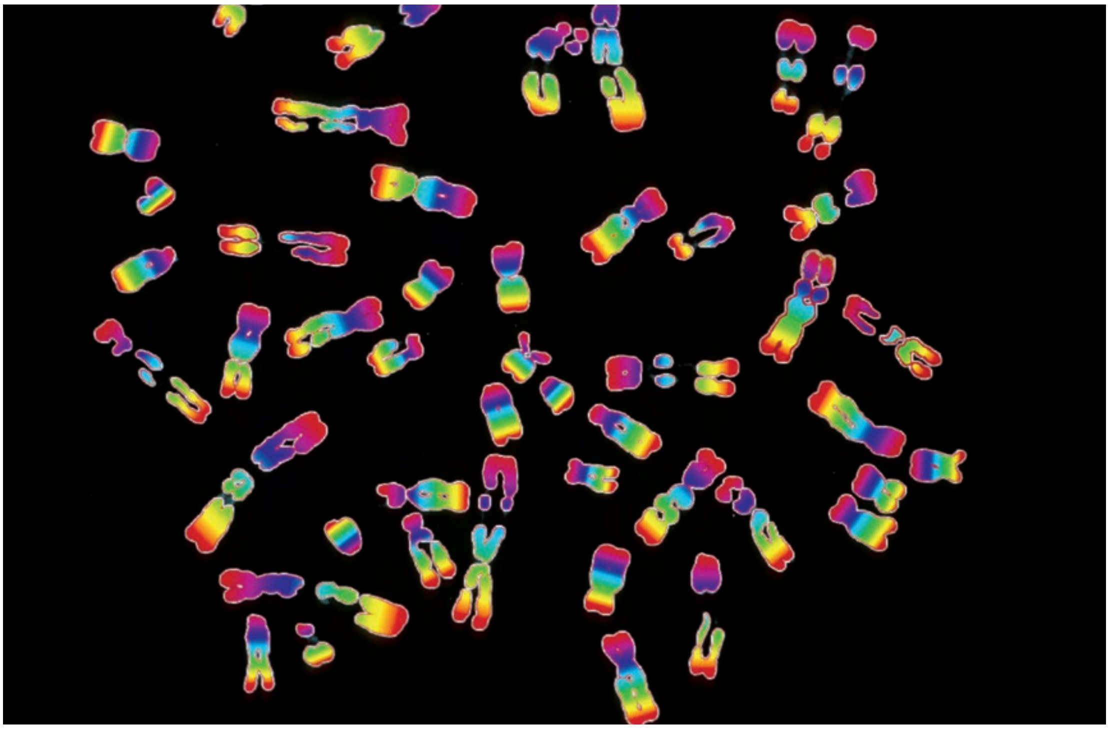
At low doses, there is both cell radiosensitivity and individual radiosensitivity, which could concern about 5 to 10% of the population. Recent methods of immunofluorescence of molecular targets for signalling and repairing DNA damage help to document the effects of ionising radiation at low doses, reducing the detection thresholds by a factor of 100. The biochemical and molecular effects of a simple X-ray examination then become visible and measurable. The results of the research work conducted using these new investigation methods must still be confirmed in the clinical environment before being integrated into medical practices.

This then raises delicate issues, some of which go beyond the strict context of radiation protection:
- If tests for evaluating individual radiation hypersensitivity become available, should screening prior to any radiotherapy or repeated computed tomography examinations be recommended?
- Should one try to determine the degree of radiosensitivity of workers who could be exposed to ionising radiation?
- Should the general regulations provide for specific protection for persons concerned by high radiosensitivity to ionising radiation?

These questions have ethical implications owing to the potential use of the results of individual radiation sensitivity tests, for example to discriminate between potential employees.

All things considered, there should be no unnecessary exposure of individuals to ionising radiation, in other words without justification. Children should receive particularly close attention in the event of exposure to ionising radiation for medical purposes.

After the publication in 2014 of the conclusions of the seminar ASN organised on 16th December 2013, ASN remains attentive to progress in the knowledge and international reflections (IRCP in particular) to prepare for the statutory resolutions that might or will have to be taken.


Pairs of chromosomes have characteristic bands of colouring (Inserm).

1.3.2 Effects of low doses

The Linear No-Threshold (LNT) relationship. The hypothesis of this relationship, adopted to model the effects of low doses on health (see point 1.2), albeit practical from the regulatory standpoint and albeit conservative from the health standpoint, is not as scientifically well-grounded as might be hoped for: some feel that the effects of low doses could be higher, while others believe that these doses could have no effect below a certain threshold, and some others even assert that low doses have a beneficial effect. Research in molecular and cellular biology is progressing, as are epidemiological surveys of large cohorts. But faced with the complexity of the DNA repair and mutation phenomena, and the methodological limitations of epidemiology, uncertainties remain and the public authorities must exercise caution.

Dose, dose rate and chronic contamination. The epidemiological studies performed on individuals exposed to the Hiroshima and Nagasaki bombings have given a clearer picture of the effects of radiation on health, concerning exposure due to external irradiation (external exposure) received in a few fractions of a second at high dose and high dose rate. The studies carried out in the countries most affected by the Chernobyl accident (Belarus, Ukraine and Russia) were also able to improve our understanding of the effects of radiation on health resulting from exposure through internal contamination (internal exposure) more specifically through radioactive iodine. Studies on nuclear workers have given a clearer picture of the risk due to chronic exposure established over many years, whether as a result of external exposure or internal contamination.

Hereditary effects. The appearance of possible hereditary effects from ionising radiation in humans remains uncertain. Such effects have not been observed among the survivors of the Hiroshima and Nagasaki bombings. However, hereditary effects are well documented in experimental work on animals: mutations induced by ionising radiation in embryonic germ cells can be transmitted to descendants. The recessive mutation of one gene on one chromosome will produce no clinical or biological indications as long as the same gene carried by the other counterpart chromosome is not affected. Although it cannot be absolutely ruled out, the probability of this type of event nonetheless remains low.

Environmental Protection. The purpose of radiation protection is to prevent or mitigate the harmful effects of ionising radiation on individuals, directly or indirectly, including in situations of environmental contamination. Over and beyond environmental protection aiming at the protection of humans and present or future generations, the protection of non-human species as such forms part of the environmental protection prescribed in the French constitutional Charter for the Environment. This subject has been taken into consideration by the ICRP since 2007 (ICRP 103), and the practical means of dealing with the protection of nature in the specific interests of animal and plant species has been the subject of several publications since 2008 (ICRP 108, 114 and 124).

1.3.3 Signature of mutations in radiation-induced cancers

It is currently impossible to distinguish a radiation-induced cancer from a cancer that is not radiation induced. The reason for this is that the molecular lesions caused by ionising radiation seem no different to those resulting from the normal cellular metabolism, with the involvement of free radicals – oxygenated in particular – in both cases. Furthermore, to date, neither anatomopathological examinations nor research for specific mutations have been able to distinguish a radiation-induced tumour from a sporadic tumour. Recent work however (Behjati et al. 2016) seems to indicate that two types of mutations are apparently more frequent; the small sample size nevertheless necessitates the validation of these data through more extensive studies.

It is known that in the first stages of carcinogenesis a cell develops with a particular combination of DNA lesions that enables it to escape from the usual control of cellular division, and that it takes about ten to one hundred DNA lesions (mutations, breaks, etc.) at critical points to pass through these stages. All the agents capable of damaging cellular DNA (tobacco, alcohol, various chemical substances, ionising radiation, high temperature, other environmental factors, notably nutritional and free radicals of normal cellular metabolism, etc.) contribute to cellular aging, and ultimately to carcinogenesis.

Consequently, in a multi-risk approach to carcinogenesis, can we still talk about radiation-induced cancers? Yes we can, given the large volumes of epidemiological data which indicate that the frequency of cancers increases as the dose increases, but the approach is undoubtedly more complex, since in certain cases cancer results from an accumulation of lesions originating from different risk factors. However, the radiation-induced event can also in certain cases be the only event responsible (radiation-induced cancers in children).

Highlighting a radiation signature of cancers, that is to say the discovery of markers that could indicate whether a tumour has a radiation-induced component or not, would be of considerable benefit in the evaluation of the risks associated with exposure to ionising radiation.

The multifactorial nature of carcinogenesis pleads in favour of a precautionary approach with regard to all the risk factors, since each one of them can contribute to DNA impairment. This is particularly important in persons displaying high individual radiosensitivity and for the most sensitive organs such as the breast and the bone marrow, and all the more so if the persons are young. Here, the principles of justification and optimisation are more than ever applicable (see chapter 2).

2. The different sources of ionising radiation

2.1 Natural radiation

In France, exposure to the different types of natural radioactivity (cosmic or terrestrial) represents on average about 65% of the total annual exposure.

2.1.1 Natural terrestrial radiation (excluding radon)

Natural radionuclides of terrestrial origin are present at various levels in all the compartments of our environment, including inside the human body. They lead to external exposure of the population owing to gamma rays emitted by the uranium-238 and thorium-232 daughter products and by the potassium-40 present in the soil, but also to internal exposure by inhalation of particles in suspension and by ingestion of foodstuffs or drinking water.

The levels of natural radionuclides in the ground are extremely variable. The external exposure dose rate values in the open air in France, depending on the region, range from a few nanosieverts per hour (nSv/h) to 100 nSv/h.

The dose rate values inside residential premises are generally higher owing to the contribution of construction materials (about 20% higher on average).

Based on assumptions covering the time individuals spend inside and outside residential premises (90% and 10% respectively), the average effective dose due to external exposure to gamma radiation of terrestrial origin in France is estimated at about 0.5 mSv per person per year.

The doses due to internal exposure of natural origin vary according to the quantities of radionuclides of the uranium and thorium families incorporated through the food chain, which depend on each individual's eating habits. According to IRSN (the Institute of Radiation Protection and Nuclear Safety) (2015), the average dose per individual would be about 0.32 mSv per year. The average concentration of potassium-40 in the organism is about 55 Bq per kilogram, resulting in an average effective dose of about 0.18 mSv per year.

Waters intended for human consumption, in particular groundwater and mineral waters, become charged in natural radionuclides owing to the nature of the geological strata in which they spend time. The concentration of uranium and thorium daughters, and of potassium-40, varies according to the resource exploited, given the geological nature of the ground.

For waters displaying high radioactivity, the annual effective dose resulting from daily consumption (2 litres/inhabitant/day) may reach several tens or hundreds of microsieverts (µSv).

2.1.2 Radon

Some geological areas have a high radon exhalation potential due to the geological characteristics of the ground (granitic bedrock, for example). The concentration measured inside homes also depends on the tightness of the building (foundations) and the ventilation of the rooms.

So-called "domestic" exposure to radon (radon in dwellings) was estimated by IRSN (French Institute for Radiation Protection and Nuclear Safety) through measurement campaigns followed by statistical interpretations (see *www.irsn.fr*). The average radon activity value measured in France is 63 Bq/m^3, with about half the results being below 50 Bq/m^3, 9% above 200 Bq/m^3 and 2.3% above 400 Bq/m^3.

These measurements have allowed the French *départements* to be classified according to the radon exhalation potential of the ground (see map below).

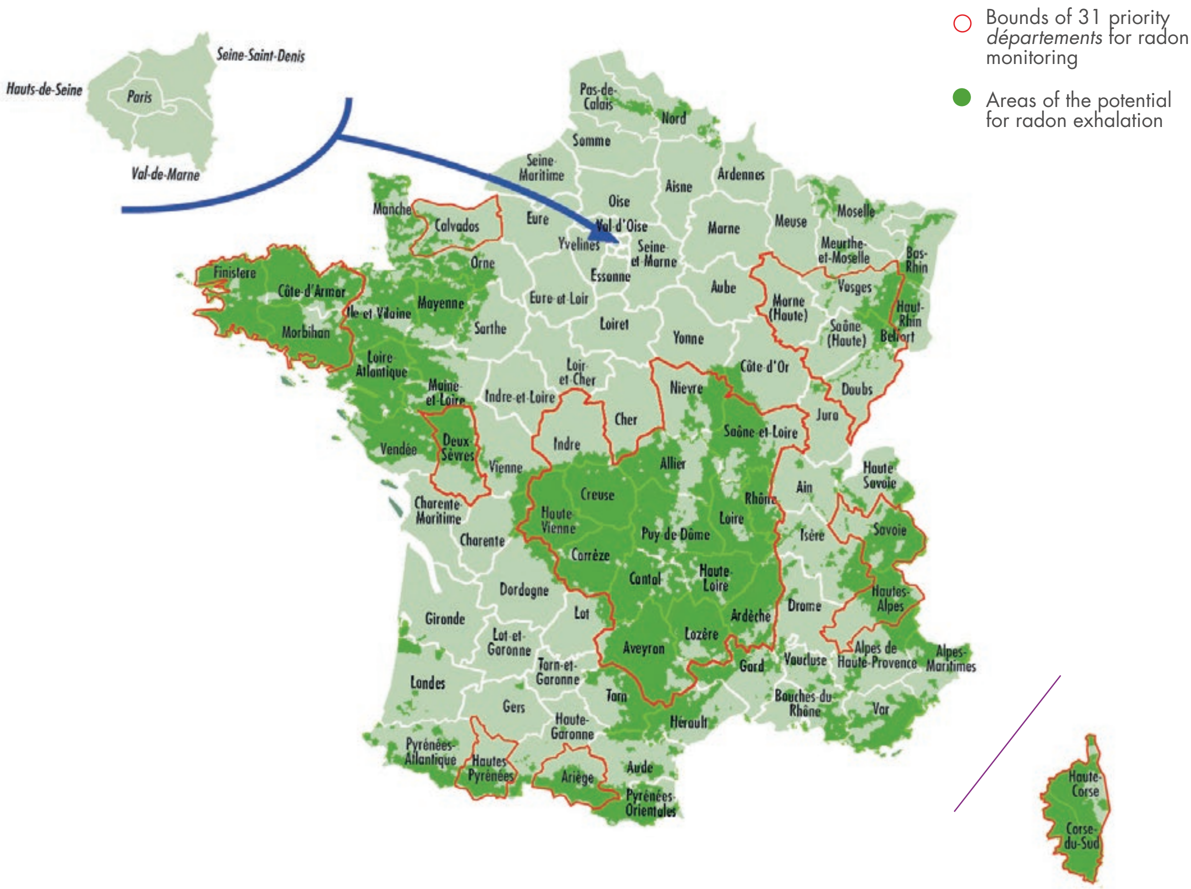
In 2011, IRSN published a new map of France considering the radon exhalation potential of the ground, based on data from the French Geological and Mining Research Office. A finer classification per municipality will be based on this and will be available in 2017.

2.1.3 Cosmic radiation

The cosmic radiation from ionic and neutronic components is also accompanied by electromagnetic radiation. At sea level, the dose rate resulting from electromagnetic radiation is estimated at 32 nSv per hour and that resulting from the neutronic component at 3.6 nSv per hour.

Considering the average time spent inside the home (which itself attenuates the ionic component of the cosmic radiation), the average individual effective dose

RADON exhalation potential in metropolitan France (source: IRSN)



in a locality at sea level in France is 0.27 mSv per year, whereas it could exceed 1.1 mSv per year in a mountain locality situated at an elevation of about 2,800 metres. The average annual effective dose per individual in France is 0.32 mSv. It is lower than the global average value of 0.38 mSv per year published by UNSCEAR.

On account of the increased exposure to cosmic radiation due to extensive periods spent at high altitude, flight personnel must be subject to dosimetric monitoring (see point 3.1.3).

2.2 Ionising radiation arising from human activities

The human activities involving a risk of exposure to ionising radiation, called nuclear activities, can be grouped into the following categories:
- operation of Basic Nuclear Installations;
- transport of radioactive substances;
- small-scale nuclear activities;
- disposal of radioactive waste;
- management of contaminated sites;
- activities enhancing natural ionising radiation.

2.2.1 Basic nuclear installations

Regulations classify nuclear facilities, called Basic Nuclear Installations (BNI), in various categories corresponding to more or less restrictive procedures, depending on the significance of the potential risks (see chapter 3, point 3).

The main BNI categories are:
- nuclear reactors;
- some particle accelerators;
- the plants that prepare, enrich or transform radioactive substances, particularly nuclear fuel production plants, irradiated fuel processing plants, and the facilities for processing and storing the radioactive waste produced by these plants;
- the installations intended for the processing, disposal, storage or use of radioactive substances, including waste, when the quantities involved exceed thresholds set by regulations.

The list of BNIs as at 31st December 2016 figures in an appendix to this report.

Accident prevention and nuclear safety

The fundamental internationally adopted principle underpinning the specific organisational system and regulations applicable to nuclear safety is that of the responsibility of the licensee (see chapter 2). The public authorities ensure that this responsibility is fully assumed, in compliance with the regulatory requirements.

As regards the prevention of risks for workers, BNI licensees are required to implement all necessary means to protect workers against the hazards of ionising radiation. They must more particularly ensure compliance with the general rules applicable to all workers exposed to ionising radiation (work organisation, accident prevention, medical monitoring of workers, including those from outside contractors , etc.) (see chapter 3).

As regards protection of the population and the environment, the BNI licensee must also take all necessary steps to achieve and maintain an optimum level of protection. Discharges of liquid and gaseous effluents, whether radioactive or not, are in particular strictly limited (see chapter 4).

2.2.2 Transport of radioactive substances

When transporting radioactive substances, the main risks are those of internal or external exposure, criticality, as well as risks of a chemical nature. Safe transport of radioactive substances relies on an approach called defence in depth:
- The robustness of the packaging is the first line of defence. The packaging plays a vital role and must withstand the foreseeable transport conditions.
- The reliability of the transport operations constitutes the second line of defence.
- Finally, the third line of defence consists of the response resources implemented to deal with an incident or accident.

2.2.3 Small-scale nuclear activities

Ionising radiation, whether emitted by radionuclides or generated by electrical equipment, is used in many areas, including medicine (radiology, radiotherapy, nuclear medicine, cell irradiators), biology, research, industry, but also for veterinary and forensic applications as well as for the conservation of foodstuffs.

The employer is required to take all necessary measures to protect workers against the hazards of ionising radiation. The facility licensee must also implement the provisions of the Public Health Code for the management of the ionising radiation sources in its possession (radioactive sources in particular) and, where applicable, manage the waste produced and limit discharges of liquid and gaseous effluents. In the case of use for medical purposes, patient protection issues are also taken into account (see chapter 3).

2.2.4 Radioactive waste management

Like all industrial activities, nuclear activities can generate waste, some of which is radioactive. The three fundamental principles on which strict radioactive waste management is based are the accountability of the waste producer, the traceability of the waste and public information.

The technical management provisions to be implemented must be tailored to the hazard presented by the radioactive waste. This hazard can be assessed primarily through two parameters: the activity level, which contributes to the toxicity of the waste, and the half-life, the time after which the activity level is halved.

Finally, management of radioactive waste must be determined prior to any creation of new activities or modification of existing activities in order to:
- ensure the availability of processing channels for the various categories of waste likely to be produced, from the front-end phase (production of waste and packaging) to the back-end phase (storage, transport and disposal);
- optimise the waste disposal routes.

2.2.5 Management of contaminated sites

Management of sites contaminated by residual radioactivity resulting either from a past nuclear activity or an activity which generated deposits of natural radionuclides warrants specific radiation protection actions, in particular if rehabilitation is envisaged.

Depending on the current and future uses of the site, decontamination objectives must be set. The removal of the waste produced during post-operation clean-out of the contaminated premises and remediation of soil must be managed from the site through to storage or disposal. The management of contaminated objects also follows these same principles.

2.2.6 Industrial activities resulting in the enhancement of natural ionising radiation

Exposure to ionising radiation of natural origin, when increased due to human activities, justifies measures to monitor or even to assess and manage the risk, if it is likely to create a hazard for the exposed workers and, where applicable, the neighbouring population.

Thus, certain professional activities now included in the definition of «nuclear activities» (see chapter 3) can significantly increase the exposure of the workers to ionising radiation and, to a lesser extent, exposure of the populations in the vicinity of the locations where these activities are carried out, for example in the event of discharge of effluents into the environment. This is particularly the case with activities using raw materials or industrial residues containing natural radionuclides which are not used for their fissile or fertile radioactive properties.

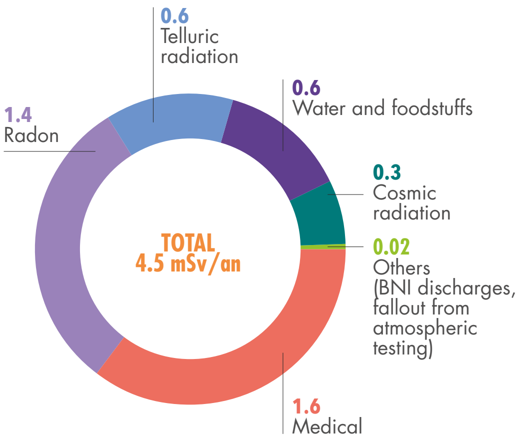
The natural families of uranium and thorium are the main radionuclides found. Among the industries concerned we can mention phosphate extraction and phosphate fertiliser production industries, granite mining industries, colouring pigment industries, especially those using titanium oxide and those working certain ores and rare earth elements, and facilities performing filtration treatment of groundwater flowing through crystalline rocks.

The radiation protection actions required in this field are based on the precise identification of the activities, the estimation of the impact of the exposure on the individuals concerned, and the implementation of corrective actions to reduce this exposure if necessary and monitoring.

Transportation of a shielded syringe containing a radioisotope by a radiographer wearing a monthly and daily dosimeter in the Georges-Pompidou hospital.

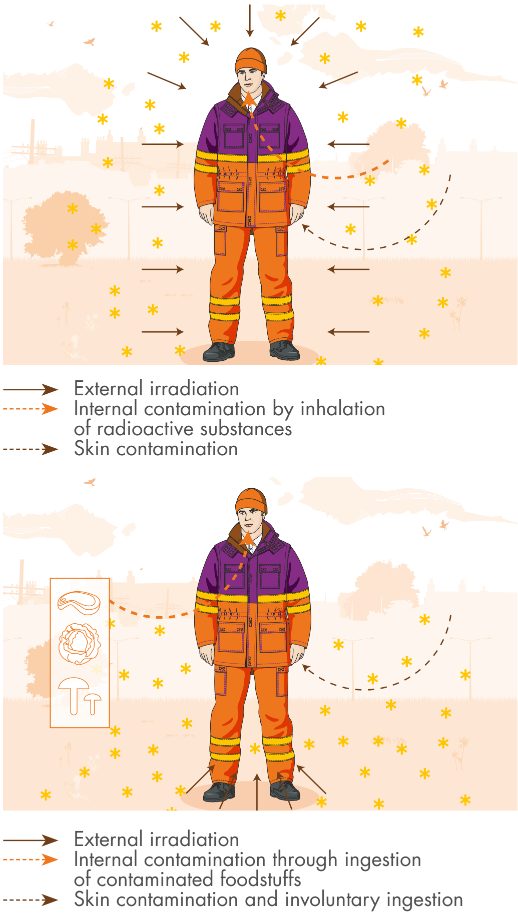
3. Monitoring of exposure to ionising radiation

DIAGRAM 1: Average exposure of the French population to ionising radiation (mSv/year)



Source: IRSN 2015

SOURCES AND ROUTES OF EXPOSURE to ionising radiation



Given the difficulty in attributing a cancer solely to the ionising radiation risk factor, "risk monitoring" is performed by measuring ambient radioactivity indicators (measurement of dose rates for example), internal contamination or, failing this, by measuring values (activities in radioactive effluent discharges) which can then be used – by modelling and calculation – to estimate the doses received by the exposed populations.

The entire population of France is exposed to ionising radiation of natural or anthropogenic origin, but to different extents across the country. The average exposure of the French population is estimated at 4.5 mSv (see diagram 1) per person per year, but this exposure is subject to wide individual variability, particularly depending on the place of residence and the number of radiological examinations received (source: IRSN 2015); the average annual individual effective dose can thus vary by a factor of up to 5 depending on the *département*. Diagram 1 represents an estimate of the respective contributions of the various sources of exposure to ionising radiation for the French population.

These data are however still too imprecise to allow identification of the most exposed categories or groups of individuals for each exposure source category with the exception of the radon risk.

3.1 Doses received by workers

3.1.1 Exposure of persons working in nuclear facilities

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, particularly those working in BNIs or in small-scale nuclear facilities, has been in place for several decades. This system is primarily based on the mandatory wearing of a passive dosimeter by workers liable to be exposed and it is used to check compliance with the regulation limits applicable to workers: these limits concern, on the one hand, the total exposure (since 2003, the annual limit, expressed in terms of effective dose, has been 20 mSv for 12 consecutive months), obtained by adding the dose due to external exposure to that resulting from any internal contamination; other limits, called equivalent dose limits, are defined for the external exposure of certain parts of the body such as the hands and the lens of the eye (see chapter 3).

The recorded data allow the identification of the cumulative exposure dose for a given period (month or quarter) for each person working in nuclear facilities, including workers from subcontractor companies. They are grouped together in Siseri (Ionizing radiation exposure monitoring information system) managed by IRSN and are published annually. The monitoring system does not include worker exposure to radon.

TABLE 1: Monitoring of external exposure of nuclear workers (year 2015)

Source: IRSN

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv*)	INDIVIDUAL DOSE >20 mSv
Reactors and energy production (EDF)	25,569	7.91	0
Fuel cycle; decommissioning	8,187	2.31	0
Transport	609	0.12	0
Logistics and maintenance (contractors)	12,992	10.04	0
Effluent, waste	83	0	0
Others	20,681	6.68	0

TABLE 2: Monitoring of external exposure of workers in small-scale nuclear activities (year 2015)

Source: IRSN

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv*)	INDIVIDUAL DOSE > 20 mSv
Medicine	131,612	11.47	1
Dental	51,103	2.06	0
Veterinary	20,824	0.52	0
Industry	36,797	17.99	1
Research	13,223	0.42	0
Miscellaneous	24,835	1.35	0

** Man.Sv: Unit of quantity of collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.*

For each sector, tables 1 and 2 give the breakdown into the populations monitored, the collective dose and the number of times the annual limit of 20 mSv was exceeded. They clearly show a significant disparity in the breakdown of doses depending on the sector. For example, the medical and veterinary activities sector, which comprises a significant share of the population monitored (nearly two thirds of the total), in fact only accounts for about 25% of the collective dose, the nuclear industry however, which represents about 20% of the headcount, accounts for more than 40% of the collective dose. The industrial sector, which represents just 10% of the headcount, accounts for 30% of the collective dose.

The latest statistics show a slight but regular increase in the number of persons subject to dosimetric monitoring since 2005 (see diagram 2); the mark of 350,000 individuals was exceeded in 2012. This trend is largely due to the increase in the number of persons monitored in the fields of medical and veterinary activities. After a slight decrease in 2013, for the first time since 2001, the years 2014 and 2015 again show a slight increase in the number of persons monitored.

At the same time, the overall collective annual dose has decreased (by about 50% since 1996, whereas the number of people monitored has increased by about 60%). The collective dose did however display an upward trend between 2006 and 2009, followed

Wearing of active dosimeter and passive dosimeter by hospital personnel.

by a levelling off over the 2009 -2012 period. After a singular increase in 2013, the collective dose for 2015 (61.9 man.Sv) is returning to values similar to those observed over the 2009-2012 period.

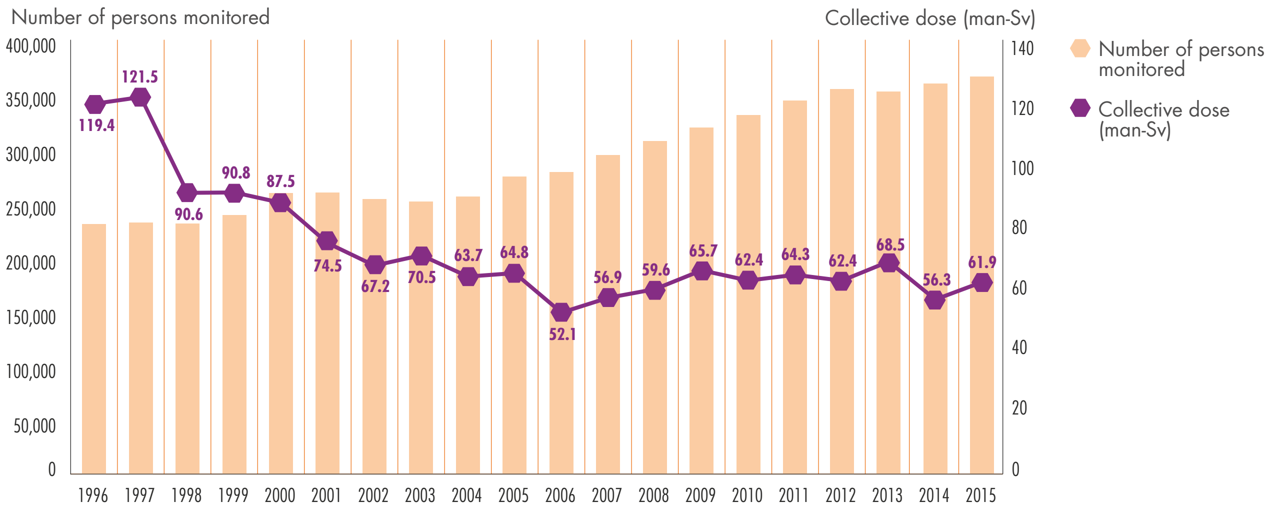
The number of monitored workers whose annual effective dose exceeded 20 mSv dropped in 2015; only two cases exceeding the annual effective dose limit were observed: one in the medical sector, the other in the industrial activities sector (effective dose of 81.9 mSv for an operator during an industrial radiography activity (see diagram 3).

With regard to the dosimetry of the extremities (fingers and wrist), 28,070 workers were monitored in 2015 (i.e. 7.7% of the total number of persons monitored). Of all the persons monitored, there was just one case where the 500 mSv regulatory equivalent dose limit at the extremities was exceeded (about 685 mSv for a medical worker).

For the first time, the data concerning monitoring of exposure of the lens of the eye are available, but the number of persons monitored remains very low (200 persons) and does not enable any conclusions to be reached with regard to compliance with the new regulatory dose limit for the lens of the eye (20 mSv/year).

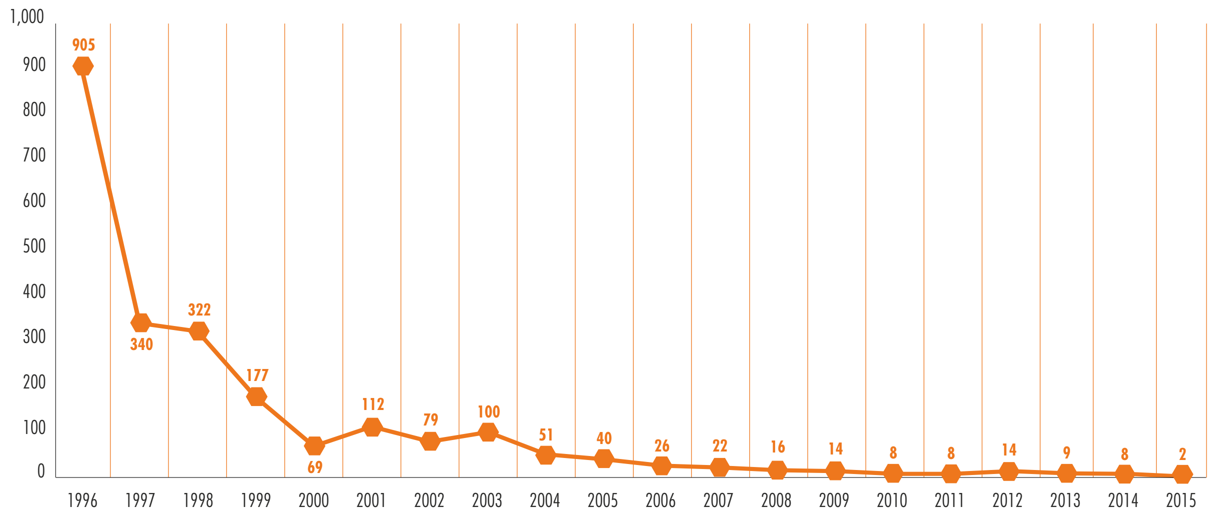
The results of dosimetric monitoring of worker external exposure in 2015 published by IRSN in June 2016 show on the whole that the prevention system introduced in facilities where sources of ionising radiation are used is effective, because for more than 96% of the population monitored, the annual dose remained lower than 1 mSv (effective annual dose limit for the public as a result

DIAGRAM 2: Monitored population and collective dose trends, from 1996 to 2015



Source: IRSN

DIAGRAM 3: Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2015



Source: IRSN

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Results of dosimetry monitoring of worker external exposure to ionising radiation in 2015

(source: Occupational exposure to ionising radiation in France - 2015 results, IRSN, June 2016)

- Total population monitored: 365,830 workers.
- Monitored population for whom the dose remained below the detection threshold: 280,047 workers, or nearly 77%.
- Monitored population for whom the dose remained between the detection threshold and 1 mSv: 71,645 workers, or about 19%.
- Monitored population for whom the dose remained between 1 mSv and 20 mSv: 14,136 workers, or nearly 4%.
- Monitored population for whom the annual effective dose of 20 mSv was exceeded: 2 including 1 above 50 mSv.
- Collective dose (sum of individual doses): 61.94 man-Sv.
- Annual average individual dose in the population which recorded a dose higher than the detection threshold: 0.72 mSv

Results of internal exposure monitoring in 2015

- Number of routine examinations carried out: 279,877 (of which fewer than 0.5% were considered positive).
- Population for which dose estimation was made: 588 workers.
- Number of special monitoring examinations or verifications performed: 11,196 (of which 16% were above the detection threshold).
- Population having recorded a committed effective dose exceeding 1mSv: 2 workers.

Results of cosmic radiation exposure monitoring in 2015 (civil aviation)

- Collective dose for 19,565 flight crew members: 38.65 man-Sv.
- Annual average individual dose: 1.98 mSv.

of nuclear activities). Exceeding the regulatory limit values remains exceptional.

3.1.2 Worker exposure to TENORM (Technologically Enhanced Naturally Occurring Radioactive Materials)

Occupational exposure to enhanced natural ionising radiation is the result either of the ingestion of dust containing large amounts of radionuclides (phosphates, metal ore), or of the inhalation of radon formed by uranium decay (poorly ventilated warehouses, thermal baths) or of external exposure due to process deposits (scale forming in piping for example).

The results of the studies carried out in France since 2005 and published by ASN in January 2010, as well as the studies received since then, show that 85% of the doses received by workers in the industries concerned remained below 1 mSv/year. The industrial sectors in which worker exposure is liable to exceed 1mSv/year are the following: titanium ore processing, heating systems and recycling of refractory ceramics, maintenance of parts comprising thorium alloys in the aeronautical sector, chemical processing of zircon ore, mechanical transformation and utilisation of zircon and processing of rare earths. In its last assessment concerning the information collected in 2015, IRSN notes that the trends observed and published in 2010 remain valid in the light of the files received.

3.1.3 Flight crew exposure to cosmic radiation

Airline flight crews and certain frequent flyers are exposed to significant doses owing to the altitude and the intensity of cosmic radiation at high altitude. These doses can exceed 1 mSv/year.

Since 1st July 2014, the date of entry into effect of the Order of 17th July 2013 relative to the medical and dosimetric monitoring card for workers exposed to ionising radiation, the Sievert system (system put in place by the DGAC - General Directorate for Civil Aviation, IRSN, the Paris Observatory and the French Institute for Polar Research Paul-Emile Victor (*www.sievert-system.com*), has been changed. It is IRSN that calculates the individual doses via the SievertPN application on the basis of the flight and personnel presence data provided by the airlines. These data are subsequently transmitted to Siseri, the French national worker dosimetry registry.

The year 2015 constitutes a period of consolidation of the SievertPN system. As at 31st December 2015, seven airlines had joined the system, leading to a total of 19,565 flight crew members monitored by this new system.

In 2015, 17% of the individual doses were below 1 mSv and 83% of the individual doses were between 1 mSv and 5 mSv per year.

3.2 Doses received by the population

3.2.1 Doses received by the population as a result of nuclear activities

The automated monitoring networks managed nationwide by IRSN (*Téléray, Hydrotéléray* and *Téléhydro networks*) offer real-time monitoring of environmental radioactivity and can highlight any abnormal variation. In the case of an accident or incident leading to the release of radioactive substances, these measurement networks would play an essential role by providing data to back the decisions to be taken by the authorities and by notifying the population. In a normal situation, they contribute to the evaluation of the impact of BNIs (see chapter 4).

However, there is no overall monitoring system able to provide an exhaustive picture of the doses received by the population as a result of nuclear activities. Consequently, compliance with the population exposure limit (effective dose set at 1 mSv per year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the reference groups chosen, from a few microsieverts to several tens of microsieverts per year.

There are no known estimates for nuclear activities other than Basic Nuclear Installations, owing to the methodological difficulties involved in identifying the impact of the facilities and in particular the impact of discharges containing small quantities of artificial radionuclides resulting from the use of unsealed radioactive sources in research or biology laboratories, or in nuclear medicine units. To give an example, the impact of hospital discharges could lead to doses of a several tens of microsieverts per year for the most exposed persons, particularly for certain jobs in sewage networks and wastewater treatment plants (IRSN studies 2005 and 2015).

Situations inherited from the past, such as atmospheric nuclear tests and the Chernobyl accident (Ukraine), can make a marginal contribution to population exposure. Thus the average individual effective dose currently being received in metropolitan France as a result of fall-out from the Chernobyl accident is estimated at between 0.01 mSv and 0.03 mSv/year (IRSN 2001). That due to the fall-out from atmospheric testing was estimated in 1980 at about 0.02 mSv. Given a decay factor of about 2 in 10 years, current doses are estimated at well below 0.01 mSv per year (IRSN, 2015). With regard to the fall-out in France from the Fukushima Daiichi accident (Japan), the results published for France by IRSN in 2011 show the presence of radioactive iodine at very low levels, resulting in very much lower doses for the populations than those estimated for the Chernobyl accident, and having negligible impact.

3.2.2 Exposure of the population to NORM (Naturally Occurring Radioactive Materials)

Exposure due to natural radioactivity in drinking water. The results of the Regional Health Agencies' monitoring of the radiological quality of the tap water distributed to consumers between 2008 and 2009 (DGS/ASN/IRSN report published in 2011) showed that 99.83% of the population receives tap water whose quality complies at all times with the total indicative dose of 0.1mSv/year set by the regulations. This overall assessment can also be applied to the radiological quality of packaged mineral waters and spring waters produced in France (DGS/ASN/IRSN report published in 2013).

Exposure due to radon. Since 1999, it is compulsory to take periodic radon measurements in places open to the public, especially in educational establishments and health and social institutions, due to the risk of lung cancer attributable to prolonged exposure to radon. Since August 2008, this compulsory monitoring has been extended to workplaces located in the priority geographical areas.

The results of the campaigns conducted by the ASN-approved organisations since 2005 show that the percentages of measurement results exceeding the action levels (400 and 1,000 Bq/m^3) remain comparable from one year to the next. A new ten-yearly screening cycle was started in 2009.

The results of the inspections in places open to the public are not appropriate for precisely assessing the doses linked to exposure of the general public due to the fact that exposure in the home accounts for the largest part of the doses received during one's lifetime. It should be noted that the data for the average activity concentrations of radon in the home date from the national radon exposure measurement campaign carried out in the years 1980-1990.

Over and beyond the regulatory aspects (see chapter 3), the management of radon risks formed the subject of an interministerial action plan for the period 2016-2019, coordinated by ASN.

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The 3rd national radon risks management plan

In January 2017, ASN published the *2016-2019 national action plan for management of the radon risk*. Attached to the 2015-2019 French national health environment plan (PNSE 3), this third edition is the fruit of a collaboration between ASN, the ministers responsible for health, the environment, construction and labour, the national experts (IRSN, Public Health France, CSTB - Scientific and Technical Centre for Building), the regional stakeholders (ARS - Regional Health Agencies, Regional Directorates for the Environment, Planning and Housing), radon monitoring professionals and the associations involved in this subject.

This plan follows through on the momentum developed under the 2011-2015 national action plan, for which ASN also published the results. The new context of development of this third plan, linked in particular to the transposition of Council Directive 2013/59/Euratom of 5th December 2013, now gives this plan a regulatory dimension.

In this new edition, informing and heightening the awareness of the public and the main stakeholders concerned by the radon risk (regional authorities, employers, etc.) are now top priority strategic directions. This strategy of informing and raising awareness is based on the new measures adopted in 2016. These include two flagship measures: 1) making it obligatory to inform real-estate property buyers and renters of the health risks linked to radon in the home and 2) taking radon into account in the indoor air quality management system provided for by Act 2016-41 of 26th January 2016.

In view of the experience feedback from the preceding national action plans, this third plan includes support for local stakeholders in implementing local campaigns to raise awareness of the radon risk in the existing buildings, within the framework more specifically of the development and application of regional health environment plans.

3.3 Doses received by patients

In France, exposure for medical purposes represents the greatest part of the artificial exposures of the public to ionising radiation. This medical exposure has been increasing over the last thirty years or so due to the rise in the number of radiological examinations – and computed tomography examinations in particular, to the ageing of the population, and to the strategies implemented to ensure better patient care, particularly in the context of patient monitoring after cancer treatment and coronary diseases. It has been regularly reviewed by IRSN since 2002.

The average effective dose per inhabitant resulting from diagnostic radiological examinations has been evaluated at 1.6 mSv for the year 2012 (IRSN report 2014) for some 81.8 million diagnostic procedures performed (74.6 million in 2007), i.e. 1,247 procedures for 1,000 inhabitants per year. It is to be noted that the individual exposure in 2012 is very varied. Thus, although about one third of the French population underwent at least one procedure (excluding dental procedures), 85% of that population was either not exposed or received doses of less than 1 mSv.

The average effective individual dose increased by 23% between 2007 and 2012 (it was 1.3 mSv in 2007); it had already increased by 50% between 2002 and 2007 (IRSN/InVS report 2010). It must nevertheless be underlined that the methodologies used for the 2002-2007 period and the 2007-2012 period were not identical.

Conventional radiology (54%), computed tomography (10.5%) and dental radiology (34%) account for the largest number of procedures. However, the contribution of computed tomography to the effective collective dose remains preponderant and more significant in 2012 (71%) than in 2007 (58%) whereas that of dental radiology remains very low (0.2%).

To give an example, thoracic and abdominal pelvic CT scans remain the most frequent (50% in 2012 vs 30% in 2007), more particularly in men after the age of 50 years (4.2% in 2012 vs 1.4% in 2007). Women underwent more conventional radiology procedures (mammograms and limb examinations) than men.

In adolescents, conventional radiology and dental procedures are more numerous (1,020 and 1,220 procedures respectively for 1,000 individuals in 2012). Despite their frequency in this population, dental radiology procedures represent only 0.5% of the collective dose.

Lastly, it is noteworthy that in a sample of about 600,000 persons covered by health insurance, the analysis of the effective doses for these people who effectively underwent an examination shows that 70% of them received less than 1 mSv, 18% received between 1 and 10 mSv, 11% between 10 and 50 mSv and 1% more than 50 mSv. The substantial uncertainties in this study with regard to the average effective dose values per type of procedure must nevertheless be taken into account, which justifies the need for progress in estimating doses in the next exposure study of the general population.

TABLE 3: Total number of procedures and associated collective effective dose for each imaging method (rounded values) in France in 2012

IMAGING METHOD	PROCEDURES		COLLECTIVE EFFECTIVE DOSE	
	NUMBERS	%	mSv	%
Conventional radiology (dentistry excluded)	44,175,500	54.0	18,069,200	17.7
Dental radiology	27,616,000	33.8	165,700	0.2
Computed Tomography	8,484,000	10.4	72,838,900	71.2
Diagnostic interventional radiology	377,000	0.5	3,196,400	3.1
Nuclear medicine	1,103,000	1.3	7,928,300	7.8
TOTAL	**81,755,500**	**100.0**	**102,198,500**	**100.0**

Source: IRSN 2014

Particular attention is required in order to control and reduce the doses linked to medical imaging, more specifically when alternative techniques can be used for a same given indication, because the multiplication of the most heavily irradiating examinations for the same person could lead to the effective dose value of several tens of millisieverts being reached; at this level of exposure, certain epidemiological surveys have revealed the occurrence of radiation-induced cancers.

Based on a sample of 100,000 children (1% of the French population), IRSN (2013 report) estimated that in 2010 one out of three children was exposed to ionising radiation for diagnostic purposes. The mean and median values for the effective dose are estimated at 0.65 mSv and 0.025 mSv respectively for all the children exposed. They are 5.7 mSv and 1.7 mSv respectively for children who have undergone at least one computed tomography procedure (1% of the population monitored).

Controlling the doses delivered to patients remains a priority for ASN, which has undertaken since 2011 – in collaboration with the stakeholders (institutional and professional) – a programme of actions in various areas (quality and safety of practices/quality assurance, human resources/training, etc.).

3.4 Exposure of non-human species (animal and plant species)

The international radiation protection system was created to protect humans against the effects of ionising radiation. Environmental radioactivity is thus assessed with respect to its impact on human beings and, in the absence of any evidence to the contrary, it is today considered that the current standards also protect other species.

Protection of the environment from the radiological risk and more specifically the protection of non-human species, must however be guaranteed independently of the effects on humans. Pointing out that this objective is already incorporated in the national legislation, ASN will ensure that the impact of ionising radiation on non-human species be effectively included in the regulations and in the authorisations for nuclear activities as soon as evaluation methods are available. On the basis of the IRSN appraisal report, the Advisory Committee of Experts on radiation protection for industrial and research applications of ionising radiation and on the environment adopted an opinion in September 2015. In 2016, ASN started work with a view to adopting a position on this subject which should be published as an opinion in mid-2017.

4. Outlook

As in the preceding years, the results for the doses received by the workers in 2015 remained stable, with the annual dose received remaining below 1 mSv for about 95% of the workers liable to be exposed, and with two cases exceeding the annual limit dose of 20 mSv. Monitoring of exposure of the lens of the eye, and, for this tissue, compliance with the new limit set at 20 mSv/year as from 2017, constitute the main objectives of radiation protection in the immediate years and more specifically in the area of interventional medical practices.

Following publication of the Ordinance of 10th February 2016 containing new requirements relative to radon exposure, deployment of the third national plan should allow communication to the public on the risks linked to radon to be stepped up in order to encourage the setting up of measuring systems in existing buildings and to progressively organise collection and analysis of the results.

02

Principles and stakeholders in the regulation of nuclear safety and radiation protection


« Présentation du rapport
Mercredi 25 mai 2016

Nuclear safety is defined in the Environment Code as *"the set of technical provisions and organisational measures – related to the design, construction, operation, shutdown and decommissioning of Basic Nuclear Installations (BNIs), as well as the transport of radioactive substances – which are adopted with a view to preventing accidents or limiting their effects"*. Radiation protection is defined as *"protection against ionising radiation that is the set of rules, procedures and means of prevention and surveillance aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination"*.

Nuclear safety and radiation protection obey principles and approaches that have been put in place progressively and continually enhanced by a process of feedback. The basic guiding principles are advocated internationally by the International Atomic Energy Agency (IAEA). In France, they are included in the Constitution or enacted in law, as well as now figuring in European Directives.

In France, the regulation of nuclear safety and radiation protection for civil nuclear activities is carried out by the French Nuclear Safety Authority, ASN, an independent administrative Authority, in liaison with Parliament and other State stakeholders, within the Government and the offices of the Prefects. This regulation is based on technical expert assessment services provided more particularly by the French Institute for Radiation Protection and Nuclear Safety (IRSN).

1. The principles of nuclear safety and radiation protection

1.1 Fundamental principles

Nuclear activities must be carried out in compliance with the principles that underlie the legislative texts.

This primarily concerns:
- at the national level, the principles enshrined in the Environment Charter, which has the same value as the Constitution, and in the various codes (Environment Code and Public Health Code);
- at the European level, rules defined by Directives establishing a community framework for the safety of nuclear facilities and for the responsible and safe management of spent fuel and radioactive waste;
- at an international level, ten fundamental safety principles defined by IAEA (see box below and chapter 7, point 3.1) implemented by the Convention on Nuclear Safety (see chapter 7 point 4.1), which established the international framework for the oversight of nuclear safety and radiation protection.

These various measures of differing origins extensively overlap. They can be grouped into the eight main principles presented below.

1.1.1 Principle of licensee responsibility

This principle, defined in Article 9 of the Convention on Nuclear Safety, is the first of IAEA's fundamental safety principles. It stipulates that responsibility for the safety of nuclear activities entailing risks lies with those who undertake or perform them.

It applies directly to all nuclear activities.

1.1.2 "Polluter-pays" principle

The "polluter-pays" principle, stipulating the principle of the operator's responsibility, ensures that the cost of measures to prevent or reduce pollution is borne by those responsible for environmental damage. This principle is defined in Article 4 of the Environment Charter in these terms: *"An individual must contribute to reparation of the environmental damage he or she has caused"*.

This principle entails the taxation of Basic Nuclear Installations (BNI) ("BNI" tax and contribution to IRSN), the taxation of radioactive waste producers (additional waste taxes), of disposal facilities (additional "disposal" tax) and of Installations Classified on Environmental Protection grounds (ICPE) (fraction of the General Tax on Polluting Activities). These taxes are presented in greater detail in point 3.

RESPONSIBILITY of licensees and responsibility of ASN

1.1.3 Precautionary principle

The precautionary principle, defined in Article 5 of the Environment Charter, states that: *"the absence of certainty, in the light of current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures to prevent a risk of serious and irreversible damage to the environment"*.

Application of this principle results, for example, in the adoption of a linear, no-threshold dose-effect relationship where the biological effects of exposure to low doses of ionising radiation are concerned. This point is clarified in chapter 1 of this report.

1.1.4 Public participation principle

This principle allows public participation in the taking of decisions by public authorities. In line with the Aarhus Convention, it is defined in Article 7 of the Environment Charter as follows: *"Within the conditions and limits defined by law, all individuals are entitled to access environmental information in the possession of the public authorities and to participate in the taking of public decisions affecting the environment"*.

In the nuclear field, this principle leads in particular to the organisation of national public debates, which are mandatory prior to the construction of a nuclear power plant for example, as well as public inquiries, in particular during the examination of the files concerning the creation or decommissioning of nuclear facilities, to public consultation concerning draft resolutions with an impact on the environment, or to the basic nuclear installation licensee providing access to its file on the modification of its installation, which is liable to cause a significant increase in water intake or discharges into the environment of the installation.

1.1.5 The principle of justification

The principle of justification, defined in Article L. 1333-2 of the Public Health Code, states that: *"A nuclear activity or an intervention may only be undertaken or carried out if its individual or collective benefits, more specifically its health, social, economic or scientific benefits so justify, given the risks inherent in the human exposure to ionising radiation that it is likely to entail"*.

Assessment of the expected benefit of a nuclear activity and the corresponding drawbacks may lead to prohibition of an activity for which the benefit would not seem to outweigh the health risk. For existing activities, justification may be reassessed if the state of know-how and technology so warrants.

1.1.6 The principle of optimisation

The principle of optimisation, defined by Article L. 1333-2 of the Public Health Code, states that: *"The level of exposure of individuals to ionising radiation [...], the probability of occurrence of this exposure and the number of persons exposed must be kept as low as is reasonably achievable, given the current state of technical knowledge, economic and social factors and, as necessary, the medical goal in question"*.

This principle, referred to as the ALARA (As Low As Reasonably Achievable) principle, leads for example to reducing the quantities of radionuclides present in the radioactive effluents from nuclear installations allowed in the discharge licenses, to requiring surveillance of exposure in the working environment in order to reduce it to the strict minimum and to ensuring that medical exposure as a result of diagnostic procedures remains close to the pre-determined reference levels.

1.1.7 The principle of limitation

The principle of limitation, defined in Article L. 1333-2 of the Public Health Code, states that: *"Exposure of an individual to ionising radiation [...] may not increase the sum of the doses received beyond the limits set by regulations, except when the individual is exposed for medical or biomedical research purposes"*.

The exposure of the general public or of workers as a result of nuclear activities is subject to strict limits. These limits include significant safety margins to prevent deterministic effects from appearing, as well as aiming to reduce the appearance of probabilistic effects in the long term to the lowest level possible.

Exceeding these limits leads to an abnormal situation and one which may give rise to administrative or legal sanction.

In the case of medical exposure of patients, no strict dose limit is set, provided that this voluntary exposure is justified by the expected health benefits to the person exposed.

1.1.8 The principle of prevention

To anticipate any environmental damage, the principle of prevention, defined in Article 3 of the Environment Charter, stipulates the implementation of rules and measures which must take account of *"the best available technology at an economically acceptable cost"*.

In the nuclear field, this principle underlies the concept of defence in depth, presented below.

1.2 Some aspects of the safety approach

The safety principles and approaches presented below were gradually implemented and incorporate experience feedback from accidents. Absolute safety can never be guaranteed. Despite all the precautions taken in the design, construction and operation of nuclear facilities, an accident can never be completely ruled out. The willingness to move forward and to create a continuous improvement approach is thus essential if the risks are to be reduced.

FUNDAMENTALS

The fundamental safety principles

IAEA establishes the following 10 principles in its publication "SF-1":

1. Responsibility for safety must rest with the person or organisation responsible for facilities and activities that give rise to radiation risks.

2. An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.

3. Effective leadership and management of safety must be established and maintained in organisations concerned with radiological risks, and in facilities and activities that give rise to such risks.

4. Facilities and activities that give rise to radiation risks must yield an overall benefit.

5. Protection must be optimised to provide the highest level of safety that can reasonably be achieved.

6. Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.

7. People and the environment, both present and future, must be protected against radiation risks.

8. All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.

9. Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.

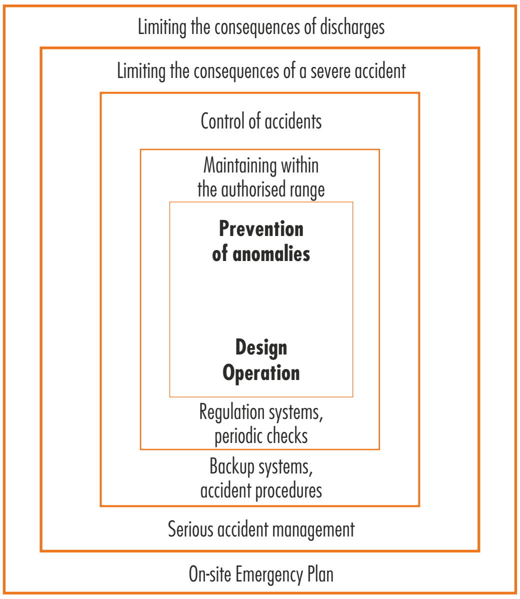
10. Protective actions to reduce existing or unregulated radiation risks must be justified and optimised.

1.2.1 Safety culture

Safety culture is defined by the International Nuclear Safety Advisory Group (INSAG), an international nuclear safety consultative group reporting to the General Director of IAEA, as: *"that assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance"*.

Safety culture therefore determines the ways in which an organisation and individuals perform their duties and accept responsibility, with safety in mind. It is one of the key fundamentals in maintaining and improving safety. It commits organisations and individuals to paying particular and appropriate attention to safety. At the individual level it is given expression by a rigorous and cautious approach and a questioning attitude making it possible to both obey rules and take initiatives. In operational terms, the concept underpins daily decisions and actions relating to activities.

THE 5 LEVELS of "Defence in Depth"



1.2.2 The "Defence in Depth" concept

The main means of preventing accidents and limiting their potential consequences is "Defence in Depth". This consists in implementing material or organisational provisions (sometimes called lines of defence) structured in consecutive and independent layers, and which are capable of preventing the development of an accident. If one level of protection fails, the next level takes over.

An important element for the independence of the levels of defence is the use of different technologies ("diversified" systems).

The design of nuclear installations is based on a defence in depth approach. Five levels of protection are defined for nuclear reactors:

Level 1: Prevention of abnormal operation and system failures

This is a question firstly of designing and building the facility in a robust and conservative manner, integrating safety margins and planning for resistance with respect to its own failures or to hazards. It implies conducting the most exhaustive study possible of normal operating conditions to determine the severest stresses to which the systems will be subjected. It is then possible to produce an initial design basis for the facility, incorporating safety margins. The facility must then be maintained in a state at least equivalent to that planned for in its design through appropriate maintenance. The facility must be operated in an informed and careful manner.

Level 2: Keeping the installation within authorised limits

Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. Condition monitoring and correct operation of systems form part of this level of defence.

Level 3: Control of accidents without core meltdown

The aim here is to postulate that certain accidents, chosen for their "envelope" characteristics (the most penalising in a given family) can happen, and to design and size backup systems to withstand those conditions.

Such accidents are generally studied with pessimistic hypotheses, that is to say the various parameters governing this accident are assumed to be as unfavourable as possible. In addition, the single failure criterion is applied, in other words we postulate that in the accident situation and in addition to the accident, there will be the most prejudicial failure of one of the components used to manage this situation. As a result of this, the systems coming into play in the event of an accident (safeguard systems ensuring emergency shutdown, injection of cooling water into the reactor, etc.) comprise at least two redundant and independent channels.

Level 4: Control of accidents with core meltdown

These accidents have been considered since the Three Mile Island accident (1979) and are now taken into account in the design of new reactors such as the EPR. The aim is to preclude such accidents or to design systems that can withstand them.

Level 5: Mitigation of the radiological consequences of significant releases

This requires implementation of the measures provided for in the emergency plans, including measures to protect the general public: shelter, taking of stable iodine tablets to saturate the thyroid and avoid fixation of released radioactive iodine, evacuation, restrictions on consumption of water and of agricultural products, etc.

1.2.3 Positioning of barriers

To limit the risk of releases, several barriers are placed between the radioactive substances and the environment. Barriers must be designed to have a high degree of reliability and must be monitored to detect any weaknesses or failures. There are three such barriers for pressurised water reactors: the fuel cladding, the boundary of the reactor primary system, and the containment (see chapter 12).

1.2.4 Deterministic and probabilistic approaches

Postulating the occurrence of certain accidents and verifying that, thanks to the planned functioning of the equipment, the consequences of these accidents will remain limited, is known as a deterministic approach. This approach is simple to apply in principle and allows an installation to be designed (and its systems to be sized) with good safety margins, by using so-called "envelope" cases. The deterministic approach is however unable to identify the most probable scenarios because it focuses attention on accidents studied with pessimistic hypotheses.

The deterministic approach therefore needs to be supplemented by an approach that better reflects possible accident scenarios in terms of their probability, that is to say the probabilistic approach used in the "Probabilistic Safety Assessments" (PSA).

Thus for nuclear power plants, the level 1 Probabilistic Safety Assessments (PSA) consist in establishing event trees for each «initiating event» leading to the activation of a safeguard system (level 3 of defence in depth), defined by the failure (or the success) of the actions provided for in the reactor management procedures and the failure (or correct operation) of the reactor. The probability of each sequence is then calculated based on statistics on the reliability of systems and on the rate of success of actions (including data on "human reliability"). Similar sequences of events that correspond to the same initiating event are grouped into families, making it possible to determine the contribution of each family to the probability of reactor core meltdown.

Although the PSAs are limited by uncertainties concerning the reliability data and approximations in the modelling of the facility, they consider a broader set of accidents than the deterministic assessments and enable the design resulting from the deterministic approach to be verified and supplemented if necessary. They are therefore to be used as a complement to deterministic studies and not as a substitute for them.

The deterministic studies and probabilistic assessments constitute an essential element in the demonstration of nuclear safety that addresses equipment internal faults, internal and external hazards, and plausible combinations of these events.

To be more precise, the internal faults correspond to malfunctions, failures or damage to facility equipment, including as a result of inappropriate human action. Internal or external hazards correspond to events originating inside or outside the facility respectively and which can call into question the safety of the facility.

Internal faults include for example:
- loss of the electrical power supplies or the cooling systems;
- ejection of a rod cluster control assembly;
- rupture of a pipe in the primary or secondary system of a nuclear reactor;
- reactor emergency shutdown failure.

With regard to internal hazards, the following in particular must be considered:
- flying projectiles, notably those resulting from the failure of rotating equipment;
- pressure equipment failures;
- collisions and falling loads;
- explosions;
- fires;
- hazardous substance emissions;
- floods originating within the perimeter of the facility;
- electromagnetic interference;
- malicious acts.

Finally, external hazards more specifically comprise:
- the risks induced by industrial activities and communication routes, including explosions, hazardous substance emissions and airplane crashes;
- earthquakes;
- lightning and electromagnetic interference;
- extreme meteorological or climatic conditions;
- fires;
- floods originating outside the perimeter of the facility;
- malicious acts.

1.2.5 Operating experience feedback

Operating Experience Feedback (OEF), which contributes to defence in depth, is one of the essential safety management tools. It is based on an organised and systematic collection and analysis of the signals emitted by a system. It should enable acquired experience to be shared (for implementation of preventive measures in a structure that learns from past experience). A first goal of OEF is to understand, and thus ensure progress in technological understanding and knowledge of actual operating practices, so that whenever pertinent, a fresh look can be taken at the design (technical and documentary). As OEF is a collective process, a second goal is to share the resulting knowledge, by memorising and recording the anomaly, the lessons learned from it and how it was rectified. A third goal of OEF is to act on working organisations and processes, on working practices (both individual and collective) and on the performance of the technical system.

Operating experience feedback encompasses events, incidents and accidents occurring both in France and abroad, whenever their assessment is relevant to enhancing nuclear safety or radiation protection.

1.2.6 Social, organisational and human factors

The importance of SOHF for nuclear safety, radiation protection and environmental protection

The contribution of humans and organisations to safety, radiation protection and environmental protection is decisive in the design, construction, commissioning, operation and decommissioning of facilities, as well as in the transport of radioactive substances. Similarly, the way in which people and organisations manage deviations from the regulations, from the baseline requirements and from the state of the art, plus the corresponding lessons learned, is also decisive. Therefore, all those involved, regardless of their position in the hierarchy and their functions, make a contribution to safety, radiation protection and environmental protection, owing to their ability to adapt, detect and correct errors, rectify degraded situations and counter certain difficulties involved in the application of procedures.

ASN defines Social, Organisational and Human Factors (SOHF) as being all the aspects of working situations and of the organisation which have an influence on the work done by the operators. The elements considered concern the individual (training received, fatigue or stress, etc.) and the organisation within which he or she works (functional and hierarchical links, joint contractor work, etc.), the technical arrangements (tools, software, etc.) and, more broadly, the working environment with which the individual interacts. The working environment for instance concerns the heat, sound or light environment of the workstation, as well as the accessibility of the premises.

The variability in worker characteristics (vigilance varies with the time of day, the level of expertise varies according to the seniority in the position) and in the situations encountered (unexpected failure, social tension) explains that workers constantly need to adapt how they work so as to optimise effectiveness and efficiency. This goal must be achieved at an acceptable cost to the persons concerned (in terms of fatigue or stress) and provide a benefit to them (the feeling of a job well done, recognition by both peers and the hierarchy, development of new skills). Thus, an operating situation or a task achieved at very high cost to the operators is a potential source of risks: a small variation in the working context, human environment or working organisation can prevent the persons concerned from performing their tasks as expected.

Integration of SOHF

ASN considers that SOHF must be taken into account in a manner commensurate with the safety implications of the facilities and the radiation protection of workers during:
- the design of a new facility, equipment, software, transport package, or the modification of an existing one. ASN in particular wants to see design focusing on the human operator, through an iterative process comprising an analysis phase, a design phase and an evaluation phase. Therefore, the ASN resolution of 13th February 2014 concerning physical modifications to BNIs requires that *"the design of the physical modification envisaged shall, when it is applied and put into operation, take account of the interactions between the modified or newly installed equipment on the one hand and the users and their needs on the other"*;
- operations or activities performed by the workers during the commissioning, operation and decommissioning of nuclear facilities, as well as during the transportation of radioactive substances.

ASN also considers that the licensees must analyse the root causes (often organisational) of the significant events and identify, implement and assess the effectiveness of the corresponding corrective measures, on a long-term basis.

ASN's SOHF requirements

The Order of 7th February 2012 setting the general rules for BNIs, requires that the licensee define and implement an Integrated Management System (IMS) designed to ensure that the safety, radiation protection and environmental protection requirements are systematically taken into account in all decisions concerning the facility. The IMS specifies the steps taken with regard to all types of organisation and resources, in particular those adopted to manage important activities. ASN thus asks the licensee to set up an IMS able to maintain and continuously improve safety, notably through the development of a safety culture.

2. The stakeholders

The organisation of the regulation of nuclear safety in France complies with the Convention on Nuclear Safety, Article 7 of which requires that *"Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations"* and Article 8 of which requires that each Member State *"shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7 and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities"*. These provisions were confirmed by the European Directive of 25th June 2009 concerning nuclear safety, the provisions of which were in turn reinforced by the amending Directive of 8th July 2014.

In France, the regulation of nuclear safety and radiation protection is primarily the responsibility of three parties: Parliament, the Government and ASN.

2.1 Parliament

Parliament's principal role in the field of nuclear safety and radiation protection is to make laws. Two major acts were therefore passed in 2006: the TSN Act of 13th June 2006, on Transparency and Security in the Nuclear field and the Programme Act of 28th June 2006, on the sustainable management of radioactive materials and waste.

In 2015, Parliament adopted the Energy Transition for Green Growth Act, an entire section of which is devoted to nuclear matters (Title VI - *"Reinforcing nuclear safety and information of the citizens"*). This Act reinforces the framework which was created in 2006.

Like the other independent administrative authorities and in application of the provisions of the Environment Code, ASN makes regular reports on its activity to Parliament, notably to the OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices) and to the parliamentary commissions concerned.

The role of the OPECST is to inform Parliament of the consequences of scientific or technological choices so that it can make informed decisions; to this end, it gathers information, implements study programmes and conducts evaluations. ASN regularly reports on its activities to the OPECST, particularly by submitting the annual Report on the State of Nuclear Safety and Radiation Protection in France to it each year.

ASN also reports on its activities to the Parliamentary Commission of the National Assembly and the Senate, notably on the occasion of hearings held by the commissions responsible for the environment or economic affairs.

The exchanges between ASN and elected officials are presented in more detail in chapter 6.

2.2 The Government

The Government exercises regulatory powers. It is therefore in charge of laying down the general regulations concerning nuclear safety and radiation protection. The Environment Code also tasks it with taking major decisions concerning BNIs, for which it relies on proposals or opinions from ASN. The Government can also call on consultative bodies such as the High Committee for Transparency and Information on Nuclear Security (HCTISN).

The Government is also responsible for civil protection in the event of an emergency.

2.2.1 Ministers responsible for Nuclear Safety and Radiation Protection

On the advice of and, as applicable, further to proposals from ASN, the Minister responsible for Nuclear Safety defines the general regulations applicable to BNIs and those concerning the construction and use of Pressure Equipment (ESP) specifically designed for these installations.

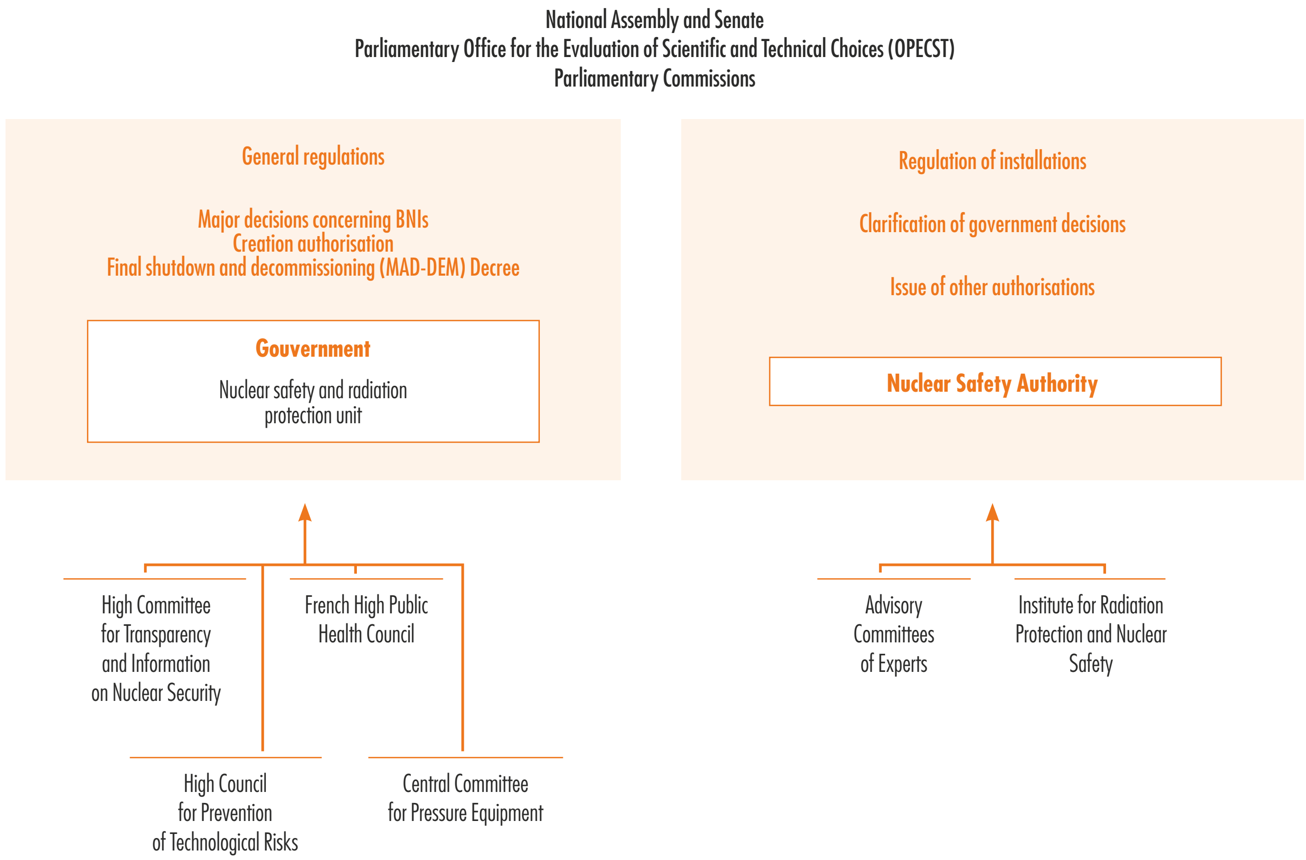
Also on the advice of and, as applicable, further to proposals from ASN, this same Minister takes major individual decisions concerning:
- the design, construction, operation and decommissioning of BNIs;
- the design, construction, operation, closure and decommissioning, as well as the surveillance, of radioactive waste disposal facilities.

If an installation presents serious risks, the above-mentioned Minister can suspend the operation of an installation on the advice of ASN.

Furthermore - and on the basis of ASN proposals if necessary - the Minister responsible for Radiation Protection defines the general regulations applicable to radiation protection.

The regulation of worker radiation protection is the responsibility of the Minister for Labour. That concerning the radiation protection of patients is the responsibility of the Minister for Health.

REGULATION of nuclear safety and radiation protection in France



The Ministers responsible for Nuclear Safety and for Radiation Protection approve the ASN internal regulations by means of an Interministerial Order. Each of them also approves ASN technical statutory resolutions and certain individual resolutions (setting BNI discharge limits, delicensing a BNI, etc.) affecting their own particular field.

The Nuclear Safety and Radiation Protection Mission

The Nuclear Safety and Radiation Protection Mission, within the General Directorate for Risk Prevention at the Ministry for the Environment, Energy and the Sea, is in particular tasked - in collaboration with ASN - with proposing Government policy on nuclear safety and radiation protection, except for defence-related activities and installations and the radiation protection of workers against ionising radiations.

Defence and Security High Official

The purpose of nuclear security, in the strictest sense of the term (IAEA definition, less wide-ranging than that of Article L 591-1 of the Environment Code) is to protect and monitor nuclear materials, their facilities and their transportation. It aims to ensure protection of the populations and environment against the consequences of malicious acts, in accordance with the provisions of the Defence Code.

This responsibility lies with the Minister for the Environment, Energy and the Sea, with the support of the Defence and Security High Official (HFDS) and more specifically the Nuclear Security Department. The HFDS thus acts as the nuclear security Authority, by drafting regulations, issuing authorisations and conducting inspections in this field, with the support of IRSN.

Although the two regulatory systems and approaches are clearly different, the two fields, owing to the specificity of the nuclear field, are closely linked. ASN and the HFDS are therefore regularly in contact with each other.

2.2.2 The decentralised State services

The decentralised services of the French State are those which locally implement the decisions taken by the central administration and which manage the State's services at the local level. These services are placed under the authority of the Prefects.

ASN maintains close relations with the Regional Directorates for the Environment, Planning and Housing (Dreal), the Regional Directorates for Companies, Competition, Consumer affairs, Labour and Employment and the Regional Health Agencies which, although not strictly speaking decentralised services, but public institutions, have equivalent powers.

The Prefects are the State's local representatives. They are the guarantors of public order and play a particularly important role in the event of an emergency, in that they are responsible for measures to protect the general public.

The Prefects are involved in the various procedures presented in chapter 3. In particular, they send the Minister their opinion on the report and on the conclusions of the inquiry commissioner following the public inquiry into authorisation applications. At the request of ASN, they refer to the Departmental Council for the environment and health and technological risks for an opinion on the water intake, discharges and other detrimental effects of BNIs.

2.3 ASN

The Nuclear Safety Authority (ASN), created by the TSN Act, is an independent administrative Authority which takes part in regulating nuclear safety, radiation protection and the nuclear activities mentioned in Article L. 1333-1 of the Public Health Code. Its roles are to regulate, authorise, monitor and support the public authorities in the management of emergency situations and to contribute to information of the public and transparency within its fields of competence.

ASN is run by a Commission of Commissioners and has departments placed under the authority of its Chairman. From a technical point of view, ASN relies on the expertise with which it is provided, notably by IRSN and by the Advisory Committees of Experts (GPEs).

2.3.1 Role and duties

Regulation

ASN is consulted on draft decrees and Ministerial Orders of a regulatory nature dealing with nuclear safety as defined in Article L.591-1 of the Environment Code.

It can issue statutory resolutions of a technical nature to complete the implementing procedures for decrees and orders adopted in the nuclear safety or radiation protection field, except for those relating to occupational medicine. These resolutions must be approved by the Minister responsible for Nuclear Safety or the Minister responsible for Radiation Protection.

Approval orders and approved resolutions are published in the *Official Journal*.

Authorisation

ASN reviews BNI authorisation or decommissioning applications, issues opinions and makes proposals to the Government concerning the decrees to be issued in these fields. It authorises significant modifications to a BNI. It defines the requirements applicable to these installations with regard to the prevention of risks, pollution and detrimental effects. It authorises commissioning of these installations and pronounces delicensing following completion of decommissioning.

Some of these ASN resolutions require approval by the Minister responsible for Nuclear Safety.

ASN issues the licenses, carries out registration and receives the notifications provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations.

The ASN resolutions and opinions defined by its Commission are published in its *Official Bulletin* on its website (*www.asn.fr*).

Chapter 3 of this report describes ASN's roles in the fields of regulation and authorisation.

Control

ASN verifies compliance with the general rules and specific requirements for nuclear safety and radiation protection applicable to BNIs, to the pressure equipment designed specifically for such facilities and to the transport of radioactive substances. It also regulates the activities mentioned in Article L. 1333-1 of the Public Health Code and the ionising radiation exposure situations defined in Article L.1333-3 of the same Code.

ASN organises a permanent radiation protection watch throughout the national territory.

From among its staff, it appoints nuclear safety inspectors and radiation protection inspectors.

It issues the required approvals and certifications to the organisations participating in the verifications and in nuclear safety or radiation protection monitoring, as well as with regard to nuclear pressure equipment.

Ordinance 2016-128 of 10th February 2016, issued pursuant to authorisation by the Energy Transition for Green Growth Act, reinforces ASN's regulatory and sanction powers and broadens the scope of its competences.

The effect of ASN's reinforced regulation, policing and sanction powers will be to improve the effectiveness of the regulation of nuclear safety and radiation protection. These policing and sanction powers are extended to the activities performed outside BNIs and participating in the technical and organisational measures mentioned in the 2nd paragraph of Article L. 595-2 of the Environment Code, by the licensee, its suppliers, contractors or sub-contractors and in the same conditions as within the facilities themselves.

The sanctions commission set up within ASN will determine the administrative fines in order to comply with the principle of separation between the investigation, charging and sentencing functions instituted in French law and in international conventions with regard to the right to a fair trial. Chapter 4 of this report describes ASN actions in this field.

Emergency situations

ASN takes part in managing radiological emergency situations. It provides technical assistance to the competent Authorities for the drafting of emergency response plans, taking account of the risks resulting from nuclear activities.

When such an emergency situation occurs, ASN verifies the steps taken by the licensee to make the facility safe. It assists the Government with all matters within its field of competence and submits its recommendations on the medical or health measures or civil protection steps to be taken. It informs the general public of the situation, of any releases into the environment and their consequences. It acts as the Competent Authority within the framework of international conventions, by notifying international organisations and foreign countries of the accident.

Chapter 5 of this report describes ASN actions in this field.

In the event of an incident or accident concerning a nuclear activity and pursuant to Decree 2007-1572 of 6th November 2007 concerning technical inquiries into accidents or incidents concerning a nuclear activity, ASN may carry out a technical inquiry.

Information

ASN participates in informing the public in its areas of competence. Chapter 6 of this report describes ASN actions in this field.

Research monitoring

The quality of ASN's resolutions and decisions relies primarily on robust technical expertise which, in turn, requires the best and most up-to-date knowledge. In this respect, Ordinance 2016-128 of 10th February 2016 issued pursuant to the Energy Transition for Green Growth Act, comprises measures giving ASN competence to monitor the adaptation of public research to the needs of nuclear safety and radiation protection.

Consequently, ASN is already concerned about the availability of the knowledge required to underpin the expertise it may need to call upon in the medium and long term. ASN is also attentive to the quality of research initiatives with a view to their integration by the licensees into their safety cases and impact assessments.

ASN takes part in the steering committee on IRSN research and draws on the expertise of a scientific committee to examine its proposed orientations concerning the research work to be conducted or taken further in the fields of nuclear safety and radiation protection. In a resolution dated 8th July 2014, the ASN Commission renewed for a further four years the mandates of the nine members of the Committee, appointed for their expertise in the field of research. Under the Chairmanship of Ashok Thadani, former head of research at the United States Nuclear Regulatory Commission (NRC), the Committee comprises Bernard Boullis, Jean-Claude Lehmann, Michel Schwarz, Michel Spiro and Victor Teschendorff, as well as Christelle Roy and Catherine Luccioni, appointed in 2015 following the departure of Marie-Pierre Comets. The Scientific Committee met twice in 2016.

TECV Act

Ordinance 2016-128 of 10th February 2016, issued following authorisation by the Energy Transition for Green Growth Act, enables ASN:
- within BNIs, to exercise certain competencies concerning products and equipment entailing risks (for example equipment for explosive atmospheres), or chemical products;
- in order to back up its resolutions, to resort to third party assessments, inspections and studies at the expense of the party being assessed or inspected, in a manner comparable to that used for ICPEs;
- to ensure that public research is tailored to the needs of nuclear safety and radiation protection.

On the basis of the work done by the Scientific Committee, ASN issued a first opinion in April 2012 underlining the importance it attaches to research, and identifying the initial research topics to be further investigated in the fields of nuclear safety and radiation protection.

A second opinion was issued in early 2015 on the research topics to be taken further in the following fields:
- waste packaging;
- deep geological disposal;
- transport of radioactive substances;
- severe accidents.

In 2016, a map of the various nuclear safety and radiation protection research players was produced for an end-of-training course professional thesis entrusted by ASN to a trainee engineer. On the basis of this map, ASN established numerous contacts with public research organisations active in fields directly linked to those areas which it felt needed to be reinforced. This approach will be consolidated to enable ASN to inform these players of the research fields it considers to be priorities for improving nuclear safety and radiation protection.

The Fukushima Daiichi nuclear accident also highlighted the need for more research in the field of nuclear safety. A call for projects in the field of nuclear safety was therefore issued by the French National Research Agency under the Investing in the Future programme. ASN is a member of the steering committee for this call for projects.

THE COMMISSION

From left to right: Margot Tirmarche, Pierre-Franck Chevet, Lydie Évrard, Sylvie Cadet-Mercier and Philippe Chaumet-Riffaud.

2.3.2 Organisation

ASN Commission

The ASN Commission comprises five full-time Commissioners. Their mandate is for a period of six years and may not be renewed. The Commissioners perform their duties in complete impartiality and receive no instructions either from the Government or from any other person or institution. The President of the Republic may terminate the duties of a member of the Commission in the event of a serious breach of his or her obligations.

The Commission defines ASN strategy. More specifically, it is involved in developing overall policy, i.e. the doctrines and principles that underpin ASN's main missions of regulation, inspection, transparency, management of emergency situations and international relations.

Pursuant to the Environment Code, the Commission submits ASN's opinions to the Government and issues the main ASN resolutions. It decides on the public position to be adopted on the main issues within ASN's sphere of competence. The Commission adopts the ASN internal regulations which set out its organisation and working rules, as well as its ethical guidelines. The Commission's resolutions and opinions are published in ASN's *Official Bulletin*.

In 2016, the ASN Commission met 76 times. It issued 32 opinions and 42 resolutions.

ASN head office departments

The ASN head office departments comprise an Executive Committee, an Office of Administration, a Management and Expertise Office and eight departments covering specific themes.

Under the authority of the ASN Director-General, the Executive Committee organises and manages the departments on a day to day basis. It ensures that the orientations determined by the Commission are followed and that ASN's actions are effective. It oversees and coordinates the various entities.

The role of the departments is to manage national affairs concerning the activities under their responsibility. They take part in defining the general regulations and coordinate and oversee the actions of the ASN regional divisions.

- The Nuclear Power Plant Department (DCN) is responsible for the regulation and monitoring of the safety of the NPPs in operation, as well as the safety of future power generating reactor projects. It contributes to the development of regulation/monitoring strategies and ASN actions on subjects such as facility ageing, reactor service life, assessment of NPP safety performance and harmonisation of nuclear safety in Europe. The DCN comprises six branches: «Hazards and Safety Reviews», «Equipment and Systems Monitoring», «Operation», «Core and Studies», «Radiation Protection, Environment and Labour Inspectorate» and «Regulation and New Facilities».

- The Nuclear Pressure Equipment Department (DEP) is responsible for monitoring the safety of pressure equipment installed in BNIs. It monitors the design, manufacture and operation of nuclear pressure equipment and application of the regulations by the manufacturers and their subcontractors and by the nuclear licensees. It also monitors the approved organisations performing the regulation checks on this equipment. The DEP comprises four Branches: "Design" , "Manufacturing", "In-service Monitoring" and "Relations with Divisions and Operations".

- The Transport and Radiation Sources Department (DTS) is responsible for monitoring activities relating to sources of ionising radiation in the non-medical sectors and to transport of radioactive substances. It contributes to the development of technical regulations, to monitoring their application and to managing authorisation procedures (installations and equipment emitting ionising radiation in non-medical sectors, suppliers of medical and non-medical sources, accreditation of packaging and of relevant organisations). It is preparing to take charge of regulating radioactive source security. The DTS comprises two Branches: "Transport Monitoring" and "Radiation Protection and Sources", plus a "Source Security" section.

- The Waste, Research Facilities and Fuel Cycle Department (DRC) is responsible for monitoring nuclear fuel cycle facilities, research facilities, nuclear installations being decommissioned, contaminated sites and radioactive waste management. It takes part in monitoring and inspecting the Bure underground research laboratory and the research facilities covered by international conventions, such as CERN or ITER. The DRC comprises four Branches: "Cross-discipline topics and Research facilities", "Fuel cycle facilities", "Management of Radioactive Waste" and "Decommissioning and Clean-out".

- The Ionising Radiation and Health Department (DIS) is tasked with regulating medical applications of ionising radiation and - in collaboration with IRSN and the various health authorities - with organising the scientific, health and medical watch with regard to the effects of ionising radiation on health. It contributes to the drafting of the regulations in the field of radiation protection, including with respect to natural ionising radiation, and the updating of health protection measures should a nuclear or radiological event take place. The DIS comprises two Branches: "Exposure in the Medical Sector" and "Exposure of Workers and the Public".

THE EXECUTIVE COMMITTEE

From left to right: Jean-Luc Lachaume, Guillaume Bouyt, Henri Legrand, Julien Collet, Olivier Gupta, Ambroise Pascal and Alain Delmestre.

- The Environment and Emergency Department (DEU) is responsible for monitoring environmental protection and managing emergency situations. It establishes policy on nationwide radiological monitoring and on the provision of information to the public and helps to ensure that discharges from BNIs are as low as reasonably achievable, in particular by establishing general regulations. It contributes to defining the framework of the organisation of the public authorities and nuclear licensees in the management of emergency situations. Finally, it defines ASN's oversight and regulation policy. The DEU comprises three Branches: "Safety and Emergency Preparedness", "Environment and Prevention of Nuisances" and "Development of Regulations".

- The International Relations Department (DRI) is in charge of ASN's bilateral and multilateral international relations. It develops exchanges with ASN's counterpart organisations in other countries, to gain understanding of their practices, to provide information about and explain the French approach and practices and to provide the countries concerned with useful information on the safety of French nuclear installations close to their borders. The DRI coordinates ASN representation within international bodies such as the European Union, IAEA or the OECD's Nuclear Energy Agency (NEA).

- The Communication and Public Information Department (DCI) is responsible for developing and implementing ASN's policy on communication and information regarding nuclear safety and radiation protection. It coordinates communication and information actions targeting different audiences, with a focus on handling requests for documentation, making ASN's position known and explaining regulations. The DCI comprises two Branches: "Public Information" and "Publications and Multimedia".

THE DIRECTORS

From left to right: Daniel Delalande, Christophe Kassiotis, Frédéric Joureau, Alain Rivière, Anne-Cécile Rigail, Bénédicte Genthon and Jean-Luc Godet (Not in photo: Fabien Feron, Rémy Catteau and Alain Delmestre).

THE REGIONAL DIVISION HEADS

From left to right: Pierre Siefridt, Rémy Zmyslony, Marc Champion, Bastien Poubeau, Jean-Michel Férat and Laurent Deproit (Not in photo : Paul Bougon, Hélène Héron, Marie Thomines, Pierre Boquel and Pierre Bois).

THE REGIONAL REPRESENTATIVES

From left to right: Annick Bonneville, Vincent Motyka, Emmanuelle Gay, Patrice Guyot, Jérôme Goellner, Christophe Chassande, Patrick Berg, Françoise Noars, Thierry Vatin and Corinne Tourasse.

- The Office of Administration (SG) helps to provide ASN with the adequate, appropriate and long-term resources necessary for it to function. It is responsible for managing human resources, including with regard to skills, and for developing social dialogue. It is also responsible for ASN real estate policy and its logistical and material resources. It is in charge of ASN budget policy and ensures optimised use of its financial resources. Finally, it provides legal expertise for ASN as a whole. The SG comprises four Branches: "Human Resources", "Budget and Finance", "Logistics and Real Estate" and "Legal Affairs".

- The Management and Expertise Office (MEA) provides ASN with IT resources and a high level of expertise. It ensures that ASN's actions are coherent, by means of a quality approach and by overseeing coordination of the workforce. The MEA comprises three Branches: "Information Technology and Telephony", "Expertise and Research" and "Coordination and Quality".

ASN regional divisions

For many years, ASN has benefited from a regional organisation built around its eleven regional divisions. These regional divisions operate under the authority of the regional representatives. The Director of the Regional Directorate for the Environment, Planning and Housing (DREAL) or of the Regional and Interdepartmental Directorate for the Environment and Energy (DRIEE) in which the division in question is located takes on this responsibility as regional representative. He or she is placed at the disposal of ASN to fulfil this role which is not exercised under the authority of the Prefect. This person is delegated with power of signature by the ASN Chairman for decisions at the local level.

The regional divisions carry out most of the direct inspections on the BNIs, on radioactive substance transport operations and on small-scale nuclear activities, and review most of the authorisation applications filed with ASN by the nuclear activity licensees within their regions. They are organised into two to four hubs, depending on the activities to be regulated in their territory.

In emergency situations, the regional divisions assist the Prefect, who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility on the site. To ensure preparedness for these situations, they take part in drawing up the emergency plans drafted by the Prefects and in periodic emergency exercises.

The regional divisions contribute to ASN's public information duty. They for example take part in the meetings of the Local Information Committees (CLIs) and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

ASN's regional divisions are presented in chapter 8 of this report.

2.3.3 Operation

Human resources

As at 31st December 2016, the total ASN workforce stood at 483, divided between the head office departments (263 staff members), the regional divisions (216 staff members) and various international organisations (4 staff members).

This workforce can be further broken down as follows:
- 388 tenured or contract staff members;
- 95 staff members seconded by public establishments (Andra, *Assistance publique – Hôpitaux de Paris*, CEA, IRSN, Departmental Fire and Emergency Response Service).

ASN implements a diversified hiring policy in terms of profiles and experience, with the aim of ensuring that it has enough qualified and complementary human resources to perform its duties. In its opinion of 6th May 2014 concerning preparations for the Budget Bill for the period 2015-2017, it considered that 125 positions would need to be created by the end of 2017 in order to address the unprecedented safety challenges with which it is faced. Following budget discussions and decisions, it noted the 50 additional positions (including 30 in 2017) which had been granted to it for this same period.

In order to obtain the required experience and level of expertise, ASN sets up training programmes and procedures for integrating new arrivals and handing down specific know-how. It also aims to offer a variety of career paths, commensurate with its needs, based in particular on the experience of its staff.

FOCUS

The State's regional reforms and ASN

Following the adoption by Parliament of the Act constituting the regional reorganisation of the Republic and then the Prime Minister's presentation to the Cabinet of Ministers on 31st July 2015 of the provisional list of the capitals of the new regions and the reorganisation of the local government administrations, ASN analysed the impact of these reforms on its regional organisation.

The ASN Commission and Director General's office, in close liaison with the regional divisions, thus initiated a review to take account of the new locations of the DREAL and the offices of the Prefects and the geographical situation of the new regional capitals.

On the basis of a report from the General Council for the Economy, asked by ASN in 2015 to support it in this review, and exchanges with the regional delegates, the division heads and the personnel, the Commission adopted a number of orientations on 24th May 2016, defining the regional organisation adopted.

An oversight committee was set up to monitor the implementation of these orientations.

The orientations adopted on 24th May 2016

1. All of ASN's current geographical sites are maintained as they stand.

2. For implementation by the autumn of 2016, the Director General's office will define an organisation and a working method such as to reinforce integration of the DEP within the head office departments and develop its relations, more specifically with the DCN and the DRC.

3. The Lille division will be taking charge of oversight of radiation protection within the perimeter of the former Picardie region. Jointly with the regional division heads and in consultation with the personnel, the regional delegates concerned will be tasked with studying the practicalities of this assumption of responsibility and will submit proposals to the Director General's office.

4. The Bordeaux division will be taking charge of oversight of radiation protection within the perimeter of the former Limousin region. Jointly with the regional division heads and in consultation with the personnel, the regional delegates concerned will be tasked with studying the practicalities of this transfer of oversight process and will submit proposals to the Director General's office.

5. For the Grand Est region, jointly with the regional division heads and in consultation with the personnel, the regional delegate will be tasked with studying the practicalities that could be envisaged for the organisation and working of ASN in this region, in which it will have two sites in Strasbourg and Châlons-en-Champagne. It will then submit its proposals to the Director General's office.

6. Jointly with the regional delegates and the heads of the regional divisions concerned, the Director General's office will examine the practicalities of the oversight of nuclear safety and radiation protection in the Occitanie region.

Skills management

Competence is one of the four key values of ASN. The tutor system, initial and continuing training, whether general, linked to nuclear techniques, the field of communication, or legal matters, as well as day-to-day practices, are essential aspects of the professionalism of ASN staff.

Management of the skills of ASN personnel is based primarily on a technical training programme tailored to each staff member, based on professional training requirements that include minimum experience conditions.

Pursuant to the provisions of Articles L. 592-22 and L. 592-23 of the Environment Code, which more specifically state that *"ASN shall appoint nuclear safety inspectors […] and radiation protection inspectors […] from among its staff"* and Decree 2007-831 of 11th May 2007 setting the procedures for appointing and qualifying nuclear safety inspectors, which states that the *"nuclear safety inspectors and the staff responsible for checking nuclear pressure equipment […] are chosen for their professional experience and their legal and technical knowledge"*, ASN set up an official process for accrediting certain of its staff members to perform its inspections and, as necessary, carry out judicial policing roles. ASN also carries out labour Inspectorate duties in the nuclear power plants, pursuant to Article R. 8111-11 of the Labour Code. For each of the inspectors it qualifies, the accreditation decision taken by ASN is based on the adequacy of the skills acquired, both within and outside ASN, with those specified in the professional baseline requirements.

Furthermore, and in order to recognise the expertise and experience of its inspectors, ASN has set up a process enabling it to select senior inspectors from among its staff, to whom it can entrust inspections that are more complex or with more significant implications. As at 31st December 2016, 43 ASN nuclear safety and radiation protection inspectors were senior inspectors, or nearly 15% of the 283 ASN staff members holding at least one accreditation.

In 2016, nearly 3,950 days of training were provided to ASN staff through 210 sessions forming part of 122 different courses. The financial cost of the courses provided by organisations other than ASN, amounted to €430 k.

Social dialogue

ASN comprises various entities enabling it to maintain and develop high-quality social dialogue.

During the course of 2016, the ASN Social Dialogue Committee (SDC) met on four occasions, including one extraordinary session to address on the one hand the orientations adopted within the context of the State's regional reforms and, on the other, the project to relocate the Marseille division. On other matters, numerous discussions were held with the personnel representatives: operating experience feedback on implementation of the travel charter for head office staff and international travel, social audit, training audit, budget implementation, comparison between ASN and the Dreal in terms of working times, convention between ASN and the Ministries for the Economy and Finance, actions resulting from the management seminar, headquarters redevelopment project, etc.

Complementing the action of the ASN SDC, the Joint Consultative Commission (CCP) - which has competence for contract staff - met twice. In addition to prolonging the tenure system for contractual staff set out in the Decree of 3rd August 2016, the discussions mainly concerned the general situation of ASN contractual staff and their career prospects.

Finally, the ASN health, safety and working conditions committee met five times in 2016, including twice in extraordinary session, to examine in advance the conditions for performance of an audit more particularly concerning labour inspectorate duties at ASN and, subsequently, the recommendations resulting from this audit. Moreover, discussions with the personnel representatives covered a variety of subjects: experience feedback on implementation of the hydrostatic testing security guide, ASN procedure for severe and imminent dangers, examination of the occupational risks assessment document and validation of the annual prevention programme for 2016-2017, radiation protection audit, audit of general health, safety and working conditions situation at ASN.

Professional ethics

Three legislative texts set specific rules of professional ethics applicable to ASN:

- The Environment Code stipulates that as soon as the ASN Commission members are appointed, they shall draw up a declaration indicating the interests they hold or have held in the course of the previous five years in the areas falling under the competence of ASN. This declaration, which is filed at the ASN headquarters and is held at the disposal of the members of the Commission, is updated at the initiative of the Commissioner concerned as soon as any change occurs. No member of the Commission may, during their mandate, hold an interest that could affect their independence or impartiality (Article L. 592-6 of the Environment Code).
- The Act of 29th December 2011 relative to reinforcing the safety of medicines and health products, known as the "Medicines Act", establishes a modernised framework for professional ethics and sanitary expertise with which the Authorities involved in the area of health and sanitary safety must comply. For ASN, these particular ethical rules apply to its activity relative to the safety of health products. The declarations of interests of the persons

concerned within ASN, and the members of the ASN Commission in particular, are published on *www.asn.fr*.
- Act 2013-907 of 11th October 2013 concerning transparency in public life, requires that a declaration of the interests held as at the date of nomination and for the five years preceding this date be sent to the High Authority for Transparency in Public Life, along with an exhaustive, accurate and true declaration of individual or common assets, more specifically by the members of independent administrative Authorities. For ASN, the members concerned are the members of the Commission. This Act was modified by Act 2016-1691 of 9th December 2016 on transparency, the fight against corruption and the modernisation of economic life. It now states that as of 1st January 2017, these declarations also concern the Director General and the Deputy Director Generals of ASN.

In addition, Act 2016-483 of 20th April 2016 concerning professional ethics and the rights and obligations of civil servants reinforced Act 83-634 of 13th July 1983 on the rights and obligations of civil servants applicable to ASN staff. Chapter 3 of the ASN's Rules of Procedure sets out the rules applicable to all ASN employees, focusing in particular on:
- observance of professional secrecy and duty of discretion;
- abuse of authority and breaches of the duty of integrity;
- conflicts of interest;
- guarantees of independence with regard to persons or entities subject to ASN oversight.

Financial resources

ASN's financial resources are presented in point 3.

In the same way as its request for additional staff expressed in its opinion of 6th May 2014, ASN considered that with regard to preparations for the Budget Bill for the period 2015-2017, it would need a budget increase in order to address the unprecedented safety challenges with which it is faced.

Following budget discussions and decisions, it duly noted the stability of its operating budget for this same period.

ASN management tools

The Multi-year Strategic Plan

The Multi-year Strategic Plan (PSP), produced under the authority of the ASN Commission, develops ASN's strategic lines for a period of several years. It is presented

FOCUS

In 2017, the French system for the regulation of nuclear safety and radiation protection will undergo an IAEA assessment of the steps taken following the review carried out at the end of 2014

In November 2014, an Integrated Regulatory Review Service (IRRS) mission was carried out by a team of 29 international experts under the auspices of IAEA, concerning all the activities regulated by ASN. It examined the strengths and weaknesses of the French nuclear safety and radiation protection oversight system with respect to IAEA standards.

Several good practices were identified, primarily in terms of stakeholder involvement in the regulatory processes, transparency and communication, personnel independence in the performance of their duties and coordination between the oversight bodies involved in emergency planning and management.

A few points were identified as meriting particular attention, checks, or improvements, in particular the following:
- The regulatory framework for monitoring exposure in the medical field should be evaluated to ensure that there are no shortcomings and that the coordination between the organisations involved is appropriate.
- The system used by ASN to assess and modify its regulatory framework should be reinforced.
- All the processes ASN needs in order to perform its role should be specified in its integrated management system and implemented in full.
- New means must be examined in order to guarantee that ASN has the human and financial resources it needs for effective oversight of nuclear safety and radiation protection in the future.

ASN considers that the IRRS missions make a significant contribution to the international safety and radiation protection system. ASN is thus closely involved in hosting missions in France and in participating in missions in other countries. Commissioner Philippe Jamet thus headed an IRRS mission in Japan in January 2016.

In 2006, ASN hosted the first IRRS (Integrated Regulatory Review Service) mission concerning all the activities of a safety regulator, with a follow-up mission in 2009.

These audits are the result of the European Nuclear Safety Directive which requires a peer review mission every ten years.

The reports for the 2006, 2009 and 2014 IRRS missions are available for consultation on *www.asn.fr*.

annually in an operational orientation document that sets the year's priorities for ASN, and which is in turn adapted by each entity into an annual action plan that is subject to periodic monitoring. This three-level approach is an essential part of ASN's development, organisation and management. The PSP for the period 2013-2015, entitled "Taking up the challenges of nuclear safety and radiation protection: regulation, independence and transparency", was prolonged for 2016 and comprises the following five strategic lines:

- enhance the legitimacy of ASN's resolutions and position statements;
- develop an efficient working environment and enhance skills;
- develop ASN's forward-looking, proactive approach;
- make the European hub a driving force for nuclear safety and radiation protection around the world;
- raise and fuel discussions and debates on the topic of nuclear safety and radiation protection.

The PSP is accessible on *www.asn.fr*.

The ASN internal management system

Within ASN, there are many forums for discussion, coordination and oversight.

These bodies, supplemented by the numerous cross-disciplinary structures, reinforce the safety culture of its staff through experience sharing and the definition of coherent common positions.

Quality management system

To guarantee and improve the quality and effectiveness of its actions, ASN defines and implements a quality management system inspired by the International Standard Organisation (ISO) and IAEA international standards. This system is based on:

- an organisation manual containing organisation notes and procedures, defining the rules to be applied for each task;
- internal and external audits to check rigorous application of the system's requirements;
- listening to the stakeholders;
- performance indicators for monitoring the effectiveness of action taken;
- a periodic review of the system, to foster continuous improvement.

Internal communication

Reinforcing the internal culture and reasserting the specific nature of ASN's remit, rallying the staff around the strategic orientations defined for their missions, and developing strong group dynamics: ASN's internal communication endeavours, in the same way as human resources management, to foster the sharing of information and experience between teams and professions.

2.4 The consultative and discussion bodies

2.4.1 The High Committee for Transparency and Information on Nuclear Security

The TSN Act created a High Committee for Transparency and Information on Nuclear Security (HCTISN), an information, discussion and debating body dealing with the risks inherent in nuclear activities and the impact of these activities on human health, the environment and nuclear safety.

The High Committee can issue an opinion on any question in these fields, as well as on controls and the relevant information. It can also deal with any issue concerning the accessibility of nuclear safety information and propose any measures such as to guarantee or improve nuclear transparency. It can be called on by the Government, Parliament, the Local Information Committees or the licensees of nuclear facilities, with regard to all questions relating to information about nuclear safety and its regulation and monitoring.

The HCTISN's activities in 2016 are described in chapter 6.

2.4.2 The High Council for Public Health

The High Council for Public Health (HCSP), created by Act 2004-806 of 9th August 2004 concerning public health policy, is a scientific and technical consultative body reporting to the Minister responsible for Health.

The HCSP contributes to defining the multi-year public health objectives, reviews the attainment of national public health objectives and contributes to their annual monitoring. Together with the health agencies, it provides the public authorities with the expertise necessary for managing health risks and for defining and evaluating prevention and health safety policies and strategies. It also anticipates future developments and provides advice on public health issues.

2.4.3 The High Council for Prevention of Technological Risks

Consultation about technological risks takes place before the High Council for Prevention of Technological Risks (CSPRT), created by Order 2010-418 of 27th April 2010. Alongside representatives of the State, the Council comprises licensees, qualified personalities and representatives of environmental associations. The CSPRT, which takes over from the high council for classified facilities, has seen the scope of its remit extended to pipelines transporting gas, hydrocarbons and chemicals, as well as to BNIs.

The Government is required to submit Ministerial Orders concerning BNIs to the CSPRT for its opinion. ASN may also submit resolutions relating to BNIs to it.

By Decree of 28th December 2016, the scope of competence of the CSPRT was again expanded. A standing sub-committee responsible for preparing the Council's opinions in the field of pressure vessels takes the place of the Central Committee for Pressure Equipment (CCAP). The role of this sub-committee is to examine non-regulatory decisions falling within this scope of competence.

It comprises members of the various administrations concerned, persons chosen for their particular competence and representatives of the pressure equipment manufacturers and users and of the technical and professional organisations concerned.

It must be referred to by the Government and by ASN for all questions affecting ministerial orders concerning pressure equipment. The accident files concerning this equipment are also copied to it.

2.4.4 Local Information Committees for the Basic Nuclear Installations

The Local Information Committees (CLI) for BNIs are tasked with a general duty of monitoring, information and consultation on the subject of nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment, with respect to the site or sites which concern them. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

The CLIs, whose creation is incumbent upon the President of the General Council of the *département*, comprise various categories of members: representatives of General Councils, of the municipal councils or representative bodies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations, economic interests and representative labour trade union and representative medical profession union organisations, and qualified personalities.

The status of the CLIs was defined by the TSN Act of 13th June 2006 and by Decree 2008-251 of 12th March 2008.

The duties and activities of the CLIs are described in chapter 6.

2.5 Technical support organisations

ASN benefits from the expertise of technical support organisations to prepare its resolutions. IRSN is the main one. For several years now, ASN has been devoting efforts to ensuring greater diversification of its experts.

2.5.1 IRSN

IRSN was created by Act 2001-398 of 9th May 2001 and by Decree 2002-254 of 22nd February 2002 as part of the national reorganisation of nuclear safety and radiation protection regulation, in order to bring together public expertise and research resources in these fields. IRSN reports to the Ministers for the Environment, Health, Research, Industry and Defence.

Articles L.592-41 to L.592-43 of the Environment Code specify that IRSN is a State public industrial and commercial institution which carries out expert appraisal and research missions in the field of nuclear safety – excluding any responsibility as nuclear licensee. IRSN contributes to information of the public and publishes the opinions requested by a public authority or ASN, in consultation with them. It organises the publicity of scientific data resulting from the research programmes run at its initiative, with the exception of those relating to defence matters.

For the performance of its missions, ASN receives technical support from IRSN. As the ASN Chairman is now a member of the IRSN Board, ASN contributes to setting the direction of IRSN's strategic planning.

TECV Act

This Act clarifies the organisation of the system built around ASN and IRSN:

- It enshrines the existence and duties of IRSN within a new section 6 of the Environment Code entitled "The Institute for Radiation Protection and Nuclear Safety" in Chapter II concerning "The Nuclear Safety Authority (ASN)" of Title IX of Book V of the Environment Code.
- It recalls that ASN benefits from IRSN technical support, indicating that this support comprises expert appraisal activities *"supported by research"*.
- It clarifies the relations between ASN and IRSN, indicating that ASN *"guides IRSN's strategic decisions concerning this technical support"* and that the ASN Chairman is a member of the Board of the Institute.
- Finally, it also makes provision for the principle of the publication of IRSN opinions.

IRSN conducts and implements research programmes in order to build its public expertise capacity on the very latest national and international scientific knowledge in the fields of nuclear and radiological risks. It is tasked with providing technical support for the public authorities with competence for safety, radiation protection and security, in both the civilian and defence sectors.

IRSN also has certain public service responsibilities, in particular monitoring of the environment and of populations exposed to ionising radiation.

IRSN manages national databases (national nuclear material accounting, national inventory of radioactive sources, file for monitoring worker exposure to ionising radiation, etc.), and thus contributes to information of the public concerning the risks linked to ionising radiation.

IRSN workforce

As at 31st December 2016, IRSN's overall workforce stood at 1,700 employees, of which 400 are devoted to ASN technical support.

IRSN budget

The IRSN budget is presented in point 3.

A five-year agreement defines the principles and procedures for the technical support provided to ASN by the Institute. This agreement is clarified on a yearly basis by a protocol identifying the actions to be performed by IRSN to support ASN.

2.5.2 Advisory Committees of Experts

To prepare its resolutions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPE), with competence for waste, nuclear pressure equipment, reactors, transport, laboratories and factories, medical radiation protection, radiation protection in non-medical sectors and the environment, respectively.

At the request of ASN, the GPEs issue opinions on certain technical dossiers with significant consequences. They can also be consulted about changes in regulations or doctrine.

For each of the subjects covered, the GPEs examine the reports produced by IRSN, by a special working group or by one of the ASN departments. They issue an opinion backed up by recommendations.

The GPEs consist of experts appointed individually for their competence and are open to civil society. Their members come from university and association backgrounds and from appraisal and research organisations. They may also be licensees of nuclear facilities or come from other sectors (industrial, medical, etc.). Participation by foreign experts can help diversify the approach to problems and provide the benefit of experience acquired internationally.

Each GPE member produces a declaration of interest. Experts with a direct interest in the subject being addressed do not take part in establishing the position of the GPE.

Since 2009, as part of its commitment to transparency in nuclear safety and radiation protection, ASN has published the GPE letters of referral, the opinions of the GPEs and ASN's position statements based on these opinions. IRSN for its part publishes the syntheses of the technical investigation reports it presents to the GPEs.

Advisory Committee for Waste (GPD)

The Advisory Committee for Waste (GPD) is chaired by Pierre Bérest and comprises 35 experts appointed for their competence in the nuclear, geological and mining fields.

In 2016, it held an information meeting and a three-day bipartite meeting with German experts in Lyon, during which it visited the Bugey 1 reactor undergoing decommissioning and the activated waste packaging and storage facility located on the Bugey NPP site, yet to be commissioned.

Advisory Committee for Nuclear Pressure Equipment (GPESPN)

Since 2009, the GPESPN has replaced the standing nuclear section of the CCAP, itself replaced since 28th December 2016 by the standing sub-committee of the CSPRT. The GPESPN is chaired by Philippe Merle and comprises 27 experts appointed for their competence in the field of pressure equipment.

In 2016, it held one plenary meeting and two information meetings.

Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED)

Chaired by Bernard Aubert, the GPMED comprises 36 experts appointed for their competence in the field of radiation protection of health professionals, the general public and patients and for medical and forensic applications of ionising radiation.

The composition of the GPMED was renewed on 16th December 2016.

In 2016, it held six meetings, two of which were organised jointly with the GPRADE.

Advisory Committee for Radiation Protection for Industrial and Research Applications of Ionising Radiation and in the Environment (GPRADE)

Chaired by Jean-Paul Samain, the GPRADE comprises 35 experts appointed for their competence in the fields of radiation protection of workers (other than health professionals) and the public, for industrial and research applications using ionising radiation and for exposure to ionising radiation of natural origin, and protection of the environment.

The composition of the GPRADE was renewed on 16th December 2016.

In 2016, it held four meetings, two of which were organised jointly with the GPMED.

Advisory Committee for Nuclear Reactors (GPR)

The Advisory Committee for Nuclear Reactors is chaired by Philippe Saint Raymond and comprises 34 experts appointed for their competence in the field of nuclear reactors.

In 2016, it held six plenary meetings, three of which were over two days, one joint information meeting with the GPU and visited the EPR construction site in Flamanville.

Advisory Committee for Transport (GPT)

The GPT is chaired by Jérôme Joly and comprises 25 experts appointed for their competence in the field of transport.

The GPT did not meet in 2016.

Advisory Committee for Laboratories and Plants (GPU)

The Advisory Committee for Laboratories and Plants is chaired by Jérôme Joly and comprises 31 experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances.

In 2016, it held two plenary meetings, one joint information meeting with the GPR and visited two BNIs.

2.5.3 The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €0.22 million in 2016.

In 2013, it also set up a framework agreement with expert appraisal organisations to ensure more dynamic use of a diversified panel of expertise.

In 2016, ASN continued or initiated collaboration with:
- the Ernst & Young et Associés company: environmental assessment of the 2016-2018 National Radioactive Materials and Waste Management Plan (PNGMDR) pursuant to the provisions of Article L. 122-4 et seq. of the Environment Code;
- IAEA for the purposes of a peer review of *Cigéo*;
- a group of several organisations approved for nuclear pressure equipment for an analysis of the regulatory and standards reference system concerning the evaluation of the conformity of certain equipment items.

2.6 The pluralistic working groups

ASN has set up several pluralistic working groups; they enable the stakeholders to take part in developing doctrines, defining action plans or monitoring their implementation.

2.6.1 The working group on the National Radioactive Materials and Waste Management Plan

Article L.542-1-2 of the Environment Code requires the production of a National Radioactive Materials and Waste Management Plan (PNGMDR), which is revised every three years and serves to review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, specify the necessary capacity of these facilities and the storage durations and, for radioactive waste for which there is as yet no final management solution, determine the objectives to be met.

The Working Group (WG) tasked with producing the PNGMDR comprises environmental protection associations, experts, representatives from industry and regulatory authorities, alongside the radioactive waste producers and managers. It is co-chaired by the General Directorate for Energy and the Climate of the Ministry for the Environment, Energy and the Sea and by ASN.

The work of the PNGMDR WG is presented in greater detail in chapter 16.

2.6.2 The Steering Committee for Managing the Nuclear Post-Accident Phase

Pursuant to the Interministerial Directive of 7th April 2005, ASN, in association with the Ministerial departments concerned, is responsible for defining, preparing and implementing the steps necessary for managing a post-accident situation.

In order to develop a doctrine and after testing post-accident management during national and international exercises, ASN brought all the players concerned together within the Codirpa (Steering Committee responsible for Post-Accident Management). This committee, headed by ASN, has representatives from the ministerial departments concerned, the health agencies, associations, the CLI, and IRSN.

The work of the Codirpa is presented in greater detail in chapter 5.

2.6.3 The pluralistic working groups

Considering that it was necessary to move forward with regard to the reflections and work being done on the contribution of humans and organisations to the safety of nuclear facilities, ASN therefore decided in 2012 to set up the Steering Committee for Social, Organisational and Human Factors (COFSOH). The purpose of the COFSOH is on the one hand to allow exchanges between stakeholders on such a difficult subject as social, organisational and human factors and, on the other, to draft documents proposing common positions by the various members of the COFSOH on a given subject, along with guidelines for future studies to shed light on subjects that are insufficiently understood or which are lacking in clarity.

In 2015, the national committee responsible for monitoring the national plan for management of radon risks, chaired by ASN, carried out an assessment of the 2011-2015 national action plan and in January 2017 published the third plan for the period 2016-2019 (see chapter 1).

TABLE 1: Advisory Committee meetings and visits in 2016

GPE	MAIN TOPIC	DATE
GPR/GPU	Information meeting to present the conclusions of SIGMA	7th January
GPMED	Subjects concerning the transposition of Directive 2013/59/Euratom	19th January
GPR	Deployment of the post-Fukushima hardened safety core: extreme external hazards for Pressurised Water Reactors	28th January
GPMED	Orientation report on the transposition of Directive 2013/59/Euratom: regulatory part of the medical field	2nd February
GPRADE	Set of observations on radon and recommendations on the use of dose constraints for protection of the public	11th February
GPR	Storage/handling of EPR fuel	30th and 31st March
GPRADE/GPMED	Transposition of Directive 2013/59/Euratom: planned modifications in the Public Health Code and opinion concerning the recommendations on the use of dose constraints for protection of the public	12th April
GPESPN	In-service strength of PWR austenitic-ferritic cast elbows	8th June
GPD	Information meeting on geochemistry, Cigéo, WIPP and ASN opinion on the PNGMDR	16th June
GPESPN	Information meeting on the EPR vessel domes anomaly and on the problem of positive carbon macrosegregations on the EDF NPPs in operation	24th June
GPRADE/GPMED	Transposition of Directive 2013/59/Euratom: planned modifications to the Labour Code	28th June
GPU	Visit to BNI 55	29th June
GPR	EPR safety case studies	30th June and 1st July
GPR	Deployment of the post-Fukushima hardened safety core: severe accidents management	7th July
GPU	Periodic safety review of BNI 55	12th July
GPD	Meeting between the GPD and its German counterpart in Lyon with a visit to Bugey 1 and Iceda	12th and 14th September
GPR	Visit to the EPR construction site	23rd September
GPMED	Death of patients being treated in nuclear medicine or brachytherapy with permanent implants and recommendations on the use of dose constraints in the medical field – Persons taking part in care and support for patients and volunteers taking part in medical or biomedical research	4th October
GPRADE	Recommendations on the use of dose constraints for protection of the public and recommendations for discharge into sewage networks of effluents containing radionuclides	7th October
GPU	Visit to BNI 98	13th October
GPU	Periodic safety review of BNI 98	2nd November
GPR	Draft guide on the design of pressurised water reactors	22nd November
GPMED	Recommendations concerning the estimation of doses received by workers handling radioactive human remains, recommendations on the use of dose constraints in the medical field and consideration given to the reassessment of the recommendations on the conditions for use of lutetium-177 in nuclear medicine	29th November
GPESPN	Information concerning the updating of the ESPN Order, the final repair of the Gravelines 4 vessel bottom head penetration and topical subjects	7th December
GPR	EPR systems and hazards	14th and 15th December

2.7 Other stakeholders

As part of its mission to protect the general public from the health risks of ionising radiation, ASN cooperates closely with other competent institutional stakeholders addressing health issues.

2.7.1 The National Agency for the Safety of Medication and Health Products

The National Agency for the Safety of Medication and Health Products (ANSM) was created on 1st May 2012. The ANSM, a public body reporting to the Ministry of Health, has taken up the duties of the AFSSAPS alongside other new responsibilities. Its key role is to offer patients equitable access to innovation and to guarantee the safety of health products throughout their life cycle, from initial testing through to monitoring after receiving marketing authorisation.

The Agency and its activities are presented on its website: *www.ansm.sante.fr*. The ASN-ANSM convention was renewed on 2nd September 2013.

2.7.2 French National Authority for Health

The French National Authority for Health (HAS), an independent administrative authority created by the French Government in 2004, is tasked primarily with maintaining an equitable health system and with improving patient care.

The Authority and its activities are presented on its website *www.has-sante.fr*. An ASN-HAS convention was signed on 4th December 2008..

2.7.3 French National Cancer Institute

Created in 2004, the French National Cancer Institute (INCa) is primarily responsible for coordinating activities in the fight against cancer.

The Institute and its activities are presented on its website: *www.e-cancer.fr*. An ASN-INCa convention was signed on 17th February 2014.

3. Financing the regulation of nuclear safety and radiation protection

Since 2000, all the personnel and operating resources involved in the performance of the responsibilities entrusted to ASN have been covered by the State's general budget.

In 2016, the ASN budget amounted to €80.79 million in payment credits. It comprised €41.93 million in ASN payroll credits and €38.86 million in operating credits for the ASN central services and its eleven regional divisions.

The total IRSN budget for 2016 amounted for its part to €217 million, of which €85 million were devoted to the provision of technical support for ASN. IRSN credits for ASN technical support are covered in part (€42 million) by a subsidy from the State's general budget allocated to IRSN and included in action 11 "Research in the field of risks" of programme 190 "Research in the fields of energy and sustainable development and spatial planning", of the interministerial "Research and higher education" mission. The rest (€43 million) is covered by a contribution from the nuclear licensees. This contribution was put into place by the budget amendment Act of 29th December 2010. Each year, ASN is consulted by the Government concerning the corresponding part of the State subsidy to IRSN and the amount of the annual contribution due from the BNI licensees.

In total, the State's budget for transparency and the regulation of nuclear safety and radiation protection amounted to €176.54 million in 2016: €80.79 million for the ASN budget, €85 million for IRSN technical

TABLE 2: Breakdown of licensee contributions

LICENSEE	AMOUNT FOR 2016 (MILLIONS OF EUROS)			
	BNI TAX	ADDITIONAL WASTE AND DISPOSAL TAXES	SPECIAL ANDRA CONTRIBUTION	CONTRIBUTION TO IRSN
EDF	543.63	112.01	104.58	48.42
Areva Group	16.55	7.18	6.68	6.10
CEA	6.51	21.48	22.80	7.14
Andra	5.41	3.30	-	0.40
Others	4.72	1.95	-	0.70
TOTAL	**576.82**	**145.92**	**134.06**	**62.76***

** The amount allocated to IRSN is capped at €62.52 M*

TABLE 3: Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France (January 2017)

				BUDGET RESOURCES				REVENUE
				INITIAL BUDGET ACT 2016		INITIAL BUDGET ACT 2017		
MISSION	PROGRAMME	ACTIONS	NATURE	AE (M€)	CP (M€)	AE (M€)	CP (M€)	BNI TAX 2016 (€M)
Ministerial mission **Ecology, sustainable development and spatial planning**	**Programme 181:** Risk Prevention	**Action 9:** Regulation of nuclear safety and radiation protection	Staff costs (including seconded employees)	41.93	41.93	44.92	44.92	576.82
			Operating and intervention spending	12.93	17.94	12.88	17.88	
			TOTAL	**54.86**	**59.87**	**57.80**	**62.80**	
		Action 1: Prevention of technological risks and pollution	Operation of the HCTISN (High Committee for Transparency and Information on Nuclear Security)	0.15	0.15	0.15	0.15	
	Programme 217: Management and coordination of policies for ecology, energy and sustainable development and the sea	-	Operation of ASN's 11 regional divisions	13.35 [1]	13.35 [1]	13.35 [1]	13.35 [1]	
Ministerial mission **Oversight of government actions**	**Programme 333:** Resources shared by decentralised administrations	-		1.15	1.15	1.15	1.15	
Interministerial mission **Management of public finances and human resources**	**Programme 218:** Implementation and oversight of economic and financial policy	-	Operation of the ASN central services [2]	6.27	6.27	6.27	6.27	
			SUB-TOTAL	75.78	80.79	78.72	83.72	
Interministerial mission **Research and higher education**	**Programme 190:** Research in the fields of energy and sustainable development and spatial planning	**Sub-action 11-2 (area 3):** IRSN	IRSN technical support activities for ASN [3]	42.00	42.00	41.60	41.60	
		Sub-action 11-2 (3 others area): IRSN		132.50	132.50	131.10	131.10	
Annual contribution to IRSN instituted by Article 96 of Act 2010-1658 of 29th December 2010				42.95 [4]	42.95 [4]	43.35 [5]	43.35 [5]	
			SUB-TOTAL	217.45	217.45	216.05	216.05	576.82
			GRAND TOTAL	**293. 23**	**298.24**	**294.77**	**299.77**	**576.82**

(1) Source: Budget Acts for 2013 and 2014 (annual performance project 2014 of programme 181).
(2) Source: 2006 Budget Act (after deduction of transfer made under 2008 Budget Bill).
(3) Source: Budget Acts for 2015 and 2016 (annual performance project 2015 of programme 190).
(4) Out of a total contribution income of €53.10 million in 2014.
(5) Out of a total expected contribution income estimated at €59.90 million in 2016.

FUNDAMENTALS

BNI Tax, additional waste taxes, additional disposal tax, special Andra contribution and contribution to IRSN

Pursuant to the Environment Code, the ASN Chairman is responsible for assessing and ordering payment of the BNI tax, introduced under Article 43 of the 2000 Budget Act (Act 99-1172 of 30th December 1999). The revenue generated by this tax, the amount of which is set yearly by Parliament, came to €576.82 million in 2016. The proceeds go to the central State budget.

Furthermore, for nuclear reactors and spent nuclear fuel reprocessing plants, the «Waste» Act creates three additional «research, «support» and «technological dissemination» taxes. The revenue from these taxes is allocated to funding economic development measures and research into underground disposal and storage by the National Agency for Radioactive Waste Management (Andra). The revenue from these taxes represented €145.92 million in 2016, of which €3.3 million were paid in 2016 to the municipalities and the local public cooperation bodies situated around the disposal centre.

In addition, since 2014, ASN has been tasked with assessing and ordering payment of the special contribution on behalf of Andra created by Article 58 of the 2013 budget amendment Act 2013-1279 of 29th December 2013, which will be payable up until the date of the deep geological disposal facility's creation authorisation. In the same way as the additional taxes, this contribution is due by BNI licensees, as of the creation of their facility and up until the delicensing decision. The revenue from this contribution represented €134.06 million in 2016.

Finally, Article 96 of Act 2010-1658 of 29th December 2010 creates an annual contribution to IRSN to be paid by BNI licensees. This contribution is in particular designed to finance the review of the safety cases submitted by the BNI licensees. The revenue from this contribution amounted to €62.52 million in 2016.

support to ASN, €10.6 million for other IRSN missions and €0.15 million for the working of the HCTISN.

As shown in the table 3, these credits are split between five programmes (181, 217, 333, 218 and 190) to which must be added the annual contribution on behalf of IRSN.

To put this into perspective, the amount of the BNI Tax, paid to the general State budget, amounted in 2016 to €576.83 million.

This complex funding structure is detrimental to the overall clarity of the cost of regulation. It moreover leads to difficulties in terms of budgetary preparation, arbitration and implementation.

4. Outlook

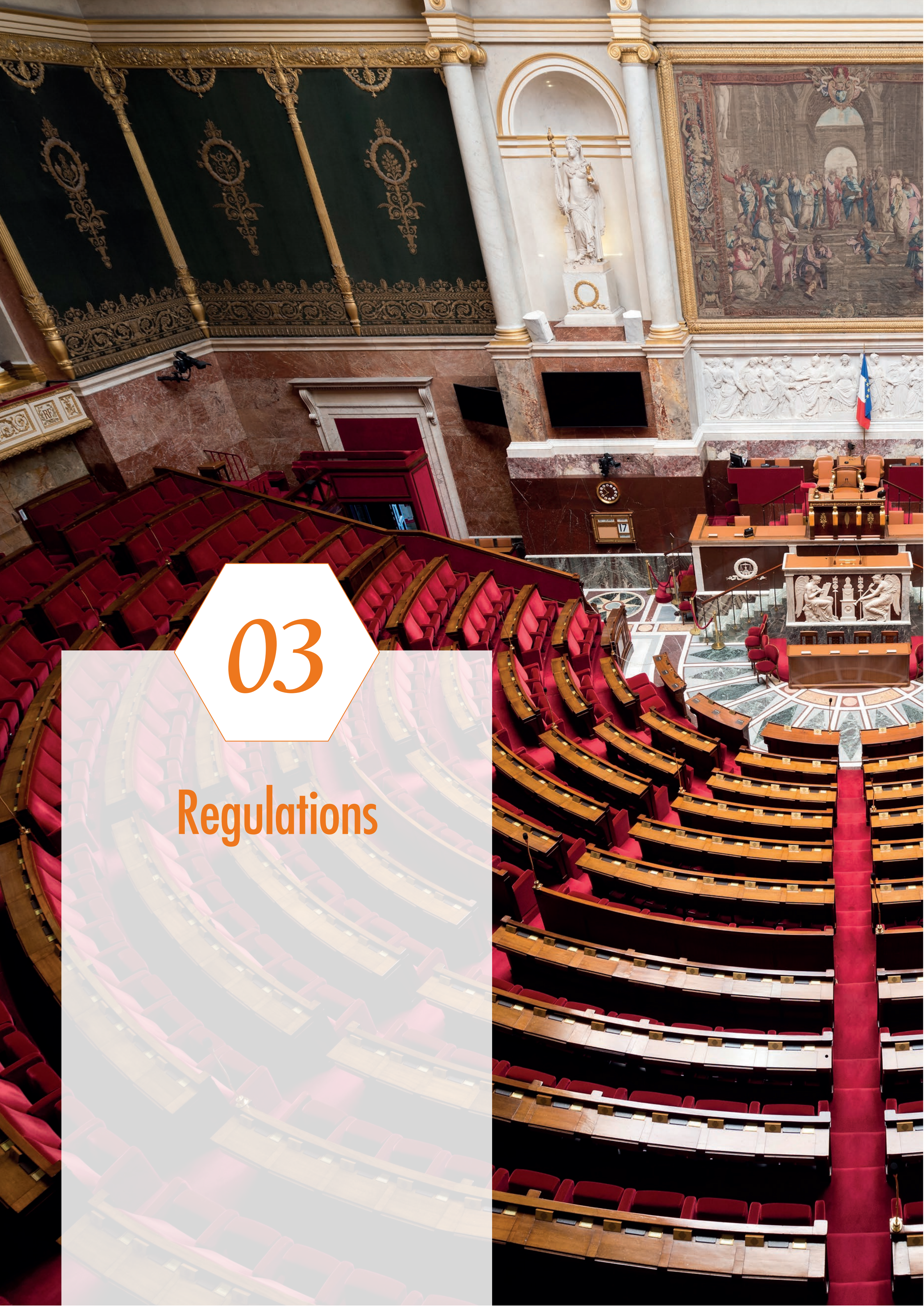
Even if the Act stipulates that the share of nuclear energy in the production of electricity is to be halved by 2025, it will nonetheless remain considerable. The French nuclear NPP fleet will thus continue to be one of the largest in the world. Safety will continue to be enhanced, with reference to the requirements applicable to the new reactors and by learning the lessons from the Fukushima Daiichi accident.

In the light of the unprecedented safety challenges it faces, ASN recalls that in 2014 it asked for an additional 190 staff by the end of 2017 (125 for ASN, 65 for IRSN) and a budget increase of €36 million (€21 million for ASN, €15 million for IRSN). Even though the budget decisions made accorded it an additional 50 staff for the period 2015-2017 and maintained its operating credits, ASN nonetheless remains concerned by the inadequacy of these budgetary measures.

In the coming years, ASN will maintain strong ties - while retaining its full independence - with the other stakeholders involved in the oversight and information duties, in the field of nuclear safety and radiation protection. ASN will in particular promote the involvement of the stakeholders in pluralistic working groups.

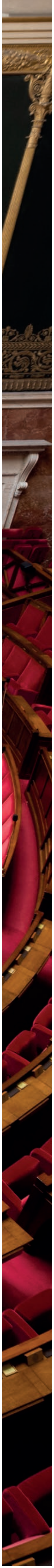
When preparing its resolutions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPE). ASN aims to continue to reinforce the guarantees of independence of the expertise on which it relies and transparency in the process of drafting its resolutions and decisions.

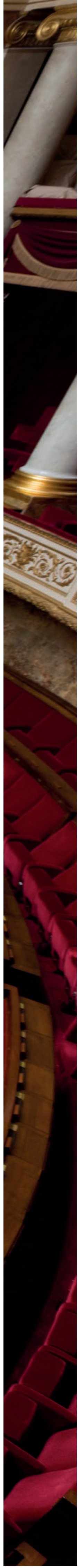
In the second half of 2017, ASN will also host the IAEA follow-up mission to assess the corrective measures taken or progress made within the framework of the specific action plan to address the recommendations made following the IRRS mission of November 2014.



03

Regulations





Nuclear activites are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. Nuclear activities are covered by a legal framework that, depending on the nature of the activity and the associated risks, aims to guarantee that, they will not be likely to be detrimental to safety, public health or the protection of nature and the environment.

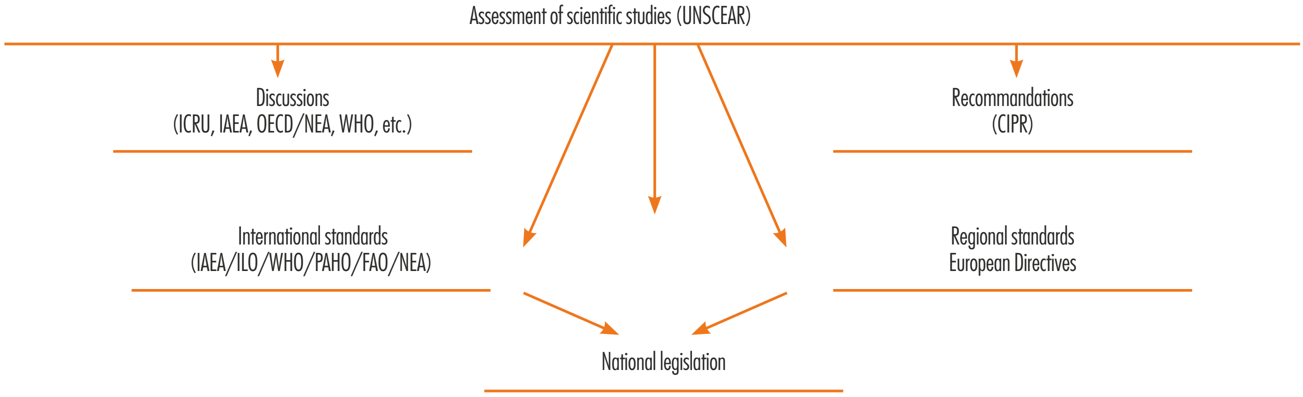
These activities are subject to the general provisions of the Public Health Code and, depending on their nature and the risks that they involve, to a specific legal system:
- the system for Installations Classified on Environmental Protection grounds (ICPE) for those activities covered by the list in Article L. 511-2 of the Environment Code (industrial activities using unsealed radioactive sources, depot, storage or disposal facilities for solid ore residues, etc.);
- the Basic Nuclear Installations (BNI) system specified in Article L. 593-1 of the Environment Code;
- the Defence Basic Nuclear Installations (DBNI) system, which is subject to the Defence Code;
- the small-scale nuclear activities system for the other activities (medical or industrial activities using ionising radiation or radioactive sources).

The transposition into French law of European Council Directive 2013/59/Euratom of 5th December 2013 setting basic standards for health protection against the hazards arising from exposure to ionising radiation, will renovate the general legal framework for nuclear activities by 2018.

1. The general legal framework applicable to nuclear activities

Nuclear activities are defined in Article L. 1333-1 of the CSP (Public Health Code). They are subject to various specific requirements aiming to protect individuals and the environment and apply either to all these activities, or only to certain categories. This set of regulations is described in this chapter.

DIAGRAM 1: Drafting of radiation protection doctrine and basic standards



1.1 The regulatory basis of nuclear activities

1.1.1 Radiation protection international baseline requirements

The specific legal requirements for radiation protection are based on various standards and recommendations issued by various international organisations. The following in particular can be mentioned:

- The International Commission on Radiological Protection (ICRP), a non-governmental organisation comprising international experts from various backgrounds, which publishes recommendations for the protection of workers, the population and patients against ionising radiation, based on the analysis of available scientific and technical knowledge and that published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). The latest ICRP recommendations were published in 2007 in ICRP Publication 103.
- The International Atomic Energy Agency (IAEA) regularly publishes and revises standards in the fields of nuclear safety and radiation protection. The basic requirements concerning protection against ionising radiation and the safety of radiation sources, based on the latest ICRP recommendations (Publication 103), were published in July 2014.
- The International Standard Organisation (ISO) publishes international technical standards constituting a major component of the radiation protection system. They form the interconnection between the principles, concepts, units of measurement and body of regulations for which they guarantee harmonised application.

At the European level, the EURATOM Treaty, in particular the Articles 30 to 33, defines the procedures for drafting EU provisions concerning protection against ionising radiation and specifies the powers and obligations of the European Commission with respect to their enforcement. The corresponding Euratom Directives are binding on the various countries, such as the new European Council Directive 2013/59/Euratom of 5th December 2013 setting basic standards for health protection against the hazards arising from exposure to ionising radiation. This Directive, published in the *Official Journal of the European Union* (JOUE) on 17th January 2014, repeals Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

FOCUS

The new 2013/59/Euratom Directive of 5th December 2013

It supersedes the previous five Directives:
- Directive 89/618/Euratom of 27th November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency;
- Directive 90/641/Euratom of 4th December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas;
- Directive 96/29/Euratom of 13th May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation;
- Directive 97/43/Euratom of 30th June 1997 on the health protection of individuals against the dangers of ionising radiation in relation to medical exposure, repealing Directive 84/466/Euratom;
- and Directive 2003/122/Euratom of 22nd December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

It also takes account of the latest recommendations from the International Commission on Radiological Protection (ICRP 103) and the basic standards published by IAEA. The Member States have a period of four years in which to transpose this Directive (the transposition deadline is set in the case of France for 6th February 2018).
In November 2013, with the approval of the Government, ASN set up a transposition committee for this new Directive for which it handled coordination and technical secretariat duties until June 2016. The committee's working priority was the legislative changes to be made, in particular to the Public Health Code. These changes were introduced through Ordinance 2016-128 of 10th February 2016 containing various nuclear-related provisions, as provided for in Article 128 of the Energy Transition for Green Growth Act 2015-992 of 17th August 2015.

Over and above these legislative subjects, ASN took part in all the work initiated in 2014 to update the regulatory parts of the Public Health Code, the Labour Code and the Environment Code. The publication of two decrees and of ASN opinions is expected for the first half of 2017.

DIAGRAM 2: Various levels of regulation in the field of small-scale nuclear activities in France

ICRP, IAEA, WENRA	Orientation, Recommendations	Not legally binding
European Union	Directives	
Parliament	Acts	
Government	Decrees and Orders	Legally binding
ASN/ Government Approval	Technical Statutory Resolutions	
ASN	Individual Resolutions (Technical requirements)	
ASN	ASN guides: BSR*	Legally binding

* *Basic Safety Rules.*

1.1.2 The Codes and the main Acts applicable to the regulation of nuclear activities in France

The legal framework for nuclear activities in France, which has been extensively modified since 2000, will once again be updated with the ongoing transposition of Directive 2013/59 Euratom: Ordinance 2016-128 of 10th February 2016 containing various nuclear-related provisions more specifically enabled the legislative provisions of Chapter III of Title III of Book III of the first part of the Public Health Code concerning radiation protection to be rewritten, while retaining the existing fundamental principles and requirements.

The Public Health Code

The provisions of Chapter III of the Ordinance of 10th February 2016, concerning nuclear activities covered by the Public Health Code, enter into force at a date set by decree of the Council of State, and no later than 1st July 2017.

Article L. 1333-1 of the Public Health Code defines nuclear activities as *"activities comprising a risk of human exposure to ionising radiation related to the use either of an artificial source, whether substances or devices, or of a natural source, whether natural radioactive substances or materials containing natural radionuclides. They also include the steps taken to protect individuals from a risk following radioactive contamination of the environment or products from contaminated areas or manufactured from contaminated materials"*.

Article L.1333-2 of the Public Health Code defines the general principles of radiation protection (justification, optimisation and limitation). These principles, described in point 2 below, constitute guidelines for the regulatory actions for which ASN is responsible.

The scope of application of Chapter III of Title III of Book III of the first part of the Public Health Code includes the measures necessary to prevent or mitigate the risks in various radiological exposure situations. In addition to steps taken to protect individuals from a risk following radioactive contamination of the environment or from products from contaminated areas or manufactured from contaminated materials, the steps taken in a radiological emergency situation or in the event of exposure to a natural source of ionising radiation, radon in particular, are also concerned. All of these steps must now meet the justification and optimisation principles.

The administrative system described in this chapter will change with the introduction of a simplified intermediate authorisation procedure, called the registration procedure, in addition to the existing notification and authorisation procedures. These changes will allow a graduated approach to risks to be adopted. A specific Article (L. 1333-7) defining the protected interests has been added. These interests are *"the protection of public health, salubrity and safety, as well as of the environment, against the risks or detrimental effects resulting from ionising radiation. The risks to be considered are not only those linked to the performance of the nuclear activity, but now also those linked to malicious acts, from creation of the activity to the phase following its cessation."*

The Public Health Code also institutes the radiation protection inspectorate, in charge of verifying compliance with its radiation protection requirements. This inspectorate, set up and coordinated by ASN, is presented in chapter 4. The Code also defines a system of administrative and criminal sanctions, described in the same chapter. Through the Ordinance of 10th February 2016, the Code was reinforced with the creation of a complete system of monitoring, policing and administrative and criminal sanctions, carried out primarily by ASN and the radiation protection inspectors, with reference to that mentioned in Chapter I of Title VII of Book I of the Environment Code.

Environment Code

The Environment Code defines various notions. According to Article L.591-1 of the Environment Code, nuclear security is a concept comprising *"nuclear safety, radiation protection, the prevention and fight against malicious acts, and also civil protection actions in the event of an accident"*. In some texts, however, the expression "nuclear security" remains limited to the prevention and mitigation of malicious acts.

Nuclear safety is *"the set of technical provisions and organisational measures - related to the design, construction, operation, shutdown and decommissioning of Basic Nuclear Installations (BNIs), as well as the transport of radioactive substances - which are adopted with a view to preventing accidents or limiting their effects"*[1].

Radiation protection is defined as *"the set of rules, procedures and prevention and surveillance means aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination"*. Article L. 593-42 of the Environment Code, created by the Ordinance of 10th January 2016, specifies that *"the general rules, prescriptions and measures taken in application of this Chapter and of Chapters V and VI for the protection of public health, when they concern occupational radiation protection, apply to the collective protection measures which are the responsibility of the licensee and are designed to ensure compliance with the principles of radiation protection defined in Article L. 1333-2 of the Public Health Code. They apply to the design, operation and decommissioning phases of the installation and are without prejudice to the obligations incumbent on the employer in application of Articles L. 4121-1 et seq. of the Labour Code"*.

Nuclear transparency is defined as *"the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security as defined in Article L.591-1"*.

Article L. 591-2 of the Environment Code, stipulates the State's role in nuclear security: it *"defines the nuclear security regulations and implements the checks necessary for their application"*.

The Ordinance of 10th February 2016 supplements this Article, stipulating that the State *"ensures that the regulations concerning nuclear safety and radiation protection and their oversight are assessed and improved, taking into account, where applicable, experience acquired in operation, lessons learned from the nuclear safety analyses carried out for the nuclear installations in operation, technological developments and the results of research on nuclear safety if they are available and relevant"*. In accordance with Article L. 125-13 of the Environment Code, *"the State ensures that the public is informed of risks linked to nuclear activities defined in the first paragraph of Article L. 1333-1 of the Public Health Code and of their impact on individual health and safety as well as on the environment"*. The general principles applicable to nuclear activities are mentioned in turn in Articles L. 591-3 and L. 591-4 of the Environment Code. These principles are presented in point 1.1 of chapter 2.

Chapter II of Title IX of Book V of the Environment Code creates ASN, defines its general duties and attributions, and specifies its composition and operation. Its missions are presented in points 2.3.1 and 2.3.2 of chapter 2.

Chapter V of Title II of Book I of the Environment Code addresses information of the public about nuclear security. This subject is developed in greater detail in chapter 6.

Other codes or acts containing requirements specific to nuclear activities

The Labour Code defines specific requirements for the protection of workers, whether or not salaried, exposed to ionising radiation. They are presented in point 1.2.1 of this chapter.

Chapter II of Title IV of Book V of the Environment Code, which codifies Planning Act 2006-739 of 28th June 2006 concerning sustainable management of radioactive materials and waste, sets the framework for the management of radioactive materials and waste. It obliges the BNI licensees to make provision for the cost of managing their waste and spent fuel, and for decommissioning their facilities. Chapter 16 describes the main contributions of this act in detail.

Finally, the Defence Code contains various measures concerning protection against malicious acts in the nuclear field, or the regulation of defence-related nuclear activities and installations. They are presented in point 5.3 of this chapter.

1. *Nuclear safety, within the meaning of Article L. 591-1 of the Environment Code, is thus a more limited concept than that of the objectives of the BNI legal system as described in point 3 of this chapter.*

TECV Act

Act 2015-992 of 17th August 2015 on Energy Transition for Green Growth (TECV) comprises a title devoted to nuclear matters (Title VI - "Reinforcing nuclear safety and information of the public") and a number of provisions in Title VIII concerning the organisation of the regulation of nuclear safety and radiation protection.

The provisions to be considered concern:

Enhanced transparency and information of citizens

Reinforcing and expanding the roles of the Local Information Committees (CLI)

Provision is thus made for the following (Articles L. 125-17 to L. 125-26 of the Environment Code):
- organisation of an annual public meeting by the CLI, open to all;
- the possibility for the CLI to address any subject within its field of competence (monitoring, information and consultation concerning nuclear safety, radiation protection and the impact of nuclear activities on individuals and the environment);
- the possibility for the CLI Chairman to ask the licensee (who cannot refuse) to organise visits to the nuclear facilities;
- the possibility for the CLI Chairman to ask the licensee (who cannot refuse, subject to an assessment of "restoration of normal conditions of safety») to organise visits to the facilities after a "cooling off" period following an incident rated level 1 or higher on the INES scale;
- mandatory consultation of the CLI for any changes to the Off-site Emergency Plans (PPI);
- mandatory consultation of the CLI concerning information of the persons living within the perimeter of a PPI;
- in the case of sites located in a département on one of the country's borders, inclusion of members of neighbouring states in the composition of the CLI.

Reinforcement of certain information procedures

- with the principle of regular information, at the expense of the licensee, of persons living within the perimeter of a PPI (concerning the nature of the accident risks and the envisaged consequences, the safety measures and the steps to be taken in application of this plan) (Article L. 125-16-1 of the Environment Code);
- with the holding of a public inquiry on the measures proposed by the licensee during the periodic safety review of the NPP reactors after their 35th year of operation (Article L. 593-19 of the Environment Code).

Confirmation of the BNI System

Management of subcontracting

- New Article L. 593-6-1 of the Environment Code strengthens the rule preventing the licensee from delegating the surveillance of outside contractors performing an activity that is important for the protection of the interests mentioned in Article L. 593-1 of the Environment Code. This ban which is included in the BNI Order of 7th February 2012 setting out the general rules for BNIs now carries legislative weight.
- This same Article makes it possible for a Decree by the Council of State to circumscribe or limit the use of contracting or subcontracting for the performance of certain activities important for the protection of interests (see box «Understand» Regulatory management of subcontracting, point 3.1.3).

Evolution in the BNI authorisation system

- Articles L. 593-14 and L. 593-15 of the Environment Code use the same terminology as the system of Installations Classified on Environmental Protection grounds (ICPE).
- The "substantial" modifications (previously referred to as "significant") are those modifications requiring a new and complete authorisation procedure with public inquiry (Article L. 593-14 of the Environment Code).
- The "significant" modifications now represent modifications with a more limited impact on the protection of the interests mentioned in Article L. 593-1 of the Environment Code. Article L. 593-15 of the same Code states that "significant" modifications are "depending on their importance" subject to authorisation by ASN or notification to it and that these "significant" modifications "may be opened to public consultation" (see point 3.3.5).

Renovation of the BNI final shutdown and decommissioning system

- The principle of immediate dismantling is enshrined in law (Article L. 593-25).
- The law differentiates between final shutdown and decommissioning of a BNI.
- The final shutdown of a BNI is the responsibility of the licensee, who must notify the Minister responsible for Nuclear Safety and ASN of the date no later than two years (or less if justified) prior to final shutdown. As of this date, the installation is considered to have final shutdown status and must be decommissioned (Article L. 593-26).
- Decommissioning (time-frame and procedures) is prescribed (and no longer authorised) by Decree (Article L. 593-28).
- An installation which has ceased to function for two consecutive years is considered to be finally shut down (Article L. 593-24).

Clarification of the organisation of the oversight of nuclear safety and radiation protection by ASN and IRSN

The law enshrines the Institute for Radiation Protection and Nuclear Safety (IRSN) in the Environment Code (new Articles L. 592-41 to L. 592-45). It clarifies the organisation of the oversight of nuclear safety and radiation protection between ASN and IRSN.

The law gives IRSN *"research and expert assessment duties in the field of nuclear safety defined in Article L.591-1 of the Environment Code"* (that is nuclear safety, radiation protection, prevention and combating of malicious acts, and civil protection actions in the event of an accident).

The law requires that ASN draw on IRSN expertise in the performance of its regulation of nuclear safety and radiation protection. In order to guarantee that IRSN's expert assessment capacity matches ASN's requirements, the law requires that the latter offer guidance for IRSN's strategic programming with respect to this technical support and that its chairman be a member of the Institute's board.

Article L. 592-43 of the Environment Code introduces the principle of publication of all the opinions issued by IRSN at the request of ASN.

"Early" entry into force in French law of the protocols signed on 12th February 2004, reinforcing the Paris Convention of 29th July 1960 and the Brussels Convention of 31st January 1963 concerning civil liability in the field of nuclear energy

By modifying Articles L. 597-2 et seq. of the Environment Code, the Act of 17th August 2015 reinforces the civil liability of the licensees in the event of damage linked to a nuclear activity. Without waiting for entry into force of the 2004 protocols related to their ratification by all the States of the European Union, this modification enforces certain provisions of the 2004 protocols, significantly re-evaluating the liability ceilings, which are raised from €23 million to €70 million for "low risk facilities" and from €91.50 million to €700 million for the other facilities. The law also extends its scope of application to new categories of installations (for example certain ICPE).

Interconnection between the BNI System and the Energy Code

The Energy Code stipulates that authorisation is required for the operation of any electricity generating installation. For nuclear installations generating electricity, this authorisation is obtained independently of the commissioning authorisation granted by ASN pursuant to the Environment Code.

As the nuclear electricity generating capacity is capped at 63.2 gigawatts by law (Article L. 311-5-6 of the Energy Code), Article L. 311-5-5 of this same Code stipulates that it is impossible to issue an operating authorisation pursuant to the Energy Code when this would have the effect of exceeding this maximum.

As the 63.2 GW cap corresponds to the installed power in France, commissioning of new nuclear power reactors would thus imply the need to revoke the generating authorisation for existing reactors up to the value of the power of the new reactor.

Revocation of the operating authorisation would lead to shutdown of the installation and, after a two-year period, would thereby lead to its final shutdown pursuant to Articles L. 593-24 and following of the Environment Code.

The same Article L. 311-5-6 of the Energy Code also stipulates that when a nuclear power installation is subject to the BNI System, the operating authorisation application in accordance with the Energy Code must be submitted no later than 18 months before commissioning (as determined in the Environment Code) and, in any case, no later than 18 months before the commissioning date mentioned in its creation authorisation decree.

An authorisation led to the Ordinance of 10th February 2016.

The other regulations concerning nuclear activities

Some nuclear activities are subject to a variety of rules with the same goal of protecting individuals and the environment as the above-mentioned regulations, but with a scope that is not limited to the nuclear field alone. This for example includes International Conventions, European or Environment Code provisions concerning impact assessments, public information and consultation, and the regulations governing hazardous materials transport or pressure equipment. The applicability of some of these rules to nuclear activities is mentioned in the applicable chapters of this report.

Signed on 25th June 1998 in Aarhus (Denmark), the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention), was ratified by France on 8th July 2002 and entered into force in France on 6th October 2002. With the aim of helping to protect the right to live in a clean environment that guarantees health and wellbeing, the signatory States guarantee the right of access to information about the environment, public participation in the decision-making process and access to justice in environmental matters.

In line with the Aarhus Convention, Article 7 of the Environment Charter states that *"everyone has the right, within the conditions and limits defined by the law […] to take part in the drafting of public decisions with an impact on the environment"*. Most of the resolutions issued by ASN, whether statutory or individual, fall within this category.

Articles L. 123-19-1 and L. 123-19-2 of the Environment Code set the conditions and limits for implementation of the principle of public participation in the statutory and individual resolutions with an impact on the environment. In both cases, these are "subsidiary" public participation procedures, in other words, procedures which apply if specific texts do not stipulate a particular procedure.

For statutory resolutions with an impact on the environment, Article L. 123-19-1 of the Environment Code requires that the draft resolution be made available to the public in electronic format for a time which may not be less than 21 days, except in the event of urgency relating to protection of the environment, public health or public order.

For individual resolutions with a direct or significant impact on the environment, Article L. 123-19-2 of the Environment Code, requires that the draft resolution or, when the resolution is issued on request, the application file, be made available to the public in electronic format for a time that may not be less than 15 days except in the case of urgency relating to protection of the environment, public health, or public order.

ASN has adopted a structured approach towards implementing this procedure for public participation in the drafting of its resolutions (see chapter 6).

1.2 The regulations applicable to the various categories of individuals and the various situations involving exposure to ionising radiation

The various exposure levels and limits set by the regulations are presented in the appendix to this chapter.

1.2.1 General protection of workers

The Labour Code contains various specific provisions for the protection of workers, whether or not salaried, exposed to ionising radiation (Title V of Book IV of part IV) which supplement the general prevention principles. It establishes a link with the three radiation protection principles contained in the Public Health Code.

Its legislative part is only little affected by the transposition of Directive 2013/59/Euratom. However, it does require that the authorisations issued by ASN in accordance with the BNI Systems and the Public Health Code be examined on the basis of information concerning occupational exposure, thus making it necessary to clarify the responsibilities of the employer and those of the party responsible for a corresponding nuclear activity. Articles L.1333-27 of the Public Health Code and L.593-41 of the Environment Code were thus introduced. They specify that the general rules, prescriptions, means and measures aimed at protecting the health of workers from ionising radiation, implemented pursuant to the Public Health Code and BNI System, concern the collective protection measures to be taken by the party responsible for a nuclear activity and designed to ensure compliance with the radiation protection principles defined in Article L. 1333-2 of the Public Health Code. These measures concern the design, operation and decommissioning phases of the installation and are without prejudice to the obligations incumbent on the employer in application of Articles L. 4121-1 et seq. of the Labour Code.

A General Directorate for Labour/ASN joint Circular No. 4 of 21st April 2010 indicates the conditions of application of the provisions of the Labour Code concerning the radiation protection of workers.

Articles R. 4451-1 to R. 4451-144 of the Labour Code create a single radiation protection system for all workers (whether salaried or not) liable to be exposed to ionising radiation during the course of their professional activities. The updating of this regulatory part of the Labour Code is under way (decree awaiting publication, see box).

FOCUS

The draft decree modifying the Labour Code (what will change)

The changes to the Labour Code are not simply the transposition of new provisions of the 5th December 2013 Directive, but also propose a total overhaul of the provisions of the Labour Code, with a search for greater efficiency, in the light of the work done in recent years at the request of the General Directorate for Labour (DGT) and ASN, to tailor the requirements more closely to the actual potential risks facing the workers.

Dose limits. For workers liable to be exposed to ionising radiation, the draft decree maintains the annual effective dose limit of 20 mSv (for 12 consecutive months). However, the dose equivalent limit of 150 mSv for 12 consecutive months for the lens of the eye will be lowered to 20 mSv per year in 2023, with an interim cumulative value of 100 mSv over 5 years, provided that the dose received during the course of one year does not exceed 50 mSv.

Advice. In the small-scale nuclear sector, the employer advisory system is now based on the following, as chosen by the employer:
- either on the Person Competent in Radiation protection (PCR) who continues to benefit from a certificate issued by a certified organisation;
- or on a certified competent organisation (the certification parameters have yet to be defined by Order), which puts an end to the possibility of resorting to an external PCR (who only intervened for activities requiring notification).

The advisory role. The duties of the PCR and the external organisation are extended to questions concerning protection of the population and the environment (this will require amendments to the Public Health Code).

In BNIs, the PCR is replaced by an organisation based on one or more "centres of competence" (group of designated experts). This internal organisation requires ASN approval under the existing procedures of the BNI System. To this effect, provisions will be introduced into Decree 2007-1557 of 2nd November 2007 relative to basic nuclear installations and to the regulation of the transport of radioactive substances in terms of nuclear safety.

Radiation protection checks. Internal radiation protection checks (measurement of dose rate, contamination, etc.) are performed at a frequency determined by the employer. An order will specify the activities for which external checks will be required for radiation protection organisations.

With a view to simplification and with the consent of ASN, the approval of organisations responsible for occupational dosimetry is scrapped. Only the existing accreditation system and the obligation to take part in the inter-laboratory tests organised by IRSN are maintained.

Radon in the workplace. The monitoring of exposure to radon is extended to all workplaces within the priority zones (only underground environments were already subject to mandatory surveillance). The employer decides on the measurement means, the intervention by organisations approved by ASN is no longer an obligation unless values in excess of 1,000 becquerels per cubic metre (Bq/m^3) were brought to light during the risk assessment performed by the employer.

The reference level for radon in the workplace is lowered to 300 Bq/m^3 from 400 Bq/m^3. If measurements exceeding 1,000 Bq/m^3 are recorded, the workers would be considered as category A or B exposed workers.

Respondents in an emergency situation. The provisions of the Public Health Code concerning the health and safety of workers intervening in a radiological emergency situation are transferred in full to the Labour Code. This should allow harmonised implementation of the provisions applicable to workers intervening in a radiological emergency situation, whether on the site of the accident, within the perimeter of the facility, or outside in the areas in which special measures have been taken to protect the populations. The two groups of respondents are however retained, with exposure reference levels of 100 mSv and, in exceptional situations, of 500 mSv (instead of 300 mSv).

The following provisions of the Labour Code should be mentioned:
- application of the optimisation principle to the equipment, processes and work organisation (Articles R. 4451-7 to R. 4451-11), which leads to clarification of where responsibilities lie and how information is circulated between the head of the facility, the employer, in particular when he or she is not the head of the facility, and the radiation protection officer;
- the annual dose limit (Articles R. 4451-12 to 4451-15) set at 20 mSv for 12 consecutive months, barring waivers resulting from exceptional exposure levels justified in advance, or emergency occupational exposure levels;
- the dose limits for pregnant women (Article D. 4152-5) or more accurately for the unborn child (1 mSv for the period from the declaration of pregnancy up until birth).

Zoning

Provisions concerning the demarcation of monitored areas, controlled areas and specially regulated areas (subject to special checks) were issued, regardless of the activity sector, by the Order of 15th May 2006. This Order also defines the health, safety and maintenance rules to be observed in these zones. It will be revised in depth following the publication of the decree updating the regulatory part of the Labour Code.

When defining the regulated zones, different levels of protection are taken into account: the effective dose for external exposure and, as applicable, internal exposure of the whole body; the equivalent doses for external exposure of the extremities and, as applicable, the dose rates for the whole body. A General Directorate for Labour/ASN joint circular of 18th January 2008 specifies the implementation procedures.

Person Competent in Radiation protection (PCR)

The Person Competent in Radiation protection (PCR) is placed under the responsibility of the employer and tasked with numerous radiation protection duties, including optimisation, implementation of radiological monitoring, information about risks, but also demarcation of regulated areas and job analyses.

The Order of 26th October 2005 concerning PCR training procedures and trainer certification was repealed by the Order of 24th December 2013, on the basis of the recommendations issued by the Advisory Committee of Experts for Radiation Protection for the Medical and Forensic Applications of Ionising Radiation (GPMED) and the Advisory Committee of Experts for Radiation Protection for Industrial Applications and Research into Ionising Radiation and the Environment (GPRADE). This Order defined the new conditions of training of the PCR. The number of days of training was modified according to the potential risks, with an increase in the number of days for the most complex installations or those with the highest risk. It will be supplemented following the publication of the decree updating the regulatory part of the Labour Code, according to the new duties entrusted to the PCR.

Radiation protection checks

These radiation protection technical checks concern sources and devices emitting ionising radiation, the ambient environment, measuring instruments and protection and alarm devices, management of sources and of any waste and effluents produced. Some of these controls are carried out as part of the licensee's in-house inspection processes and some by outside organisations. These external controls can be entrusted to the French Institute for Radiation Protection and Nuclear Safety (IRSN), to the department with competence for radiation protection or to organisations approved under application of Article R. 1333-97 of the Public Health Code. The nature and frequency of the radiation protection technical checks are defined by ASN resolution 2010-DC-0175 of 4th February 2010 (this approved decision will be replaced by an Interministerial Order, with a significant reduction in the frequency of the checks).

Radon in the workplace

(See point 2.3.1).

1.2.2 General protection of the general public

Apart from the special radiation protection measures included in individual nuclear activity licenses for the benefit of the general public and the workers, a number of general measures included in the Public Health Code help to protect the public against the dangers of ionising radiation. This regulatory part under the Public Health Code is currently being updated (decree pending publication, see box).

Public dose limits

The annual effective dose limit (Article R. 1333-8 of the Public Health Code) received by a member of the public as a result of nuclear activities, is set at 1 mSv/year; the equivalent dose limits for the lens of the eye and the skin are set at 15 mSv/year and 50 mSv/year respectively. These limits are not modified by the draft decree amending the Public Health Code. The calculation method for the effective and equivalent dose rates and the methods used to estimate the dosimetric impact on a population are defined by the Ministerial Order of 1st September 2003.

Radioactivity in consumer goods and construction materials

The intentional addition of natural or artificial radionuclides in all consumer goods and construction materials is prohibited (Article R. 1333-2 of the Public Health Code). Waivers may however be granted by the Minister of Health after receiving the opinion of the French High Council for Public Health and ASN, except with respect to foodstuffs and materials placed in contact with them, cosmetic products, toys and personal ornaments. The Interministerial Order of 5th May 2009 specifies the content of the waiver application file and the consumer information procedures stipulated in Article R. 1333-5 of the Public Health Code. This waiver arrangement was used in 2011 to cover the gradual phase-out of ionisation smoke detectors (see chapter 10) used in fire protection. This prohibition principle does not concern the radionuclides naturally present in the initial components or in the additives used to prepare foodstuffs (for example potassium-40 in milk) or for the manufacture of constituent materials of consumer goods or construction products (for example: uranium and its daughter products in granite).

Furthermore, the use of materials or waste from a nuclear activity is also prohibited, when they are contaminated or likely to have been contaminated by radionuclides, including by activation, as a result of this activity.

Further to a proposal from ASN, the French High Committee for Transparency and Information on Nuclear Security (HCTISN) set up a working group for the information and consultation procedures in the event of a request for waivers concerning the ban on the intentional addition of radionuclides in consumer goods or construction products (see chapter 6).

These provisions will be updated by the draft decree amending the Public Health Code (see box).

Radioactivity and the environment

A National Network for the Measurement of Environmental Radioactivity (RNM) was set up in 2002 (Article R. 1333-11 of the Public Health Code). A centralised system for collection of these measurements was implemented in 2009. The data collected must be used to help estimate the doses received by the population. The network's orientations are defined by ASN and it is managed by IRSN (ASN resolution 2008-DC-0099 of 29th April 2008, amended, on the organisation of a national network for the measurement of environmental radioactivity and setting the conditions for laboratory approval). To guarantee the quality of the measurements, the laboratories in this network must meet approval criteria, which in particular include participation in inter-comparison benchmarking tests.

A detailed presentation of the RNM (*www.mesure-radioactivite.fr*) is given in chapter 4.

The radiological quality of water intended for human consumption

Pursuant to Article R. 1321-3 of the Public Health Code, water intended for human consumption is subject to radiological quality inspection. The monitoring procedures are specified in the Order of 12th May 2004. They form part of the sanitary monitoring carried out by the Regional Health Agencies (ARS). The Order of 11th January 2007 concerning water quality limits and benchmarks introduces four radiological quality indicators for water intended for human consumption. With regard to the transposition of Council Directive 2013/51/Euratom of 22nd October 2013 which sets requirements for protecting the health of the population with respect to radioactive substances in water intended for human consumption, the Order of 11th January 2007 was modified by the Order of 9th December 2015 (Order modifying several Orders concerning water intended for human consumption issued pursuant to Articles R. 1321-2, R. 1321-3, R. 1321-7, R. 1321-20, R. 1321-21 and R. 1321-38 of the Public Health Code) thereby introducing a quality reference for radon in groundwater.

The Order of 9th December 2015 also sets procedures for measuring radon in water intended for human consumption, including packaged water, with the exception of natural mineral water, and in water used in a food company which does not come from the public mains supply, for the purposes of health checks pursuant to Articles R. 1321-10, R. 1321-15 and R. 1321-16 of the Public Health Code.

The indicators and the limits adopted are the total alpha activity (0.1 Bq/L), the total residual beta activity (1 Bq/L), the tritium activity (100 Bq/L) and the indicative dose (0.1mSv/year) The quality reference for radon is 100 Bq/L.

The Circular from the General Directorate for Health (DGS) dated 13th June 2007, accompanied by recommendations from ASN, specifies the policy underpinning this regulation. It will need to be supplemented to take account of the question of radon in water intended for consumption (work in progress).

Radiological quality of foodstuffs

Restrictions on the consumption or sale of foodstuffs may be necessary in the event of an accident or of any other radiological emergency situation.

In Europe, these restrictions are determined by Council Regulation 2016/52/Euratom of 15th January 2016, laying down maximum permitted levels of radioactive contamination of foodstuffs and livestock feedstuffs. The maximum permitted levels were defined to *"safeguard the health of the population while maintaining the unified nature of the market"*.

In the event of a nuclear accident, "automatic" application of this regulation cannot exceed a period of three months, after which it will be superseded by specific measures (see the regulation specific to the Chernobyl accident, the values of which are given in the appendix). Following the accident which struck Fukushima Daiichi on 11th March 2011, this system was activated by the European Commission on numerous occasions between 2011 and 2013, to take account of the changing radiological situation in the regions concerned[2] For example, in the EU's first post-Fukushima regulation (297/2011 of 25th March 2011), the maximum permitted levels for 134/137Cs in milk were 1,000 Bq/L as stipulated in Euratom regulation 3954/87. They were lowered a first time

2. *European regulation (EU) 297/2011, then modified by regulations 351/2011, 506/2011, 657/2011, 961/2011, 1371/2011, 284/2012, 561/2012, 996/2012 and 495/2013.*

in April 2011 to 200 Bq/L and then a second time in April 2012 to 50 Bq/L, in line with the lowering of the maximum permitted levels in Japan.

Radioactive waste and effluents

Management of waste and effluents from BNIs and Installations Classified on Environmental Protection grounds (ICPEs) is subject to the provisions of the special regulations concerning these installations (for BNIs, see point 3.4.4). For the management of waste and effluents from other establishments, including hospitals (Article R. 1333-12 of the Public Health Code), general rules are established in ASN resolution 2008-DC-0095 of 29th January 2008. These effluents and waste must be disposed of in duly authorised facilities, unless there are special provisions for on-site organisation and monitoring of their radioactive decay (this concerns radionuclides with a radioactive half-life of less than 100 days).

French policy for the management of very low level waste in BNIs and facilities subject to the Public Health Code is clear and protective: it makes no provision for a "clearance level" for this waste (in other words a generic radioactivity level below which effluents and waste produced by a nuclear activity can be disposed of without control), but on the contrary ensures that they are managed in a special stream to ensure traceability. ASN considers that the use of clearance levels would have three major drawbacks:
- the difficulty in having internationally defined levels accepted nationally;
- the difficulty in controlling the clearance of this waste;
- and the incentive to dilute this waste in the environment.

1.2.3 Protection of persons in a radiological emergency situation

The general public is protected against the hazards of ionising radiation in the event of an accident or of radiological emergency situations through the implementation of specific actions (or countermeasures) appropriate to the nature and scale of the exposure. In the particular case of nuclear accidents, these actions were defined in the government Circular of 10th March 2000 which amended the Off-site Emergency Plans (PPI) applicable to BNIs, by expressing intervention levels in terms of doses. These levels constitute reference points for the public authorities (Prefects) who have to decide locally, on a case-by case basis, what action is to be taken.

Reference and intervention levels

The intervention levels were updated in 2009 by ASN statutory resolution 2009-DC-0153 of 18th August 2009, with a reduction of the level concerning exposure of the thyroid. Henceforth, the protection measures to be taken in an emergency situation, and the corresponding intervention levels, are:
- sheltering, if the predicted effective dose from the releases exceeds 10mSv;
- evacuation, if the predicted effective dose from the releases exceeds 50mSv;
- administration of Thyroid Blocking stable Iodine (TBI) when the predicted equivalent dose to the thyroid from the releases is liable to exceed 50mSv.

The regulatory exposure limits set by the Labour Code do not apply to emergency workers. On the basis of the optimisation principle, "reference levels", comparable to guideline values to be considered for the performance of any intervention in circumstances such as these, are defined by the regulations (Article R. 1333-84 and R. 1333-86 of the Public Health Code). Two groups of emergency workers are thus defined:
- The first group comprises the personnel making up the special technical or medical response teams set up to deal with a radiological emergency. These personnel benefit from radiological surveillance, a medical aptitude check-up, special training and equipment appropriate to the nature of the radiological risk.
- The second group comprises personnel who are not members of the special response teams but who are called in on the basis of their expertise. They are given appropriate information.

The reference individual exposure levels for the workers, expressed in terms of effective dose, should be set as follows:
- The effective dose which may be received by personnel in group 1 is 100 mSv. It is set at 300 mSv when the intervention measure is aimed at protecting other people.
- The effective dose which may be received by personnel in group 2 is 10 mSv. In exceptional circumstances, volunteers informed of the risks involved in their acts may exceed the reference levels, in order to save human life.

The system concerning response personnel is to be transferred to the Labour Code and updated (see box page 97).

Public information in a radiological emergency

The ways in which the general public is informed in a radiological emergency situation are covered by a specific EU Directive (Directive 89/618/Euratom of 27th November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency). This Directive was transposed into French Law by Decree 2005-1158 of 13th September 2005 concerning the Off-site Emergency Plans for certain fixed structures or installations, implementing Article 15 of Act 2004-811 of 13th August 2004 on the modernisation of civil protection.

FOCUS

The draft decree modifying the Public Health Code (what will change)

The changes to the Public Health Code are not simply the transposition of new dispositions of the 5th December 2013 Directive but they also propose a complete overhaul of the regulatory provisions, in the light of the experience acquired during their implementation and monitoring.

The ban on the addition of radioactive substances
The principle of the ban on the addition of radioactive substances to foodstuffs, consumer goods and building materials is maintained:
- A waiver nonetheless remains possible except for foodstuffs, animal feedstuffs, materials placed in contact with foodstuffs or animal feedstuffs, or water intended for human consumption, toys, jewellery, clothing accessories, cosmetic products or bodily hygiene products.
- This ban also applies to the introduction into building materials of substances containing natural radionuclides at concentrations higher than the exemption levels defined by decree. It should also be noted that the natural radioactivity in building materials is now regulated, with an obligation to measure the natural radionuclides, along with any usage restrictions.

Justification
Any "new" nuclear activities shall be justified (the principle is enshrined in law). In this respect, an order shall give a classification of the existing activities, per category, considered in principle to be justified (because not prohibited). The demonstration of justification shall be required if the new activity does not fall into any of the defined categories.

Optimisation
For nuclear activities, it is possible to set a «dose constraint» for implementation of the optimisation principle on the emitting source, to ensure protection of the population and the environment. This requirement would supplement the obligation of meeting the annual limit of 1 mSv/year (which takes account of the possible addition of the combined impacts of several nuclear activities). An analysis is currently in progress, based on the opinions of the GPRADE, to identify the activities likely to be concerned.

Reference levels
Reference levels were introduced by the Ordinance of 10th February 2016. When used in the case of radiological emergency and post-accident situations, exposure situations following radiological contamination of the environment, or natural radiation exposure situations (radon for example), they constitute a "benchmark" in the optimisation process. The upper bound values of the Euratom Directive were chosen:
- 100 mSv/year for exposure of the populations in a radiological emergency situation, while retaining the current response levels of 50 mSv and 10 mSv for the duration of the releases, when deciding on evacuation or sheltering;
- 20 mSv the first year, for management of the post-accident phase, with a gradual reduction over the following years, eventually reaching 1 mSv/year;
- 1 mSv/year for the management of polluted sites and soils (outside post-accident situations);
- 300 Bq/m^3 for exposure to radon.

Two Orders specify these measures:
- the Order of 4th November 2005 concerning public information in the event of a radiological emergency situation;
- the Order of 8th December 2005 concerning the medical aptitude check-up, radiological surveillance and training or information of the personnel involved in managing a radiological emergency situation.

1.2.4 Protection of the general public in a long-term exposure situation

The contamination of sites by radioactive substances is the result of a nuclear activity in the remote or more recent past (use of unsealed sources, radium industry, etc.) or an industrial activity utilising raw materials containing non-negligible quantities of natural radionuclides of the uranium or thorium family (activity generating exposure to "enhanced" natural radiation, see point 2.3.2). Most of these sites are listed in the inventory sent out and updated periodically by the French National Agency for Radioactive Waste Management (Andra).

The contamination of the sites can also be the result of accidental releases of radioactive substances into the environment (see chapter 5).

These different exposure situations are qualified as "lasting exposure" in the Public Health Code (since 2007, ICRP publication 103 uses the expression "existing exposure situation"). In accordance with the international texts, for these situations, no exposure limit for the general public has been set at the regulatory level, as the management of these sites is chiefly based on a case-by-case application of the optimisation principle.

A guide on the management of sites potentially polluted by radioactive substances (published in December 2011), drafted under the coordination of ASN and the Ministry of the Environment, assisted by IRSN, describes how to deal with the various situations that could be encountered in the framework of the remediation of sites (potentially) contaminated by radioactive substances.

2. Regulatory requirements applicable to small-scale nuclear activities

The expression "small-scale nuclear" refers to medical, industrial and research applications of ionising radiation when not covered by the BNI or ICPE systems. This more specifically concerns the manufacture, possession, distribution – including import and export – and use of radionuclides or products and devices containing them.

2.1 Procedures and rules applicable to small-scale nuclear activities

The procedures and rules applicable to small-scale nuclear activities, when they are not the beneficiaries of an exemption, are described in section 3 of Chapter III of Title III of Book III of the first part of the Public Health Code. ASN issues licenses and approvals and is responsible for registration. Notifications are filed with the ASN regional divisions.

2.1.1 The licensing system

The licensing system applies indiscriminately to companies or facilities which have and use radionuclides on-site, and to those that trade in them or use them without directly possessing them.

The ASN license may be issued for a limited period and may be renewed. The license application or notification is made with a form that can be downloaded from the *www.asn.fr* website or obtained from the ASN regional divisions. The conditions for filing license applications, established by Articles R. 1333-23 et seq. of the Public Health Code, are set out by ASN resolution 2010-DC-192 of 22nd July 2010, which establishes the content of the dossiers enclosed with the license application. The requirements applicable to the medical and non-medical fields are harmonised.

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Impact of the transposition of the BSS Directive on the administrative systems applicable to small-scale nuclear activities

The European Directive of 5th December 2013 provides for a more graduated approach to regulatory oversight as applied to nuclear activities. Its transposition into French Law will more particularly make it possible to implement a third system, between notification and authorisation: this is the simplified authorisation system, referred to as the "registration system". Nuclear activities will thus be broken down into:

- activities with risks or detrimental effects that are moderate, or which could be prevented by compliance with the general prescriptions, without it being necessary to examine an authorisation application file. These nuclear activities are subject to notification;
- activities with risks or detrimental effects that are severe but which could be prevented by compliance with the general prescriptions specific to each type of nuclear activity concerned, but, owing to the potential consequences, said compliance shall be substantiated prior to implementation. These nuclear activities are subject to the registration system; In the event of non-compliance with the general prescriptions, ASN may refuse the registration of a nuclear activity;
- the other activities with severe risks of detrimental effects, which will be subject to the authorisation system. The authorisation application shall in particular comprise a file to demonstrate the protection of public health and safety, as well as of the environment. The authorisation or license shall set out individual prescriptions specific to the nuclear activity.

For 2017, ASN is preparing a list giving the breakdown of the various categories of nuclear activities into these three systems, the definition of general prescriptions applicable to some of these activities and the definition of the content of the notification and registration application files (simple justification of compliance with the general prescriptions) or authorisation application files (demonstration of protection of interests).

The forms implementing the resolutions have been available on-line since 2011 and are regularly updated.

It should be noted that the licenses issued under the authorisation systems for BNI, ICPE and Mining Code industries (for ICPE and Mining Code industries, the license is issued by the Prefect) constitute the authorisation for manufacturing or owning ionising radiation sources (see chapter 10), but do not constitute exemption from compliance with the provisions of the Public Health Code.

Licensing in the medical and research field involving human beings

ASN issues licenses for the use of radionuclides, products or devices containing them, used in nuclear medicine, brachytherapy, and for the use of particle accelerators in external radiotherapy and computed tomography devices. For medical applications and biomedical research, owing to specific patient radiation protection issues, the decision was taken not to use the clearance levels given in the Public Health Code; the licensing system thus comprises no exemptions.

Licensing of non-medical activities

ASN is responsible for issuing licenses for industrial and non-medical research applications. This concerns:
- the import, export and distribution of radionuclides and products or devices containing them;
- the manufacture, possession and use of radionuclides, products or devices containing them, devices emitting ionising radiation, the use of accelerators other than electron microscopes and the irradiation of products of any nature, including foodstuffs, with the exception of activities which are licensed under the terms of the Mining Code, the BNI legal system or that applicable to ICPEs.

The licence exemption criteria are given in the appendix to the Public Health Code (Table A, appendix 13-8).

Exemption will be possible if one of the following conditions is met:
- the total quantity of radionuclides possessed is less than the exemption values in Bq;
- the radionuclide concentrations are less than the exemption values in Bq/kg.

2.1.2 The registration system

The Ordinance transposing Directive 2013/59/Euratom of 5th December 2013 introduces a simplified authorisation system known as “registration”. This system can be utilised for nuclear activities representing serious risks or detrimental effects for the interests mentioned in Article L.1333-7, when these risks and detrimental effects can, in principle and in the light of the characteristics of these activities and the conditions of their implementation, be prevented by compliance with the general prescriptions. Utilisation of this new system will require relevant regulations and, for the activities concerned, the drafting of general prescriptions.

2.1.3 The notification system

The list of activities requiring notification pursuant to Article R.1333-19-1 of the Public Health Code was updated in 2009 by ASN resolution 2009-DC-0146 of 16th July 2009, supplemented by ASN resolution 2009-DC-0162 of 20th October 2009. As in low-dose medical radiology, radiology in veterinary practices is included in the activities requiring notification. It is added to the list of non-medical activities requiring notification, pursuant to Article R.1333-19-3 of the Public Health Code.

The resolution of 16th July 2009 was modified in 2015 (resolution of 10th November 2015) in order to add X-ray generators used for irradiation of blood products.

ASN acknowledges receipt of the notification filed by the natural or artificial person responsible for the nuclear activity. As the maximum validity period for a notification has been abolished, a new notification for activities requiring regular notification only becomes necessary if significant changes have been made to the installation (replacement or addition of an appliance, transfer or substantial modification of the premises or change in party responsible for the nuclear activity).

Finally, the X-ray facilities used for forensic procedures (for example, radiological examination to determine the skeletal age of an individual, use of X-rays to detect objects hidden within the human body, etc.), are regulated by the licensing or notification system applicable to facilities designed for medical uses, depending on the type of equipment used (see point 2.2).

2.1.4 Licensing the suppliers of ionising radiation sources

ASN resolution 2008-DC-0109 of 19th August 2008 concerns the licensing system for the distribution, import and/or export of radionuclides and products or devices containing them. This resolution covers products intended for industrial and research purposes, but also health products: drugs containing radionuclides (radiopharmaceutical drugs, precursors and generators), medical devices (gamma-ray teletherapy devices, brachytherapy sources and associated applicators, blood product irradiators, etc.) and in vitro diagnosis medical devices (for radioimmunology assay).

ASN resolution 2008-DC-0108 of 19th August 2008 concerns the license to possess and use a particle accelerator (cyclotron) and the manufacture of radiopharmaceuticals containing a positron emitter.

2.1.5 Approval of radiation protection technical supervision organisations

Technical supervision of the radiation protection organisation, including supervision of the management of radioactive sources and any associated waste, is entrusted to approved organisations (Article R. 1333-97 of the Public Health Code). The conditions and procedures for approval of these organisations are set by ASN resolution 2010-DC-0191 of 22nd July 2010. ASN is responsible for issuing these approvals. The list of approved organisations is available on the ASN website (*www.asn.fr*). The nature and frequency of the radiation protection technical checks are defined in the ASN resolution mentioned in point 1.2.1.

2.1.6 The rules for the design of facilities

ASN technical resolutions, subject to approval by the Ministers responsible for Radiation Protection, may be adopted to determine the design and operating rules for facilities in which sources of ionising radiation are used.

With regard to the design of the facilities, the *Union technique de l'électricité* (UTE) conducted a revision of standards NF-C 15-160 and the associated specific standards (general installation rules for X-ray generators). On the basis of this work, ASN has initiated an update of the design and layout rules for facilities inside which X-rays are produced and used. After several consultations of GPRADE and GPMED, ASN adopted resolution 2013-DC-0349 of 4th June 2013 laying down minimum technical rules for the design of facilities in which X-rays may be emitted. This resolution entered into force on 1st January 2014, subject to certain provisions, for all facilities commissioned or for which the calculation parameters are modified. It concerns medical facilities such as conventional radiology, dental radiology and scanners; industrial and scientific (research) facilities such as industrial radiography using X-rays in a bunker and veterinary radiology. This resolution also replaces the Order of 30th August 1991 determining the installation conditions to be met by X-ray generators.

ASN inspection on the theme of interventional radiology at Libourne hospital, June 2016.

To take account of the lessons learned from the difficulties experienced with application of this resolution, ASN prepared a revision of the text in 2016, no longer based on standard NF C 15-160 but setting objectives to be achieved in terms of radiation protection and according to a graduated approach to the risk created (see chapters 9 and 10).

The minimum technical rules for design, operation and maintenance to be met by in vivo nuclear medicine facilities were defined by the resolution of 23rdOctober 2014. The new rules replacing the rules which existed since 1981, mainly concern the ventilation of the laboratory in which the radiopharmaceutical drugs are prepared and the hospitalisation rooms for patients having received a therapeutic treatment (more particularly iodine-131).

2.1.7 Radioactive resources management rules

The general radioactive source management rules are contained in section 4 of Chapter III of Title III of Book III of the first part of the Public Health Code. These rules are as follows:

- No person may transfer or acquire radioactive sources without a license.
- Prior registration with IRSN is compulsory for the purchase, distribution, import and export of radionuclides as sealed or unsealed sources, or of products or devices containing them; this prior registration makes it possible to track the sources from their entry onto the market until the end of their life.
- Each establishment is required to ensure the traceability of radionuclides in the form of sealed or unsealed sources and of products or devices that contain them.
- ASN must be notified in the event of loss or theft of radioactive sources.
- Users of sealed sources are obliged to have the expired, damaged or end-of-life sources taken back by the supplier, who is obliged to recover them.

ASN resolution 2015-DC-0521 of 8th September 2015 concerning the monitoring and registration procedures for radionuclides in the form of radioactive sources and products or devices containing them, clarified the regulatory framework with regard to the procedures for this registration of movements and for the monitoring rules concerning radionuclides in the form of radioactive sources (see chapter 10).

On this latter point, Decree 2015-231 of 27th February concerning the management of used sealed sources, which came into force on 1st July 2015, modified Articles R.1333-52 and R.1337-14 of the Public Health Code, in order to enable those in possession of sources to have the used sealed radioactive sources that have expired or reached the end of their service life recovered not only by their initial supplier, but also by any other authorised supplier of radioactive sources or, as a final resort, by Andra. The spirit of this modification is to address the difficulties experienced by those in possession of sources with regard to locating the original suppliers, the cost of recovery and the monopoly enjoyed by certain suppliers.

The conditions of implementation and payment of the financial guarantees incumbent on the source suppliers must be defined by an Order from the Ministers responsible for Health and Finance (Articles R. 1333-53 and R. 1333-54-2 of the Public Health Code). In the absence of such an order, the particular licensing conditions established by the CIREA (Interministerial Commission on Artificial Radioelements) in 1990 are taken up as requirements in the licenses and are consequently applicable to the licensees.

2.2 Protection of persons exposed for medical and forensic purposes

Radiation protection for individuals exposed for medical purposes is based on two principles mentioned in paragraphs 1 and 2 of Article L. 1333-1 of the Public Health Code respectively: justification of the procedures and optimisation of exposure, which are under the responsibility of both the practitioners prescribing medical imaging examinations entailing exposure to ionising radiation and the practitioners carrying out these procedures. These principles cover all the diagnostic and therapeutic applications of ionising radiation, including radiological examinations requested for screening, occupational health, sports medicine and forensic purposes.

In medical imaging (see chapter 9), the final responsibility for exposure lies with the practitioners performing the exams. The rules applicable for the radiation protection of patients set out in the Public Health Code are different from those established for the protection of professionals, set out in the Labour Code, even if the competence of the physicians and professionals involved in delivering the dose must cover both domains.

2.2.1 Justification of practices

A written exchange of information between the prescribing practitioner and the practitioner carrying out the procedure exposing the patient should provide justification of the benefit of the exposure for each procedure. This "individual" justification is required for each procedure. Articles R. 1333-70 and R. 1333-71 of the Public Health Code respectively require the publication of "prescription of routine procedures and examinations" guides (also called *"indication guides"*) and "performance of procedures" guides (called "procedure guides").

TABLE 1: List of Referral Criteria for Imaging and Procedure Guides for the performance of medical procedures entailing exposure to ionising radiation

	SPECIALTIES				
	MEDICAL RADIOLOGY		NUCLEAR MEDICINE	RADIOTHERAPY	DENTAL RADIOLOGY
DOCUMENTS	Procedure guide	Indication guide	Indication and procedure guide	Procedure guide in external radiotherapy	Indication and procedure guide
AVAILABLE ON	www.sfrnet.org www.irsn.org	www.sfrnet.org www.irsn.org	www.sfmn.org	www.sfro.org	www.adf.asso.fr www.has-sante.fr

2.2.2 Optimisation of exposure

Optimisation in medical imaging (radiology and nuclear medicine) consists in delivering the lowest possible dose compatible with obtaining a quality image that provides the diagnostic information being sought. Optimisation in therapy (external radiotherapy, brachytherapy and nuclear medicine) consists in delivering the prescribed dose to the tumour to destroy cancerous cells while limiting the dose to healthy tissues to the strict minimum.

Standardised guides for conducting procedures using ionising radiation have been prepared and are regularly updated by health professionals, or are currently being prepared, to facilitate practical application of the optimisation principle (Table 1).

Diagnostic reference levels

The Diagnostic Reference Levels (DRL) are one of the tools used for dose optimisation. As required in Article R. 1333-68 of the Public Health Code, the DRL are defined in the Order of 24th October 2011 concerning diagnostic reference levels in radiology and nuclear medicine. For radiology, this consists of dose values, while for nuclear medicine it consists of activity levels administered in the course of the most common or most heavily irradiating examinations. Depending on the type of examination, periodic measurements or readings must be taken in each radiology and nuclear medicine unit. On the basis of the information received by IRSN, an update of these diagnostic reference levels is planned during the course of 2017 by an approved ASN resolution.

Dose constraints

In the field of research involving human beings to evaluate or use methods entailing exposure to ionising radiation, dose constraints to optimise the doses delivered must be established by the physician, according to the nature of the protocol and the risk/benefit trade-off for the participating subject.

Medical physics

The safety of radiotherapy and optimisation of the doses delivered to the patients in medical imaging require particular expertise in the field of medical physics.

The employment of a Specialised Medical Radiation Physicist (PSRPM), formerly called a "radiophysicist", has been extended to radiology, having already been compulsory in radiotherapy and nuclear medicine. The PSRPM will from now on be called "medical physicists" (26th January 2016 Act to modernise our health system).

Their duties were clarified and broadened by the Order of 19th November 2004. Thus they must ensure the appropriateness of the equipment, data and computing processes for determining and delivering the doses and activity levels administered to the patient in any procedure involving ionising radiation. In the field of radiotherapy, they guarantee that the radiation dose received by the tissues due to be irradiated matches that prescribed by the prescribing physician.

Furthermore, they estimate the dose received by the patient during diagnostic procedures and play a part in quality assurance including inspecting the quality of the medical devices.

Temporary criteria determining the conditions for the presence of medical physicists in radiotherapy centres have been defined by decree (Decree 2009-959 of 29th July 2009). Since the end of the transitional period (May 2012), the criteria defined by the National Cancer Institute are now applicable pursuant to Decree 2007-388 of 21st March 2007, and in particular the criterion concerning the obligatory presence of a medical physicist during the treatment sessions.

Since 2005, heads of facilities have had to draw up plans for medical physics, defining the resources allocated, primarily in terms of staffing, in the light of the medical procedures carried out in the establishment, the actual or probable patient numbers, existing dosimetry skills and resources allocated to quality assurance and control.

The conditions of training of the medical physicists were updated by the Orders of 28th February and 6th December 2011.

In the same way as the physician or the radiographer, the medical physicist can be designated as the PCR by the employer in accordance with the Labour Code. In operating theatres using X-ray generators, optimisation of the doses delivered to the patients, which is the competence of the medical physicist, also contributes to reducing the doses received by the professionals performing the procedure.

Radiotherapy quality assurance

The quality assurance obligations of radiotherapy centres, stipulated in Article R.1333-59 of the Public Health Code, were specified by ASN resolution 2008-DC-0103 dated 1st July 2008, which mainly concerns the Quality Management System (QMS), the management's commitments as stipulated in the QMS, the documentary system, staff responsibility, the analysis of the risks incurred by the patients during the radiotherapy process, and the identification and handling of undesirable situations or malfunctions, whether organisational, human or equipment-related.

These obligations entered into force in September 2011.

Medical imaging quality assurance obligations also appear in the Public Health Code but have not yet been clarified by an ASN resolution. Faced with the regular increase in the doses of ionising radiation delivered to patients over the past decade, ASN intended to publish this resolution in 2017. This action is part of the Cancer Plan 3 adopted by the Minister responsible for Health in January 2014.

Maintenance and quality control of medical devices

Maintenance and quality control, both internal and external, of medical devices using ionising radiation (Articles R. 5211-5 to R. 5211-35 of the Public Health Code) have been mandatory since publication of the Order of 3rd March 2003. External quality control is entrusted to organisations approved by the Director General of the ANSM (French National Agency for the Safety of Medication and Health Products) who is responsible for issuing a decision defining the acceptability criteria, the monitoring parameters and the frequency of the inspections on the medical devices concerned. The published decisions are posted on the ANSM website.

Training and information

Additional major factors in the optimisation approach are the training of health professionals and the information of patients.

Thus the objectives and content of training programmes for personnel conducting procedures using ionising radiation, or who take part in these procedures, were defined in the Order of 18th May 2004. To ensure the traceability of the data on application of the justification and optimisation principles, the report on the procedure, written by the medical practitioner carrying out the examination, must provide information justifying the

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The draft decree modifying the Public Health Code (what will change)

Most of the new requirements of the Directive of 5th December 2013, for example those concerning the notification of significant patient radiation protection events and, for radiotherapy, the risks assessment, are already integrated into the existing regulations.

Justification of new practices. The main change introduced by the draft decree concerns the operational application of the justification principle for new medical practices. Therefore, if a new and innovative technology is used for radiotherapy, radio-surgery, diagnosis or interventional imaging, or a new type of practice is performed using an existing technology, taking account of the committed doses and the potential risks for the patients, an order could as a temporary measure set out special prescriptions to organise the collection and analysis of information concerning the expected benefits for the patient and the corresponding risks. If necessary, an ASN resolution could introduce specific requirements to ensure the protection of patients, workers and the public.

Medical physicists (formerly PSRPM). The Euratom Directive of 5th December 2013 introduces the obligation to define a *"system for recognition of experts in medical physics"*. This was taken into account by the Government which, in Ordinance 2017-480 of 19th January 2017, decided to create a new medical profession to recognise the status of medical physicists. Their roles and duties will be subsequently defined by decree.

Forensic applications. The system in place since 2003 will be revised to allow improved application of the justification principle. The expression *"forensic applications of ionising radiation"*, considered to be too imprecise, is abandoned in favour of the expression *"radiological examination with no direct medical indication"*. The examination categories concerned will be explicitly defined (examples: preventive examinations carried out for occupational medicine or sports medicine purposes, to carry out inspections to identify objects or narcotic products hidden in the human body).

procedures and the operations carried out as well as the data used to estimate the dose received by the patient (Order of 22nd September 2006). These training courses were evaluated by ASN in 2012 and work is in progress to improve this training system, with updating of the Order by means of a resolution being planned for 2017. This resolution will refer to professional guides submitted to ASN for approval. It should be possible to distribute these guides at the same time as the resolution.

Finally, before carrying out a diagnostic or therapeutic procedure using radionuclides (nuclear medicine), the physician must give the patient oral and written guidelines on radiation protection that are of use to them, their relations, the public and the environment. In the case of a therapeutic nuclear medicine procedure, this information - which is provided in writing – gives advice on day to day living such as to minimise external exposure of the patient's friends and family and the risk of any contamination, for example by specifying the number of days during which contact with the spouse and children must be limited. Recommendations (French High Public Health Council, learned societies) were distributed by ASN (January 2007) to enable the content of the information already sent out to be harmonised.

2.2.3 Forensic applications of ionising radiation

In the forensic field, ionising radiation is used in a wide variety of sectors such as occupational medicine, sports medicine or for investigative procedures required by the courts or insurance companies. The principles of justification and optimisation apply to both the person requesting the examinations and the person performing them.

In occupational medicine, ionising radiation is used for medical monitoring of workers (whether or not professionally exposed to ionising radiation, for example workers exposed to asbestos).

2.3 Protection of persons exposed to a natural source of ionising radiation

2.3.1 Protection of persons exposed to radon

The regulatory framework applicable to management of the radon-related risk in premises open to the public (Article R. 1333-15 et seq. of the Public Health Code) introduces the following clarifications:
- The radon monitoring obligation applies in geographical areas in which radon of natural origin is likely to be measured in high concentrations and in premises in which the public is likely to stay for extended periods.
- The measurements are made by organisations approved by ASN, these measurements being repeated every 10 years and whenever work is carried out to modify the ventilation or the radon tightness of the building.

In addition to introducing action trigger levels of 400 and 1,000 Bq/m^3, the implementing Order of 22nd July 2004 concerning management of the radon risk in premises open to the public defined geographical zones and premises open to the public for which radon measurements are now mandatory:
- the geographical areas are the 31 *départements* classified as having priority for radon measurement (see chapter 1);
- the categories of premises open to the public cover teaching institutions, health and social institutions, spas and prisons.

The obligations of the owner of the facility are also specified when the action levels are found to have been exceeded. The Order of 22nd July 2004 was followed by the publication in the *Official Journal* of 22nd February 2005 of an opinion concerning the definition of the actions and work to be carried out in the event the action levels of 400 and 1,000 Bq/m^3 are exceeded. The accreditation conditions for the organisations approved to carry out activity concentration measurements, the measurement conditions and the data transmission procedures are clarified by four ASN resolutions:
- ASN resolution 2009-DC-0134 of 7th April 2009, amended by resolution 2010-DC-0181 of 15th April 2010, sets the approval criteria, provides the detailed list of information to be enclosed with the approval application and specifies the conditions of issue, verification and withdrawal of approval;
- ASN resolution 2009-DC-0136 of 7th April 2009 concerning the objectives, duration and content of the training programmes for the individuals carrying out radon activity concentration measurements;
- ASN resolution 2015-DC-0506 of 9th April 2015 concerning the conditions in which radon activity is measured, repealing resolution 2009-DC-0135 of 7th April 2009;
- ASN resolution 2015-DC-0507 of 9th April 2015 concerning the technical rules for the transmission of the radon measurement results produced by approved organisations and the conditions for access to these results, pursuant to the provisions of Article R. 1333-16 of the Public Health Code.

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The draft decree modifying the Public Health Code (what will change)

The main modification resulting from the decree modifying the Public Health Code is to lower the reference level from 400 Bq/m^3 to 300 Bq/m^3 in all premises open to the public. Publication of the decree should be accompanied by publication of the Order defining the new priority zones for radon measurement (see chapter 1).

The list of approved organisations is published in the ASN Official Bulletin on the ASN website: *www.asn.fr*.

The Ordinance of 10th February 2016 thus introduced new legislative provisions into the Public Health Code (which will come into force no later than 1st July 2017) and the Environment Code, to ensure lasting information of the population and to better estimate the exposure of the French population to radon.

These new provisions aim to:
- consider the radon concentration as an indoor air quality parameter;
- set up a system of mandatory information of owners, new buyers of real estate and landlords, in areas with a high radon potential;
- collect the results of the radon measurements taken in homes, at the initiative of the owners or local authorities, in order to gain a clearer estimate of the exposure of the French population to radon.

2.3.2 Other sources of exposure to "enhanced" natural radiation

Professional activities which use materials which naturally contain radionuclides not used for their radioactive properties but which are liable to create exposure likely to harm the health of workers and the public ("enhanced" natural exposure) are subject to the provisions of the Labour Code (Articles R. 4451-131 to 135) and the Public Health Code (Article R. 1333-13).

The Order of 25th May 2005 defines the list of professional activities using raw materials naturally containing radionuclides, the handling of which can lead to significant exposure of the general public or of workers[3].

For these activities, the Public Health Code requires an estimation of the doses to which the general public is exposed on account of the installation or the production of consumer goods or construction materials (see chapter 1). In addition, and if protection of the public so warrants, it will also be possible to set radioactivity limits for the construction materials and consumer goods produced by some of these industries (Article R. 1333-14 of the Public Health Code). This latter measure complements the ban on the intentional addition of radioactive materials to consumer goods.

For the occupational exposure resulting from these activities, the Labour Code requires a dose assessment to be carried out under the responsibility of the employer. Should the dose limit of 1 mSv/year be exceeded, steps to reduce exposure should be taken. The above-mentioned Order of 25th May 2005 specifies the technical procedures for evaluating the doses received by the workers.

Finally, the Labour Code (Article R. 4451-140) stipulates that for aircrews likely to be exposed to more than 1 mSv/year, the employer must evaluate the exposure, take steps to reduce it (particularly in the event of a declared pregnancy) and inform the personnel of the health risks. The Order of 7th February 2004 defines the procedures for implementing these measures. The transposition of the new Euratom Directive 2013/59/Euratom should lead to these activities being subject to the legal system for nuclear activities as defined in Article L. 1333-1 of the Public Health Code.

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The draft decree modifying the Public Health Code (what will change)

The activities enhancing exposure to natural radiation. The activities using raw materials containing radioactive substances of natural origin are now considered to be nuclear activities (they were previously subject to a specific system defined in the Public Health Code), provided that the radionuclide concentrations exceed the exemption levels set by decree and appear on a list, also determined by decree. From now on they will be subject to the ICPE system.

3. *This concerns: the combustion of coal in coal-fired power stations; the treatment of tin, aluminium, copper, titanium, niobium, bismuth and thorium ores; the production of refractory ceramics and the glasswork, foundry, iron and steel and metallurgy activities that use them; the production or use of compounds containing thorium; the production of zircon and baddaleyite, and the foundry and metallurgy activities that use them; the production of phosphated fertilisers and phosphoric acid; the treatment of titanium dioxide; the treatment of rare earths and the production of pigments containing them; the treatment of underground water by filtration for the production of water for human consumption and mineral waters and spas.*

3. The legal system applicable to basic nuclear installations

Basic Nuclear Installations (BNIs) are installations which, due to their nature or to the quantity or activity of the radioactive substances they contain, are subject to particular provisions in order to protect the general public and the environment.

3.1 The legal bases

3.1.1 International conventions and standards

On proposals from Member States, IAEA develops reference texts called "Safety Standards" describing safety principles and practices. They concern installation safety and radiation protection, the safety of waste management and the safety of radioactive substances transportation. Although these documents are not binding, they do nonetheless constitute references which are widely drawn on in the drafting of national regulations.

Several legislative and regulatory provisions relative to BNIs are derived from or take up international conventions and standards, notably those of IAEA.

Two Conventions deal with safety (Convention on Nuclear Safety and Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management), while two others deal with the operational management of the consequences of any accidents (Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency). France is a contracting party to these four international Conventions. These Conventions are presented in detail in chapter 7.

The other conventions linked to nuclear safety and radiation protection

Other international conventions, the scope of which does not fall within the remit of ASN, may be linked to nuclear safety. Of particular relevance is the Convention on the Physical Protection of Nuclear Material, the purpose of which is to reinforce protection against malicious acts and against misappropriation of nuclear materials. This Convention entered into force in February 1987 and as at 7th December 2016, it comprises 157 Contracting Parties.

For France, these conventions are a tool to be used to reinforce nuclear safety, periodically presenting the international community with the status of the facilities concerned and the steps taken to ensure their safety.

3.1.2 European texts

Several European community texts apply to BNIs. The more important ones are described below.

The EURATOM Treaty

The EURATOM Treaty, which was signed in 1957 and came into force in 1958, aimed to develop nuclear power while protecting the general public and workers from the harmful effects of ionising radiation.

Chapter III of Title II of the EURATOM Treaty deals with health protection as linked to ionising radiation.

Articles 35 (implementation of means for checking compliance with standards), 36 (information to the Commission on environmental radioactivity levels) and 37 (information to the Commission on planned effluent discharges) deal with the issues of discharges and environmental protection.

The provisions regarding information of the Commission were integrated into Decree 2007-1557 of 2nd November 2007, relative to Basic Nuclear Installations and to the regulation of the nuclear safety of the transport of radioactive substances, known as the "BNI Procedures Decree". In particular, the decrees authorising BNI creation, prescribing final shutdown, or authorising significant modifications to the facilities leading to an increase in discharge limit values, are only issued once the opinion of the Commission has been obtained.

The Directive of 25th June 2009 establishing a Community framework for the nuclear safety of nuclear facilities, amended by Directive 2014/87/Euratom of 8th July 2014

Council Directive 2009/71/Euratom of 25th June 2009 creates an EU framework for nuclear safety and paves the way for the creation of a common legal framework for nuclear safety among all Member States.

This Directive defines basic obligations and general principles in this field. It strengthens the role of the national regulatory organisations, contributes to harmonising the safety requirements between the Member States in order to develop a high level of safety in the installations and encourages a high level of transparency on these issues.

It comprises stipulations regarding cooperation between nuclear regulators, in particular the creation of a peer review mechanism, staff training, regulation and inspection of nuclear installations and public transparency. In this respect, it reinforces cooperation between the Member States.

Finally, it takes account of the harmonisation work being carried out by the Western European Nuclear

Regulators Association (WENRA), (see chapter 7, point 2.7).

Directive 2014/87/Euratom of 8th July 2014 modified Directive 2009/71/Euratom of 25th June 2009 and made the following substantial improvements:
- concepts converging with those of IAEA (incident, accident, etc.);
- highlighting of the principles of "defence in depth" and "safety culture";
- clarification of responsibilities in the oversight of the safety of nuclear installations;
- the safety objectives for nuclear installations which stem directly from the safety requirements used by the WENRA association;
- a safety reassessment of each nuclear facility at least once every ten years;
- every six years, the organisation of peer reviews by the European counterparts on specific safety topics, conducted in the spirit of the stress tests performed in the aftermath of the Fukushima Daiichi accident;
- the obligation for nuclear facility licensees and the nuclear safety authorities to inform local populations and the stakeholders.

These provisions significantly reinforce the Community framework for oversight of the safety of nuclear facilities (see chapter 7, point 2.3). For those which require legislative weight, transposition is ensured by Articles L. 591-2 and L. 591-6 to L. 591-8 of the Environment Code, resulting from the Ordinance of 10th February 2016 constituting various nuclear provisions, issued on the basis of the authorisation given in the Energy Transition for Green Growth Act of 17th August 2015 (TECV Act).

Directive of 19th July 2011 establishing a European Community framework for the responsible and safe management of spent fuel and radioactive waste

Council Directive 2011/70/Euratom of 19th July 2011 establishes a European Community framework for the responsible and safe management of spent fuel and radioactive waste. It applies to the management of spent fuel and the management of radioactive waste, from production to disposal, when this waste is the result of civil activities. Like the Euratom Directive of 25th June 2009, it calls for each Member State to set up a coherent and appropriate national framework and sets various requirements for the States, the safety regulators and the licensees. By the 23rd August 2013 deadline set by this Directive for its transposition into the laws of the Member States, most of this Directive had been transposed into French law. The additional legislative measures necessary were implemented by the Ordinance of 10th February 2016.

The institutions of the European Union benefitted from the work done by the WENRA association (see chapter 7, point 2.7) for the drafting of these two Directives.

TECV Act

Ordinance containing various nuclear-related provisions

The Ordinance of 10th February 2016 constituting various nuclear provisions ensures the transposition of several Directives with respect to the TECV Act.

Issued on the basis of the authorisation given in the Act of 17th August 2015, the Ordinance of 17th February 2015 comprises measures which, with respect to the Act, transpose the following European Directives into French Law:
- Council Directive 2011/70/Euratom of 19th July 2011 establishing a European Community framework for the responsible and safe management of spent fuel and radioactive waste;
- Directive 2014/87/Euratom, modifying Directive 2009/71/Euratom of 25th June 2009 establishing a Community framework for the nuclear safety of nuclear facilities;
- Directive 2010/75/EU of 24th November 2010 (known as the "IED Directive") concerning industrial emissions;
- Directive 2012/18/EU of 4th July 2012 (known as the "Seveso III" Directive) on the control of major accident hazards involving dangerous substances.

The IED and Seveso III Directives are the two European environmental protection instruments applying to industrial installations. The purpose of the first is to reduce pollutant emissions during normal operation, while the second is designed to mitigate the consequences of a major accident on human health and the environment.

3.1.3 National texts

The legal system applicable to BNIs was revised in depth by Act 2006-686 of 13th June 2006 on transparency and security in the nuclear field, called the "TSN Act", and its application decrees, and in particular Decree 2007-1557 of 2nd November 2007, concerning BNIs and the regulation of nuclear safety in the transport of radioactive substances, called the "BNI Procedures Decree".

Since 6th January 2012, the provisions of the three main Acts specifically concerning BNIs – the 13th June 2006 Act, the 28th June 2006 Programme Act and the 30th October 1968 Act – are codified in the Environment Code.

FUNDAMENTALS

Regulatory management of subcontracting

Article L. 593-6-1 of the Environment Code, created by the 17th August 2015 Act, stipulates that *"owing to the particular importance of certain activities for the protection of the interests mentioned in Article L. 593-1 [of the Environment Code], a decree of the Council of State may regulate or limit their performance by contractors or subcontractors"* and that *"the licensee shall monitor activities important for the protection of the interests mentioned in the same Article L. 593-1 when they are performed by outside contractors. It shall ensure that these outside contractors have appropriate technical expertise for the performance of said activities. It may not delegate this monitoring action to a contractor."*

Decree 2016-846 of 28th June 2016 concerning the modification, final shutdown and decommissioning of BNIs and subcontracting clarifies these provisions.

The principle whereby the licensee of a BNI is effectively responsible for its operation entails a ban on entrusting operational responsibility and oversight of the operation of a BNI to an outside contractor, including with regard to the handling of accidents, incidents and deviations, as well as preparedness for and management of emergency situations.

This Decree also specifies the conditions in which a BNI licensee may call on outside contractors for the performance of Activities Important for the Protection (AIP) of the interests mentioned in Article L. 593-1 of the Environment Code (public health and safety, protection of nature and the environment). The principle of the text is that the licensee must limit the number of subcontracting tiers as far as possible. This principle applies to all the phases in the life of a BNI, including during its construction. The need to resort to subcontracting shall be assessed in the light of the need for specific and exceptional skills.

In any case, the licensee shall retain the ability to manage the subcontracted activities. In its general operating rules, it shall describe the methods used to monitor the outside contractors.

The text also introduces a condition limiting to three the total number of successive subcontracting tiers, with the licensee's contractor being able to call on no more than two successive subcontractors. There are however the following two possibilities for a waiver to this limitation, provided that the licensee presents sufficient justifications:

- *"in the case of an unforeseeable event affecting the conditions of performance of the activity or requiring specific operations"*. The licensee shall inform ASN beforehand and specify the relevant reasons;
- *"when the use of an outside contractor or of more than two tiers of subcontractors ensures better protection of the protected interests"*. In this case and at the request of the licensee, ASN may issue a waiver, giving full reasons for its decision.

The limitation rule applies as of commissioning of the BNI and runs until delicensing, for all provision of services or works important for the protection of interests and performed within the perimeter of the BNI. It should be noted that simple compliance with the limit on the number of subcontracting tiers is not in itself sufficient justification that all attempts have been made to limit the number of subcontracting tiers as far as is possible. In 2017, ASN will clarify its doctrine on this point, as well as on the granting of waivers.

In any case, the licensee shall monitor the AIP performed by outside contractors. To this end, it shall collect information from them, in particular for the purposes of operating experience feedback.

When a licensee intends to entrust the performance of an AIP to an outside contractor, it shall assess the proposals taking account of criteria giving priority to the protection of the above-mentioned interests; it shall first of all ensure that the companies it intends to call on have the technical capability to carry out the work and are able to manage the corresponding risks.

Finally, the licensee shall notify the outside contractors of the document containing its policy with regard to the protection of interests. The contract with the outside contractors shall specify the obligations necessary for application of the provisions of the BNI regulations incumbent upon each of the parties.

These provisions apply to contracts following a call for tenders published after 1st January 2017.

Title VI and a few provisions of Title VIII of the 17th August 2015 Act on Energy Transition for Green Growth and the Ordinance of 10th February 2016 constituting various nuclear provisions, make substantial modifications to the legislative framework for the regulation of nuclear activities, BNIs in particular. ASN assists the Ministry responsible for the Environment with the drafting of regulatory texts clarifying these new legislative provisions and with drafting of the regulatory part of the Environment Code with regard to nuclear matters.

Environment Code

The provisions of Chapters III, V and VI of Title IX of Book V of the Environment Code underpin the BNI licensing and regulation system.

The legal system applicable to BNIs is said to be "integrated" because it aims to cover the prevention or control of all the risks and detrimental effects, whether or not radioactive, that a BNI could create for man and the environment.

About fifteen decrees specify the legislative provisions of Title IX of Book V of the Environment Code, in particular the Decree of 11th May 2007 concerning the list of BNIs and Decree 2007-1557 of 2nd November 2007 (see below).

The provisions of Chapter II of Title IV of Book V of the Environment Code (drawn in particular from the codification of the "Waste Act") introduce a coherent and exhaustive legislative framework for the management of all radioactive waste.

"BNI Procedures Decree" of 2nd November 2007

The Decree of 2nd November 2007 implements Article L. 593-43 of the Environment Code.

It defines the framework in which the BNI procedures are carried out and covers the entire lifecycle of a BNI, from its creation authorisation and commissioning, to final shutdown, decommissioning and delicensing. Finally, it determines the relations between the Minister responsible for Nuclear Safety and ASN in the field of BNI safety.

The Decree clarifies the applicable procedures for adoption of the general regulations and for issuing individual resolutions concerning BNIs. It defines how the Act is implemented with regard to inspections, policing and administrative or criminal sanctions. Finally, it defines the particular conditions for application of certain administrative systems within the perimeter of the BNIs.

In 2016, work began on modification of this Decree in order to take account of the changes brought about by the TECV Act and by the Ordinance of 10th February 2016 constituting various nuclear provisions. Once this work is completed, it will be codified.

3.2 General technical regulations

The general technical regulations provided for by Article L. 593-4 of the Environment Code comprise all general texts setting technical rules for nuclear safety, whether Ministerial Orders or ASN statutory resolutions. They are supplemented by Circulars, Basic Safety Rules (BSR) and ASN guidelines, which are not binding.

Following the TSN Act of 13th June 2006, ASN began work on overhauling the general technical regulations applicable to BNIs, with the Order of 7th February 2012, called the "BNI Order", setting general rules for Basic Nuclear Installations, and about fifteen ASN statutory resolutions, some of which are still being drafted.

3.2.1 Ministerial Orders

The BNI Order of 7th February 2012 is a key milestone in the overhaul of the general technical regulations applicable to BNIs.

"BNI Order" of 7th February 2012

Issued pursuant to Article L. 593-4 of the Environment Code, the "BNI Order" of 7th February 2012 defines the essential requirements applicable to the BNIs to protect the interests listed in the Act: public safety, health and salubrity; protection of nature and the environment.

The BNI Order of 7th February 2012, modified by the Order of 26th June 2013, applies throughout the existence of the facility, from design through to delicensing. It recalls the principle of "integrated safety", that is the protection of all the interests mentioned in Article L. 593-1 of the Environment Code (safety, public health and protection of nature and the environment) - in addition to simply preventing accidents - and of the "graded approach" (in other words the graduated nature of the requirements and oversight, which must be proportionate to the potential consequences of the issues being dealt with).

The BNI Order addresses the following subjects:
- organisation and responsibility;
- the demonstration of nuclear safety;
- control of detrimental effects and the impact on health and the environment;
- pressure equipment designed specifically for BNIs;
- waste management;
- preparation and management of emergency situations.

In addition, the Order of 7th February 2012 defines some particular provisions applicable to certain categories of installations or to certain activities within a BNI: nuclear power reactors, on-site transport of hazardous goods, decommissioning, storage of radioactive substances and radioactive waste disposal facilities.

It incorporates into French regulations the “reference levels” drawn up by WENRA which defined a common baseline of requirements. The work done by WENRA was built around the IAEA safety standards and the regulations or best practices employed in the Member States of the association. This work led to the definition of a range of requirements designed to harmonise the safety of the reactors in operation in Europe.

The provisions of the Order concerning the performance of probabilistic assessments, the practical preclusion of certain events, the qualification system for Elements Important for Protection (EIP) or the application of certain new rules drawn from the regulations applicable to ICPEs (except for large cooling towers) may require the revision of certain points of the safety case and in-depth analyses, which could entail the revision of certain construction or operating provisions. They enter into force on the occasion of the first periodic review or the first significant modification of the BNI, or at final shutdown and decommissioning of the facility following the date of 1st July 2015.

3.2.2 ASN statutory resolutions

Pursuant to Article L. 592-20 of the Environment Code, ASN may issue statutory resolutions to clarify decrees and orders in the field of nuclear safety or radiation protection, which have to be approved by the Minister in charge of Nuclear Safety and Radiation Protection.

ASN has defined a programme for drafting these statutory resolutions aimed at clarifying the Decree of 2nd November 2007 or the BNI Order of 7th February

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General technical regulations applicable to BNIs

Following the adoption of the 13th June 2006 Act, ASN and the Ministry responsible for Nuclear Safety initiated an overhaul of the regulations applicable to BNIs.

The BNI Order of 7th February 2012 brings about a fundamental but nonetheless gradual change in the technical regulatory framework applicable to BNIs, already clarified by a number of ASN statutory resolutions.

As part of its role of drafting or contributing to the drafting of regulations, ASN’s goal is to promote the adoption of clear, complete reference regulations reflecting the best safety standards but also proportionate to the actual safety and radiation protection issues.

ASN thus carries out this work with the aim of involving all the stakeholders in the drafting of the regulations, given that broader consultation is a means of ensuring that the regulations will be appropriate and will be easier to understand and implement.

At the end of 2016, ASN thus adopted Guide No. 25 *“Drafting an ASN statutory resolution or guide. Procedures for consultation with stakeholders and the public”*, which was itself subject to prior consultation. This guide describes the procedures whereby the licensees and industrial firms concerned, as well as the general public and associations, will contribute to the drafting of ASN statutory resolutions or guides, concerning the Basic Nuclear Installations (BNI).

This guide will make it possible to:
- improve stakeholder involvement as early as possible in the process. The stakeholders and public will thus be consulted as of the beginning of the text drafting process, with regard to the orientations and the objectives, and then throughout this process;
- provide a better analysis of the impact of the draft texts, with a reinforced framework for the drafts by means of the production of three documents: an orientation and justification document, an assessment of the impact of the draft text and experience feedback analysis, these documents themselves being subject to consultation. The final goal is to obtain regulations that are appropriate and proportionate to the actual issues;
- to support and follow up the implementation of the regulatory texts by drafting guides intended for the licensees and industrial firms concerned and by integrating experience feedback after a few years of application of the texts.

Participation by the stakeholders and the public is either by means of consultation on the ASN website, or by means of exchanges, for which ASN is always available, or by consultation of consultative bodies which - depending on the subject or nature of the draft text - are the CSPRT, the advisory committees of experts, the CLIs or the HCTISN.

A special section was created on *www.asn.fr* in which ASN makes a certain number of documents available, in particular No. 197 of *Contrôle magazine* - which looks back at the various steps in the process to overhaul the general technical regulations applicable to BNIs, and provides a forum for the various stakeholders concerned by its implementation.

2012. Even before being required by law, ASN has from the outset submitted its draft statutory resolutions for public consultation on *www.asn.fr* (see chapter 6, point 2.2).

It should be pointed out that ASN proposed that some of its statutory resolutions also be presented to the Higher Council for the Prevention of Technological Risks (CSPRT) (more specifically with regard to resolutions covering topics that the CSPRT examines within the context of the ICPE system) in order to ensure greater consistency between the requirements applicable to ICPEs and BNIs (see chapter 2, point 2.4.3).

Diagram 3 shows the degree of progress of the project to overhaul the general technical regulations applicable to BNIs.

In 2016, three resolutions were adopted to supplement the implementation procedures of the BNI Order of 7th February 2012.

Resolution 2016-DC-0569 of 29th September 2016 modifying resolution 2013-DC-0360 of 16th July 2013 relative to control of detrimental effects and the impact of basic nuclear installations on health and the environment

This resolution modifies the "environment" resolution of 16th July 2013 and:
- updates or clarifies certain definitions in order to take account of changes to the regulations and introduce certain terms not yet defined;
- harmonises the terminology employed in the text of the resolution with the provisions regarding labelling present in regulation (EC) No. 1272/2008 of the European Parliament and Council of 16th December 2008 concerning the classification, labelling and packaging of substances and mixtures;
- specifies the scope of application of the provisions of article 2.3.2 concerning the means of collecting emission sources, not applicable to diffuse discharges;
- revises certain provisions, in order to adopt an approach that is proportionate to the actual issues;
- clarifies certain requirements, in particular those concerning the content of the environmental monitoring programme presented in appendix II to the resolution;
- specifies the conditions for application of certain regulatory requirements of the BNI Order of 7th February 2012;
- updates certain provisions in order to take account of recent changes to the regulations, in particular the entry into force on 1st June 2015 of Directive 2012/18/UE from the European Parliament and Council of 4th July 2012 concerning management of the hazards linked to major accidents involving hazardous substances modifying and then repealing Council Directive 96/82/CE known as the "Seveso 3 Directive";
- updates certain provisions to take account of recent changes to the Environment Code, following the publication of the Ordinance of 10th February 2016 containing various nuclear provisions.

Resolution 2016-DC-0571 of 11th October 2016 containing various provisions regarding nuclear pressure equipment conformity

This resolution was issued following changes to the Environment Code (Decree of 1st July 2015 on hazardous products and equipment, which transposes into the Environment Code Directive 2014/68/EU of 15th May 2014 on the harmonisation of the legislations of the Member States concerning the marketing of pressure equipment) and the publication of the Order of 30th December 2015 on nuclear pressure equipment.

The resolution contains provisions concerning:
- the changes necessary for application of the conformity evaluation modules (II of Article 6 of the nuclear pressure equipment Order of 30th December 2015);
- the conformity declaration model (Article R. 557-12-6 of the Environment Code);
- and the state of the art for the design and manufacture of category 0 nuclear pressure equipment (Article R. 557-12-4 of the Environment Code).

Resolution 2016-DC-0578 of 6th December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling installations

The resolution reinforces the prevention of risks resulting from the dispersal of pathogenic micro-organisms. It stipulates requirements concerning:
- the design, upkeep and monitoring of the facility;
- the maximum legionella concentrations in the facility cooling water and downstream of it for amoeba;
- the steps to be taken in the event of proliferation of microorganisms in the systems or identified infection in the vicinity of the facility;
- information of the public and the administrations in the event of proliferation of micro-organisms.

To the extent possible, the resolution aims to align the requirements applicable to the NPP large cooling towers with those applicable to cooling towers of other industries with respect to legionella.

However, owing to the considerable flow rates and volumes of water in the NPP cooling towers, certain requirements applicable to other industries would lead to an excessive environmental impact from biocidal treatments. Certain provisions were therefore adapted.

Furthermore, the resolution also regulates the prevention of amoeba risks, already specified in the individual regulations of the NPPs.

These resolutions are in addition to the statutory resolutions already in force:

- **ASN resolution 2015-DC-0532 of 17th November 2015 concerning the BNI safety analysis report:** It specifies the contents of the safety analysis report the licensee is required to transmit to ASN in its BNI creation or commissioning authorisation application file or in its BNI decommissioning file. The main provisions of this resolution more specifically concern the objectives of the safety analysis report, the principles underpinning the drafting and updating of the safety analysis report, compliance with the legislative and regulatory requirements, the description of the BNI and provisions intended for management of the risks it presents, the nuclear safety case (management of the risks presented by the facility), the on-site emergency plan design study, particular operations such as BNI construction, management of radioactive sources and on-site transport operations, plus requirements specific to certain BNIs, more particularly BNIs for example comprising one or more nuclear reactors.
- **ASN resolution 2015-DC-0508 of 21st April 2015 concerning the study of waste management and the inventory of waste produced in the BNIs:** It specifies the rules applicable to the management of the wastes produced in BNIs, more particularly the content of the waste management study required by 3° of II of Article 20 of the Decree of 2nd November 2007 and Article 6.4 of the BNI Order of 7th February 2012, the procedures for the creation and management of the waste zoning plan mentioned in Article 6.3 of the BNI Order of 7th February 2012 and the content and procedures for drawing up the waste summary specified in Article 6.6 of the BNI Order of 7th February 2012.
- **Resolution 2014-DC-0462 of 7th October 2014 concerning the control of the criticality risk in BNIs:** It sets the technical rules applicable within BNIs in order to meet the goal of controlling the criticality risk. This resolution applies to all BNIs containing fissile material, except for those in which criticality is impossible owing to the physical-chemical characteristics of this material. Guidelines for implementation of this resolution should be published in 2017.
- **Resolution 2014-DC-0444 of 15th July 2014 concerning PWR shutdowns and restarts stipulates that ASN approval is required to restart a reactor after a refuelling outage:** It mainly defines the information to be sent to ASN by the licensee before, during and after the reactor outage, so that ASN can check the pertinence of the inspections and maintenance work performed by the licensee and then stay informed of the overall results of the outage.
- **Resolution 2014-DC-0420 of 13th February 2014 concerning physical modifications to BNIs:** This resolution, which supplements the provisions of Chapter VII of Title III of the Decree of 2nd November 2007, clarifies the provisions that the licensee of a BNI implements, on the one hand to assess and minimise the possible consequences of a physical modification to the facility for the protected interests and justify the acceptability of the remaining consequences and, on the other, to prepare for and then carry out this modification.
- **Resolution 2014-DC-0417 of 28th January 2014 concerning the rules applicable to BNIs with regard to the management of fire risks:** It sets the technical rules applicable within BNIs in order to meet the fire risk control objectives. In accordance with the defence in depth approach, the resolution defines requirements concerning measures to prevent the outbreak of fire, detection and fire-fighting measures and measures to prevent the propagation of a fire and mitigate its consequences.
- **Resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs:** This resolution supplements the implementation conditions in Title IV of the BNI Order of 7th February 2012. Its main provisions concern methods for water intake and liquid or gaseous, chemical or radioactive discharges, the monitoring of water intake and discharges, environmental monitoring, prevention of detrimental effects and information of the regulatory authority and the public. It was modified by resolution 2016-DC-0569 of 29th September 2016.
- **Resolution 2013-DC-0352 of 18th June 2013 concerning public access to modification project files specified in Article L. 593-15 of the Environment Code:** This specifies the implementation procedures for Article L. 593-15 of the Environment Code (and Article 26 of the BNI Procedures Decree of 2nd November 2007) which sets out the procedure for public access to the draft resolutions modifying the facility or its operating conditions which, without being significant, are nonetheless liable to cause a significant rise in water intake or environmental discharges. This public access procedure is run by the licensee (see chapter 6, point 2.2).
- **Resolution 2012-DC-0236 of 3rd May 2012 supplementing certain conditions for application of ministerial decision JV/VF DEP-SD5-0048-2006 of 31st January 2006** which defines the conditions for the use of spare parts in the main primary system and the main secondary systems of pressurized water nuclear reactors and specifies the documentation associated with each spare part. The resolution of 3rd May 2012 defines the technical and manufacturing surveillance documentation required for these components in order to establish consistency between these provisions and those applicable to the manufacture of pressure equipment.
- **Resolution 2008-DC-0106 of 11th July 2008 concerning the use of internal authorisation systems in BNIs:** The purpose of a system of internal authorisations is to reinforce the licensee's responsibility for nuclear safety and radiation protection. The regulations thus enable the licensee to carry out minor operations provided that it implements a system of reinforced and systematic internal controls,

offering sufficient guarantees of quality, independence and transparency. Within this context, it may use the notification procedure specified in Article 27 of the Decree of 2nd November 2007.

3.2.3 Basic Safety Rules and ASN guides

ASN has drafted Basic Safety Rules (BSR) on a variety of technical subjects concerning BNIs. These are recommendations which specify safety objectives and describe practices ASN considers to be satisfactory. As part of the ongoing reorganisation of the general technical regulations applicable to BNIs, the BSR are gradually being replaced by ASN guides. Work is under way to identify the BSR which can be repealed and the guides needing to be updated.

The ASN guides collection was created as an educational tool for professionals. In 2016, it comprised twenty-six non-binding guides designed to affirm ASN doctrine, detail the recommendations, propose methods for achieving the objectives set in the texts and present methods and best practices stemming from experience feedback from significant events.

The ASN guides collection is presented in the appendix to this chapter.

3.2.4 French nuclear industry professional codes and standards

The nuclear industry produces detailed rules dealing with the state of the art and industrial practices. It groups these rules in "Industrial Codes". These rules allow concrete transposition of the requirements of the general technical regulations, while reflecting good industrial practice. They thus facilitate contractual relations between customers and suppliers.

In the particular field of nuclear safety, the Industrial Codes are drafted by the French association for NSSS equipment design, construction and in-service monitoring rules, of which EDF and Areva are members. The RCC Codes of design and construction rules have been drafted for the Design, Manufacture and Commissioning of Electrical Equipment (RCC-E), Civil Engineering (RCC-G) and Mechanical Equipment (RCC-M). A collection of In-service Monitoring Rules for Mechanical Equipment (RSE-M) has also been drafted.

These codes do not take the place of the regulations but are industrial tools which can be usefully employed as a basis for meeting the requirements of the regulations.

ASN's actions in this field are to oversee the drafting and updating of the codes and their usage in activities subject to its regulation.

ASN examines the codes drafting and utilisation processes, even if it does not carry out a complete analysis of their contents. It helps with the drafting and updating of codes in areas in which it considers that this would allow better implementation of the regulations.

ASN submits its comments on the use of the codes and, if it so deems necessary, sends requests for changes to the organisations responsible.

3.3 Plant authorisation decrees and commissioning licenses

Chapter III of Title IX of Book V of the Environment Code contains a creation authorisation procedure, which may be followed by a number of licensing operations throughout the life of a BNI, from its commissioning up to final shutdown and decommissioning, including any modifications made to the facility.

3.3.1 Safety options

Any industrial concern intending to operate a BNI may, even before starting the creation authorisation application procedure, ask ASN for an opinion on all or part of the safety options it has adopted for its installation. The applicant is notified of the ASN opinion and will produce any additional studies and justifications as necessary for a possible creation authorisation application.

The safety options will then be presented in the creation authorisation application file, in a preliminary version of the safety analysis report.

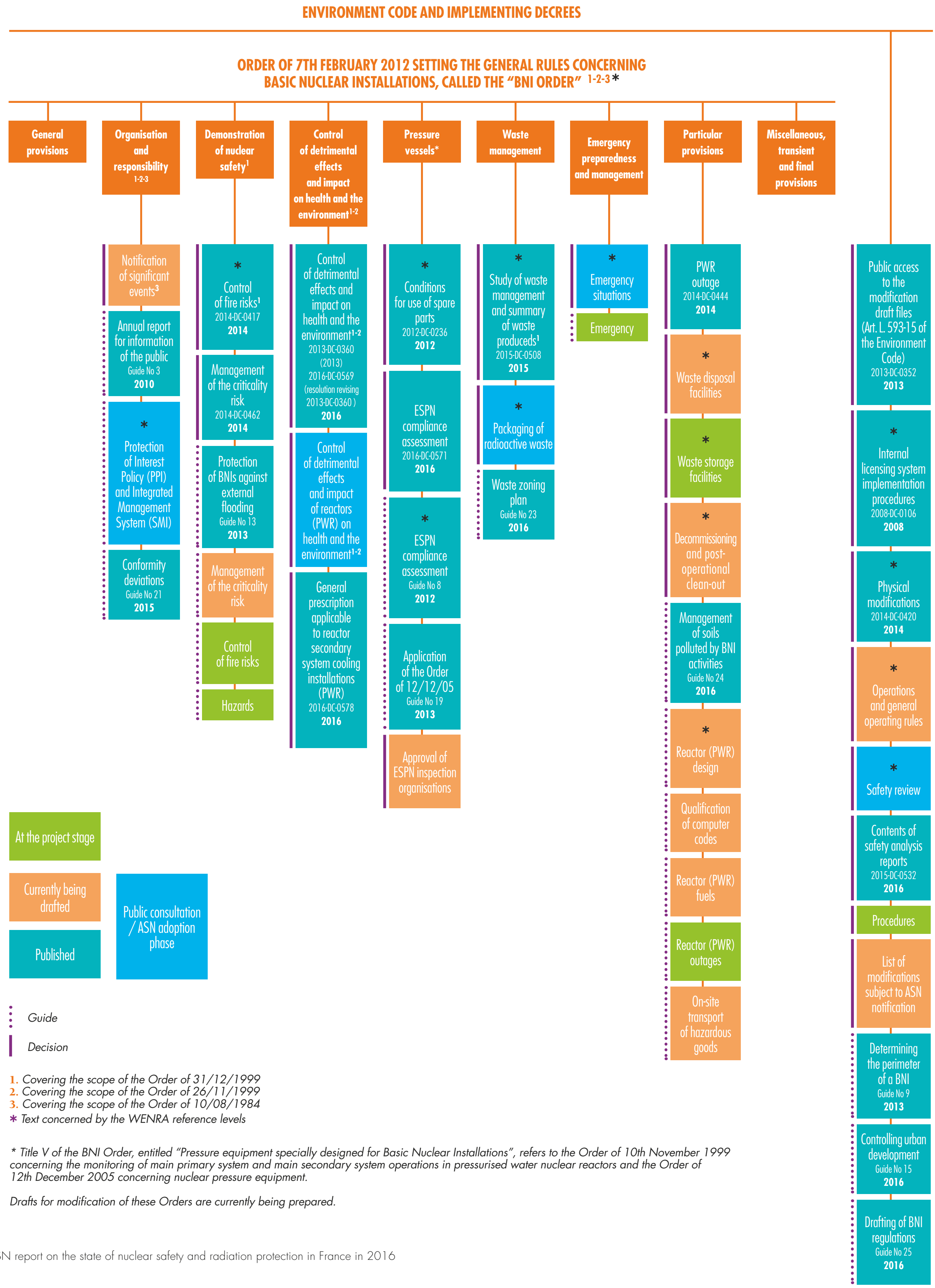
This preparatory procedure in no way exempts the applicant from the subsequent regulatory examinations but simply facilitates them.

3.3.2 Public debate

Pursuant to Articles L. 121-1 et seq. of the Environment Code, the creation of a BNI is subject to a public debate procedure when dealing with a new nuclear power generation site or a new site (other than for nuclear power generation) costing more than €300 million and, in certain cases, a new nuclear power generation site, or a new site (other than for nuclear power generation) costing between €150 million and €300 million (Article R. 121-1 of this same Code).

The public debate looks at the need and suitability, objectives and characteristics of the project.

DIAGRAM 3: Status of progress of the overhaul of the general technical regulations applicable to BNIs, as at 24th January 2017



1. Covering the scope of the Order of 31/12/1999
2. Covering the scope of the Order of 26/11/1999
3. Covering the scope of the Order of 10/08/1984
* Text concerned by the WENRA reference levels

* Title V of the BNI Order, entitled "Pressure equipment specially designed for Basic Nuclear Installations", refers to the Order of 10th November 1999 concerning the monitoring of main primary system and main secondary system operations in pressurised water nuclear reactors and the Order of 12th December 2005 concerning nuclear pressure equipment.

Drafts for modification of these Orders are currently being prepared.

3.3.3 The Creation Authorisation Decree

The creation authorisation application for a BNI is filed with the Minister responsible for Nuclear Safety by the industrial concern which intends to operate the facility, which thus acquires the status of licensee. The application is accompanied by a file comprising several items, including the detailed drawing of the installation, the impact assessment, the preliminary version of the safety analysis report, the risk management study and the decommissioning plan.

ASN is responsible for reviewing the file, jointly with the Minister responsible for Nuclear Safety. This is followed by a period of parallel consultation of the public and technical experts.

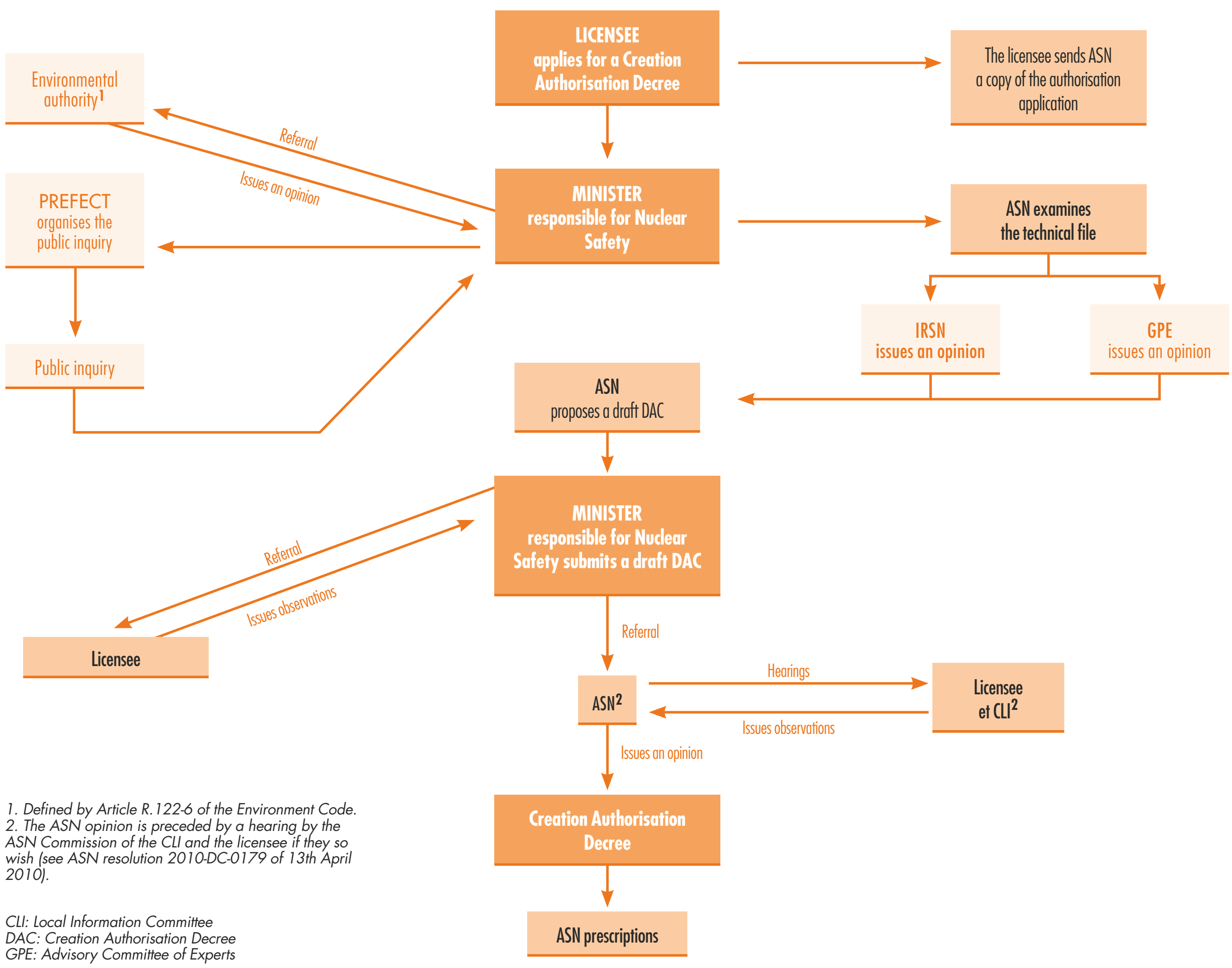
The impact assessment is submitted for its opinion to the environmental authority of the General Council for the Environment and Sustainable Development.

The public inquiry

Article L.593-8 of the Environment Code stipulates that the authorisation can only be granted after holding a public inquiry. The purpose of the inquiry is to inform the public and collect their opinions, suggestions and counterproposals, in such a way as to provide the competent authority with all the elements necessary for it then to make an informed decision.

The inquiry is carried out in accordance with the provisions of Articles L. 123-1 to L. 123-18 and R. 123-1 to R. 123-27 of the Environment Code. The Prefect opens the public inquiry at least in each of the communities of which any part is situated less than five kilometres from the perimeter of the installation. This inquiry lasts from a minimum of one month to a maximum of two months (except if the inquiry is suspended or in the event of an additional inquiry). The dossier submitted by the licensee in support of its authorisation application is made available in the public

DIAGRAM 4: Creation authorisation procedure for a Basic Nuclear Installation (BNI) defined in Chapter III of Title IX of Book V of the Environment Code



1. Defined by Article R.122-6 of the Environment Code.
2. The ASN opinion is preceded by a hearing by the ASN Commission of the CLI and the licensee if they so wish (see ASN resolution 2010-DC-0179 of 13th April 2010).

CLI: Local Information Committee
DAC: Creation Authorisation Decree
GPE: Advisory Committee of Experts

inquiry dossier. However, as the safety analysis report (containing the inventory of the risks the installation can present, the analysis of the measures taken to prevent these risks and a description of the measures designed to limit the probability of accidents and their effects) is a bulky document and is difficult for non-specialists to understand, it is supplemented by a risk control study, which itself comprises a non-technical summary of this study designed to make it easier to understand.

Furthermore, the procedures concerning BNIs subject to a public inquiry are within the scope of Decree 2011-2021 of 29th December 2011, determining the list of projects, plans and programmes to be communicated electronically to the general public under the experiment specified in II of Article L. 123-10 of the Environment Code. This states that the Authority responsible for opening and holding the public inquiry shall communicate the main documents in the inquiry dossier to the general public in electronic format. This approach aims to make it easier for the public to become informed about the projects, in particular those who do not live in the places where the inquiry is being held. Using this means of providing access to information and the possibility of submitting observations in electronic format aims to facilitate and improve the way in which the public can express their opinions. As of 1st January 2017, the provisions of Article L. 123-12 of the Environment Code will apply; they state that the *"public inquiry file is placed on-line for the duration of the inquiry. It remains open for consultation, for this same period, on paper in one or more places determined as of opening of the public inquiry. Free access to the file is also guaranteed on one or more computer terminals in a place open to the public"*.

Construction of a BNI requires the issue of a building permit by the Prefect, according to procedures specified in Articles R. 421-1 et seq. and Article R. 422-2 of the Town Planning Code. Article L. 425-12 of the Town Planning Code, created by the TSN Act of 13th June 2006, states that *"when the project concerns a basic nuclear installation requiring creation authorisation pursuant to Article L. 593-7 of the Environment Code […], the work may not be performed before the closure of the public inquiry held prior to this authorisation."*

The creation of a Local Information Committee (CLI)

The TSN Act of 13th June 2006, codified in Books I and V of the Environment Code, gave a legislative basis to the status of the BNI Local Information Committees (CLI). The CLIs are presented in chapter 6.

The corresponding provisions can be found in sub-section 3 of section 2 of Chapter V of Title II of Book I of the Environment Code. The CLI can be created as soon as the BNI creation authorisation application is made. Whatever the case, it must be constituted once the authorisation decree has been issued.

The modifications made to the CLI's responsibilities by the TECV Act of 17th August 2015 are detailed in chapter 6, point 2.2.1. The specific nature of the CLIs of BNIs located close to a border is taken into account because the Act enables foreign nationals to sit on these CLIs (this in particular concerns Germany, Belgium, Luxembourg and Switzerland).

Consultation of other European Union countries

Pursuant to Article 37 of the Treaty instituting the European Atomic Energy Community and to the BNI Procedures Decree of 2nd November 2007, the creation of a facility liable to discharge radioactive effluents into the environment can only be authorised after consulting the European Commission.

Consultation of technical organisations

The preliminary version of the safety analysis report appended to the creation authorisation application is transmitted to ASN, which may submit it for examination to the Advisory Committees, following a report from IRSN.

Further to its investigation and the results of the consultations, ASN sends the Minister responsible for Nuclear Safety a draft decree proposal authorising or rejecting creation of the installation.

Creation Authorisation Decree

The Minister responsible for Nuclear Safety sends the licensee a preliminary draft Decree granting or refusing Creation Authorisation (DAC, see Diagram 4). The licensee has a period of two months in which to present its observations. The Minister then obtains the opinion of ASN. ASN resolution 2010-DC-0179 of 13th April 2010 gives licensees and the CLIs the possibility of being heard by the ASN Commission before it gives its opinion.

The creation authorisation for a BNI is delivered by a decree from the Prime Minister and countersigned by the Minister responsible for Nuclear Safety.

The Creation Authorisation Decree (DAC) establishes the perimeter and characteristics of the facility. It also specifies the duration of the authorisation, if applicable, and the installation commissioning deadline. It also specifies the essential elements required to protect public health and safety, or to protect nature and the environment.

The requirements defined by ASN for application of the Creation Authorisation Decree

For application of the DAC, ASN defines the requirements regarding the design, construction and operation of the BNI that it considers to be necessary for nuclear safety.

ASN defines the requirements regarding the BNI water intakes and effluent discharges. The specific requirements setting limits on the environmental discharges from the BNI under construction or in operation are subject to approval by the Minister responsible for Nuclear Safety.

3.3.4 Commissioning authorisation

Commissioning corresponds to the first utilisation of radioactive materials in the installation or the first operation of a particle beam.

Prior to commissioning, the licensee sends ASN a dossier comprising the updated safety analysis report of the "as-built" installation, the general operating rules, a waste management study, the on-site emergency plan and the decommissioning plan.

After checking that the installation complies with the objectives and rules specified in Chapter III of Title IX of Book V of the Environment Code and its implementing texts, ASN authorises commissioning of the installation and communicates this decision to the Minister responsible for Nuclear Safety and to the Prefect.

It also communicates it to the CLI.

3.3.5 BNI modifications

The BNI System, as modified by the Act of 17th August 2015, makes provision for two cases when dealing with modifications to the facility or its operating conditions:

- "substantial" modifications to the facility, its authorised operating procedures or elements which led to its authorisation, specified in Article L. 593-14 of the Environment Code: these modifications are the subject of a procedure similar to that of a creation authorisation application in accordance with the procedure specified in Articles L. 593-7 to L. 593-12 of this same Code.

  A modification is considered to be "substantial" in the cases mentioned in Article 31 of the BNI Procedures Decree of 2nd November 2007, that is:
  - a change in the nature of the installation or an increase in its maximum capacity;
  - a modification of the key elements protecting the interests mentioned in the first paragraph of Article L. 593-1 of the Environment Code, which appear in the authorisation decree;
  - the addition, within the perimeter of the facility, of a new BNI, the operation of which is linked to that of the facility in question.
- The other modifications having an impact on the protected interests are "significant» modifications to the installation, its authorised operating procedures, elements which led to its authorisation or its commissioning (they correspond to the former modifications subject to "Article 26 notification" of the Procedures Decree of 2nd November 2007). Depending on their importance, they require either notification to ASN or authorisation by ASN under the terms of Article L. 593-15 of the Environment Code (the version resulting from the Act of 17th August 2015). This same Article states that these modifications may be opened up for public consultation.

In its version resulting from the Decree of 28th June 2016, the Decree of 2nd November 2007 states that the breakdown between modifications subject to ASN authorisation or to ASN notification must be determined by an ASN resolution. The "default" choice made is to require authorisation for BNI modifications.

However, pending ASN's resolutions listing the operations subject to notification, an interim provision states that *"the notification waiver resolutions issued by ASN pursuant to Article 27 of the Decree of 2nd November 2007, in its version in force before 29th June 2016 (date of publication of the Decree of 28th June 2016) are considered to be resolutions setting the list of modifications requiring notification, pursuant to Article 27 of the Decree of 2nd November 2007 in its version resulting from the decree of 28th June 2016"*.

This interim provision will apply until ASN has issued a resolution setting the list of modifications subject to notification and in any case no later than 1st January 2018.

The procedure whereby the licensee gives the public access to the files for a BNI modification project that

> **FUNDAMENTALS**
>
> **General Operating Rules**
>
> The General Operating Rules are the "highway code" for nuclear reactors. They are defined by the licensee and examined by ASN prior to commissioning of the facility and then with each modification affecting the protected interests. They constitute an interface document between design and operation. They determine a set of specific rules, for which compliance guarantees that operation of the facility remains within the range covered by the nuclear safety case.

TABLE 2: The BNI modifications system

SYSTEM APPLICABLE SINCE THE TSN ACT AND THE BNI PROCEDURES DECREE BEFORE THE MODIFICATION OF 28TH JUNE 2016		TECV SYSTEM
IF THE LICENSEE HAS NO SAI*	IF THE LICENSEE HAS AN SAI**	ALL BNI LICENSEES
Significant modification subject to a complete authorisation procedure Authorisation by decree after public inquiry *Article 31 of the BNI Procedures Decree*		**Substantial** modification subject to a complete authorisation procedure Authorisation by decree after public inquiry *Article 31 of the amended BNI Procedures Decree*
Non-significant modification subject to notification to ASN and liable to lead to a significant increase in water intake or environmental discharges. Licensee file made available to the public by the licensee Implementation time of 6 months barring express approval by ASN or extension for an additional period of 6 months *II of Article 26 of the BNI Procedures Decree*		Significant modification subject to ASN authorisation with participation of the public ** *II and III of Article 26 of the amended BNI Procedures Decree*
Non-significant modification subject to notification to ASN. Implementation time of 6 months barring express approval by ASN or extension *Article 26 of the BNI Procedures Decree*	Non-significant modification subject to notification to ASN. Implementation time of 6 months barring express approval by ASN or extension *Article 26 of the BNI Procedures Decree*	Significant modification subject to ASN authorisation without participation of the public *Article 26 of the amended BNI Procedures Decree*
	Notification waiver *Article 27 of the BNI Procedures Decree*	Significant modification subject to notification to ASN. *Article 27 of the amended BNI Procedures Decree*

** SAI: Internal Authorisation System*
*** If the modification is incompatible with compliance with a prescription, It may not be implemented before a possible change to the prescription by ASN.*

could cause a significant increase in its water intake or effluent discharges to the environment, as specified by the ASN resolution of 18th June 2013, remained in force until 31st December 2016 (see chapter 6, point 2.2).

The other installations located within a BNI perimeter

The following co-exist within the perimeter of a BNI:
- The equipment and installations which are part of the BNI: they constitute an element of this facility necessary for its operation. Technically, depending on its type, this equipment may be considered comparable to classified installations but, as a part of the BNI, it is subject to the BNI System and BNI regulations.
- The equipment and installations which are not necessarily linked to the BNI.
  The "not necessary" equipment and installations on the IOTA or ICPE lists, situated within the perimeter of the BNI remain subject to these systems, with ASN retaining competence for individual measures concerning this equipment and these installations and oversight thereof. As of 2017, ASN shall issue the environmental authorisation (which replaces the ICPE or IOTA authorisations) for this equipment as an ICPE or as an IOTA with risks for the water resources and aquatic ecosystems. However, this equipment shall continue to be the responsibility of the Prefect with regard to other systems mentioned in the texts covering the environmental authorisation and their licensees do not benefit from the integrated nature of the environmental authorisation.

3.4 Particular requirements for the prevention of pollution and detrimental effects

3.4.1 The OSPAR Convention

The international OSPAR Convention (resulting from the merging of the Oslo and Paris conventions) is the mechanism whereby the European Commission and fifteen Member States, including France, cooperate to protect the marine environment of the North-East Atlantic. The strategic orientations for radioactive substances consist in *"preventing pollution of the maritime zone by ionising radiation by progressively and substantially reducing discharges, emissions and losses of radioactive substances. The ultimate aim is to achieve environmental concentrations that are close to the ambient values in the case of naturally occurring radioactive substances, and close to zero in the case of man-made radioactive substances"*. To achieve these objectives, the following are taken into account:
- the radiological impacts on humans and biota;
- the legitimate uses of the sea;
- technical feasibility.

Within the French delegation, ASN takes part in the work of the committee tasked with assessing application of this strategy.

3.4.2 The ESPOO Convention

The Convention on the assessment of environmental impacts in a transboundary context, more commonly called the "ESPOO Convention", requires that the contracting parties conduct an environmental assessment of the impacts of activities liable to have a transboundary environmental impact before licensing this activity and that they notify the neighbouring country concerned of this assessment. Certain nuclear facilities – such as NPPs, nuclear fuel production or enrichment facilities, radioactive waste disposal or reprocessing facilities – fall within the scope of this Convention.

The ESPOO Convention was adopted in 1991 and entered into force in September 1997.

3.4.3 ASN resolution 2013-DC-0360 of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs

Resolution of 16th July 2013 concerning the control of detrimental effects and the health and environmental impact of BNIs supplements the implementation procedures of Title IV of the BNI Order of 7th February 2012. Its main provisions concern methods for water intake and liquid or gaseous, chemical or radioactive discharges, the monitoring of water intake and discharges, environmental monitoring, prevention of detrimental effects and information of the regulatory authority and the public. With regard to environmental protection, the BNI Order of 7th February 2012 and the resolution of 16th July 2013 more specifically aim to address the following main objectives or issues:

- implement the integrated approach specified by law, whereby the BNI System governs all the risks, pollution and detrimental effects created by these installations;
- modify the regulations applicable to basic nuclear installations prior to 1st July 2013;
- incorporate into the regulations the requirements applicable to the BNI licensees by certain individual ASN decisions concerning water intake and effluent discharge, in order to create a more general and uniform framework;
- set binding unified principles and rules applicable to the BNIs;
- for BNIs, adopt requirements at least equivalent to those applicable to ICPEs and (IOTA) concerned by the list specified in Article L. 214-2 of the Environment Code, more specifically those of the Order of 2nd February 1998 concerning water intake and consumption and emissions of all types from installations classified on environmental protection grounds subject to authorisation, in accordance with the provisions of the BNI Order of 7th February 2012;
- adopt provisions, the implementation of which is such as to guarantee the quality of the steps taken by the BNI licensees for monitoring of their facilities (monitoring of effluents and of the environment); improve public information practices, making the corresponding steps taken by the licensees more legible.

The resolution of 16th July 2013 was revised by the ASN resolution of 29th September 2016. This modification aims to clarify certain provisions more specifically concerning the content of the environmental monitoring programme to be put into place by the licensees, set out in appendix II to the resolution. It also updates the prescriptions to take account of regulatory changes in European Environmental Law (regulation 1272/2008 of the European Parliament and Council of 16th December 2008 concerning the classification, labelling and packaging of substances and mixtures, Directive 2012/18/UE of the European Parliament and Council of 4th July 2012 concerning the management of hazards linked to major accidents involving hazardous substances modifying and then repealing Council Directive 96/82/CE, known as the "Seveso 3 Directive").

3.4.4 BNI discharges

BNI discharges management policy

Like all industries, nuclear activities (nuclear industry, nuclear medicine, research installations, etc.) create by-products, which may or may not be radioactive. Steps are being taken to minimise their quantity through reduction at source.

The radioactivity discharged in effluents represents a marginal fraction of that which is confined in the waste.

The choice of the means of discharge (liquid or gaseous) is part of a more general approach aimed at mitigating the overall impact of the installation.

ASN makes sure that in the impact assessment, the BNI creation authorisation application explains the licensee's choices regarding in particular the reduction at source measures and the decisions taken between confinement, treatment or dispersal of substances, based on safety and radiation protection considerations.

The optimisation efforts encouraged by the authorities and made by the licensees have - for "equivalent operation" - resulted in these emissions being constantly reduced. ASN hopes that setting discharge limit values will encourage the licensees to maintain their discharge optimisation and management efforts. It ensures that discharges are kept to the minimum possible by using the best techniques available and has undertaken a revision of the discharge limits in recent years. In 2016, ASN thus issued eleven resolutions updating the water intake and discharge limits and setting the prescriptions applicable to water intake and discharges from the NPPs of Fessenheim and Cruas-Meysse, as well as the Mélox, Atalante, Gammatec and Centraco facilities in Marcoule.

The impact of BNI chemical discharges

The substances discharged can have an impact on the environment and the population owing to their chemical characteristics.

ASN considers that BNI discharges should be regulated in the same way as those of other industrial facilities. The TSN Act of 13th June 2006, codified in Books I and V of the Environment Code, and more broadly the general technical regulations concerning discharges and the environment, take this question into account. This integrated approach is little used abroad, where chemical discharges are often regulated by an Authority different from that in charge of radiological issues.

ASN wants the impact of chemical discharges on the populations and the environment to be as low as possible, in the same way as for radioactive substances.

The impact of thermal discharges from BNIs

Some BNIs, especially nuclear power plants, discharge cooling water into watercourses or the sea, either directly or after cooling in cooling towers. Thermal releases lead to a temperature rise in the receiving environment of up to several degrees.

The regulatory limits aim to prevent a modification of the receiving environment, in particular fish life, and to ensure acceptable health conditions if water is taken for human consumption downstream. These limits can thus differ according to the environment and the technical characteristics of each installation.

3.4.5 Prevention of accidental pollution

The BNI Order of 7th February 2012 and the ASN resolution of 16th July 2013 amended concerning the control of detrimental effects and the health and environmental impact of BNIs, impose obligations designed to prevent, or in the event of an accident, to minimise direct or indirect discharges of toxic, radioactive, flammable, corrosive or explosive liquids into the sewer systems or the environment.

3.5 Requirements concerning radioactive waste and decommissioning

3.5.1 Management of BNI radioactive waste

The management of waste in the BNIs, whether or not radioactive, is regulated by ASN, notably to prevent and minimise the production and harmfulness of the waste – in particular at source – more specifically by means of requirements concerning the design, classification, treatment and packaging.

In order to perform this regulation, ASN more specifically relies on a number of documents produced by the BNI licensees:
- the impact assessment, which is part of the creation authorisation application as described in Article 8 of the BNI Procedures Decree of 2nd November 2007;
- the waste management study, which is part of the commissioning authorisation application as described in Article 20 of the BNI Procedures Decree of 2nd November 2007, the contents of which are specified in Article 6.4 of the BNI Order of 7th February 2012. This study in particular includes an analysis of the waste produced or to be produced in the facility and the steps taken by the licensee to manage it, as well as the waste zoning plan;
- the waste summary specified in Article 6.6 of the BNI Order of 7th February 2012. This summary aims to verify that waste management complies with the provisions of the waste management study and to identify areas for improvement.

In a resolution of 21st April 2015, ASN set requirements concerning the study of the management of waste and the summary of the waste produced in BNIs and specifies the operational procedures for waste management.

On 30th August 2016, in its Guide No. 23, ASN clarified the procedures for determining and modifying the waste zoning plan in BNIs.

3.5.2 Decommissioning

The legal framework for BNI decommissioning, in particular the modifications made by the Act of 15th August 2015, are described in detail in chapter 2015.

The final shutdown of a BNI is the responsibility of the licensee, who must notify the Minister responsible for Nuclear Safety and ASN no later than two years prior to final shutdown (this period may be shorter if so justified by the licensee). As of that date, the licensee is no longer authorised to operate its facility, which is considered to be finally shut down and must be decommissioned. Article L. 593-26 of the Environment Code states that until the decommissioning decree comes into force, the facility remains governed by the provisions of its Creation Authorisation Decree and the ASN prescriptions, which may be added to or modified if necessary. In 2017, ASN will prescribe the date for submission of the decommissioning file for facilities finally shut down before 28th June 2016.

Article L. 593-28 of the version of the Environment Code subsequent to the Act of 15th August 2015, states that decommissioning of a nuclear facility must be prescribed by a decree, issued on the advice of ASN. The decommissioning file presented by the licensee undergoes the same consultations and inquiries as those applicable to a BNI creation authorisation application and in accordance with the same procedures.

This same Article stipulates that the decommissioning decree in particular determines the characteristics of decommissioning, its completion deadline and, as necessary, the operations under the responsibility of the licensee after decommissioning.

Finally, Article L. 593-28 provides for the possibility of decommissioning a part of a BNI.

On 30th August 2016, in a revised version of Guide No. 6, ASN specified the regulatory framework for the BNI decommissioning operations, following extensive work to clarify the implementation of the administrative procedures (see chapter 15).

Installation delicensing

Following decommissioning, a nuclear installation can be delicensed. It is then removed from the BNI list and is no longer subject to the BNI System. To support its delicensing application, the licensee must provide a dossier demonstrating that the envisaged final state has indeed been reached and describing the state of the site after decommissioning (analysis of the state of the soil and remaining buildings or equipment, etc.). Depending on the final state reached, institutional controls may be implemented, according to the intended subsequent use of the site and buildings. These may contain a certain number of restrictions on use (to be used only for industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of excavation, etc.). ASN can make the application of such institutional controls a prerequisite for delicensing.

Guides No. 14 and 24 published on 30th August 2016 set out the recommendations concerning the procedures for remediation of structures and soils in BNIs with a view to delicensing.

3.5.3 The financing of decommissioning and radioactive waste management

Sections 1 and 2 of Chapter IV of Title IX of Book V of the Environment Code (previously Article 20 of the "Waste Act") create an arrangement for ring-fencing funds to meet the costs of decommissioning nuclear facilities and managing radioactive waste (see chapter 15, point 1.4). These arrangements are clarified by the Decree of 23rd February 2007 concerning the secure financing of nuclear costs, modified by the Decree of 24th July 2012 and the Order of 21st March 2007 concerning the secure financing of nuclear costs. The legal system created by these texts aims to secure the financing of these costs, through implementation of the "polluter-pays" principle. It is therefore up to the nuclear licensees to ensure this financing, by setting up a portfolio of assets dedicated to the expected costs. This is done under the direct control of the State, which analyses the situation of the licensees and can prescribe measures should it be seen to be insufficient or inadequate. In any case, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

It stipulates that the licensees must make a prudent assessment of the cost of decommissioning their installations or, for radioactive waste disposal facilities, their final shutdown, maintenance and monitoring costs. They also evaluate the cost of managing their spent fuel and radioactive waste, according to Article L. 594-1 of the Environment Code. Pursuant to the Decree of 23rd February 2007, ASN issues an opinion on the consistency of the decommissioning and spent fuel and radioactive waste management strategy presented by the licensee with regard to nuclear safety. In 2017, ASN will issue its opinion on the consistency of the strategy submitted by the licensees in their three-yearly reports in 2016.

From among the assets liable to be accepted to cover the provisions for the costs mentioned in Article L. 594-1 of the Environment Code (decommissioning of facilities, final shutdown, maintenance and monitoring costs, spent fuel and radioactive waste management costs), the Decree of 24th July 2013 identifies those which are mentioned by the provisions of the Insurance Code and those which are specific to the licensees of nuclear facilities. It makes certain types of debts acceptable (notably certain medium-term negotiable bonds and securitisation mutual funds) and, in certain conditions, unquoted stock; as a result of this extension, it more specifically clarifies the exclusion criteria for unquoted intra-group stock. It sets the maximum value of the assets within a given category or from the same issuer and determines new ceilings for assets that have become acceptable.

TABLE 3: Regulations applicable to pressure equipment

	NUCLEAR PRESSURE EQUIPMENT		NON-NUCLEAR PRESSURE EQUIPMENT
	PWR REACTOR MAIN PRIMARY AND SECONDARY SYSTEMS	OTHER NUCLEAR PRESSURE EQUIPMENT	
GENERAL PROVISIONS	Chapter VII of Title V of Book V of the Environment Code		
	Titles I and IV of the Order of 30th December 2015		Titles I, IV and V of Decree 99-1046 of 13th December 1999
PROVISIONS CONCERNING NEW EQUIPMENT	Articles R.557-12-1 et seq. of the Environment Code Title II of the Order of 30th December 2015		Articles R.557-9-1 et seq. of the Environment Code
PROVISIONS CONCERNING IN-SERVICE MONITORING	Articles R.557-14-1 et seq. of the Environment Code Order of 10th November 1999	Articles R.557-14-1 et seq. of the Environment Code Title III of the Order of 12th December 2005	Title III of Decree 99-1046 of 13th December 1999 Order of 15th March 2000

3.6 Particular requirements for pressure equipment

Pressure equipment is subject to the provisions of Chapter VII of Title V of Book V of the Environment Code, which integrates the principles of the "new European approach". New equipment must thus be designed and manufactured by its manufacturer in compliance with the essential conformity requirements set out in the regulations and must undergo a conformity assessment by an approved organisation.

These provisions are supplemented by requirements applicable to in-service monitoring of the equipment, set out in section 14 of Chapter VII of Title V of Book V of the Environment Code. These provisions will gradually enter into force with publication of the corresponding orders and no later than 1st January 2018. This is also the deadline by which Decree 99-1046 of 13th December 1999 on pressure equipment will be repealed.

Pressure equipment specially designed for BNIs, known as "Nuclear Pressure Equipment" (ESPN) is subject to both the BNI System and the pressure equipment system. For this equipment, specific Orders stipulate the provisions defined by the Environment Code. The latest Order in force is that of 30th December 2015 relative to nuclear pressure equipment.

ASN assesses the conformity of the ESPN most important for safety and qualifies organisations for the other ESPN. Once in service, ESPN must be monitored and maintained by the licensee under ASN control and must undergo periodic technical inspections by ASN-approved organisations. The list of approved organisations and the associated approval resolutions are available on *www.asn.fr*.

Furthermore, II of Article L. 593-33 of the Environment Code gives ASN competence to issue individual resolutions and check the in-service monitoring of non-nuclear pressure equipment installed in a BNI.

Table 3 summarises the texts applicable to the pressure equipment present in BNIs.

4. Regulations governing the transport of radioactive substances

4.1 International regulations

The regulations applicable to transports of radioactive substances are based on the transport regulation called SSR-6, published by IAEA. ASN takes part in the work by the IAEA committee tasked with drafting and updating this regulation.

This regulation is not binding but its provisions, which are specific to radioactive substances, are integrated into the appendices of international agreements on the safety of the carriage of hazardous goods (which includes radioactive substances): the appendices of the European agreement on the International Carriage of Dangerous Goods by Road (ADR) for road transport, the regulation on the International Carriage of Dangerous Goods by Rail (RID) for rail transport, the appendices of the European agreement on the International Carriage of Dangerous goods by Inland Waterways (ADN) for river transport, the International Maritime Dangerous Goods Code (IMDG Code) for carriage by sea and the technical instructions of the International Civil Aviation Organisation (ICAO) for carriage by air.

France is a signatory to these various agreements, which are transposed in full into national law. For carriage by land (road, rail and inland waterways), European Directive 2008/68/CE of 24th September 2008 requires the application of the appendices to the ADR, RID and ADN within the European Union. This Directive is transposed into French law by a single Order covering all carriage by land on the national territory. This is the Order of 29th May 2009 as amended concerning the carriage of dangerous goods by land, known as the “TMD” Order.

For carriage by sea, the Order of 23rd November 1987 concerning vessel safety, known as the “RSN Order” renders application of the IMDG code mandatory. Finally, for carriage by air, European regulation 859/2008 of 20th August 2008, known as “regulation EU OPS1”, renders the ICAO’s technical instructions directly applicable in French law and clarifies certain aspects.

The regulatory requirements applicable to the various modes of transport are all derived from IAEA regulation SSR-6. They in particular concern the robustness of the packages containing radioactive substances, the operational provisions for ensuring the satisfactory performance of transport operations, including from the viewpoint of radiation protection of workers and the public, and provisions dealing with effective emergency management in the event of an accident (see chapter 11).

4.2 National regulations

The Transport Code, more particularly its Articles L. 1252-1 et seq., makes provision for the TMD Order and empowers the nuclear safety inspectors designated by ASN to monitor application of its provisions concerning the transport of radioactive substances. It also states that ASN is consulted with regard to the modifications made to the TMD Order concerning it and is asked to sit on the Interministerial Committee for the Carriage of Dangerous Goods (CITMD).

The Environment Code, more specifically its Article L. 595-1, and Article 62 of its implementing Decree of 2nd November 2007, state that ASN is the French competent Authority to take individual resolutions and issue certificates for the carriage of radioactive substances. Pursuant to these provisions, the approvals required for the package models with the most significant potential consequences must be issued by ASN (see chapter 11).

Article R. 1333-44 of the Public Health Code also requires that companies transporting radioactive substances in France be subject to either notification or licensing by ASN. On 12th March 2015, ASN issued a resolution (2015-DC-0503) creating a system of notification for all companies transporting radioactive substances on French territory. This obligation entered into force in 2016. It is carried out on-line via the Internet and provides ASN with the information it needs to conduct more targeted inspections.

5. Requirements applicable to certain risks or certain particular activities

5.1 Contaminated sites and soils

The tools and the approach to be followed for management of polluted sites and soils are described in detail in chapter 16. On 4th October 2012, ASN published a doctrine on the management of sites polluted by radioactive substances based on several principles. These principles are applicable to all sites contaminated by radioactive substances. ASN’s prime objective is to achieve the most thorough remediation possible, aiming for complete removal of the radioactive pollution to allow unrestricted use of the cleaned out premises and land. Nevertheless, when this objective cannot be technically and financially achieved, justification must be given and appropriate measures implemented to guarantee the compatibility of the site’s condition with its actual or planned use.

ASN inspection on the Tricastin site - LR65 tanker used to transport uranyl nitrate, September 2016.

The modifications made by the Act of 15th August 2015 in this field are described in detail in chapter 16.

5.2 ICPEs utilising radioactive substances

The ICPE system comprises objectives that are similar to those for BNIs, but it is not specialised and applies to a large number of installations involving risks or detrimental effects of all types.

Licensing by the Prefect, registration or simple notification is required for ICPEs according to the scale of the hazards they represent.

For installations requiring licensing, this license is issued by order of the Prefect following a public inquiry. The license comprises requirements which may be subsequently modified by a further order.

The list of ICPEs is given in column A of the appendix to Article R. 511-9 of the Environment Code. It defines the types of installations subject to the system and the applicable thresholds.

Four sections of the ICPE list concerned radioactive materials:
- section 1716 for radioactive substances in unsealed form;
- section 2797 for radioactive waste;
- section 2798 for the temporary management of waste resulting from a nuclear or radiological accident;
- section 1735 which requires licensing of repositories, storage or disposal facilities for solid residues of uranium, thorium or radium ore, as well as their processing by-products not containing uranium enriched with isotope 235 and for which the total quantity exceeds one ton.

It should be recalled that:
- The activities and installations for the management of radioactive waste [pursuant to Council Directive 2011/70/Euratom of 19th July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste] are subject to licensing.
- Only radioactive substances in unsealed form with potential environmental implications are subject to the ICPE system; all sealed sources are subject to the Public Health Code.
- As a transitional measure, the license or notification issued in accordance with section 1715 continues to carry the same value as a license or notification under the Public Health Code, until a new license is obtained under the Public Health Code or, failing which, for a maximum period of five years, in other words no later than 4th September 2019.

In accordance with Article L. 593-3 of the Environment Code, a facility located within the perimeter of a BNI, recorded in a section of the ICPE list but necessary for operation of the BNI, is subject to the BNI System.

By virtue of Article L.1333-9 of the Public Health Code, the licences issued to ICPEs in accordance with the Environment Code for the possession or use of radioactive sources, take the place of the licences required under the Public Health Code. However, except for the provisions concerning procedures, the legislative and regulatory provisions of the Public Health Code apply to them.

5.3 The regulatory framework for protection against malicious acts in nuclear activities

Malicious acts include theft or misappropriation of nuclear materials, acts of sabotage and attacks from outside the BNIs. These last two points must be considered in the procedures subject to the Environment Code and regulated and monitored by ASN. In this respect, in its safety analysis report, the licensee must present an assessment of the accidents liable to occur in the facility, regardless of the cause of the accident, including if it results from a malicious act. This assessment, which mentions the effects of accidents and the steps taken to prevent them or mitigate their effects, is taken into account when determining whether or not the creation authorisation can be granted. The most important risk prevention or mitigation measures can be the subject of ASN requirements.

However, ASN is not responsible either for determining the malicious threats to be considered, or for regulating and monitoring the physical protection of nuclear facilities against malicious acts. The threats to be considered when examining malicious acts are defined by the Government (General Secretariat for Defence and National Security).

With regard to protection against malicious acts, two arrangements instituted by the Defence Code apply to certain nuclear activities:
- Chapter III of Title III of Book III of the first part of the Defence Code defines the measures to protect and monitor nuclear materials. This concerns the following fusible, fissile or fertile materials: plutonium, uranium, thorium, deuterium, tritium, lithium-6, as well as chemical compounds comprising one of these elements, except ores. To prevent the dissemination of these nuclear materials, their import, export, production, possession, transfer, use and transport are subject to licensing.
- Chapter II of Title III of Book III of the first part of the Defence Code defines a system for protection of establishments which *"if unavailable, would risk significantly compromising the nation's combat or economic potential, its security or its capacity for survival"*. The TSN Act of 13th June 2006 supplemented Article L. 1332-2 of the Defence Code in order to enable the administrative authority to apply this system to facilities comprising a BNI *"when the destruction of or*

damage to (this BNI) could constitute a serious danger for the population". This protection system requires that the licensees take the protective measures stipulated in a particular protection plan prepared by them and approved by the administrative authority. These measures in particular include effective surveillance, alarm and material protection measures. If the plan is not approved and in the event of persistent disagreement, the decision is taken by the administrative authority.

With regard to nuclear activities outside the scope of national defence, these systems are monitored at the national level by the Defence and Security High Official (HFDS) at the Ministry responsible for Energy.

Within a joint working group, ASN and HFDS hold regular discussions about the accidents included in the safety analysis reports as well as how some of them could be the result of a malicious act or an act of terrorism. In this respect, analysis of accident occurrences and the steps taken to prevent them ensure that the regulation authorisation processes carried out pursuant to the Defence Code are consistent with those resulting from the Environment Code.

For radioactive sources which are not nuclear materials as specified above and which are not used in facilities subject to the protection obligations specified in the Defence Code, there are at present no arrangements for monitoring the steps taken by those in possession of these sources to prevent any malicious acts. Yet, such acts involving some of these sources could have serious consequences. This is why, in 2008, the Government adopted the principle of obligations to take preventive measures applicable to the holders, with implementation thereof being monitored by ASN. Legislative measures were therefore included in the Act of 15th August 2015 and Ordinance of 10th February 2016 (see chapte 10, point 4.6)

5.4 The particular system for defence-related nuclear activities and installations

The provisions concerning defence-related nuclear facilities and activities were codified in the Defence Code (creation of a sub-section 2 entitled "Defence-related nuclear facilities and activities" in Chapter III of Title II of Book III of the first part of the legislative part) by Ordinance 2014-792 of 10th July 2014 implementing Article 55 of Act 2013-1168 of 18th December 2013 concerning military planning for the years 2014 to 2019 and constituting various provisions concerning defence and national security.

Pursuant to Article L. 1333-15, defence-related nuclear facilities and activities are:
- Defence Basic Nuclear Installations (DBNI);
- military nuclear systems;
- defence-related nuclear experimentation sites and installations;
- the former nuclear experimentation sites in the Pacific;
- transport of fissile or radioactive materials involved in nuclear weapons and naval nuclear propulsion activities.

A part of the provisions applicable to nuclear activities governed by ordinary law also applies to defence-related nuclear activities and installations; for example, they are subject to the same general principles as all nuclear activities governed by ordinary law and the requirements of the Public Health Code, including the system of licensing and notification of small-scale nuclear activities, and they concern defence-related nuclear activities and installations in the same conditions as the ordinary law activities, except for the fact that the licenses are granted by the Delegate for Nuclear Safety and Radiation Protection for National Defence Installations and Activities (DSND), reporting to the Minister of Defence and the Minister of Industry. Oversight of these activities and installations is the responsibility of the personnel of the Defence Nuclear Safety Authority (ASND) headed by the DSND.

Other provisions are specific to defence-related nuclear activities and facilities. They are thus subject to particular information rules for protection of national defence confidentiality. Similarly, the nuclear facilities whose characteristics correspond to the BNI list but which are within the perimeter of a DBNI defined by decision of the Prime Minister, are not subject to the BNI system but to that of the special DBNI system defined by the Defence Code and implemented by the ASND (see section 2 of Chapter III of Title III of Book III of the first part of the Defence Code).

When nuclear facilities are no longer necessary for the purposes of national defence, they must be delicensed and transferred to the BNI System. The Tricastin DBNI has thus initiated a delicensing process, which should lead to registration by ASN of new BNIs, the first of which was registered on 1st December 2016.

ASN and ASND maintain close relations to ensure that the systems for which they are responsible are coherent and to ensure continuity of the oversight provided by the State on facilities making the transition from one system to the other.

6. Outlook

With regard to radiation protection, ASN will continue to play an active role in the transposition of the Euratom Basic Standards Directive and in particular in the preparation of resolutions and implementing orders for the new provisions of the Public Health Code and the Labour Code. Priority will be given to preparation of the draft resolutions regarding the implementation of the new system of procedures applicable to small-scale nuclear activities and those concerning the field of medical exposure (quality assurance in medical imaging and training for the professionals with regard to radiation protection of patients).

With regard to BNIs, ASN will in 2017 be continuing its work to overhaul the general regulations applicable to BNIs, more particularly for integration of the WENRA "reference levels" and best practices, in order to obtain a clear, complete and homogeneous framework.

The resolutions it will be adopting in 2017 include the resolution stipulated by Article 27 of the Decree of 2nd November 2007, which will determine the list of significant modifications which do not significantly call into question the safety analysis report or the impact assessment of the facility and which will be subject to notification to ASN.

ASN will apply its Guide No. 25 which will allow greater involvement by the stakeholders and the public in the drafting of these regulations and, through assessment of the impact of the draft resolutions, will allow the adoption of regulations that are more closely tailored to the actual issues.

Following the adoption of the Ordinance of 10th February 2016, ASN will take part in drafting the implementing decrees and in drafting the regulatory part of the Environment Code of the BNI System.

Appendix

The collection of ASN guides

No. 1	Final disposal of radioactive waste in deep geological formations (February 2008)
No. 2	Transport of radioactive materials in airports (February 2006)
No. 3	Recommendations for drafting annual information reports for the public concerning Basic Nuclear Installations (October 2010)
No. 4	Auto-assessment of risk exposure of patients receiving external radiotherapy (January 2009)
No. 5	Management of radiotherapy safety and quality of treatment (April 2009)
No. 6	Final shutdown, decommissioning and delicensing of Basic Nuclear Installations in France (August 2016)
No. 7	Civil transport of radioactive packages or substances on the public highway: • Volume 1: Shipment certification and approval applications (February 2016). • Volume 2: Package models safety file, European " Package Design Safety Report " guide (December 2014). • Volume 3: Conformity of package models not requiring approval (November 2015)
No. 8	Evaluation of nuclear pressure vessel conformity (September 2012)
No. 9	Determining the perimeter of a BNI (October 2013)
No. 10	Local involvement of CLIs in the 3rd ten-year outage of the 900 MWe reactors (June 2010)
No. 11	Significant radiation protection event (excluding BNIs and radioactive material transports): notification and codification of criteria (July 2015)
No. 12	Notification and codification of criteria related to significant safety, radiation protection or environmental events applicable to BNIs and radioactive material transport operations (October 2005)
No. 13	Protection of Basic Nuclear Installations against external flooding (January 2013)

No. 14	Guide concerning the remediation of structures in BNIs (August 2016)
No. 15	Control of activities in the vicinity of BNIs (March 2016)
No. 16	Significant radiation protection event affecting a radiotherapy patient: declaration and classification on the ASN-SFRO scale (July 2015)
No. 17	Contents of radioactive substance transport incident and accident management plans (December 2014)
No. 18	Disposal of effluents and waste contaminated by radionuclides, produced in facilities licensed under the Public Health Code (January 2012)
No. 19	Application of the Order of 12th December 2005 relating to nuclear pressure equipment (February 2013)
No. 20	Drafting of the Medical Physics Organisation Plan (POPM) (April 2013)
No. 21	Processing of non-compliance with a requirement defined for an Element Important for Protection (EIP) (January 2015)
No. 22	*Safety requirements for the design of pressurised water reactors (draft)*
No. 23	Definition and modification of the waste zoning plan for BNIs (August 2016)
No. 24	Management of soils polluted by BNI activities (August 2016)
No. 25	Drafting of an ASN statutory resolution or guide Procedures for consultation with the stakeholders and the public (October 2016)
No. 26	*Control of the criticality risk in BNIs (draft)*
No. 27	Tie-down of radioactive packages, materials or objects for transport (November 2016)
No. 28	*Qualification of the calculation tools used in the nuclear safety case – 1st barrier (draft)*

Appendix

Regulation exposure limits and dose levels

ANNUAL EXPOSURE LIMITS contained in the Public Health Code and in the Labour Code

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
ANNUAL LIMITS FOR THE GENERAL PUBLIC			
Article R.1333-8 of the Public Health Code.	• Effective dose	1 mSv/year	• These limits comprise the sum of effective or equivalent doses received as a result of nuclear activities. These are limits that must not be exceeded.
	• Equivalent dose for the lens of the eye	15 mSv/year	
	• Equivalent dose for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed)	50 mSv/year	
WORKER LIMITS FOR 12 CONSECUTIVE MONTHS			
Article R. 4451-13 of the Labour Code	**Adults** • Effective dose • Equivalent dose for the hands, forearms, feet and ankles • Equivalent dose for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed) • Equivalent dose for the lens of the eye	20 mSv 500 mSv 500 mSv 150 mSv	• These limits comprise the sum of effective or equivalent doses received. These are limits that must not be exceeded. • Exceptional waivers are accepted: - When justified beforehand, they are scheduled in certain working areas and for a limited period, subject to special authorisation. These individual exposure levels are planned according to a ceiling limit which is no more than twice the annual exposure limit value. - Emergency occupational exposure is possible in an emergency situation, in particular to save human life.
	Pregnant women • Exposure of the child to be born	1 mSv	
	Young people from 16 to 18 years old* : • Effective dose • Equivalent dose for the hands, forearms, feet and ankles • Equivalent dose for the skin • Equivalent dose for the lens of the eye	6 mSv 150 mSv 150 mSv 50 mSv	

** Only if covered by waivers, such as for apprentices.*

MAXIMUM PERMITTED LEVELS for the consumption and sale of foodstuffs contaminated in the event of a nuclear accident

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION FOR FOODSTUFFS (Bq/Kg OR Bq/L)	BABY FOOD	DAIRY PRODUCTS	OTHER FOODSTUFFS EXCEPT THOSE OF LESSER IMPORTANCE	LIQUIDS INTENDED FOR CONSUMPTION
Strontium isotopes, particularly strontium-90	75	125	750	125
Iodine isotopes, particularly iodine-131	150	500	2,000	500
Plutonium isotopes and alpha-emitting transuranian elements, particularly plutonium-239 and americium-241	1	20	80	20
Any other radionuclide with a half-life of more than 10 days, in particular ^{134}Cs and ^{137}Cs	400	1,000	1,250	1,000

Source: Council regulation 2016/52/Euratom of 15th January 2016.

MAXIMUM PERMITTED LEVELS of radioactive contamination in livestock feedstuffs (caesium-134 and caesium-137)

ANIMAL CATEGORIES	Bq/kg
Pork	1,250
Poultry, lamb, veal	2,500
Others	5,000

Source: Council regulation 2016/52/Euratom of 15th January 2016.

OPTIMISATION LEVELS for patient protection (Public Health Code)

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
DIAGNOSTIC EXAMINATIONS			
Diagnostic reference level Article R.1333-68, Order of 16th February 2004	Dose levels for standard diagnostic examinations	Ex. : entrance dose of 0.3 mGy or dose area product (DAP) of 25 $cGy.cm^2$ for a single incidence for a frontal posteroanterior chest X-ray)	• The diagnostic reference levels, the dose constraints and the dose target levels are used by applying the principle of optimisation. They are simply guidelines. • The reference levels are created for standard patients by dose levels for typical radiology examinations and by the radioactivity levels of radiopharmaceutical products in diagnostic nuclear medicine.
Dose constraint Article R.1333-65, Order of 7th November 2007	Used when exposure offers no direct medical benefit to the person exposed.		The dose constraint can be a fraction of a diagnostic reference level, in particular for exposure in the context of biomedical research or forensic procedures.
RADIOTHERAPY			
Target dose level Art. R.1333-63	Dose necessary for the target organ or tissue (target organ or target-tissue) during radiotherapy (experimentation)		The target dose level (specialists talk of a target volume in radiotherapy) is used to adjust the equipment.

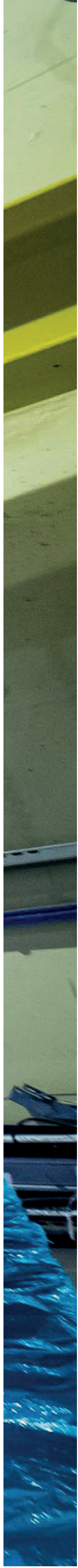
INTERVENTION TRIGGER LEVELS in cases of radiological emergencies (Public Health Code)

REFERENCES	DEFINITIONS	VALUES	OBSERVATIONS
PROTECTION OF THE GENERAL PUBLIC			
Intervention levels Art. R.1333-80, Order of 14th October 2003, Circular of 10th March 2000	Expressed in effective dose (except for iodine), these levels are designed to assist with the relevant response decision to protect the general public: • sheltering • evacuation • administration of a stable iodine tablet (equivalent dose for the thyroid)	 10 mSv 50 mSv 50 mSv	The Prefect can make adjustments to take account of local factors.
PROTECTION OF PARTICIPANTS			
Reference levels Art. R.1333-86	These levels are expressed as effective dose: • for the special technical or medical intervention teams • for the other participants	 100 mSv 10 mSv	This level is raised to 300 mSv when the intervention is designed to prevent or reduce exposure of a large number of people.

04

Regulation of nuclear activities and exposure to ionising radiation


6.3 T



In France, nuclear activity licensees are responsible for the safety of their activity. They cannot delegate this responsibility, and must ensure permanent surveillance of both this activity and the equipment used. Given the risks linked to ionising radiation for humans and the environment, the State regulates nuclear activities, a task it has entrusted to ASN.

Control and regulation of nuclear activities is a fundamental responsibility of ASN. The aim is to verify that all licensees fully assume their responsibility and comply with the requirements of the regulations relative to radiation protection and nuclear safety, in order to protect workers, patients, the public and the environment from risks associated with radioactivity.

Inspection is the key means of monitoring available to ASN. Inspection involves one or more ASN inspectors going to the site or department being inspected or to carriers of radioactive substances. The inspection is proportionate to the level of risk presented by the installation or the activity and the way in which the licensee assumes its responsibilities. It consists in performing spot checks on the conformity of a given situation with regulatory or technical baseline requirements. After the inspection, a follow-up letter is sent to the head of the inspected site or activity and published on *www.asn.fr*. Any deviations found during the inspection can lead to administrative or criminal penalties.

Nuclear activities are also regulated by ASN through various actions:
- authorisation, following analysis of the applicant's demonstration that its activities are satisfactorily managed in terms of radiation protection and safety;
- operating experience feedback, more specifically through analysis of significant events;
- approval of organisations and laboratories taking part in radioactivity measurements and radiation protection inspections.

ASN has a vision of control and regulation encompassing material, organisational and human aspects. Its regulatory duties entail the issue of resolutions, prescriptions, inspection follow-up documents, plus penalties as applicable, along with assessments of safety and radiation protection in each activity sector.

1. Verifying that the licensee assumes its responsibilities

1.1 The principles of ASN oversight duties

ASN aims to ensure that the principle of licensee responsibility for nuclear safety and radiation protection is respected.

ASN applies the principle of proportionality when determining its actions, so that the scope, conditions and extent of its regulatory action is commensurate with the health and environmental safety implications involved.

Regulation is part of a multi-level approach and is carried out with the support of the Institute for Radiation Protection and Nuclear Safety (IRSN).

It applies to all the phases of performance of the activity, including the decommissioning phase for nuclear facilities:
- before the licensee exercises an activity subject to authorisation, by reviewing and analysing the files, documents and information provided by the licensee to justify its project with regard to safety and radiation protection. This verification aims to ensure that the information and demonstration supplied are both relevant and sufficient;
- during exercise of the activity, by visits, inspections, verification of licensee operations entailing significant potential consequences, review of reports supplied by the licensee and analysis of significant events. This verification comprises sampling and the analysis of justifications provided by the licensee with regard to the performance of its activities.

To consolidate the effectiveness and quality of its actions, ASN is adopting an approach involving continuous improvement of its regulatory practices. It uses the experience feedback from forty years of nuclear activity inspections and the exchange of best practices with its foreign counterparts.

1.2 The scope of regulation of nuclear activities

Article L. 592-22 of the Environment Code states that ASN must regulate compliance with the general rules and particular requirements of safety and radiation protection, applicable to:
- licensees of BNIs;
- those in charge of the construction and operation of Pressure Equipment (PE) used in BNIs;
- those in charge of radioactive substances transport;
- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures.

In this chapter, these persons are called the "licensees". ASN also regulates the organisations and laboratories it approves to take part in the inspections and to guarantee safety and radiation protection, as well as carrying out labour inspection duties in the NPPs (see chapter 12).

Although historically based on verifying the technical conformity of facilities and activities with regulations or standards, regulation today also covers a broader field incorporating Social, Organisational and Human Factors (SOHF). It takes account of individual and collective behaviour and attitudes, management, organisation and procedures, relying on a variety of sources: significant events, inspections, relations with the stakeholders (personnel, licensees, contractors, trade unions, occupational physicians, inspection services, approved organisations, and so on).

2. Ensuring that regulation is proportionate to the implications

ASN organises its regulatory work in a way that is proportionate to the implications of the activities. The licensee is the key player in the regulation of its activities. The performance of certain inspections by organisations and laboratories offering the necessary guarantees validated by ASN approval, contributes to this action.

2.1 Definition of the implications

In order first of all to take account of the health and environmental implications and the licensees' safety and radiation protection performance, and secondly the large number of activities it has to oversee, ASN periodically identifies and directly inspects the activities and topics with major potential consequences: It conducts regular oversight of subjects entailing potential risks, which are systematically examined on a yearly basis, and also identifies topical subjects requiring more particular attention in any given year. For example, in 2016, the inspections focused on the following topics or activities:
- management of the safety and organisation of NPPs; management of deviations, worker radiation protection and criticality in fuel cycle facilities;
- industrial radiography, fields requiring high-level sealed sources and suppliers of sources for the industrial small-scale nuclear sector;
- computed tomography and teleradiology for the medical small-scale nuclear sector;
- on-site transport within BNIs, training of transport operators for the transport of radioactive substances.

In order to identify these activities and topics, ASN relies on current scientific and technical knowledge and uses the information collected by both itself and IRSN: results of inspections, frequency and nature of incidents, major modifications made to facilities, review of files, feedback of data concerning doses received by workers, information resulting from checks by approved organisations. It can adapt its priorities to take account of significant events occurring in France or around the world.

2.2 Oversight by ASN

The licensee is required to provide ASN with the information it needs to meet its regulatory responsibilities. The volume and quality of this information should enable ASN to analyse the technical demonstrations presented by the licensee and target the inspections. It should also allow identification and monitoring of the milestones in the operation of a nuclear activity.

ASN regulatory action takes the form of reviews of files, pre-commissioning visits, inspections, and consultation with professional organisations (trade unions, professional orders, learned societies, etc.).

ASN inspection in the Ionisos facility in Sablé-sur-Sarthe, November 2016.

ASN regulates nuclear activities and facilities in order to check that the licensees and those responsible for nuclear activities comply with the regulatory requirements and conditions specified in their authorisation license.

Regulation and monitoring of Basic Nuclear Installations

Safety covers the technical and organisational measures taken at all stages in the operation of nuclear facilities (design, creation, commissioning, operation, final shutdown, decommissioning) to prevent or mitigate the risks for safety, public health and the environment (see chapter 3). This notion thus includes the measures taken to optimise waste and effluent management.

The safety of nuclear installations is based on the following principles, defined by the International Atomic Energy Agency (IAEA) in its fundamental safety principles for nuclear installations (Safety series No. 110) and then to a large extent incorporated into the European Directive on Nuclear Safety of 8th July 2014, which modifies that of 2009:
- responsibility for nuclear safety lies primarily with the licensee;
- the organisation responsible for regulation and oversight is independent of the organisation responsible for promoting or using nuclear power. It must have responsibility for licensing, inspection and formal notice, and must have the authority, expertise and resources necessary for performance of the responsibilities entrusted to it. No other responsibility shall compromise or conflict with its responsibility for safety.

In France, pursuant to the Environment Code, ASN is the body that meets these criteria.

Ordinance 2016-128 of 10th February 2016 implementing the Energy Transition for Green Growth Act (TECV) expanded the scope of ASN regulation to the suppliers, contractors and subcontractors of licensees, including for activities performed outside BNIs.

In its regulatory duties, ASN is required to look at the equipment and hardware in the installations, the individuals in charge of operating it, the working methods and the organisation, from the start of the design process up to decommissioning. It reviews the steps taken concerning nuclear safety and the monitoring and limitation of the doses received by the individuals working in the facilities, and the waste management, effluents discharge monitoring and environmental protection procedures.

Regulation of pressure equipment

Numerous systems in nuclear facilities contain or carry pressurised fluids. In this respect they are subject to the regulations applicable to pressure equipment, which include ESP and ESPN (see chapter 3, point 3.6).

The Environment Code states that ASN is the administrative Authority with competence for issuing individual resolutions and checking the in-service monitoring of the pressure equipment installed within the perimeter of a BNI.

Pressure equipment operation is regulated. This regulation in particular applies to the in-service surveillance programmes, non-destructive testing, maintenance work, disposition of nonconformities affecting these systems and periodic post-maintenance testing of the systems.

ASN also assesses the regulatory conformity of the most important new nuclear pressure equipment items. It approves and monitors the organisations responsible for assessing the conformity of the other nuclear pressure equipment.

Regulation and monitoring of the transport of radioactive substances

Transport comprises all operations and conditions associated with movements of radioactive substances, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including storage in transit, unloading and receipt at the final destination of the radioactive substance consignments and packages (see chapter 11).

The safety of the transport of radioactive substances is based on three successive barriers:
- primarily, the robustness of the packages;
- the reliability of the transport operations;
- an efficient emergency response in the event of an accident.

Regulation and monitoring of activities comprising a risk of exposure to ionising radiation

In France, ASN fulfils the role by drafting and monitoring technical regulations concerning radiation protection (see chapter 3, point 1).

The scope of ASN's regulatory role in radiation protection covers all the activities that use ionising radiation. ASN exercises this duty, where applicable, jointly with other State services such as the Labour Inspectorate, the Inspectorate for Installations Classified on Environmental Protection Grounds, the departments of the Ministry of Health and the French National Agency for Medicines and Health Products Safety (ANSM). This action directly concerns either the users of ionising radiation sources, or organisations approved to carry out technical inspections on these users.

The methods of regulating the radiation protection players are presented in Table 1.

Regulating the application of Labour Law in the nuclear power plants

Labour inspection in the NPPs has been ensured from the outset by the administration tasked with technical oversight under the authority of the Minister responsible for Labour; the competence of ASN is now codified in Article R. 8111-11 of the Labour Code. The nineteen NPPs in operation, the nine reactors undergoing decommissioning and the EPR reactor under construction at Flamanville are the responsibility of the ASN labour inspectorate. The regulation of safety, radiation protection and labour inspection very often covers common topics, such as worksite organisation or the conditions of use of outside contractors (see chapter 12).

The ASN labour inspectors have four essential duties:
1. checking application of all aspects of labour legislation (health, occupational safety and working conditions, occupational accident inquiries, quality of employment, collective labour relations);
2. advising and informing the employers, employees and personnel representatives about their rights, duties and labour legislation;
3. informing the administration of changes in the working environment and any shortcomings in the legislation;
4. facilitating conciliation between the parties.

The ASN labour inspectors also have powers of decision concerning authorisation applications (firing of personnel representatives, waivers to regulations in terms of work or rest times, health and safety).

These duties are based on international standards (International Labour Organisation Convention No. 81) and national regulations. ASN carries them out in liaison with the other Government departments concerned, mainly the departments of the Ministry responsible for Labour.

ASN has set up an organisation enabling it to deal with these issues. The action of the ASN labour inspectors (6.2 Full-Time Equivalent - FTE) in the field has increased markedly since 2009, particularly during reactor outages, with inspection visits, advisory roles at the meetings of the Committee for Health, Safety and Working Conditions (CHSCT) and the Inter-company Committee on Safety and Working Conditions (CIESCT), as well as the regular discussions with the social partners.

2.3 Main checks performed by the licensees

The operations that take place in the BNIs and which have the highest potential safety and radiation protection implications require prior authorisation by ASN (see chapter 3).

TABLE 1: Methods of ASN regulation of the various radiation protection players

	INSTRUCTION/ AUTORISATION	INSPECTION	OPENNESS AND COOPERATION
Users of ionising radiation sources	• Review of the dossiers required by the Public Health Code (Articles R. 1333-1 to R. 1333-54) • Pre-commissioning inspection • Registration of notification or delivery of the authorisation	• Radiation protection inspection (Article L. 1333-17 of the Public Health Code)	• Jointly with the professional organisations, drafting of guides of good practices for users of ionising radiation
Bodies approved for radiation protection inspections	• Review of application files for approval to perform the inspections specified in Article R. 1333- 95 of the Public Health Code and Articles R. 4451-29 to R. 4452-34 of the Labour Code • Organisation audit • Delivery of approval	• Second level inspection: - in-depth inspections at head office and in the branches of the organisations - unannounced field inspections	• Jointly with the professional organisations, drafting of rules of good practices for performance of radiation protection inspections

2.3.1 Operations subject to a licensee internal authorisation procedure

ASN considers that the operations taking place in the BNIs with the highest nuclear safety and radiation protection implications must require its prior authorisation. However, it considers that operations with lesser potential consequences can be performed under the sole responsibility of the licensee. For intermediate operations presenting potential consequences that are significant but do not compromise the safety scenarios used in BNI operation or decommissioning, ASN allows the licensee to assume direct responsibility for them, provided that it sets up a system of enhanced, systematic internal checks, offering sufficient guarantees of quality, independence and transparency. The decision on whether or not to carry out the operations must be the subject of a formal authorisation issued by the licensee's duly qualified staff. This organisation is called the "internal authorisations system". It is presented to the Local Information Committee (CLI). The system of internal authorisations is governed by the Decree of 2nd November 2007 and the ASN resolution of 11th July 2008. This system is the subject of prior approval by an ASN resolution which defines:
- the nature of the operations which can be covered by an internal authorisation;
- the process used to approve the operations, more specifically with an opinion issued prior to any operation by a body within the company that is independent from the people directly in charge of operation;

- identification of the persons qualified to issue the internal authorisations;
- the procedures for periodically informing ASN of the operations planned or completed.

ASN checks the proper application of the internal authorisations systems by means of inspections, examination of the periodic reports transmitted by the licensees and counter-analysis of the files. It may temporarily or definitively suspend an internal authorisations system at any moment if it considers that implementation is not satisfactory.

2.3.2 Internal monitoring of radiation protection by the users of ionising radiation sources

The current aim of internal monitoring of radiation protection is to ensure regular assessment of the radiological safety of the activities using sources of ionising radiation. This monitoring is performed under the responsibility of the licensees. It may be carried out by the Person Competent in Radiation protection (PCR), appointed and mandated by the employer, or be entrusted to IRSN or to organisations approved by ASN. It does not replace either the periodic checks required by the regulations, or the inspections conducted by ASN. It for example concerns the performance of the protection systems, monitoring of the ambient atmosphere in regulated areas, or checks on medical appliances before they enter service or after modification. As a result of the transposition of Directive 2013/59/ Euratom of 5th December 2013 setting basic standards for health protection against the hazards arising from exposure to ionising radiation, this system may well need to be modified.

2.4 ASN approval of organisations and laboratories

Article L. 592-21 of the Environment Code states that ASN must issue the necessary approvals to the organisations taking part in the inspections and in ensuring the nuclear safety and radiation protection watch. Depending on the health or safety implications of a nuclear activity or a facility category, ASN may rely on the results of checks carried out by independent organisations and laboratories it has approved and which it monitors.

ASN thus approves organisations so that they can perform the technical inspections required by the regulations in the fields within its scope of competence:
- radiation protection checks;
- measurement of radon activity concentration in premises open to the public;
- assessment of conformity and inspection of equipment in service.

In order to approve the applicant organisations, ASN ensures that they perform the inspections in accordance with their technical, organisational and ethical obligations and in compliance with the rules of professional good practice. Compliance with these provisions should enable the required level of quality to be obtained and maintained.

ASN ensures that benefit is gained from the approval, in particular through regular exchanges with the organisations it has approved and the mandatory submission of an annual report, in order to:
- turn operating experience feedback to good account;
- improve the approval process;
- improve the conditions of intervention by the organisations.

The checks carried out by these organisations contribute to ASN's overview of all nuclear activities.

In 2015, the organisations approved for radiation protection inspections carried out more than 69,800 inspections, for which the breakdown per type of source and per field is given in the following Table 2.

The main deviations recorded during these inspections concern administrative checks. In 2015, the reports from the organisations reveal an increase in source and facility non-compliance with the applicable standards and rules.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. It thus approves laboratories for the monitoring of:
- environmental radioactivity (see point 4);
- worker dosimetry (see chapter 1).

The list of approvals issued by ASN is kept up to date on *www.asn.fr* (*"Bulletin officiel de l'ASN/agréments d'organismes"* section).

As at 31st December 2016, the following are approved by ASN:
- 40 organisations tasked with radiation protection checks, 12 approvals or approval renewals were delivered in 2016;
- 50 organisations tasked with measuring radon activity concentration in buildings. Eleven of these organisations can also carry out measurements in cavities and underground structures, while 7 are approved to identify sources and means of radon ingress into buildings. In 2016, ASN issued 35 new approvals or approval renewals;
- 13 organisations tasked with the monitoring of worker internal dosimetry, 7 for external monitoring and 2 for monitoring exposure associated with natural radioactivity). In 2016, ASN issued 4 new approvals or approval renewals;
- 5 organisations tasked with nuclear pressure equipment inspections;

TABLE 2: Number of radiation protection inspections performed in 2015 by organisations approved for radiation protection inspections

TYPE OF SOURCE / FIELD	MEDICAL	VETERINARY	RESEARCH / TEACHING	INDUSTRY OUTSIDE BNIS	BNI	TOTAL
SEALED SOURCES	1,453	13	2,617	11,223	21,831	37,137
UNSEALED SOURCES	317	6	1,466	1,880	4,651	8,320
MOBILE GERI*	3,018	214	12	547	26	3,817
FIXED GERI	7,425	668	568	5,311	174	14,146
PARTICLE ACCELERATORS	328	1	66	165	4	564
DENTAL	5,842					5,842
TOTAL	18,383	902	4,729	19,126	26,686	69,826

** Generator of ionising radiation*

- 64 laboratories for environmental radioactivity measurements covering 880 approvals, of which 127 are approvals or approval renewals delivered during 2016.

ASN gives the General Directorate for Health (DGS) an opinion on the approval of the laboratories analysing radioactivity in water intended for human consumption.

It gives the Ministers responsible for Nuclear Safety and Transport an opinion on the approval of the organisations responsible for:
- training the drivers of vehicles transporting radioactive substances (class 7 hazardous materials);
- organising safety adviser examinations for transport of dangerous goods by road, rail or navigable waterway;
- certifying the conformity of packaging designed to contain 0.1 kg or more of uranium hexafluoride (initial and periodic checks);
- approval of the types of tanks[1] ;
- the initial and periodic checks of tankers for transport of class 7 hazardous substances by land.

1. *For each new type of tank, an organisation approved by ASN must issue a type approval certificate. This certificate confirms that the tank has been checked by the organisation, that it is suitable for the intended purpose and that it complies with the requirements of the regulations. When a series of tanks is manufactured with no change to the design, the certificate is valid for the entire series.*

FOCUS

ASN reinforces the graduated approach for regulation of industrial small-scale nuclear activities

In 2016, ASN initiated work to examine the revision of its oversight system in the small-scale nuclear sector, at a time of changing regulations linked to the transposition of the European Directive on Basic Radiation Protection Standards. The purpose of this reassessment is to reinforce the efficiency of this system on the basis of an approach that is appropriate and commensurate with the risks.

3. Efficient regulation and oversight

3.1 Inspection

3.1.1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:
- The inspection aims to detect any deviations indicative of a possible deterioration in facility safety or the protection of individuals or the environment and any non-compliance with the legislative and regulatory requirements the licensee is required to apply.
- The inspection is proportionate to the level of risk presented by the facility or activity.
- The inspection is neither systematic nor exhaustive, is based on sampling and focuses on subjects with the greatest potential consequences.

3.1.2 Inspection resources implemented

To ensure greater efficiency, ASN action is organised on the following basis:
- inspections, at a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
- inspections on a representative sample of other nuclear activities;
- systematic technical inspections of all the activities by approved organisations.

The inspections may be unannounced or notified to the licensee a few weeks before the visit. They take place mainly on the site or during the course of the relevant activities (work, transport operation). They may also concern the head office departments or design and engineering departments at the major licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

ASN uses various types of inspections:
- standard inspections;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- in-depth inspections, which take place over several days, concern a number of topics and involve about ten or so inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors;
- inspections with sampling and measurements which are designed to check discharges by means of samples that are independent of those taken by the licensee;
- event-based inspections carried out further to a particularly significant event;
- worksite inspections, ensuring a significant ASN presence on the sites on the occasion of reactor outages or particular work, especially in the construction or decommissioning phases;
- inspection campaigns, grouping inspections performed on a large numbers of similar installations, following a predetermined template.

Labour inspectorate duties lead to various types of interventions, focusing in particular on[2]:
- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in meetings of the CHSCT, CIESCT and inter-firm Health, Safety and Working Conditions Committee (CISSCT) (EPR construction site);
- performance of inquiries further to requests, complaints or information, after which the inspectors can issue resolutions.

2. *The intervention is the representative unit of activity normally used by the labour inspectorate.*

ASN sends the licensee an inspection follow-up letter officially documenting:
- deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations;
- anomalies or aspects warranting additional justifications.

Some inspections are carried out with the support of an IRSN representative specialised in the facility checked or the topic of the inspection.

ASN inspectors

To meet its objectives, ASN has inspectors designated and accredited by the ASN Chairman, in accordance with the conditions defined by Decree 2007-831 of 11th May 2007, subject to their having acquired the requisite legal and technical skills through professional experience, mentoring or training courses.

The inspectors take an oath and are bound by professional secrecy. They exercise their inspection activity under the authority of the ASN Director-General and benefit from regularly updated practical aids (inspection guides, decision aids) to assist them in their inspections.

As part of its continuous improvement policy, ASN encourages the exchange and integration of best practices used by other inspection organisations:
- by organising international exchanges of inspectors between Safety Authorities, either for the duration of one inspection or for longer periods that could extend to a secondment of up to three years. Thus, after having observed its advantages, ASN has adopted the concept of in-depth inspections described earlier. However, it did not opt for the system involving a resident inspector on a nuclear site, as ASN considers that its inspectors must work within a structure large enough to allow experience to be shared and that they must take part in checks on different licensees and facilities in order to acquire a broader view of this field of activity. These guidelines also allow greater clarity in the exercise of the respective responsibilities of the licensee and the inspector;
- by taking on inspectors trained in other inspection practices. ASN encourages the integration into its departments of inspectors from other regulatory authorities, such as the Regional Directorate for the Environment, Planning and Housing, ANSM, Regional Health Agencies (ARS), etc. It also proposes organising joint inspections with these authorities concerning the activities within their joint field of competence;
- by encouraging its staff to take part in inspections on subjects in different regions and domains, notably to ensure the uniformity of its practices.

Table 3 presents the headcount of inspectors as at 31st December 2016. Some inspectors operate in

TABLE 3: Breakdown of inspectors per inspection domain (as at 31st December 2016)

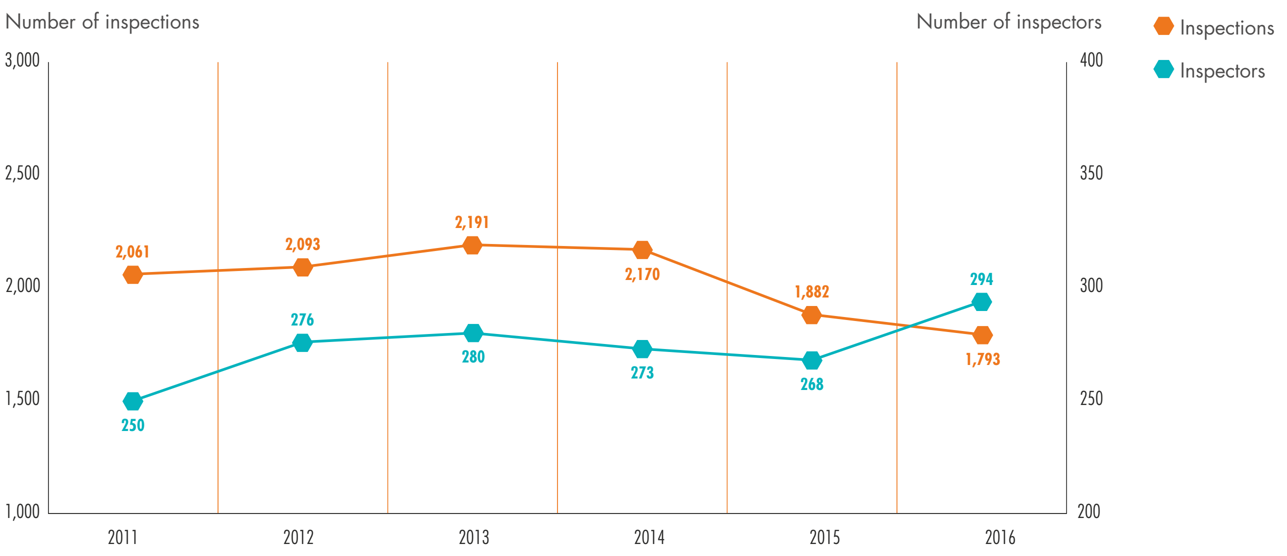
INSPECTOR CATEGORY (QUALIFICATION DOMAIN)	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear safety inspector (BNI)	100	97	**197**
of which nuclear safety inspector (transport)	*11*	*21*	***32***
Radiation protection inspector	40	106	**146**
Labour inspector	0	17	**17**
Number of inspectors all domains	129	154	**283**

** Since 2016, the staff responsible for the inspection of nuclear pressure equipment have become nuclear safety inspectors*

TABLE 4: Trend in number of inspections performed from 2011 to 2016

	NUMBER OF INSPECTIONS CARRIED OUT					
YEAR	BASIC NUCLEAR INSTALLATION (BNI)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
2016	561	88	106	911	127	**1,793**
2015	591	67	98	1,003	123	**1,882**
2014	686	87	113	1,159	125	**2,170**
2013	678	86	131	1,165	131	**2,191**
2012	726	76	112	1,050	129	**2,093**
2011	684	65	100	1,088	124	**2,061**

GRAPH 1: Trend in the number of ASN inspections and inspectors from 2011 to 2016



several inspection areas, and all the operational entity heads and their deputies fulfil both managerial and inspection functions.

Most of the inspections are carried out by inspectors assigned to the regional divisions, who represent 55% of the ASN inspectors. The 129 inspectors assigned to the departments take part in the ASN inspection effort within their field of competence; they represent 45% of the inspector headcount and performed 16% of the inspections in 2016.

Since 2009, ASN has carried out about 2,000 inspections every year, including about 37% in BNIs and activities linked to pressure equipment, 58% in small-scale nuclear activities, Approved Organisations and Laboratories (OA-LA) and 5% for the transport of radioactive substances (see Table 4).

In 2016, 1,793 inspections were carried out, including 561 in the BNIs, 88 in activities linked to Pressure Equipment, 106 in radioactive substances transport activities, 911 in activities employing ionising radiation and 127 in approved organisations and laboratories. Thirty-four inspections took place in the head office departments. These 1,793 inspections represent 1,872 days of actual inspection in the field.

Graph 1 shows the trend in the number of inspections and inspectors between 2011 and 2016.

ASN inspections programme

To guarantee a distribution of the inspection resources proportionate to the safety and radiation protection implications of the various facilities and activities, ASN drafts a forecast inspections schedule every year, taking into account the inspection implications (see point 2.1). This schedule is not communicated to the licensees or to those in charge of nuclear activities.

ASN ensures qualitative and quantitative monitoring of performance of the programme and the follow-up given to the inspections through periodic reviews. This enables the inspected activities to be assessed and contributes to the continuous improvement of the inspection process.

Information relative to the inspections

ASN informs the public of the follow-up to the inspections by posting the inspection follow-up letters on-line at *www.asn.fr*.

Moreover, for each in-depth inspection, ASN publishes an information notice on *www.asn.fr*.

3.1.3 Inspection of Basic Nuclear Installations (BNIs) and pressure equipment

In 2016, 649 inspections were carried out to check BNIs and pressure equipment, more than 23% of which were unannounced.

These inspections can be broken down into 315 inspections in the NPPs, 246 in the other BNIs (fuel cycle facilities, research facilities, facilities undergoing decommissioning, etc.) and 88 for pressure equipment. In the BNIs, three in-depth inspections were carried out in 2016, on the CEA Fontenay-aux-Roses and Saclay site, on the topic of "management of decommissioning operations" and on the Areva site at La Hague, on the topic of recovery and packaging of legacy waste.

The inspection breakdown by family of topics is shown in Graph 2. The topics related to nuclear safety and social, organisational and human factors represent more than 50% of the BNI inspections. 10% of the inspections are devoted to environmental monitoring topics and to waste and effluents in the BNIs.

Of the 315 inspections carried out in the NPPs in 2016, nearly one third covered topics related to maintenance and operation. Social, Organisational and Human Factors (SOHF), the environment and the prevention and management of hazards are the other topics most widely inspected by ASN.

The ASN labour inspectors also carried out 757 interventions during the 205.5 inspection days in the NPPs.

The 246 inspections carried out in the LUDD (Laboratories, Plants, Waste and Decommissioning) sites in 2016 primarily concerned the "general inspection" and "compliance with undertakings and licenses" topics.

With regard to pressure equipment, ASN carried out 88 inspections in 2016 including 51 on in-service equipment monitoring, 17 on monitoring of recognised inspection services and 20 regarding the inspection of the design and manufacture of nuclear pressure equipment. The ASN Nuclear Pressure Equipment Department has received ISO 17 020 accreditation from the French accreditation committee.

3.1.4 Inspection of radioactive substances transport

ASN carried out 106 inspections on transport activities, 42% of which were unannounced; their breakdown into topics is illustrated in Graph 3.

More than 51% of the inspections were carried out on the topic of "consignments" in industry, BNIs and the medical sector. Road carriage, on the one hand, and the other modes of transport, on the other, account for 15% and 6% respectively of the inspections performed.

3.1.5 Inspection in the small-scale nuclear activities

ASN organises its inspection activity so that it is proportionate to the radiological issues involved in the use of ionising radiation, and consistent with the actions of the other inspection services.

In 2016 ASN carried out 911 inspections - 15% of which were unannounced - in some of the 50,000 or so nuclear facilities and activities in the sector. These inspections were more specifically divided among the medical (54%), industrial or research (34%) and veterinary (8%) sectors.

Medical or industrial activities entailing a high risk of human exposure are the most frequently inspected. Thus, 374 inspections were carried out in radiology and radiotherapy and 72 in nuclear medicine.

In addition, of the 312 inspections of industrial activities using ionising radiation, 132 concerned the manufacture, distribution and utilisation of sealed and unsealed sources and 98 concerned industrial radiography.

The breakdown of small-scale nuclear sector inspections according to the various activity categories is described in Graph 4.

3.1.6 Inspection of ASN approved organisations and laboratories

ASN carries out a second level of inspection on approved organisations and laboratories. In addition to reviewing the application file and issuing the approval, this comprises surveillance actions such as:
- approval audits (initial or renewal audit);
- checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
- checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2016, ASN carried out 127 inspections on approved organisations and laboratories, 45% of which were unannounced, which can be broken down as follows:
- 70 inspections of organisations carrying out radiation protection technical checks;
- 33 inspections of organisations assessing nuclear pressure equipment conformity and carrying out in-service monitoring of operational equipment;
- 8 inspections of organisations measuring the activity concentration of radon;
- 13 inspections of laboratories approved for taking environmental radioactivity measurements;
- 3 inspections of organisations approved for individual monitoring of worker exposure to ionising radiation.

3.1.7 Checks on exposure to Radon and Naturally Occurring Radioactive Materials (NORM)

ASN also monitors radiation protection in premises where exposure of individuals to natural ionising radiation can be enhanced owing to the underlying geological context (radon in premises open to the public) or the characteristics of the materials used in industrial processes (non-nuclear industries).

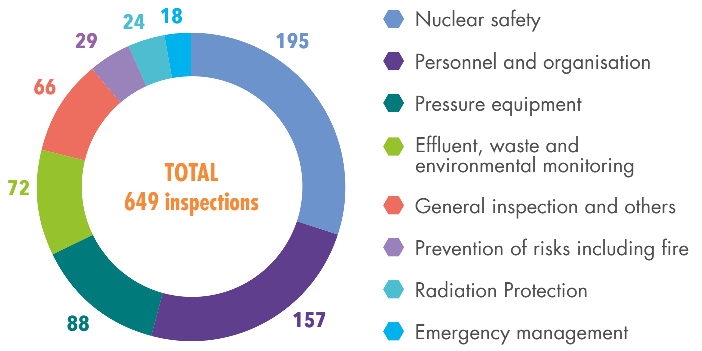
Monitoring exposure to radon

Article R. 1333-15 of the Public Health Code and Article R. 4451-136 of the Labour Code provide for the radon activity concentration to be measured either by IRSN or by ASN approved organisations.

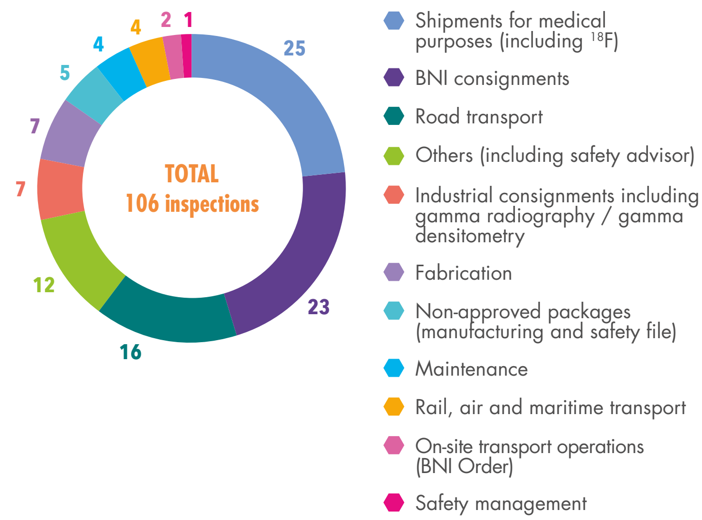
These measurements are to be taken between 15th September of a given year and 30th April of the following year.

For the 2016-2017 measurement campaign, the number of approved organisations is indicated in Table 5.

GRAPH 2: Breakdown of BNI inspections in 2016 by topic



GRAPH 3: Breakdown of radioactive substances transport inspections in 2016



GRAPH 4: Breakdown of small-scale nuclear activity inspections in 2016 per type of activity

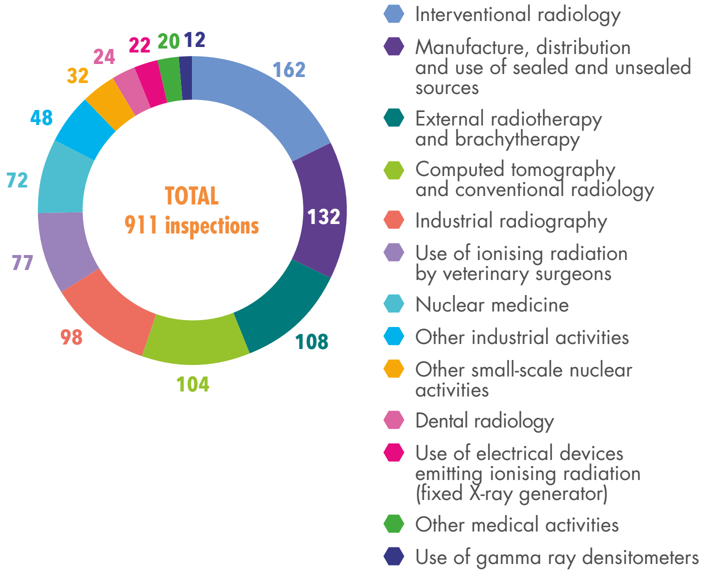


TABLE 5: Number of organisations approved for measuring radon levels

	APPROVAL UNTIL 15TH SEPTEMBER 2017	APPROVAL UNTIL 15TH SEPTEMBER 2018	APPROVAL UNTIL 15TH SEPTEMBER 2019	APPROVAL UNTIL 15TH SEPTEMBER 2020	APPROVAL UNTIL 15TH SEPTEMBER 2021
Level 1 option A*	19	1	5	9	15
Level 1 option B**	7	0	0	1	1
Level 2***	1	0	0	1	4

** Workplace and premises open to the public for all building types*
*** Workplace, cavities and underground structures (except buildings)*
**** Represents complementary investigations*

Monitoring exposure to natural ionising radiation in non-nuclear industries

The Order of 25th May 2005 defined the list of professional activities (ore or rare earth processing industries, spas and facilities treating groundwater for human consumption) requiring monitoring of human exposure to natural ionising radiation, as the materials used contain natural radionuclides and are likely to generate doses that are significant from the radiation protection standpoint.

Monitoring natural radioactivity in water intended for human consumption

Monitoring the natural radioactivity in water intended for human consumption is the role of the ARS. The procedures for these checks take account of the recommendations issued by ASN and are taken up in the DGS Circular of 13th June 2008.

The results of the checks are jointly analysed and utilised by ASN and the services of the Ministry of Health.

3.2 Assessment of the demonstrations provided by the licensee

The purpose of the files supplied by the licensee is to demonstrate compliance with the objectives set by the general technical regulations, as well as those that it has set for itself. ASN is required to check the completeness of the data and the quality of the demonstration.

The review of these files may lead ASN to accept or to reject the licensee's proposals, to ask for additional information or studies or to ask for work to be done to bring the relevant items into conformity.

3.2.1 Analysing the information supplied by Basic Nuclear Installation (BNI) licensees

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of control carried out by ASN. Whenever it deems necessary, ASN seeks the advice of technical support organisations, primarily IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety and radiation protection.

IRSN assessment relies on research and development programmes and studies focused on risk prevention and on improving our knowledge of accidents. It is also based on in-depth technical discussions with the licensee teams responsible for designing and operating the plants. For the more important issues, ASN requests the opinion of the competent Advisory Committee of Experts (GPE). For other matters, IRSN examines the safety analyses and gives its opinion directly to ASN. ASN procedures for requesting the opinion of a technical support organisation and, where required, of an Advisory Committee, are described in point 2.5.2 of chapter 2.

At the design and construction stage, ASN - aided by its technical support organisation - examines the safety analysis reports describing and justifying basic design data, equipment design calculations, utilisation rules and test procedures, and quality organisation provisions made by the prime contractor and its suppliers. It also analyses the facility's environmental impact assessment. ASN regulates and oversees the construction and manufacture of structures and equipment, in particular that of the main primary system and the main secondary systems of pressurised water reactors. In accordance with the same principles, it checks the packages intended for the transport of radioactive substances.

Once the nuclear facility has been commissioned, following ASN authorisation, all changes to the facility or its operation made by the licensee that could affect security, public health and safety, or the protection of nature and the environment, are notified to ASN or submitted to it for authorisation. Moreover, the licensee must perform periodic safety reviews to update the assessment of the facility, taking into account any changes in techniques and regulations, and experience feedback. The conclusions of these reviews are submitted by the licensee to ASN, which can issue new prescriptions in order to tighten the safety requirements (see chapter 12 point 2.9.4).

Other data submitted by BNI licensees

The licensee submits routine activity reports and summary reports on water intake, liquid and gaseous discharges and the waste produced.

Similarly, there is a considerable volume of information on specific topics such as fire protection, PWR fuel management strategies, relations with contractors, and so on.

3.2.2 Review of the applications required by the Public Health Code

ASN is responsible for reviewing applications to possess and use ionising radiation sources in the medical and industrial sectors. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy nonconformities detected during these inspections.

In addition to the internal inspections carried out under the responsibility of the facilities and the periodic checks required by the regulations, ASN carries out its own verifications. In this respect it directly carries out checks during the procedures for issue (pre-commissioning inspections) or renewal (periodic inspections) of the authorisations to possess and use radiation sources granted on the basis of Article R. 1333-23 of the Public Health Code. Authorisations and renewals can only be issued if the requests submitted by ASN following the checks have been taken into account. These checks are in particular designed to compare the data contained in the files with the actual physical reality (sources inventory, check on the conditions of production, distribution and utilisation of the sources and the devices containing them). They also enable ASN to ask the facilities to improve their in-house provisions for source management and radiation protection.

3.3 Lessons learned from significant events

3.3.1 Anomaly detection and analysis

History

The international Conventions ratified by France (Article 19vi of the Convention on Nuclear Safety of 20th September 1994; Article 9v of the Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management of 5th September 1997) require that BNI licensees, on account of the defence in depth principle, implement a reliable system for early detection of any anomalies that may occur, such as equipment failures or errors in the application of operating rules.

Based on twenty years of experience, ASN felt that it would be useful to transpose this approach, which was initially limited to nuclear safety, to radiation protection and protection of the environment. ASN thus drafted two guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:
- Guide No. 12 of 21st October 2005 contains the requirements applicable to BNI licensees and to carriers. It concerns significant events affecting nuclear safety of BNIs, radioactive material transports, radiation protection and protection of the environment.
- Guide No. 11 of 7th October 2009, updated in July 2015, is intended for those in charge of nuclear activities as defined in Article L. 1333-1 of the Public Health Code and the heads of the facilities in which ionising radiation is used (medical, industrial and research activities using ionising radiation).

These guides can be consulted on the ASN website, *www.asn.fr*.

What is a significant event?

Detection of events (deviations, anomalies, incidents, etc.) by those in charge of the activities using ionising radiation, and implementation of corrective measures decided after analysis, play a fundamental role in accident prevention. The nuclear licensees detect and analyse several hundred anomalies each year for each EDF reactor and about fifty per year for any given research facility.

Prioritising the anomalies should enable the most important ones to be addressed first. ASN has defined a category of anomalies called "significant events". These are events that are sufficiently important in terms of safety or radiation protection to justify rapid notification of ASN, with a more complete analysis subsequently being sent to it. Significant events must be notified to it, as specified in the Order of 7th February 2012 (Art. 2.6.4), the Public Health Code (Articles L. 1333-3 and R. 1333-109 to R. 1333-111), the Labour Code (Article R.4451-99) and the regulatory texts applicable to the transport of radioactive substances (for instance, the Agreement on the carriage of dangerous goods by road).

The criteria for notifying the public authorities of events considered to be "significant" take account of the following:
- the actual or potential consequences for workers, the public, patients or the environment, of events that could occur and affect nuclear safety or radiation protection;
- the main technical, human or organisational causes that led to the occurrence of such an event.

This notification process is part of the continuous safety improvement approach. It requires the active participation of all players (users of ionising radiation, carriers, etc.) in the detection and analysis of deviations.

It enables the authorities:
- to ensure that the licensee has suitably analysed the event and taken appropriate measures to remedy the situation and prevent it from happening again;
- to analyse the event in the light of the experience available to other parties in charge of similar activities.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and rating on the INES scale (International Nuclear and Radiological Event Scale) of the significant events which have occurred in a nuclear facility are not on their own indicators of the facility's level of safety. On the one hand, a given rating level is an over-simplification and is unable to reflect the complexity of an event and, on the other, the number of events listed depends on the level of notification compliance. The trend in the number of events does not therefore reflect any real trend in the safety level of the facility concerned.

ASN takes part in the INES consultative committee, a body comprising experts in the evaluation of the significance of radiation protection and nuclear safety events, tasked with advising IAEA and the INES national representative of the member countries on the use of the INES scale and its updates.

3.3.2 Implementation of the approach

Event notification

In the event of an incident or accident, whether or not nuclear, with actual or potential significant consequences for the safety of the facility or the transport operation, or which is liable to harm people, property or the environment through significant exposure to ionising radiation, the licensee or person responsible for the nuclear activity or for the transport of radioactive substances is obliged to notify ASN and the State's representative in the *département* without delay.

According to the provisions of the Labour Code, employers are obliged to declare significant events affecting their workers. When the head of a facility carrying out a nuclear activity calls in an external contractor or non-salaried worker, the significant events affecting salaried or non-salaried workers are notified in accordance with the prevention plans and the agreements concluded pursuant to Article R. 4451-8 of the Labour Code.

The notifying party assesses the urgency of notification in the light of the confirmed or potential seriousness of the event and the speed of reaction necessary to avoid an aggravation of the situation or to mitigate the consequences of the event. The notification time of two working days, tolerated in the ASN notification guide, does not apply when the consequences of the event require intervention by the public authorities.

In 2016, ASN drafted a new guide on the procedures for notification of events relating to the transport of radioactive substances on the public highway. Its aim is to define the criteria and procedures for the notification of events relating to the transport of radioactive substances on the terrestrial public highway (road, rail and inland waterways), by sea or by air, with actual or potential consequences for protection of the interests mentioned in Article L. 593-1 of the Environment Code.

Once published in its final form, this guide will replace the part of the ASN Guide of 21st October 2005 on the transport of radioactive substances on the public highway, with regard to the conditions of notification and the codification of criteria related to significant safety, radiation protection or environmental events applicable to basic nuclear installations and to radioactive material transport operations.

ASN analysis of the notification

ASN analyses the initial notification to check the implementation of immediate corrective measures, to decide whether to conduct an on-site inspection to analyse the event in depth, and to prepare for informing the public if necessary.

Within two months of the notification, it is followed by a report indicating the conclusions the licensee has drawn from analysis of the events and the steps it intends to take to improve safety or radiation protection and prevent the event from happening again. This information is taken into account by ASN and its technical support organisation, IRSN, in the preparation of the inspection programme and when performing the BNI periodic safety reviews.

ASN ensures that the licensee has analysed the event pertinently, has taken appropriate steps to remedy the situation and prevent it from recurring, and has circulated the operating experience feedback.

The ASN review focuses on compliance with the applicable rules for detecting and notifying significant events, the immediate technical, organisational or human measures taken by the licensee to maintain or bring the installation into a safe condition, and the pertinence of the submitted analysis.

ASN and IRSN subsequently examine the operating feedback from the events. The assessment by ASN, the significant event reports and the periodic reviews sent by the licensees constitute the basis of operating experience feedback. This experience feedback can lead to requests for improvement of the condition of the facilities and the organisation adopted by the licensee, as well as for changes to the regulations.

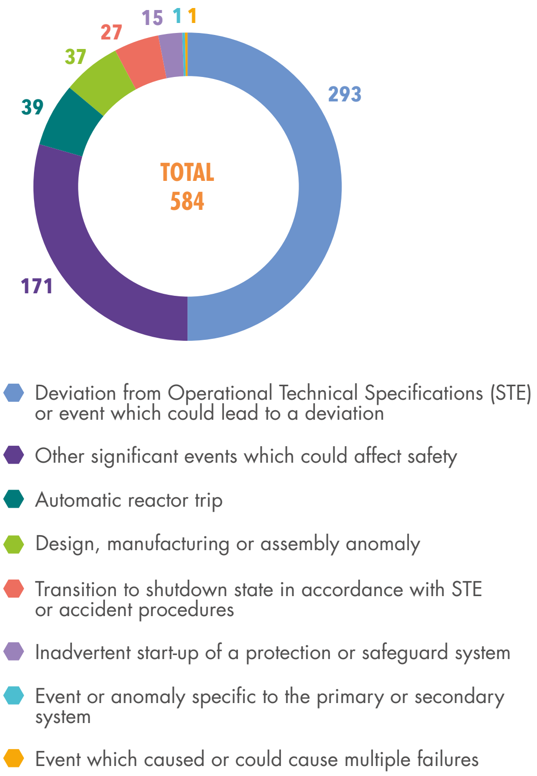
Operating experience feedback comprises the events which occur in France and abroad if it is pertinent to take them into account in order to reinforce safety or radiation protection.

3.3.3 Technical inquiries held in the event of an incident or accident concerning a nuclear activity

ASN has the authority to carry out an immediate technical inquiry in the event of an incident or accident in a nuclear activity. This inquiry consists in collecting and analysing all useful information, without prejudice to any judicial inquiry, in order to determine the circumstances and the identified or possible causes of the event, and draw up the appropriate recommendations if necessary. Articles L. 592-35 et seq. of the Environment Code give ASN powers to set up a commission of inquiry, determine its composition (ASN staff and people from outside ASN), define the subject and scope of the investigations and gain access to all necessary elements in the event of a judicial inquiry.

Decree 2007-1572 of 6th November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity specifies the procedure to be followed. It is based on the practices established for the other investigation bureaus and takes account of the specific characteristics of ASN, particularly its independence, its ability to impose prescriptions or penalties if necessary and the concurrence of its investigative and other duties.

GRAPH 5: Events involving safety in NPPs, notified in 2016



GRAPH 6: Events involving safety in BNIs other than NPPs notified in 2016

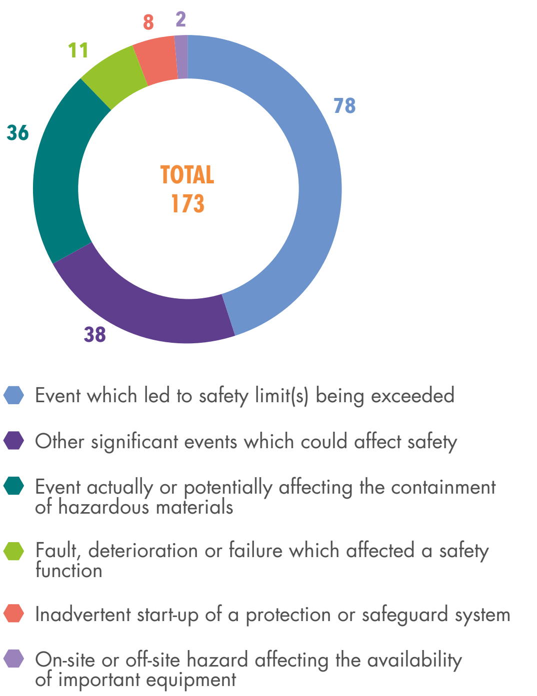
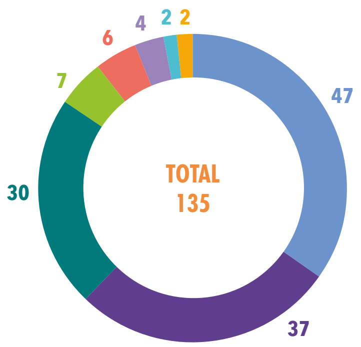


TABLE 6: Rating of significant events on the INES scale between 2011 and 2016

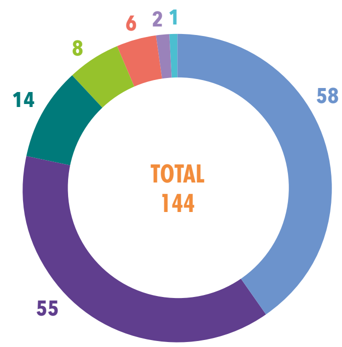
		2011	2012	2013	2014	2015	2016
Basic Nuclear Installations (BNIs)	Level 0	848	920	905	872	848	847
	Level 1	89	110	103	99	89	101
	Level 2	1	2	2	0	1	0
	Level 3 et +	0	0	0	0	0	0
	TOTAL BNI	**938**	**1,032**	**1,010**	**971**	**938**	**948**
Small-scale nuclear activities (medical and industry)	Level 0	81	118	130	157	126	111
	Level 1	15	33	22	34	25	30
	Level 2	1	1	2	4	2	0
	Level 3 et +	0	0	0	0	0	0
	TOTAL NPX	**97**	**152**	**154**	**195**	**153**	**141**
Transport of radioactive substances	Level 0	25	52	50	60	56	59
	Level 1	2	6	1	3	9	5
	Level 2	0	1	0	0	1	0
	Level 3 et +	0	0	0	0	0	0
	TOTAL TSR	**27**	**59**	**51**	**63**	**66**	**64**
	TOTAL	**1,062**	**1,243**	**1,215**	**1,229**	**1,157**	**1,153**

GRAPH 7: Significant environment-related events in BNIs notified in 2016



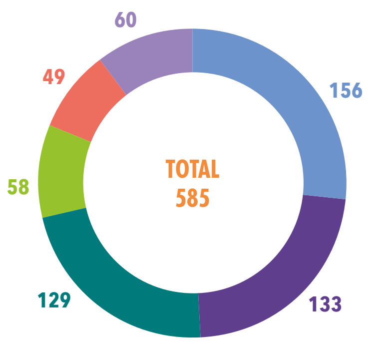
- Non-compliance with the Order of 31st December 1999
- Bypassing of normal discharge channels, with a significant impact due to chemical substances
- Other significant events which could affect the environment
- Non-compliance with the site or facility waste study
- Non-compliance with an operational requirement which could lead to a significant impact
- Bypassing of normal discharge channels, with a significant impact due to radioactive substances
- Confirmation that a discharge or concentration limit has been exceeded
- Discovery of a site significantly polluted by chemical or radioactive materials

GRAPH 8: Events involving radiation protection in BNIs notified in 2016



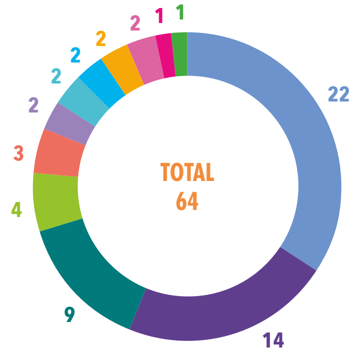
- Other significant event which could affect radiation protection
- Signage anomaly or failure to comply with zone access conditions
- Any significant deviation concerning radiological cleanness
- Abnormal situation affecting a source with activity higher than the exemption thresholds
- One quarter of the annual dose limit exceeded or event capable of leading to such a situation
- Operation with a radiological risk performed without risk assessment or ignoring its findings
- Radiological monitoring device inspection interval exceeded

GRAPH 9: Events involving radiation protection (other than BNIs and RMT) notified in 2016



- Concerning one or more patients (therapeutic purposes)
- Concerning one or more patients (diagnostic purposes)
- Concerning the general public
- Concerning one or more workers
- Loss, theft or discovery of radioactive sources or substances
- Other events concerning radiation protection

GRAPH 10: Events involving the transport of radioactive substances notified in 2016



- Non-compliance with one of the regulation limits applicable to the intensity of radiation or to contamination
- Non-compliance with regulation requirements for the transport of radioactive materials which had or could have had significant consequences
- Any other event liable to affect the safety of transport and considered to be significant by the licensee or by ASN
- Fault, deterioration or failure which affected a safety function, with actual or potential significant consequences
- Event which affected one or more of the barriers placed between the radioactive material and humans, with actual or potential dispersion of these substances or significant exposure of persons to ionising radiation in the light of limits set by the regulation
- Inadvertent discovery of a package of radioactive substances from a shipment for which no loss was notified
- Event, regardless of the severity, if liable to lead to erroneous or deliberately misleading interpretations in the media or among the public
- Confirmed malicious act or attempted malicious act liable to affect transport safety
- Hazard resulting either from natural phenomena or from human activities, actually or potentially affecting transport safety
- Repetitive event, even if minor, affecting a safety function, for which the cause has not been identified or which is liable to constitute an incident precursor
- Shipment of a package even though the consignee is not in a position to receive the shipment
- Event, whether or not nuclear in origin, leading to a fatality or severe injury requiring evacuation of the injured party or parties to a hospital, when the origin of the injuries is directly related to transport safety

3.3.4 Statistical summary of events

In 2016, ASN was notified of:
- 1,048 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 948 of these events were rated on the INES scale (847 events rated level 0 and 101 events rated level 1). Of these events, 12 significant events were rated as "generic events" including one at level 1 on the INES scale;
- 64 significant events concerning the transport of radioactive substances, including 5 level 1 events on the INES scale;
- 585 significant events concerning radiation protection in small-scale nuclear activities, including 141 rated on the INES scale (of which 30 were level 1 events).

ASN was notified of no safety event rated level 2 or higher on the INES scale in 2016.

The general trend towards the stabilisation of significant events continued in 2016. The number of significant event notifications remained on the whole stable in all areas.

As indicated earlier, these data must be used with caution: they do not in themselves constitute a safety indicator. ASN encourages the licensees to notify incidents, which contributes to transparency and the sharing of experience.

The distribution of significant events rated on the INES scale is specified in Table 6. The INES scale is not applicable to patients, who are rated on the ASN-SFRO scale of significant events affecting one or more radiotherapy patients, and is described in chapter 9[3].

Likewise, significant events concerning the environment but involving non-radiological substances are not covered by the INES scale.

Such events are classified as "out of INES scale" events.

Graphs 5 to 10 describe in detail the significant events notified to ASN in 2016, differentiating between them according to the various notification criteria for each field of activity.

3.4 Heightening the awareness of professionals and cooperating with the other administrations

Regulation is supplemented by awareness programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations that implement this approach by issuing best practice and professional information guides.

Awareness-raising also involves joint actions with other administrations and organisations which oversee the same facilities, but with different prerogatives. One could here mention the labour inspectorate, the medical devices inspectorate by the ANSM, the medical activities inspectorate entrusted to the technical services of the Ministry of Health, or the oversight of small-scale nuclear activities at the Ministry of Defence entrusted to the Armed Forces General Inspectorate (CGA), jointly with ASN. In March 2016, the cooperation protocol between CGA and ASN was renewed.

3.5 Information about ASN regulatory activity

ASN attaches importance to coordinating government departments and informs the other departments concerned of its inspection programme, the follow-up to its inspections, the penalties imposed on the licensees and any significant events.

To ensure that its inspection work is transparent, ASN informs the public by placing the following on its website *www.asn.fr*:
- inspection follow-up letters for all the activities it inspects;
- approval authorisations or rejections;
- incident notifications;
- the results of reactor outages;
- its publications on specific subjects (*Contrôle* magazine, etc.).

4. Monitoring the impact of nuclear activities and radioactivity in the environment

4.1 Monitoring discharges and the environmental and health impact of nuclear activities

4.1.1 Monitoring of discharges

Monitoring discharges from BNIs

The monitoring of discharges from an installation is essentially the responsibility of the licensee. The prescriptions regulating discharges stipulate the minimum checks that the licensee is required to carry out. The monitoring focuses on the liquid and gaseous effluents (monitoring of the activity of discharges, characterisation of certain effluents prior to discharge, etc.) and on the environment around the facility (checks during discharge, samples of air, milk, grass, etc.). The results of this monitoring are recorded in registers transmitted to ASN every month.

The BNI licensees also regularly transmit a certain number of discharge samples to an independent laboratory for additional analysis. The results of these "cross-checks" are sent to ASN. This programme of cross-checks defined by ASN is a way of ensuring that the accuracy of the laboratory measurements is maintained over time.

Finally, through dedicated inspections, ASN ensures that the licensees comply with the regulatory provisions that apply to them regarding control of discharges. These generally unannounced inspections are run with the support of specialised, independent laboratories mandated by ASN. Effluent and environmental samples are taken for radiological and chemical analyses. Since 2000, ASN has carried out ten to twenty inspections - with sampling- every year.

3. *This scale is designed for communication with the public in comprehensible, explicit terms, concerning radiation protection events leading to unexpected or unforeseeable effects on patients undergoing an radiotherapy medical procedure.*

Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by ASN resolution 2013-DC-0360 of 16th July 2016 relative to control of the detrimental effects and the impact of Basic Nuclear Installations on health and the environment, amended by the ASN resolution 2013-DC-0569 of 29th September 2016. These rules were set so as to avoid any under-estimation of the discharge values notified by the licensees.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a "reference spectrum", listing the radionuclides specific to the type of discharge in question.

The principles underlying the accounting rules are as follows:
- radionuclides for which the measured activity exceeds the decision threshold for the measurement technique are all counted;
- the radionuclides of the «reference spectrum" for which the measured activity is below the decision threshold (see box) are considered to be at the decision threshold level.

For discharges of chemical substances with an emission limit value set by an ASN prescription, when the concentration values measured are below the quantification limit, the licensee is required by convention to declare a value equal to half the quantification limit concerned.

Monitoring discharges in the medical sector

Pursuant to ASN resolution 2008-DC-0095 of 29th January 2008, radioactivity measurements are taken on the effluents coming from the places that produce them. In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m. In view of the difficulties encountered in putting in place the permits to discharge radionuclides into the public sewage networks, as provided for by the Public Health Code, ASN has created a working group involving administrations, "producers" (nuclear physicians, researchers) and sanitation professionals. The report from this working group formulating recommendations to improve the efficiency of the regulations was presented in October 2016 to the Advisory Committee for radiation protection, for industrial and research applications of ionising radiation and the environment.

In the small-scale industrial nuclear sector, few plants discharge effluents apart from cyclotrons (see chapter 10). The discharge permits stipulate requirements for the discharges and their monitoring, which are subject to particular scrutiny during inspections.

FUNDAMENTALS

With regard to the measurements

- The Decision Threshold (SD) is the value above which it is possible with a high degree of confidence to conclude that a radionuclide is present in the sample.
- The Detection Limit (LD) is the value as of which the measurement technique is able to quantify a radionuclide with a reasonable degree of uncertainty (the uncertainty is about 50% at the LD).

In general LD ≈ 2 x SD.

For the measurement results on chemical substances, the Quantification Limit is equivalent to the LD used to measure radioactivity.

Reference spectra

For the NPPs, the reference spectra of discharges comprise the following radionuclides:
- Liquid discharges: tritium, carbon-14, iodine-131, other fission and activation products (manganese-54, cobalt-58, cobalt-60, Ag-110m, tellurium-123m, antimony-124, antimony-125, caesium-134, caesium-137);
- Gaseous discharges: tritium, carbon-14, iodines (iodine-131, iodine-133), other fission and activation products (cobalt-58, cobalt-60, caesium-134, caesium-137), noble gases: xenon-133 (permanent discharges from ventilation networks, when draining "RS" effluent storage tanks and at decompression of reactor buildings), xenon-135 (permanent discharges from ventilation networks and at decompression of reactor buildings), xenon-131m (when draining "RS" tanks), krypton-85 (when draining "RS" tanks), argon-41 (at decompression of reactor buildings).

TABLE 7: Radiological impact of BNIs since 2010 calculated by the licensees on the basis of the actual discharges from the installations and for the most exposed reference groups (data provided by the nuclear licensees). The values calculated by the licensee are rounded up to the next higher unit

LICENSEE/SITE	REFERENCE GROUP MOST EXPOSED IN 2015	DISTANCE TO SITE IN KM	ESTIMATION OF RECEIVED DOSES, IN mSv [a]					
			2010	2011	2012	2013	2014	2015
Andra / CSA	CD24	2.1	2.10^{-6}	3.10^{-6}	1.10^{-5}	1.10^{-6}	2.10^{-6}	2.10^{-6}
Andra's Manche repository	Hameau de La Fosse	2.5	4.10^{-4}	4.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}
Areva / FBFC	Ferme Riffard	0.2	1.10^{-3}	6.10^{-4}	6.10^{-4}	5.10^{-4}	3.10^{-4}	3.10^{-4}
Areva / La Hague	Digulleville	2.8	1.10^{-2}	9.10^{-3}	9.10^{-3}	2.10^{-2}	2.10^{-2}	2.10^{-2}
Areva / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	[d]	[d]	3.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}
CEA / Cadarache	Saint-Paul-Lez-Durance	5	2.10^{-3}	3.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}	1.10^{-3}
CEA / Fontenay-aux-Roses [b]	Achères	30	4.10^{-6}	1.10^{-5}	3.10^{-5}	3.10^{-5}	1.10^{-4}	2.10^{-4}
CEA / Grenoble [c]	-	-	3.10^{-7}	2.10^{-9}	2.10^{-8}	5.10^{-9}	[e]	[e]
CEA / Marcoule (Atalante, Centraco, Phénix, Mélox, CIS bio)	Codolet	2	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-3}	2.10^{-5}
CEA / Saclay [b]	Christ de Saclay	1	7.10^{-4}	6.10^{-4}	1.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	6.10^{-4}	8.10^{-4}	8.10^{-4}	7.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	6.10^{-4}	6.10^{-4}	2.10^{-4}	2.10^{-3}	6.10^{-4}	5.10^{-4}
EDF / Bugey	Vernas	1.8	4.10^{-4}	5.10^{-4}	6.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Cattenom	Koenigsmacker	4.8	3.10^{-3}	3.10^{-3}	3.10^{-3}	5.10^{-3}	8.10^{-3}	7.10^{-3}
EDF / Chinon	La Chapelle-sur-Loire	1.6	4.10^{-4}	5.10^{-4}	5.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Chooz	Chooz	1.5	1.10^{-3}	1.10^{-3}	9.10^{-4}	2.10^{-3}	7.10^{-4}	6.10^{-4}
EDF / Civaux	Valdivienne	1.9	1.10^{-4}	7.10^{-4}	9.10^{-4}	2.10^{-3}	8.10^{-4}	9.10^{-4}
EDF / Creys-Malville	Creys-Mépieu	0.95	$6. 10^{-5}$	$7. 10^{-4}$	7.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-6}
EDF / Cruas-Meysse	Savasse	2.4	5.10^{-4}	5.10^{-4}	4.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	1.10^{-3}	2.10^{-3}	1.10^{-3}	9.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Fessenheim	Nambshein	3.5	1.10^{-4}	$8. 10^{-5}$	1.10^{-4}	1.10^{-4}	4.10^{-5}	4.10^{-5}
EDF / Flamanville	Flamanville	0.8	9.10^{-4}	2.10^{-3}	6.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}
EDF / Golfech	Golfech	1	9.10^{-4}	8.10^{-4}	7.10^{-4}	6.10^{-4}	2.10^{-4}	3.10^{-4}
EDF / Gravelines	Gravelines	1.8	1.10^{-3}	2.10^{-3}	4.10^{-4}	6.10^{-4}	8.10^{-4}	4.10^{-4}
EDF / Nogent-sur-Seine	Saint-Nicolas-La-Chapelle	2.3	9.10^{-4}	8.10^{-4}	6.10^{-4}	1.10^{-3}	5.10^{-4}	4.10^{-4}
EDF / Paluel	Saint-Sylvain	1.4	7.10^{-4}	8.10^{-4}	5.10^{-4}	9.10^{-4}	9.10^{-4}	4.10^{-4}

LICENSEE/SITE	REFERENCE GROUP MOST EXPOSED IN 2015	DISTANCE TO SITE IN KM	ESTIMATION OF RECEIVED DOSES, IN mSv [a]					
			2010	2011	2012	2013	2014	2015
EDF / Penly	Biville-sur-Mer	2.8	1.10^{-3}	1.10^{-3}	6.10^{-4}	7.10^{-4}	4.10^{-4}	4.10^{-4}
EDF / Saint-Alban	Saint-Pierre-de-Bœuf	2.3	4.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Saint-Laurent-des-Eaux	Saint-Laurent-Nouan	2.3	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	9.10^{-4}	7.10^{-4}	7.10^{-4}	5.10^{-4}	2.10^{-4}	2.10^{-4}
Ganil / Caen	IUT	0.6	$<3.10^{-3}$	$<3.10^{-3}$	$<3.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Egrève (liquids)	1 and 1.4	1.10^{-4}	5.10^{-5}	1.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}

a: until 2008, for installations operated by EDF, only "adult" figures are calculated. From 2010 to 2012, the dose of the most exposed reference group of each site for the two age classes (adult or infant) is mentioned. As of 2013, the dose of the reference group is provided for three age classes (adult, child, infant) for all the BNIs. The dose value indicated is the harshest value in the age classes.
b: for the Saclay and Fontenay-aux-Roses sites, CEA provided a dose estimate per radionuclide, without mentioning the total dose. As the estimations provided comprise thresholds (<0.01 μSv), the total doses in the table for these two sites take account of the dose of 0.01 μSv when the dose estimated by the licensee for a radionuclide is below this value.
c: because the outfall for the liquid discharges is geographically distant from the stack, two impact calculations are performed. One reflects the aggregate of maximum impact of gaseous discharges plus maximum impact of liquid discharges. The other corresponds to an actual reference group.
d: information not provided by the licensee
e: as the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been and continues to be nil since 2014.

4.1.2 Evaluating the radiological impact of the facilities

In accordance with the optimisation principle, the licensee must reduce the radiological impact of its facility to values that are as low as possible under economically acceptable conditions.

The licensee is required to assess the dosimetric impact of its activity. As applicable, this obligation is the result of Article L. 1333-8 of the Public Health Code, or the regulations concerning BNI discharges (Article 5.3.2 of ASN resolution 2013-DC-0360 of 16th July 2013 concerning control of detrimental effects and the impact of basic nuclear installations on health and the environment). The result must be compared with the annual dose limit for the public (1 mSv/year) defined in Article R.1333-8 of the Public Health Code. This regulation limit corresponds to the sum of the effective doses received by the public as a result of nuclear activities.

In practice, only traces of artificial radioactivity are detectable in the vicinity of the nuclear facilities; most measurements taken during routine surveillance are below the decision threshold or reflect the natural radioactivity. As these measurements cannot be used for dose estimations, models for the transfer of radioactivity to humans must be used, on the basis of measurements of discharges from the installation. These models are specific to each licensee. They are detailed in the installation's impact assessment. During its assessment, ASN verifies that these models are conservative, in order to ensure that the impact assessments will in no case be underestimated.

In addition to the impact assessments produced on the basis of discharges from the facilities, the licensees are required to carry out environmental radioactivity monitoring programmes (water, air, earth, milk, grass, agricultural produce, etc.), more specifically to verify compliance with the hypotheses of the impact assessment and to monitor changes in the radioactivity in the various compartments of the environment around the facilities (see point 4.1.1).

An estimation of the doses from BNIs is presented in Table 7. For each site and per year, this table gives the effective doses received by the most exposed reference population groups.

The doses from BNIs for a given year are determined on the basis of the actual discharges from each installation for the year in question. This assessment takes account of the discharges through the identified outlets (stack, discharge pipe to river or seawater). It also includes diffuse emissions and sources of radiological exposure to the ionising radiation present in the facilities. These elements are the "source term".

The estimate is made in relation to one or more identified reference groups. These are uniform groups of people (adults, infants, children) receiving the highest average dose out of the entire population exposed to a given installation, following realistic scenarios (taking into account the distance from the site, meteorological data, etc.). All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents 1% of the limit for the public (1 mSv per year). Therefore in France,

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Environmental monitoring: verification visit by the European Commission in 2016

A verification visit by the European Commission pursuant to Article 35 of the EURATOM Treaty took place from 13th to 15th June 2016. Unlike the previous visits of this type, this one did not concern a site, but covered the environmental radioactivity monitoring installations in the Paris area. The programme of the visit was drawn up by the French authorities following consultation of the Commission. It comprises a presentation of the entire French environmental radioactivity, foodstuffs and drinking water monitoring system (participants, monitoring programme, national network of environmental radioactivity monitoring, etc.), by ASN, IRSN, DGAL, DGS and DGCCRF, as well as visits to the CEA Saclay centre, with regard to environmental monitoring around nuclear facilities (monitoring of the atmosphere and water, nuclear analyses laboratory etc.) and to the IRSN in Le Vésinet (Téléray network, sampling, nuclear analyses, organisation of inter-laboratory comparison tests, etc.).

The Commission's representatives declared themselves to be highly satisfied with the presentations and visits. They considered the French radioactivity monitoring system to be coherent, efficient and highly advanced by comparison with other European countries. They praised the analysis laboratory approval system, which guarantees the quality of the measurement results, as well as the efforts made to provide the public with data via the Internet. The report of this visit will be published at the beginning of 2017 on the European Commission's website.

The next visit of this type is scheduled for 2018 on the Areva NC site at La Hague.

the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 Monitoring carried out within a European framework

Article 35 of the EURATOM Treaty requires that the Member States establish the facilities needed to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the general public and workers against the hazards of ionising radiation. All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

Article 35 also states that the European Commission may access the monitoring facilities to verify their operation and their effectiveness. During its verifications, the European Commission gives an opinion on the means implemented by the member states to monitor radioactive discharges into the environment and the levels of radioactivity in the environment around nuclear sites and over the national territory. It gives its assessment of the monitoring equipment and methodologies used, and of the organisational setup.

Since 1994, the Commission has carried out the following inspections:
- the La Hague reprocessing plant and Andra's Manche repository in 1996;
- Chooz NPP in 1999;
- Belleville-sur-Loire NPP in 1994 and 2003;

European Commission environmental monitoring visit, June 2016

- the La Hague reprocessing plant in 2005;
- the Pierrelatte nuclear site in 2008;
- the old uranium mines in the Limousin *département* in 2010;
- the CEA site at Cadarache in 2011;
- the environmental radioactivity monitoring facilities in the Paris area in 2016.

4.2 Environmental monitoring

In France, many parties are involved in environmental radioactivity monitoring:
- the nuclear facility licensees, who perform monitoring around their sites;
- ASN, IRSN (whose roles defined by Decree 2016-283 of 10th March 2016 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health (DGS), General Directorate for Food (DGAL), General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), etc.), the State services and other public players performing monitoring duties nationwide or in particular sectors (foodstuffs for example, monitored by the Ministry responsible for Agriculture);
- the approved air quality monitoring associations (local authorities), environmental protection associations and the CLIs.

The French National Network for environmental radioactivity monitoring (RNM) brings all these players together. Its primary aim is to collate and make available to the public all the regulatory environmental measurements taken on French territory, by means of a dedicated website *www.mesure-radioactivite.fr.* The quality of these measurements is guaranteed by subjecting the measuring laboratories to an approval procedure.

4.2.1 The purpose of environmental monitoring

The licensees are responsible for monitoring the environment around their facilities. The content of the monitoring programmes to be implemented in this respect (measurements to be taken and frequency) is defined in ASN resolution 2013-DC-0360 of 16th July 2013 amended concerning the control of detrimental effects and the impact on health and the environment of basic nuclear installations and in the individual prescriptions applicable to each installation (Creation Authorisation Decree, discharge licensing orders or ASN resolutions), independently of the additional measures that can be taken by the licensees for the purposes of their own monitoring.

This environmental monitoring:
- helps gives a picture of the radiological and radio-ecological state of the facility's environment through measurement of parameters and substances regulated by the prescriptions, in the various compartments of the environment (air, water, soil) as well as in the various biotopes and the food chain (milk, vegetables, etc.): a zero reference point is identified before the creation of the facility and environmental monitoring throughout the life of the facility enables any changes to be tracked;
- helps verify that the impact of the facility on health and the environment is in conformity with the impact assessment;
- detects any abnormal increase in radioactivity as early as possible;
- ensures there are no facility malfunctions, including by analysing the ground water and checking licensees' compliance with the regulations;
- contributes to transparency and information of the public by transmitting monitoring data to the RNM.

Following initial experience feedback from application of the above-mentioned resolution of 16th July 2013, ASN has undertaken a revision, more particularly to clarify and update the requirements concerning the environmental monitoring programme to be implemented by the licensees. This modification was made by ASN resolution 2016-DC-0569 of 29th September 2016, approved by the Minister for the Environment, Energy and the Sea in an Order dated 5th December 2016.

4.2.2 Content of monitoring

All the nuclear sites in France that produce discharges are subject to systematic environmental monitoring. This monitoring is proportionate to the environmental risks or drawbacks of the facility, as presented in the authorisation file, particularly the impact assessment.

The regulatory monitoring of the BNI environment is tailored to each type of installation, depending on whether it is a power reactor, a plant, a research facility, a waste disposal facility, etc. The minimum content of this monitoring is defined by the Order of 7th February 2012 amended setting the general rules for BNIs and by the above-mentioned ASN resolution of 16th July 2013. This resolution obliges BNI licensees to have approved laboratories take the environmental radioactivity measurements required by the regulations.

Depending on specific local features, monitoring may vary from one site to another. Table 8 gives examples of the monitoring performed by an NPP and by a research centre or plant.

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has been the case, for example, on the Cadarache and Tricastin sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

Each year, in addition to sending ASN the monitoring results required by the regulations, the licensees transmit nearly 120,000 measurements to the national network for environmental radioactivity monitoring.

4.2.3 Environmental monitoring nationwide by IRSN

IRSN's nationwide environmental monitoring is carried out by means of measurement and sampling networks dedicated to:
- air monitoring (aerosols, rainwater, ambient gamma activity);
- monitoring of surface water (watercourses) and groundwater (aquifers);
- monitoring of the human food chain (milk, cereals, fish, etc.);
- terrestrial continental monitoring (reference stations located far from all industrial facilities).

This monitoring is based on:
- continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:
  - the *Téléray* network (ambient gamma radioactivity in the air) which uses a system of continuous measurement monitors around the whole country. The density of this network is being increased around nuclear sites within a radius of 10 to 30 km around BNIs;
  - the *Hydrotéléray* network (monitoring of the main watercourses downstream of all nuclear facilities and before they cross national boundaries);
  - continuous sampling networks with laboratory measurement, for example the atmospheric aerosols radioactivity monitoring network;
- processing and measurement in a laboratory of samples taken from the various compartments of the environment, whether or not close to facilities liable to discharge radionuclides.

Every year, IRSN takes more than 25,000 samples in all compartments of the environment (excluding the remote-measurement networks).

The radioactivity levels measured in France are stable and situated at very low levels, generally at the detection sensitivity threshold of the measuring instruments. The artificial radioactivity detected in the environment results essentially from fallout from the atmospheric tests of nuclear weapons carried out in the 1960s, and from the Chernobyl accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added very local contaminations resulting from incidents or past industrial activities, and which do not represent a health risk.

On the basis of the nationwide radioactivity monitoring results and in accordance with the provisions of ASN resolution 2008-DC-0099 of 29th April 2008, as amended, IRSN regularly publishes a report on the radioactive status of the French environment. The first issue of this report, published at the beginning of 2013, covered the year 2010 and the first half of 2011. The second issue, published at the end of 2015, corresponds to the period 2011-2014. In addition to this report, IRSN also produces regional radiological findings to provide more precise information about a given area

IRSN *Téléray* monitor on the roof of the ASN headquarters in Montrouge, October 2016

4.3 Measurement quality

Articles R.1333-11 and R.1333-11-1 of the Public Health Code require the creation of a National Monitoring Network (RNM) and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods are defined by the above-mentioned ASN resolution of 29th April 2008 amended.

This network is being deployed for two main reasons:
- to pursue the implementation of a quality assurance policy for environmental radioactivity measurements by setting up a system of laboratory approvals granted by ASN resolution;
- to ensure transparency by making the results of this environmental monitoring and information about the radiological impact of nuclear activities in France available to the public on a specific RNM website (see point 4.2).

TABLE 8: Example of radiological monitoring of the environment around BNIs

ENVIRONMENT MONITORED OR TYPE OF INSPECTION	CATTENOM NPP (RESOLUTION 2014-DC-0415 OF 16TH JANUARY 2014	AREVA PLANT AT LA HAGUE (ASN RESOLUTION 2015-DC-0535 OF 22 DECEMBER 2015)
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total β activity (β_G) γ spectometry if $\beta_G > 2$ mBq/m^3 Monthly γ spectometry on grouped filters per station • 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ^3H	• 5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total α activity (α_G) and total β activity (β_G). γ spectrometry if α_G ou $\beta_G > 1$ mBq/m^3 spectrometry α (Pu) mensuelle sur le regroupement des filtres par station • 5 continuous sampling stations for halogens on specific adsorbent with weekly γ spectrometry to measure iodines • 5 continuous sampling stations with weekly measurement of atmospheric ^3H • 5 continuous sampling stations with bi-monthly measurement of atmospheric ^{14}C • 5 continuous measurement stations for ^{85}Kr activity in the air
Ambient γ radiation	• Continuous measurement with recording: - 4 detectors at 1 km - 10 detectors on the site boundary - 4 detectors at 5 km	• 5 detectors with continuous measurement and recording • 11 detectors with continuous measurement at the site fencing
Rain	• 1 continuous sampling station under the prevailing winds with bi-monthly measurement of β_G and ^3H	• 2 continuous sampling stations including one under the prevailing winds with weekly measurement of α_G, β_G and ^3H γ spectometry if significant α_G or β_G
Liquid discharge receiving	• Sampling from the river upstream of the discharge point and in the good mixing area for each discharge Measurement of β_G, potassium (K)* and ^3H • Continuous sampling in the river at the good mixing point ^3H measurement (average daily mixture) • Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, free ^3H measurement, and, on fish, organically bound ^{14}C and ^3H • Periodic sampling from a stream and in the dam adjoining the site with measurements of β_G, K, ^3H	• Daily seawater samples from 2 points on the coast, with daily measurements (γ spectometry, ^3H) at one of these points and for each of the 2 points, α and γ spectometry and β_G, K, ^3H and ^{90}Sr measurements • Quarterly seawater samples at 3 points offshore with γ spectrometry and β_G, K, ^3H measurements • Quarterly samples of beach sand, seaweed and limpets at 13 points with γ spectrometry + ^{14}C measurements and α spectrometry for the seaweed and limpets at 6 points • Sampling of fish, crustaceans, shellfish and molluscs in 3 coastal zones of the Cotentin with α and γ spectrometry and ^{14}C measurement • Quarterly sampling of offshore marine sediments at 8 points with α and γ spectrometry and ^{90}Sr measurement • Weekly to six-monthly samples of water from 19 streams around the site, with α_G, β_G, K and ^3H measurements • Quarterly sampling of sediments from the 4 main streams adjacent to the site, with γ and α spectrometry • Quarterly samples of aquatic plants in 3 streams in the vicinity of the site with γ spectrometry and ^3H measurement
Groundwater	• Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with β_g, K and ^3H measurement	• 5 sampling points (monthly check) with α_G, β_G, K and ^3H measurement
Water for consumption	• Annual sampling of water intended for human consumption, with β_G, K and ^3H measurements	• Periodic sampling of water intended for human consumption at 15 points, with α_G, β_G, K and ^3H measurements
Soil	• 1 annual sample of topsoil with γ spectrometry	• Quarterly samples at 7 points with γ spectrometry and ^{14}C measurement
Vegetation	• 2 grass sampling points, including one under the prevailing winds, monthly γ spectrometry and quarterly ^{14}C and C measurements • Annual campaign for the main agricultural crops, with γ spectrometry, ^3H and ^{14}C measurements	• Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ^3H and ^{14}C measurements, Annual α spectrometry a each point • Annual campaign for the main agricultural crops, with α and γ spectrometry, ^3H, ^{14}C and ^{90}Sr measurements
Milk	2 sampling points situated at 0 to 10 km from the installation, including one under the prevailing winds, with monthly γ spectrometry, quarterly ^{14}C measurement and annual ^{90}Sr and ^3H measurement	5 sampling points (monthly check) with γ spectrometry, K, ^3H, ^{14}C and ^{20}Sr measurement

$\alpha_G = \alpha$ total; $\beta_G = \beta$ total
** Measurements of total concentration of potassium and by spectrometry for ^{40}K.*

The approvals cover all components of the environment; water, soils or sediments, all biological matrices (fauna, flora, milk), aerosols and atmospheric gases. The measurements concern the main artificial or natural gamma, beta or alpha emitting radionuclides, as well as the ambient gamma dosimetry (see Table 9). The list of the types of measurements covered by an approval is set by the above-mentioned ASN resolution of 29th April 2008 amended.

In total, about fifty types of measurements are covered by approvals. There are just as many corresponding inter-laboratory comparison tests. These tests are organised by IRSN in a 5-year cycle, which corresponds to the maximum approval validity period.

4.3.1 Laboratory approval procedure

ASN resolution 2008-DC-0099 of 29th April 2008 amended, specifies the organisation of the national network and sets the approval arrangements for the environmental radioactivity measurement laboratories.

The approval procedure includes:
- presentation of an application file by the laboratory concerned, after participation in an Inter-laboratory Comparison Test (ILT);
- review of it by ASN;
- review of the application files - which are made anonymous - by a pluralistic approval commission which delivers an opinion on them.

The laboratories are approved by ASN resolution, published in its Official Bulletin. The list of approved laboratories is updated every six months.

4.3.2 The approval commission

The approval commission is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the RNM with high-quality measurement results.

The commission is authorised to propose approval, rejection, revocation or suspension of approval to ASN. It issues a decision on the basis of an application file submitted by the candidate laboratory and its results in the inter-laboratory comparison tests organised by IRSN. It meets every six months.

The commission, chaired by ASN, comprises qualified persons and representatives of the State services, laboratories, standardising authorities and IRSN. ASN resolution 2013-CODEP-DEU-2013-061297 of 12th November 2013, appointing candidates to the environmental radioactivity measurement laboratories approval commission, renewed the mandates of the commission's members for a further five years.

FUNDAMENTALS

The national network's website *(www.mesure-radioactivite.fr)*

In order to meet the transparency goal, the RNM launched a website *(www.mesure-radioactivite.fr)* in 2010 to present the environmental radioactivity monitoring results and information on the health impact of nuclear activities in France. In order to guarantee the quality of the measurements, only those taken by an approved laboratory or by IRSN may be integrated into the RNM. The RNM management report is also available on it.

ASN considers that the launch of the RNM website is a decisive step forward in terms of transparency and makes efforts to ensure that the expectations of the public and web users concerning development of the site are taken into account. A panel of users was set up in 2012 to test the website which led ASN and IRSN to initiate an overhaul of the site, in order to enhance the functions and information enabling the public to understand and interpret the measurement results. The new version was placed on-line on 18th October 2016.

The main development is the creation of a guided mode, which enables each person to gain a clearer understanding of the radioactivity in their immediate environment. This "general public" mode gives access to a selection of 15 "standard measurements" that are more representative of the radiological status of the environment (ambient gamma dose, total alpha activity index in the air, caesium-137, tritium and krypton-85 in the air, tritium in continental surface waters and in sea and estuary water, uranium and total alpha activity index in surface waters, carbon-14 in fish, grass and milk, tritium and iodine-129 in milk, iodine-129 in algae). The guided mode gives statistical data per département or per nuclear site. The results of the standard measurements are present in the form of pictograms, annotated and accompanied by graphic and contextual reference points (more particularly the national reference levels). The advanced mode enables an audience more familiar with reading measurement results to access all the data in the RNM base (about 2 million results).

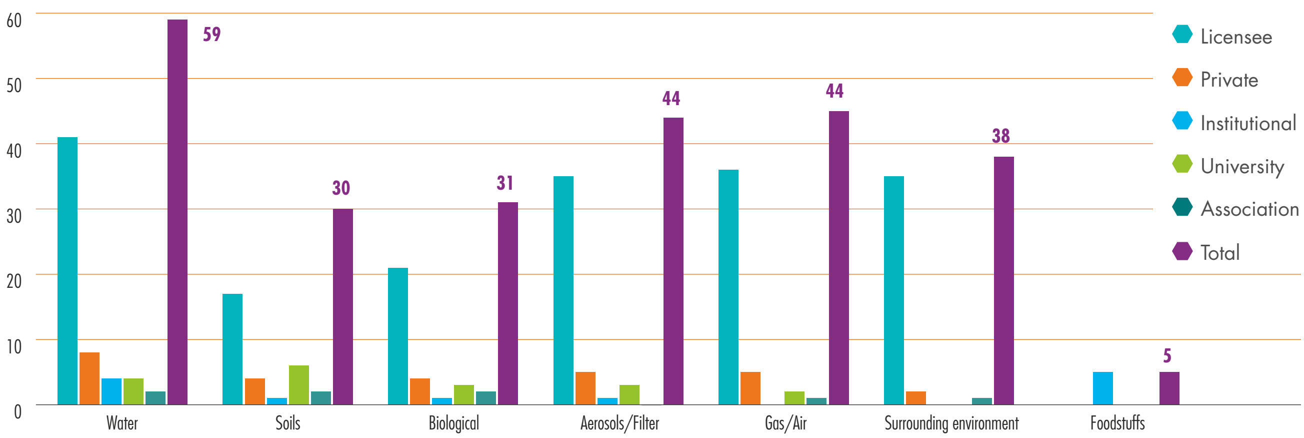
TABLE 9: Approval chart and forecast five-year Inter-Laboratory Test (ILT) programme

		TYPE 1			TYPE 2		TYPE 3		TYPE 4		TYPE 5		TYPE 6		TYPE 7	
Code	Radioactive measurements category	Sea water	Water		Soil matrices		Biological matrices		Aerosols on filter		Gas air		Ambient medium (soil/air)		Foodstuffs for health inspection	
..-01	Emitting radionuclides γ > 100 keV		2nd half 2019	1_01	1st half 2020	2_01	2nd half 2017	3_01	2nd half 2019	4_01	1st half 2021	5_01		-	S (2017), L (2018), S (2019), L (2020), S (2021)	7_01
..-02	Emitting radionuclides γ < 100 keV		2nd half 2019	1_02	1st half 2020	2_02	2nd half 2017	3_02		4_02	1st half 2021	5_02		-	S (2017), L (2018), S (2019), L (2020), S (2021)	7_02
..-03	Total alpha		2nd half 2017, 1st half 2019	1_03		-		-	2nd half 2017	4_03		-		-	-	-
..-04	Total bêta	1st half 2019	2nd half 2017, 1st half 2019	1_04		-		-	2nd half 2019	4_04		-		-	-	-
..-05	^{3}H	1st half 2019	2nd half 2017, 1st half 2019	1_05		2_05	2nd half 2020	3_05		-		Cf. water		-	-	-
..-06	^{14}C		1st half 2020	1_06		2_06	2nd half 2018	3_06		-	1st half 2017	Cf. water/Na OH		-	-	-
..-07	$^{90}Sr/^{90}Y$		1st half 2017	1_07	1st half 2021	2_07	2nd half 2020	3_07	2nd half 2019	4_07		-		-	-	-
..-08	Other pure beta emitters (Ni-63,...)			1_08	2nd half 2021	2_08 ^{99}Tc	1st half 2017	3_08 ^{99}Tc		-		-		-	-	-
..-09	U Isotopes		2nd half 2018	1_09	1st half 2019	2_09	2nd half 2021	3_09	2nd half 2018	4_09		-		-	-	-
..-10	Th Isotopes			1_10	1st half 2019	2_10	2nd half 2021	3_10		4_10		-		-	-	-
..-11	^{226}Ra + desc.		2nd half 2018	1_11	1st half 2019	2_11	2nd half 2021	3_11		-		Rn 222 : 5_11		-	-	-
..-12	^{228}Ra + desc.		2nd half 2018	1_12	1st half 2019	2_12	2nd half 2021	3_12		-		Rn 220 : 5_12		-	-	-
..-13	Pu, Am, (Cm, Np) Isotopes		2nd half 2020	1_13	2nd half 2021	2_13	1st half 2018	3_13	2nd half 2017	4_13		-		-	-	-
..-14	Halogenated gases			-		-		-		-	1st half 2021	5_14		-	-	-
..-15	Noble gases			-		-		-		-	1st half 2019	5_15 ^{85}Kr		-	-	-
..-16	Gamma dosimetry			-		-		-		-		-	1st half 2018	6_16	-	-
..-17	Total uranium		2nd half 2018	1_17	1st half 2019	2_17	2nd half 2021	3_17	2nd half 2018	4_17		-		-	-	-

L: Liquid
S: Solid

1st half year 2017 / 2nd half year 2017 · 1st half year 2018 / 2nd half year 2018 · 1st half year 2019 / 2nd half year 2019 · 1st half year 2020 / 2nd half year 2020 · 1st half year 2021 / 2nd half year 2021

GRAPH 11: Breakdown of the number of approved laboratories for a given environmental matrix as at 1st January 2017



4.3.3 Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard NF EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in Inter-laboratory Comparison Tests (ILTs) organised by IRSN. The ILT programme, which now operates on a five-yearly basis, is updated annually. It is reviewed by the approval commission and published on the national network's website (*www.mesure-radioactivite.fr*). Up to 70 laboratories sign up for each test, including a number of laboratories from other countries.

To ensure that the laboratory approval conditions are fully transparent, precise assessment criteria are used by the approval commission.

In 2016, IRSN organised four ILTs; 64 ILTs since 2003 have covered nearly 50 types of approval. The most numerous approved laboratories (59) are in the field of monitoring of radioactivity in water. About thirty to forty laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. 30 laboratories deal with soils and sediments. Although most laboratories are competent to measure gamma emitters in all environmental matrices, only about ten of them are approved to measure carbon-14, transuranic elements or radionuclides of the natural chains of uranium and thorium in water, soil and sediments and the biological matrices (grass, plant crops or livestock breeding, milk, aquatic fauna and flora, etc.).

In 2016, ASN issued 127 approvals or approval renewals. As at 1st January 2017, the total number of approved laboratories stood at 64, representing 880 currently valid approvals of all types (in 2015, one laboratory requested the suspension of its previously held approvals).

The detailed list of approved laboratories and their scope of technical competence is available on *www.asn.fr*.

TECV Act

The 17th August 2015 Energy Transition for Green Growth Act reinforces ASN oversight resources and powers of sanction.

The Ordinance of 10th February 2016 gave ASN inspectors more graduated powers of oversight and sanction, in particular the possibility of requiring payment of a daily fine (not to exceed €15,000) or an administrative fine (not to exceed €10 M).

This same Ordinance created a sanctions committee responsible for ruling on the administrative penalties. It comprises four members who neither sit on the ASN Commission nor are part of its departments, in order to comply with the principle of separation between investigating and sentencing powers.

ASN enforcement powers have also been expanded to encompass activities important for the protection of health, public security and the environment performed by the suppliers, contractors or subcontractors of licensees, including outside BNIs.

5. Identifying and penalising deviations

5.1 Ensuring that penalty decisions are fair and consistent

In certain situations in which the licensee fails to comply with the regulations or legislation, or when it is important that appropriate action be taken by it to remedy the most serious risks without delay, ASN may impose the penalties provided for by law. The principles of ASN actions in this respect are:
- penalties that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the health and environmental risks associated with the deviation identified and also take account of factors relating to the licensee (past history, behaviour, repeated nature), the context of the deviation and the nature of the requirements contravened (regulations, standards, "rules of good practice", etc.);
- administrative action initiated on proposals from the inspectors and decided on by ASN in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

ASN has a range of tools at its disposal, in particular:
- remarks made by the inspector to the licensee;
- the official letter from the ASN departments to the licensee (inspection follow-up letter);
- formal notice from ASN to the licensee to regularise its administrative situation or meet certain conditions, within a given time-frame;
- administrative penalties applied after formal notice.

In addition to ASN administrative actions, reports can be drafted by the inspector and sent to the Public Prosecutor's Office.

5.2 An appropriate policy of enforcement and sanctions

5.2.1 For the BNI licensees and entities responsible for the transport of radioactive substances

When ASN observes breaches of compliance with legislative and regulatory safety requirements, enforcement measures or sanctions can be imposed on the licensees, after an exchange of views and prior formal notice depending on the type of measures decided.

If failure to observe the applicable provisions and prescriptions is detected, the Environment Code makes provision for graduated administrative sanctions:
- deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
- have the work or prescribed measures carried out without consulting the licensee and at its expense (any sums deposited beforehand can be used to pay for this work);
- suspension of the functioning of the installation or of performance of the operation (restart for example) until the licensee has brought it into conformity;
- a daily fine (an amount set per day, to be paid by the licensee until full compliance with the requirements of the formal notice has been achieved);
- administrative penalty.

It should be noted that these last two measures, which have become available since the nuclear Ordinance of February 2016, are proportionate to the gravity of the infringements observed. The administrative fine will be the competence of the future ASN Sanctions Committee.

The Act also makes provision for interim measures to safeguard security and public health and safety or protect the environment. ASN can therefore:
- provisionally suspend operation of a BNI, immediately notifying the ministers responsible for nuclear safety, in the event of any serious and imminent risk;
- at all times require assessments and implementation of the necessary measures in the event of a threat to the abovementioned interests.

Any infringements observed are written up in reports by the nuclear safety inspectors and transmitted to the Public Prosecutor's Office, that decides on what subsequent action, if any, is to be taken. The Environment Code makes provision for criminal penalties, with regard to the infringement or offence: a fine or even a term of imprisonment (up to €150,000 and three years in prison), depending on the nature of the infringement. For legal persons found to be criminally liable, the amount of the fine can reach €10M, depending on the infringement in question and the actual prejudice to the interests mentioned in Article L.593-1.

Decree 2007-1557 of 2nd November 2007 concerning BNIs and the regulation of the transport of radioactive substances with respect to nuclear safety, also imposes class 5 fines for infringements as detailed in its Article 56.

In the field of pressure equipment, pursuant to the provisions of Chapter VII of Title V of Book V of the Environment Code, which apply to high-risk products and equipment, including pressure equipment, ASN – which is in charge of monitoring these items in BNIs – has powers of enforcement and sanction against licensees. These provisions in particular enable it to order the payment of a fine, plus an additional daily payment applicable until such time as compliance with the formal notice is effective. This Chapter also includes provisions applicable to the manufacturers, importers and distributors of such equipment, aiming to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps to ensure conformity.

5.2.2 For persons in charge of small-scale nuclear activities, approved organisations and laboratories

The Public Health Code makes provision for enforcement measures or administrative and criminal sanctions in the event of non-compliance with or breach of the radiation protection requirements.

ASN has administrative decision-making powers, which can entail:
- temporary or definitive license withdrawals after issue of formal notice;
- in an emergency involving human safety, the provisional suspension of an licensed or notified activity;
- revocation or suspension of any approvals it has issued.

The formal notices associated with revocation of a license may concern all the provisions of the "ionising radiation" Chapter of the legislative part of the Public Health Code, the regulatory measures implementing them and the prescriptions of the license. Temporary or final revocation of the license by ASN must be fully explained in a decision within one month following serving of formal notice.

The formal notices prior to criminal sanctions (based on Article L.1337-6 of the Public Health Code) are served by ASN. They concern the provisions relating to measures taken for exposure monitoring and for protection and information of persons, in particular in premises open to the public.

Infringements are written up in reports by the radiation protection inspectors and transmitted to the Public Prosecutor's Office, which decides on what subsequent action, if any, is to be taken. The Public Health Code makes provision for criminal penalties in Articles L.1337-5

TABLE 10: Number of infringement reports transmitted by the ASN inspectors between 2011 and 2016

	2011	2012	2013	2014	2015	2016
Report excluding labour inspection in the nuclear power plants	27	12	26	15	14	7
Labour inspection report in the nuclear power plants	6	11	10	9	3	1

to L.1337-9: these consist of a fine of from €3,750 to €15,000 and a term of imprisonment of six months to one year, depending on the gravity of the infringement, with additional penalties being possible for legal persons.

5.2.3 For noncompliance with Labour Law

In the performance of their duties in NPPs, the ASN labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors (pursuant to Article R.8111-11 of the Labour Code). Observation, formal notice, administrative sanction, report, injunction (to obtain immediate cessation of the risks) or even stoppage of the works, offer the ASN labour inspectors a broad range of incentive and constraining measures.

5.2.4 2016 results concerning enforcement and sanctions

As a result of infringements observed, the ASN inspectors (nuclear safety inspectors, for BNIs, the transport of radioactive substances or nuclear pressure equipment, labour inspectors and radiation protection inspectors) transmitted eight infringement reports to the public prosecutor's offices, one of which concerned labour inspections in the NPPs.

ASN issued nine administrative measures, including eight formal notices against contractors and parties responsible for nuclear activities. Moreover, for the first time, ASN took the decision to suspend a test certificate, concerning a Steam Generator (SG) on Fessenheim NPP reactor 2. This SG contains manufacturing anomalies that are important enough to compromise the safety demonstration used as the basis for issue of this certificate.

Table 10 shows the number of reports issued by the ASN inspectors since 2011.

6. Outlook

In 2017, ASN intends to perform about 1,800 inspections in BNIs, of radioactive substances transport activities, activities involving the use of ionising radiation, organisations and laboratories that it has approved and activities related to pressure equipment.

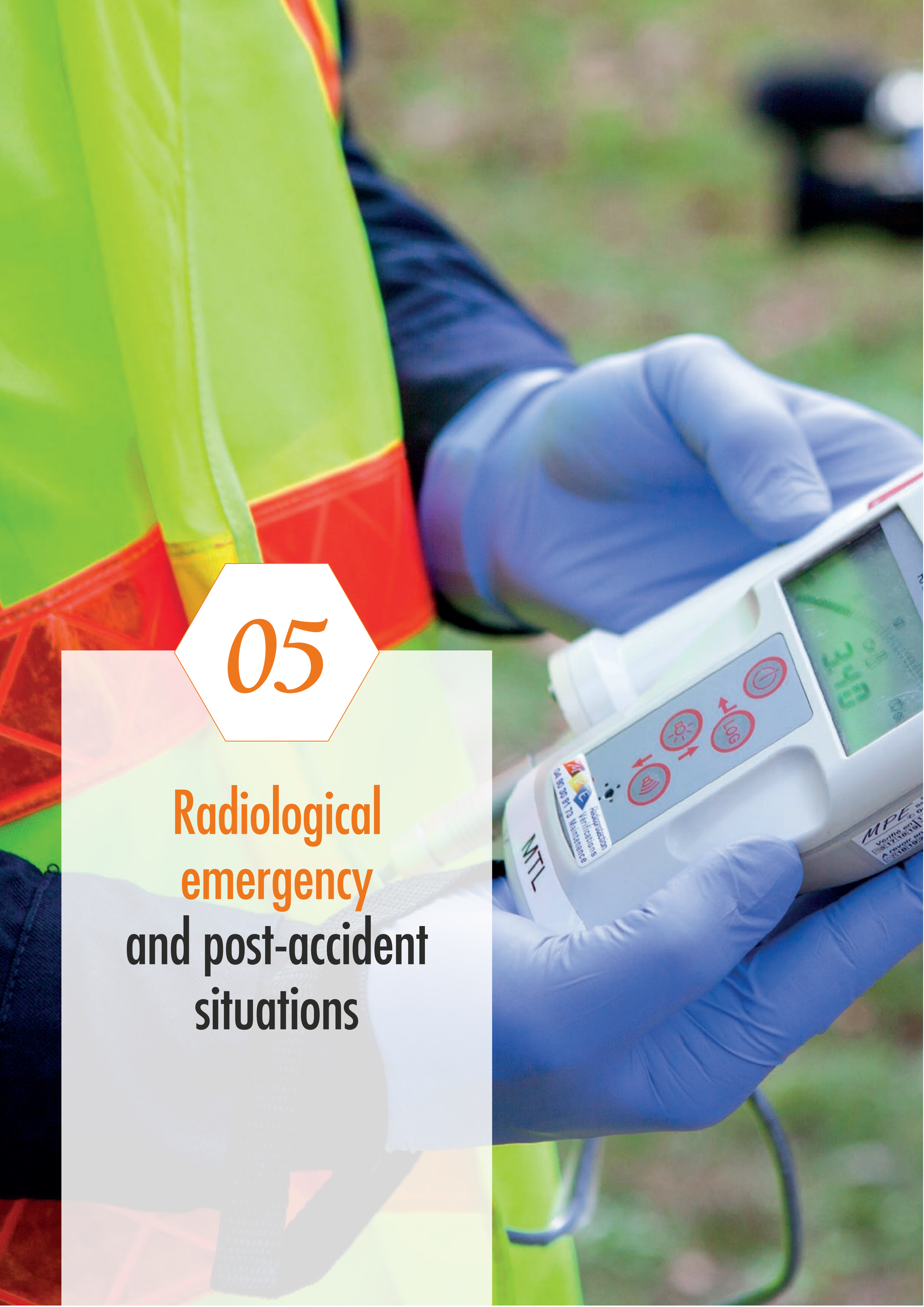
Further to the irregularities found in the manufacture of certain NPP equipment items (see chapter 12), ASN has initiated and will in 2017 be continuing a review of BNI licensee monitoring of their contractors and subcontractors, of ASN oversight and of the alert mechanisms.

In 2017, ASN will as a priority inspect the activities with potentially high consequences, taking account of the experience feedback from 2016. It will review small-scale nuclear issues in order to reinforce the effectiveness of its regulation and oversight.

At the same time, ASN will continue to revise the procedures for notification of significant events, taking into account the experience feedback from the events notification guide in small-scale nuclear activities and the changes to the regulations in the BNI sector.

It will propose changes to the sanctions policy, pursuant to the provisions of the Act on Energy Transition for Green Growth of 17th August 2015 and Ordinance 2016-128 of 10th February 2016.

In the field of environmental protection, ASN will continue with its regulatory work to implement the provisions of the 17th August 2015 Energy Transition for Green Growth Act 2015-992 and the transposition to BNIs of Directive 2010/75/UE on industrial emissions, known as the "IED Directive" and Directive 2012/18/UE of 4th July 2012 concerning major accidents involving hazardous substances, known as the "Seveso 3 Directive". ASN will also initiate a revision of the BNI Order of 7th February 2012, more specifically to take account of recent changes to the general environmental regulations.



05

Radiological emergency and post-accident situations


RADIAGEM

Nuclear activities are carried out with the two-fold aim of preventing accidents and mitigating any consequences should they occur. Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for dealing with and managing a radiological emergency situation must be planned for, and regularly tested and revised.

Radiological emergency situations, arising from an incident or accident which risk leading to an emission of radioactive substances or to a level of radioactivity liable to affect public health, include:
- emergency situations arising in a Basic Nuclear Installation (BNI);
- accidents involving the Transport of Radioactive Materials (RMT);
- emergency situations occurring in the field of small-scale nuclear activities.

Emergency situations affecting nuclear activities can also comprise non-radiological risks, such as fire, explosion or the release of toxic substances.

These emergency situations are covered by specific material and organisational arrangements, which include the contingency plans and involve both the licensee and or the party responsible for the activity and the public authorities.

The Nuclear Safety Authority (ASN) is involved in managing these situations, with regard to questions concerning the regulation of nuclear safety and radiation protection and, backed by the expertise of its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN) it has the following four key duties:
- ensure and verify the soundness of the steps taken by the licensee;
- advise the Government and its local representatives;
- contribute to the circulation of information;
- act as Competent Authority within the framework of the international conventions.

In 2005, ASN also set up a Steering Committee to prepare for management of the Post-Accident Phase (Codirpa) following on from the management of a radiological emergency. The doctrine concerning the emergency phase exit, transition and long-term periods, was published in November 2012. Work is continuing on the management of waste and manufactured products as well as on the management of water and marine environments.

1. Anticipating

Four main principles underpin the protection of the general public against BNI risks:
- risk reduction at source, wherein the licensee must take all steps to reduce the risks to a level that is as low as reasonably achievable in acceptable economic conditions;
- the emergency and contingency plans, designed to prevent and mitigate the consequences of an accident;
- controlling urban development around BNIs;
- informing the general public.

1.1 Looking ahead and planning

1.1.1 Emergency and contingency plans concerning BNIs

The emergency and contingency plans relative to accidents occurring in a BNI define the measures necessary for protecting site personnel, the general public and the environment, and for controlling the accident.

The Major Nuclear or Radiological Accident National Response Plan, published by the Government in February 2014, which ASN helped to draft, takes account of the lessons learned from the Fukushima Daiichi accident and the post-accident doctrine drafted by the Codirpa, specifies the national response organisation in the event of a nuclear accident, the strategy to be applied and the main steps to be taken. It includes the international nature of emergencies and the mutual assistance possibilities in the case of an event. In 2015, the local implementation of this plan began in the French *départements*, under the supervision of the defence and security zone Prefects.

In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L.741-6, R.741-8 and following of the Domestic Security Code, *"to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localised and fixed. The PPI* *implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises and training"*. These Articles also stipulate the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the ORSEC plan (Disaster and Emergency Response Organisation) that describes the protective measures implemented by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or zone ORSEC plan is activated.

The On-site Emergency Plan (PUI), prepared by the licensee, is designed to restore the plant to a controlled and stable condition and mitigate the consequences of an accident. It defines the organisational actions and the resources to be implemented on the site. It also comprises arrangements for informing the public authorities rapidly. Pursuant to Decree 2007-1557 of 2nd November 2007, the PUI is one of the items to be included in the file sent by the licensee to ASN for commissioning of its facility. The licensee's obligations in terms of preparedness and management of emergency situations are determined by the Order of 7th February 2012 setting the general rules for BNIs (Title VII). The corresponding provisions shall be clarified by an ASN resolution currently under preparation.

1.1.2 The accident response plans for the transport of radioactive substances

The transport of radioactive substances represents nearly a million packages carried in France every year. The dimensions, weight, radiological activity and corresponding safety implications can vary widely from one package to another.

Pursuant to the international regulations on dangerous goods, those involved in the transport of dangerous goods must take steps appropriate to the nature and scale of the foreseeable hazards, in order to avoid damage or, as applicable, to mitigate the effects. These steps are described in a management plan for events linked to RMT. The content of these plans is defined in ASN Guide No. 17.

To deal with the possibility of a radioactive substances transport accident, each *département* Prefect must include in their implementation of the national response plan a part devoted to this type of accident, the TMR ORSEC plan. Faced with the diversity of possible types of transport operations, this part of the plan defines the criteria and simple measures enabling the first respondents (Departmental Fire and Emergency Service (SDIS) and law enforcement services in particular) to initiate the first reflex response measures to protect the general public and sound the alert, based on their findings on the site of the accident.

1.1.3 The response to other radiological emergency situations

Apart from incidents or accidents affecting nuclear installations or a radioactive substances transport operation, radiological emergency situations can also occur:
- during performance of a nuclear activity, for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

In such cases, intervention is necessary to limit the risk of human exposure to ionising radiation. ASN, together with the Ministries and stakeholders concerned, thus drafted Interministerial Circular DGSNR/DHOS/DDSC 2005/1390 of 23rd December 2005.

This Circular supplements the provisions of the Interministerial Directive of 7th April 2005 presented in point 1.3 and defines the methods for the organisation of the State services in these radiological emergency situations.

Given the large number of those who could possibly issue an alert and the corresponding alert channels, all the alerts are centralised in a single location, which then distributes them to all the stakeholders: this is the fire brigade's centralised alert processing centre CODIS-CTA (Operational *Département* Fire and Emergency Centre – Alert Processing Centre), that can be reached by calling 18 or 112.

The management of accidents of malicious origin occurring outside BNIs are not covered by this Circular, but by the Government's NRBC (Nuclear, Radiological, Biological and Chemical) plan.

1.1.4 ASN role in the examination and monitoring of emergency plans and the drafting of contingency plans

Examination of emergency plans for nuclear facilities or activities

ASN reviews the On-site Emergency Plans as part of the procedure to authorise the commissioning of BNIs or the possession and utilisation of high-level sealed sources (Article R.1333-33 of the Public Health Code), as well as the management plans for events linked to radioactive substances transports and their updates.

Participation in drafting the contingency Plans

Contingency Plans, such as the PPI, identify the general public protection measures such as to mitigate the health and environmental consequences of any accident. The Prefect decides whether or not to deploy these measures on the basis of the predicted dose that would be received by a one year old child situated in the open air at the time of the accident.

Pursuant to the Domestic Security Code, the Prefect is responsible for drafting and approving the PPI. ASN provides assistance by analysing the technical data to be provided by the licensees, in particular the nature and scope of the consequences of an accident, with the help of its technical support organisation, IRSN.

The PPI currently makes it possible to plan the public authorities' response in the first hours of the accident in order to protect the population living within a 10km radius around the affected reactor. The PPI comprises a "reflex" phase which includes an immediate licensee alert of the populations within a 2 km radius of the facility, requiring them to take shelter and await instructions. The additional measures to be taken beyond the zone covered by the PPI are specified, as applicable, through a joint approach which can be based on the ORSEC arrangements, taking account of the characteristics of the accident and the weather conditions.

ASN also assists the Ministry of the Interior's General Directorate for Civil Security and Emergency Management (DGSCGC) with a view to supplementing the PPIs concerning aspects relating to post-accident management (see point 1.5).

1.2 Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of an accident for the population and property. Since 1987, this type of approach has been implemented around non-nuclear industrial facilities and it has been reinforced since the AZF facility accident that occurred in Toulouse in 2001. The TSN Act, now codified in Books I and V of the Environment Code, enables the public authorities to control urban development around BNIs, by implementing institutional controls limiting or prohibiting new constructions in the vicinity of these facilities.

The actions to control urban development entail a division of responsibilities between the licensee, the mayors and the State:
- The licensee is responsible for its activities and the related risks.
- The mayor is responsible for producing the town planning documents and issuing building permits.

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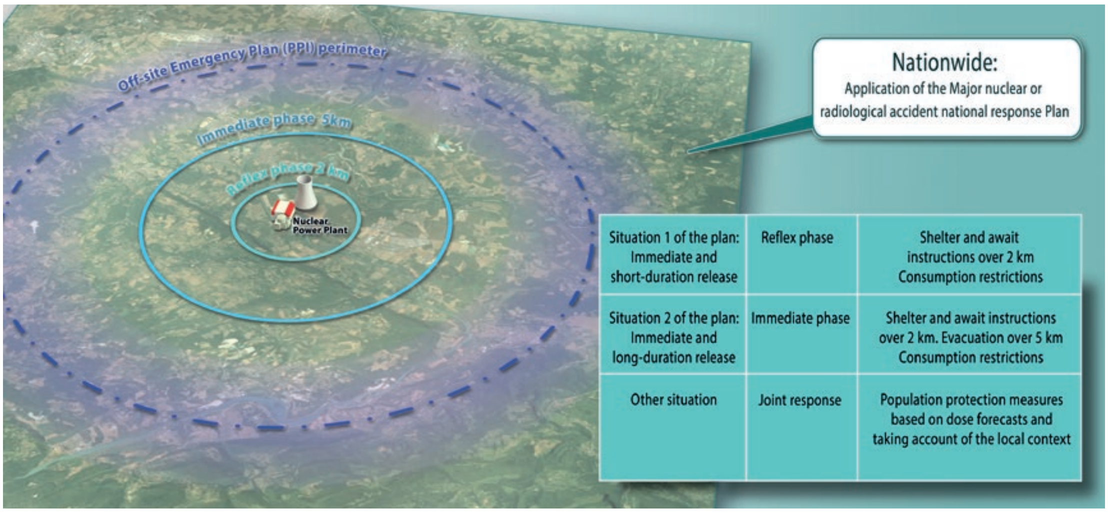
Extension of the PPI perimeter: methods currently being defined

In 2011, the Fukushima Daiichi accident showed that a severe and long-duration accident can have consequences that affect areas several tens of kilometres from an NPP. A Working Group (WG) on possible changes to the organisation of population protection measures was thus set up as part of the roadmap accompanying the National Plan for the response to a major nuclear or radiological accident. The WG guidelines were issued at the beginning of 2016 and validated by the Government over the summer. On 3rd October 2016, the Ministry for the Interior notified the Prefects of *départements* containing an NPP of the approach to be followed. More particularly the pertinence of the activation of the PPI during the reflex phase over 2 km was again confirmed, as was the response strategy covering the entire country. The new measures to be incorporated into the PPI for the NPPs are clarified: extension from 10 to 20 km of the PPI radius and the pre-distribution of stable iodine tablets, the preparation for immediate evacuation over 5 km, the introduction of initial instructions to restrict the consumption of foodstuffs as of the emergency phase, taking account of the local context for the population protection decisions.

Consistent with these provisions, ASN will ensure that the distribution of stable iodine tablets is extended to areas within a 2 km radius around each NPP.
ASN will also be involved in the future work of the WG concerning the PPIs of other BNIs.

The extension of the PPI perimeters to 20 km around NPPs and the preparation for immediate evacuation within a 5 km radius are consistent with the recommendations of the HERCA/WENRA approach (see box in point 2.2) published at the end of 2014 in order to more closely harmonise the emergency management arrangements across Europe. ASN considers that it is essential to continue the efforts to harmonise emergency planning between the European countries. Such an accident occurring in a European country would most probably affect several countries, thus strengthening the need for coordination between these countries (see points 2.2.1 and 2.2.2). See *Contrôle magazine* No. 201 on *www.asn.fr*.

DIAGRAM 1: Major nuclear or radiological accident national response plan



- The Prefect informs the mayors of the existing risks, verifies the legality of the steps taken by the local authorities and may impose institutional controls as necessary.

ASN supplies technical data in order to characterise the risk, and offers the Prefect its assistance in the urban development control process.

The current approach for controlling activities around nuclear facilities exclusively concerns those subject to a PPI and primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation. It focuses on the "reflex" zones of the PPIs, established in accordance with the Circular of 10th March 2000 and in which automatic measures to protect the general public are taken in the event of a rapidly developing accident.

A Circular from the Ministry for the Environment dated 17th February 2010 has asked the Prefects to exercise greater vigilance over urban development near nuclear installations. This Circular states that the greatest possible attention must be paid to projects that are sensitive owing to their size, their purpose, or the difficulties they could entail in terms of protection of the general public in the so-called "reflex" zone. ASN is consulted on construction or urban development projects situated within this zone. A pluralistic working group jointly overseen by ASN and the General Directorate for Risk Prevention (DGPR), comprising elected officials and the National Association of Local Information Commissions and Committees (Anccli), drafted a guide in 2011 concerning the control of activities around BNIs, based on the following principles:
- preserve the operational nature of the contingency plans;
- prefer regional development outside the "reflex" zone;
- allow controlled development that meets the needs of the resident population.

Following its public consultation process, this Guide No. 15 was published in the second half of 2016, enabling the principles on which ASN bases its opinions to be made public.

1.3 Organising a collective response

The response by the public authorities to a major nuclear or radiological accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 13th August 2004 on the modernisation of civil protection, makes provision for an updated inventory of risks, an overhaul of operational planning, performance of exercises involving the general public, information and training of the general public, an operational watching brief and alert procedures. Several Decrees implementing this Act, codified in Articles L. 741-1 to L 741-32 of the Domestic Security Code, more specifically concerning the ORSEC plans and PPIs, clarified it in 2005.

How radiological emergency situations are dealt with is specified in the Interministerial Directive of 7th April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see diagram 1).

Thus, at the national level, ASN is actively involved in interministerial work on nuclear emergency management.

Following the Fukushima Daiichi accident, considerable thought was given nationally and internationally to consolidating and, as applicable, improving the response organisation of the public authorities. Indeed, this accident showed that it was necessary to improve preparation for the occurrence of a multi-faceted accident (natural disaster, accident affecting several facilities simultaneously). The response organisations thus put into place must be robust and capable of managing a large-scale emergency over a long period of time. Better advance planning must be carried out for work done under ionising radiation and, in order to provide effective support for the country affected, international relations must be improved.

At the international level, ASN is taking part in the experience feedback work being done by international bodies such as the International Atomic Energy Agency (IAEA), the OECD's Nuclear Energy Agency (NEA) and within regulatory authority networks such as the Western European Nuclear Regulators Association (WENRA) or the Heads of the European Radiological protection Competent Authorities (HERCA) (see point 2.2.2).

1.3.1 Local response organisation

In an emergency situation, several parties have the authority to take decisions

- The licensee of the affected nuclear facilities deploys the response organisation and the resources defined in its PUI (see point 1.1.1).
- ASN has a duty to monitor the licensee's actions in terms of nuclear safety and radiation protection. In an emergency situation, aided by IRSN's assessments, it can at any time ask the licensee to perform assessments and take the necessary actions.
- The Prefect of the *département* in which the installation is located takes the necessary decisions to protect the population, the environment and the property threatened by the accident. He or she takes action according to the PPI and the ORSEC plans. The Prefect is thus responsible for coordinating the resources - both public and private, human and material - deployed in the plan. The Prefect keeps the population and the mayors informed of events. More specifically through its regional division, ASN assists the Prefect in managing the situation.
- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring consistency between *départements* of the steps taken and for coordinating regional communication with national communication.
- Owing to his or her role in the local community, the mayor has an important part to play in anticipating and supporting the measures to protect the population. To this end, the mayor of a town included within the scope of application of an Off-site Emergency Plan (PPI) must draw up and implement a local safeguard plan to provide for, organise and structure the measures to accompany the Prefect's decisions. The mayor also plays a role in passing on information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.3.2 National response organisation

In a radiological emergency situation, each Minister - together with the decentralised State services – is responsible for preparing and executing national level measures within their field of competence.

In the event of a major crisis requiring the coordination of numerous players, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with the activation of the Interministerial Crisis Committee (CIC). The purpose of this Committee is to centralise and analyse information in order to prepare the strategic decisions and coordinate their implementation at interministerial level. It comprises:

- all the ministries concerned;
- the competent safety regulator and its technical support organisation (IRSN);
- representatives of the licensee;
- administrations or public institutions providing assistance, such as *Météo-France (national weather service)*.

1.4 Protecting the population

The steps to protect the populations during the emergency phase, as well as the initial actions as part of the post-accident phase, aim to protect the population from exposure to ionising radiation and to any chemical and toxic substances that may be present in the releases. These measures are mentioned in the PPIs.

1.4.1 General protective actions

In the event of a major nuclear or radiological accident, a number of measures can be envisaged by the Prefect in order to protect the population:

- sheltering and awaiting instructions: the individuals concerned, alerted by a siren, take shelter at home or in a building, with all openings closed, and wait for instructions from the Prefect broadcast by radio;
- administration of stable iodine tablets: when ordered by the Prefect, the individuals liable to be exposed to releases of radioactive iodine are urged to take the prescribed dose of iodine tablets;
- evacuation: in the event of a risk of large-scale radioactive releases, the Prefect may order evacuation. The populations concerned are asked to prepare a bag of essential personal effects, secure and leave their homes and go to the nearest assembly point.

The Prefect may also take measures to ban the consumption of foodstuffs liable to have been contaminated by radioactive substances as of the emergency phase (before the facility has been restored to a controlled and stable state).

The dose levels triggering implementation of population protection measures in a radiological emergency situation are defined by ASN resolution 2009-DC-0153 of 18th August 2009:

- an effective dose of 10 millisieverts (mSv) for sheltering;
- an effective dose of 50 mSv for evacuation;
- an equivalent dose to the thyroid of 50 mSv for the administration of stable iodine.

The predicted doses are those that it is assumed will be received until releases into the environment are brought under control, generally calculated over a period of 24 hours for a one year old child (age at which sensitivity to ionising radiation is highest) exposed to the releases.

In the event of the release of radioactive substances into the environment, measures are decided on to prepare for management of the post-accident phase; they are based on the definition of area zoning to be implemented as of the end of the releases on exiting the emergency phase and including:

- a Population Protection Zone (ZPP) within which action is required to reduce both the exposure of the populations to ambient radioactivity and the consumption of contaminated food, as far as is reasonably possible (for example a ban on consumption of produce from the garden, restriction on access to wooded areas, ventilation and cleaning of homes, etc.);
- a Heightened Territorial Surveillance Zone (ZST), which is larger and which is more concerned with the economic management of the area, within which specific surveillance of foodstuffs and agricultural produce will be set up;
- if necessary, an evacuation perimeter is created within the ZPP, defined according to the ambient radioactivity (external exposure); the residents must be evacuated for a varying length of time depending on the level of exposure in their environment.

1.4.2 The provision of iodine tablets

Administering stable iodine tablets is a means of saturating the thyroid gland and protecting against the carcinogenic effects of radioactive iodines.

The Circular of 27th May 2009 defines the principles governing the respective responsibilities of a BNI licensee and of the State with regard to the distribution of iodine tablets. The licensee is responsible for the safety of its facilities. This Circular requires that the licensee finance the public information campaigns within the perimeter of the PPI and carry out permanent preventive distribution of the stable iodine tablets, free of charge, through the network of pharmacies.

In 2016, a new national distribution campaign for iodine tablets, supervised by ASN, was launched for the populations located within the zone covered by the PPIs around the NPPs operated by EDF (see chapter 6).

Outside the zone covered by a PPI, tablets are stockpiled to cover the rest of the country. In this respect, the Ministries for Health and for the Interior decided to create stocks of iodine tablets, positioned and managed by Santé Publique France (more particularly including the Health Emergency Preparedness and Response Organisation). In their *département*, each Prefect organises the procedures for distribution to the population, relying in particular on the mayors for this. This arrangement is described in a Circular of 11th July 2011. Pursuant to this Circular, the Prefects have drawn up plans to distribute stable iodine tablets in a radiological emergency situation, which can be included in exercises being held for the local implementation of the major nuclear or radiological accident national response plan.

1.4.3 Care and treatment of exposed persons

In the event of a radiological emergency situation, a significant number of people could be contaminated by radionuclides. These persons shall be cared for by the emergency response teams duly trained and equipped for this type of operation.

Circular 800/SGDN/PSE/PPS of 18th February 2011 specifies the national doctrine concerning the use of emergency and care resources in the event of a terrorist act involving radioactive substances. These provisions, which also apply to a nuclear or radiological accident, aim to implement a unified nationwide methodology for the use of resources, in order to optimise efficiency.

The *"Medical intervention following a nuclear or radiological event"* Guide, the drafting of which was coordinated by ASN and which was published in 2008, accompanies Circular DHOS/HFD/DGSNR No. 2002/277 of 2nd May 2002 concerning the organisation of medical care in the event of a nuclear or radiological accident, giving all the information of use for the medical response teams in charge of collecting and transporting the injured, as well as for the hospital staff. Under the aegis of the General Secretariat for Defence and National Security (SGDSN), a new version of this guide taking account of changes to certain practices, is currently under preparation.

1.5 Understanding the long-term consequences

The "post-accident" phase concerns the handling over a period of time of the consequences of long-term contamination of the environment by radioactive substances following a nuclear accident. It covers the handling of consequences that are varied (economic, health, social), by their nature complex and that need to be dealt with in the short, medium or even long term, with a view to returning to a situation considered to be acceptable.

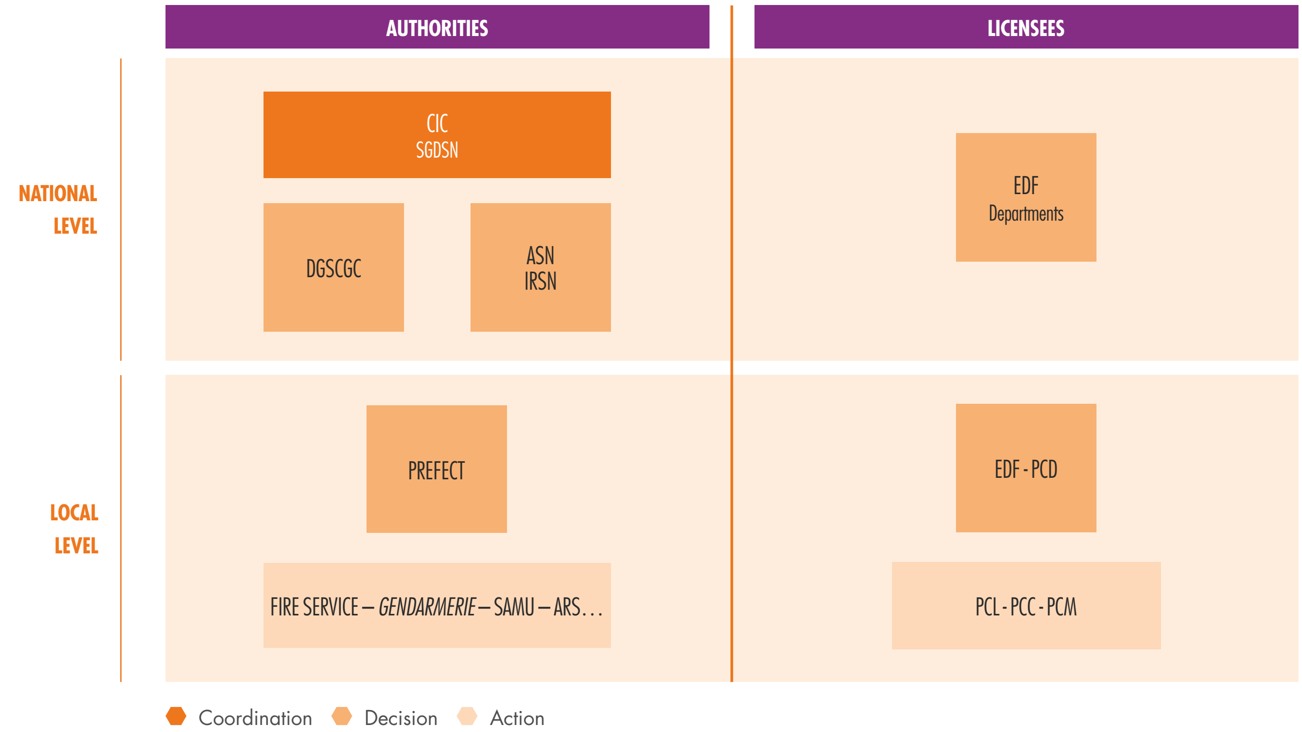
The conditions for reimbursement for the damage resulting from a nuclear accident are currently covered by Act 68-943 of 30th October 1968, amended, concerning civil liability in the field of nuclear energy. France has also ratified the protocols signed on 12th February 2004, reinforcing the Paris Convention of 29th July 1960 and the Brussels Convention of 31st January 1963 concerning civil liability in the field of nuclear energy. These protocols and the measures necessary for their implementation are codified in the Environment Code (Section I of Chapter VII of Title IX of Book V). These provisions and the new liability thresholds set by the two protocols entered into force in February 2016, pursuant to the 17th August 2015 Energy Transition for Green Growth Act (TECV Act). An Order of 19th August 2016 sets the list of sites with more limited risks which benefit from a reduced liability amount.

Pursuant to the Interministerial Directive of 7th April 2005, and in association with the ministerial departments involved, ASN was tasked with establishing the framework and with defining, preparing and participating in the implementation of the necessary provisions for the response to post-accident situations following a nuclear accident. In order to draw up the corresponding aspects of doctrine, ASN created the Steering Committee for the management of the Post-Accident Phase of a nuclear accident or radiological situation (Codirpa) in June 2005 and for which it acts as Chair and Technical Secretary. The ASN mandate was updated in a letter from the Prime Minister dated 29th October 2014.

Numerous elements of the doctrine drawn up by the Codirpa were incorporated into the major nuclear or radiological accident national response plan, disseminated in January 2014, such as post-accident zoning (see point 1.4.1).

The Codirpa is currently continuing with work to take account of the lessons learned from the post-accident management carried out in Japan following the Fukushima Daiichi disaster, but also experience feedback from emergency exercises. A new working group was set up in 2015 on waste management in a post-accident situation, involving members from Codirpa and from the French National Radioactive Material and Waste Management Plan (PNGMDR). Finally, work on the management of manufactured products, water and marine environments will be started in 2017.

DIAGRAM 2: Emergency response organisation in an accident situation affecting a nuclear reactor operated by EDF



CIC: French Inter-ministerial Crisis Committee
SGDSN: General Secretariat for Defence and National Security
DGSCGC: General Directorate for Civil Protection and Crisis management (Ministry of the Interior)
PCD: Command and Decision Post
PCL: Local Command Post
PCC: Supervision Command Post
PCM: Resources Command Post

ASN participation in the CIC strategic decision unit during an emergency exercise.

2. Acting in emergency and post-accident situations

The emergency and contingency plans require intervention by many players, whose respective roles and duties must be clearly identified, as must the way they interact, to ensure correct coordination. The organisation of each of the players involved in the State's response to a radiological emergency situation, and the way they interact, are essential to the correct management of this type of situation. The roles and organisation of ASN in an emergency situation are thus precisely defined. The coordination with the international authorities is also essential, both bilaterally and internationally.

2.1 Organising to handle four essential duties

2.1.1 ASN roles and duties

In an emergency situation, the responsibilities of ASN, with the support of IRSN, are as follows:

- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

Checking the steps taken by the licensee

As in a normal situation, ASN exercises its roles as the regulatory authority in an accident situation. In this particular context, ASN ensures that the licensee exercises in full its responsibility for keeping the accident under control, mitigating the consequences, and rapidly and regularly informing the public authorities. It draws on IRSN's expertise and assessments and can at any time ask the licensee to perform appraisals and take the necessary actions, without however taking the place of the licensee in the technical operations.

Advising the* département *and zone Prefects and the Government

The decision by the Prefect concerning the general public protection measures to be taken in radiological emergency and post-accident situations depends on the actual or foreseeable consequences of the accident around the site. The law states that it is up to ASN to make recommendations to the Prefect and the Government, incorporating the analysis carried out by IRSN. This analysis covers both a diagnosis of the situation (understanding of the situation of the installation affected, analysis of the consequences for humans and the environment) and a prognosis (assessment of possible developments, notably radioactive releases). These recommendations more specifically concern the steps to be taken to protect the population in the emergency and post-accident phases.

Circulation of information

ASN is involved in informing:

- the media and the public: publication of press releases and organisation of press conferences; it is important

that this action be carried out in close coordination with the other entities required to communicate (Prefects, licensees at both local and national levels, etc.);
- institutional and associative stakeholders: local authorities, ministries, offices of the Prefect, political authorities, general directorates of administrations, Anccli, CLI, etc.;
- foreign nuclear safety Regulators.

Function of Competent Authority as defined by International Conventions

The Environment Code provides for ASN to fulfil the role of Competent Authority under the International Conventions on Early Notification and Assistance. As such it collates and summarises information for the purpose of sending or receiving notifications and for transmitting the information required by these Conventions to the international organisations (IAEA and European Union) and to the countries possibly affected by radiological consequences on their own territory, jointly with the ministry for foreign affairs.

2.1.2 Organisation of ASN

Organising the response to accidents occurring in BNIs

The ASN emergency response organisation set up to deal with a nuclear accident in a BNI more specifically comprises:
- the participation of ASN staff in the various units of the CIC;
- at the national level, an emergency centre in Montrouge, consisting of three Command Posts (PC):
  - a "Strategy" Command Post, consisting of the ASN Commission, which, in an emergency situation could be called on to issue resolutions and impose prescriptions on the licensee of the installation concerned;
  - a Technical Command Post (PCT) in constant contact with its technical support organisation, IRSN, and with the ASN Commission. Its role is to adopt a stance for advising the Prefect, who acts as the director of emergency response operations;
  - a Communication Command Post (PCC), located close to the Technical Command Post. The ASN Chairman or his/her representative acts as spokesperson, a role which is distinct from that of the head of the Technical Command Post.

This emergency centre is regularly tested during national emergency exercises and is activated for actual incidents or accidents. At the local level, ASN representatives visit the *département* and zone Prefects to help them with their decisions and their communication actions. ASN inspectors may also go to the site affected; others take

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Transport of radioactive substances exercises in 2016: a new format

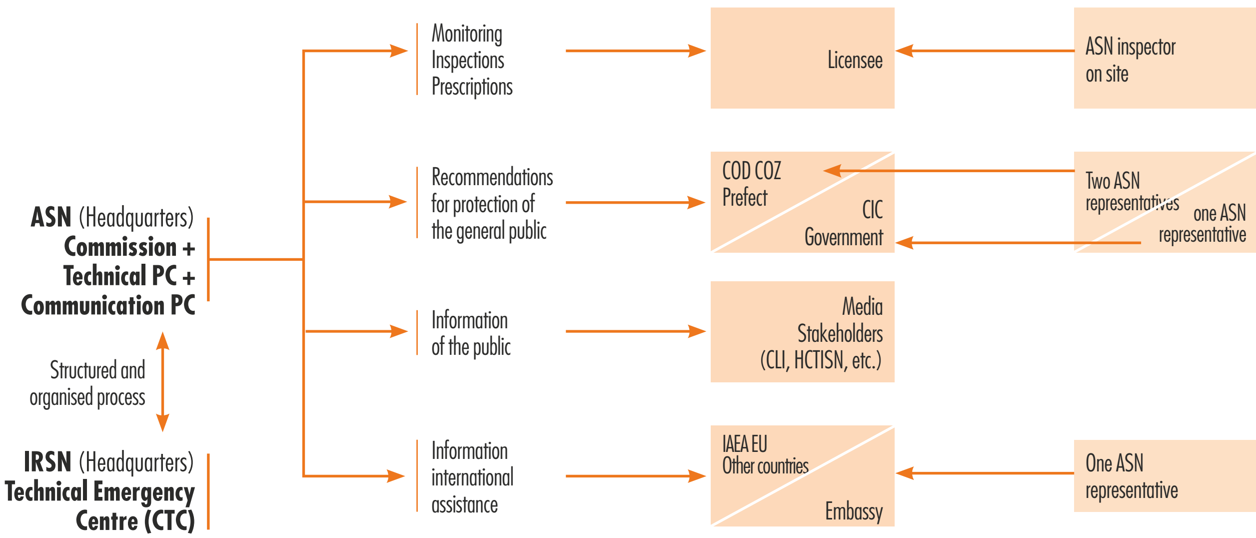
A new format for national exercises concerning a radioactive substances transport accident (nuclear fuel, waste, etc.) was trialled in 2016 in order to test the extent to which the *départements* not containing a BNI have assimilated the major nuclear or radiological accident national response plan. Three exercises of this type, based on similar scenarios and lasting half a day, were held in 2016 in the Doubs, Landes and Alpes-Maritimes *départements*. Although they did enable the objective set to be reached, it would appear difficult to train all French *départements* in this way. At the same time, ASN, IRSN and the Ministry for the Interior worked on the design of a local exercise kit concerning an accident involving the transport of radionuclides used in the hospital or industrial sector, in the form of sealed sources. As the consequences of this type of accident are more limited, situations such as these would be managed locally. This kit could enable many *départements*, in particular those in which there are no BNIs, to carry out local exercises.

TABLE 1: Positions of the various players in a radiological emergency situation

	DECISION	EXPERT APPRAISAL	INTERVENTION	COMMUNICATION
Authorities	Government (CIC) Prefect (COD, COZ)	/	Prefect (PCO) Civil protection	Government (CIC) COD Prefect
	ASN (PCT)	IRSN (CTC) *Météo-France*	IRSN (mobile units)	ASN IRSN
Licensees	National and local level	National and local level	Local level	National and local level

CIC: French Inter-ministerial Crisis Committee - COD: Departmental Operations Centre
COZ: Zone Operations Centre - CTC: Technical Emergency Centre
PCO: Operational Command Post - PCT: Technical Command Post

DIAGRAM 3: The role of ASN in a nuclear emergency situation



COD: Departmental Operations Centre
COZ: Zone Operations Centre
CIC: French Inter-ministerial Crisis Committee
CICNR: Inter-ministerial Committee for Nuclear or Radiological Emergencies
CLI: Local Information Committee
HCTISN: High Committee for Transparency and Information on Nuclear Security
PC: Command Post

part in emergency management at the headquarters of the regional division involved.

Experience feedback from the Fukushima Daiichi accident also leads ASN to envisage sending one of its representatives, if necessary, to the French embassy of a country in which an accident occurred.

In 2016, the national emergency centre was activated for seven national exercises and, for the first time, for an exercise on a national defence site, jointly with the Defence Nuclear Safety Regulator (ASND).

Three exercises concerned an accident scenario involving the transport of radioactive substances in *départements* in which there is no BNI. The national exercise on 20th and 21st September 2016 on the Areva site at La Hague was combined with the SECNUC 2016 major governmental exercise and involved activation of the Interministerial Crisis Committee (CIC).

In 2016, no real event led to activation of the national emergency centre.

During exercises, or in the event of a real emergency, ASN is supported by an analysis team located at IRSN's Technical Emergency Centre (CTC).

ASN's alert system allows mobilisation of its emergency centre staff and those of the IRSN. This automatic system sends an alert signal to the staff equipped with appropriate reception devices, as soon as it is remotely triggered by the BNI licensee originating the alert. It also sends the alert to the staff of the SGDSN, the DGSCGC, the Interministerial Emergency Management Operations Centre (Cogic), *Météo-France* and the ministerial operational monitoring and alert centre of the Ministry of the Environment, Energy and the Sea (MEEM).

The severity of the situation is evaluated by the various parties, who if necessary decide to activate their emergency management centres to manage the situation.

In 2016, the legal framework for implementing an on-call duty system at ASN was defined, jointly with the MEEM. An on-call system will enhance the robustness and efficiency of the staff rapid mobilisation system.

Diagram 3 summarises the role of ASN in a radiological emergency situation. This functional diagram illustrates the importance of the ASN representative to the Prefect, who relays and explains the recommendations coming from the ASN emergency centre.

Table 1 shows the positions of the public authorities (Government, ASN and technical experts) and the licensees in a radiological emergency situation. These players each operate in their respective fields of competence with regard to assessment, decision-making, intervention and communication, for which regular audio-conferences are held. The exchanges between the players lead to decisions and orientations concerning the safety of the facility and the protection of the general public. Similarly, relations between the communication units and the spokespersons of the emergency centres ensure that the public and media are given coherent information.

Organising a response to any other radiological emergency situation

A radiological emergency toll-free telephone number (0 800 804 135) enables ASN to receive calls notifying incidents involving sources of ionising radiation used outside BNIs or during the transport of radioactive substances. It is accessible 24 hours a day, 7 days a week. The information given during the call is transmitted to the locally competent division or to the ASN duty staff outside working hours. Depending on the seriousness of the incident, ASN may decide to activate its emergency centre in Montrouge. If not, only the ASN local level (regional division concerned) intervenes to perform its Prefect support and communication duties, if necessary calling on the expertise of the national departments. In order to enhance the graduated nature of the ASN response and organisation in the event of an emergency, for situations not warranting activation of the emergency centre, the system has been adapted for the creation of a national level support unit to assist the regional division concerned. The format and duties of this unit are tailored to each situation.

Once the public authorities have been alerted, the response generally consists of four main phases: care for the individuals involved, confirmation of the radiological nature of the incident, securing the zone and reducing the emission and, finally, clean-up.

The Prefect or the mayor coordinates the intervention response teams, taking account of their technical competence, and decides on the protective measures to be taken, on the basis of the plans they have drawn up (ORSEC for the Prefects, Local Safeguard Plans for the mayors). At the local level, the Prefects and the mayors can also call on the Mobile Radiological Intervention Units (CMIR) of the fire and emergency services.

In these situations, responsibility for the decision and for implementing protective measures lies with:
- the head of the establishment carrying out a nuclear activity (hospital, research laboratory, etc.) who implements the On-site Emergency Plan specified in Article L. 1333-6 of the Public Health Code (if the risks inherent to the installation so justify) or the owner of the site with regard to the safety of the persons on the site;
- the mayor or Prefect concerning public safety in the domain accessible to the public (in particular in the case of a radioactive substances transport incident).

2.2 ASN international duties

Considering the potential repercussions that an accident may have in other countries, it is important that the information and intervention of the various countries concerned be as well-coordinated as possible. To this end, IAEA and the European Commission offer the Member States tools for notification and assistance in the event of a radiological emergency. ASN made an active contribution to the production of these tools, more specifically the new IAEA tool called USIE (Unified System for Information Exchange in Incidents and Emergencies), which is present in ASN's emergency centre and is tested on the occasion of each exercise.

Independently of any bilateral agreements on the exchange of information in the event of an incident or accident with possible radiological consequences, France is committed to applying the Convention on Early Notification of a Nuclear Accident adopted on 26th September 1986 by IAEA and the Euratom Decision of 14th December 1987 concerning Community procedures for an early exchange of information in the event of a radiological emergency situation. On 26th September 1986, France also signed the convention adopted by IAEA concerning assistance in the event of a nuclear accident or a radiological emergency situation.

Two Interministerial Directives of 30th May 2005 and 30th November 2005 specify the procedures for application of these texts in France and instate ASN as the Competent National Authority. It is therefore up to ASN to notify the events without delay to the international institutions, to rapidly provide the pertinent information about the situation, in particular to border countries, to enable them to take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

HERCA/WENRA Workshop in Bled, Slovenia, June 2016.

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The HERCA/WENRA approach

During their joint meeting in 2014, the HERCA and WENRA associations adopted a joint position aiming to improve cross-border coordination of protection measures during the first phase of a nuclear accident. The position of HERCA and WENRA aims, in the event of an accident, to promote the rapid transmission of information between the countries concerned and the consistency of the population protection recommendations issued by the radiation protection and nuclear safety Authorities.

The approach thus recommends the following:
- outside emergency situations, exchanges between countries to promote Improved mutual familiarity with and understanding of their emergency organisations;
- in emergency situations:
  - If the emergency organisations receive sufficient information to function normally: during the first hours of an emergency situation, attempts are made to align the population protection measures in neighbouring countries with those decided on by the country in which the accident occurred.
  - In the event of a highly improbable situation which would require urgent measures to protect the population but in which very little information is available, predetermined "reflex" measures are defined.

In order to implement these principles, a minimum harmonised level of preparation is necessary. HERCA and WENRA thus consider that in Europe:
- evacuation should be prepared up to 5 km around nuclear power plants, and sheltering and ingestion of Iodine Thyroid Blocking (ITB) tablets up to 20 km;
- a general strategy should be defined in order to be able to extend evacuation up to 20 km, and sheltering and ingestion of ITB tablets up to 100 km.

On 14th and 15th June 2016, a seminar was held by the HERCA and WENRA associations in Bled (Slovenia) on the implementation of the HERCA/WENRA approach. Its main aim was to bring together representatives of nuclear safety and radiation protection authorities and civil protection representatives. Nearly 80 participants from 23 European countries discussed the deployment of communication and information channels that are essential for building trust and adopting a harmonised approach during the first few hours of an accident. The participants also identified related cooperation subjects, such as protection of the food chain or extension of protection measures beyond the predetermined perimeters. At a more practical level, the participants identified border areas where NPPs are located and for which the implementation of this approach should be given priority. The results of this seminar were presented to ENSREG in the autumn of 2016.

2.2.1 Bilateral relations

Maintaining and strengthening bilateral relations with neighbouring and other European countries is one of ASN's priorities.

In 2016, ASN thus continued regular exchanges with its European counterparts concerning the harmonisation of emergency management. Experience feedback from the Fukushima Daiichi accident and the steps taken since then in each country, were at the heart of the discussions. Finally, in 2016, protocols concerning cross-border alert mechanisms and information exchanges in an emergency situation were signed with Spain and Italy.

ASN is continuing to develop bilateral relations in emergency management with many countries, Spain, Luxembourg, Germany, Switzerland and Belgium in particular. Meetings specifically dedicated to emergency management were in particular held in 2016 with these five countries. Chinese, Norwegian, Belarusian and Japanese delegations also visited ASN in 2016 to discuss emergency situation management and took this opportunity to visit the ASN emergency centre. The Chinese, Norwegian and Belarusian delegations also took part in a national emergency exercise at ASN, as observers.

2.2.2 Multilateral relations

The Fukushima Daiichi accident occupied a substantial amount of time of many of the ASN and IRSN staff, even though it was a remote accident for which the radiological consequences in France would appear to be limited. In addition, ASN's actions were also limited, because it is not its responsibility to monitor the actions of the Japanese licensee.

This accident highlighted the problems that would be encountered by ASN, IRSN, but also their European counterparts, in managing a large-scale accident in Europe. The nuclear safety regulators confirmed the need for mutual assistance mechanisms and have already undertaken international work to improve their response organisations.

ASN takes part in IAEA's work to improve notification and information exchanges in radiological emergency situations. It is helping to define international assistance strategy, requirements and resources and to develop the Response and Assistance Network (RANET).

In addition to the four traditional committees which draft its safety standards, IAEA created a new committee in 2015 called EPReSC (Emergency Preparedness and Response Standards Committee), to deal with emergency situations. The standards in this field had hitherto been monitored by the other existing committees. The document at the top of the standards hierarchy in this field is GSR Part 7, published in November 2015. Three committee meetings, at which ASN represented France, were held in 2016.

ASN also collaborates with the NEA, under whose supervision it organised the INEX 5 exercise in 2016 (with the participation of the various French emergency management players) and takes part in the Working Party on Nuclear Emergency Matters (WPNEM).

At the European level, ASN is a participant in the "Emergencies" working group reporting to the Heads of European Radiological protection Competent Authorities Association (HERCA). It also acts as secretary. This group is tasked with proposing harmonised European actions to protect the general public, on the one hand in the event of an accident in Europe and, on the other, in the event of a more remote accident, in the light of the lessons learned from the Fukushima Daiichi accident. This group comprises members appointed by the Western European Nuclear Regulators Association (WENRA).

2.2.3 International assistance

The Interministerial Directive of 30th November 2005 defines the procedures for international assistance when France is called on or when it requires assistance itself in the event of a radiological emergency situation. For each Ministry, it contains an obligation to keep an up-to-date inventory of its intervention capability in terms of experts, equipment, materials and medical resources, which must be forwarded to ASN. As coordinator of the national assistance resources (RANET database), ASN takes part in IAEA's work on the operational implementation of international assistance.

France has been called upon several times since 2008 to assist a foreign country in a radiological emergency situation. For example, ASN has been contacted regularly in recent years for assistance requests concerning persons accidentally exposed to high-level radioactive sources.

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Observation of the nuclear emergency exercise at the Tomari NPP in Japan – November 2016

At the invitation of its Japanese counterpart (NRA), ASN observed a national emergency exercise in November 2016 on the site of the Tomari NPP (Hokkaido, Japan) which mobilised more than a hundred participants. About twenty foreign observers from five countries (United States, Canada, South Korea, Taiwan and France) and representatives from two international organisations (NEA and IAEA) were present. The Prime Minister of Japan, Shinzo Abe, took part in the exercise. A number of population protection measures, more specifically evacuation and sheltering of persons requiring assistance, were implemented with the assistance of volunteer residents.

Observation of an exercise in the emergency centre of the Tomari NPP (Hokkaido, Japan), November 2016.

3. Learning from experience

3.1 Carrying out exercises

The main aim of these nuclear and radiological emergency exercises is to test the planned response in the event of a radiological emergency in order:
- to ensure that the plans are kept up to date, that they are well-known to those in charge and to the participants at all levels and that the alert and coordination procedures they contain are effective;
- to train those who would be involved in such a situation;
- to implement the various aspects of the organisation and the procedures set out in the Interministerial Directives: the emergency plans, the contingency plans, the local safeguard plans and the various conventions;
- to develop a general public information and awareness approach so that everyone can, through their own individual behaviour, make a more effective contribution to civil protection;
- to build on emergency situation management knowledge and experience.

These exercises, which are the subject of an annual Interministerial review, involve the licensee, the Ministries, the offices of the Prefect and services of the *départements*, ASN, ASND, IRSN and *Météo-France*, which can represent up to 300 people when resources are deployed in the field. They aim to test the effectiveness of the provisions made for assessing the situation, the ability to bring the installation or the package to a safe condition, to take appropriate measures to protect the general public and to ensure satisfactory communication with the media and the populations concerned.

3.1.1 National nuclear and radiological emergency exercises

In the same way as in previous years, and together with the SGDSN, the DGSCGC and the ASND, ASN has prepared a programme of national nuclear and radiological emergency exercises for 2016, concerning BNIs and RMT operations. This programme, announced to the Prefects in the Interministerial Circular of 22nd December 2016, took account of the lessons learned from Fukushima Daiichi and the emergency exercises performed in 2015.

Generally speaking, these exercises enable the highest-level decision-making circles to be tested, along with the ability of the leading players to communicate, sometimes with simulated media pressure on them.

Table 2 describes the key characteristics of the national exercises conducted in 2016.

In addition to the national exercises, the Prefects are asked to conduct local exercises with the sites in their *département*, in order to improve preparedness for radiological emergency situations and more specifically to test the time needed to mobilise all the parties concerned.

The performance of a national nuclear and radiological emergency exercise, at maximum intervals of five years on the nuclear sites covered by a PPI, and at least one annual exercise concerning RMT, would seem to be a fair compromise between the training of individuals and the time needed to effect changes to organisations.

For 2016, the objectives chosen in the annual Circular of 22nd December 2016 concerning the national nuclear or radiological emergency exercises were:
- test the regional implementation of the national plan for response to a major nuclear or radiological accident, in particular in *départements* which do not contain a nuclear facility;
- test the ability of the entities involved to prepare input for the interministerial emergency management level, jointly with the major nuclear or radiological accident national response plan, within the framework of the SECNUC exercise;
- involve civil society in preparation of the exercises;
- systematically simulate the scheduled exchanges with IAEA and the European Union during exercises which so warrant, and make provision for an exercise in which these exchanges are actually carried out, with the approval of the Ministry for Foreign Affairs and International Development.

On the nuclear safety aspects, the various players focused on:
- carrying out most of the exercises concerning facilities in real meteorological conditions;
- testing the emergency response organisation in situations involving several facilities simultaneously.

On aspects relating to civil security, the players focused on:
- preparing the offices of the Prefects for implementing public protection measures or post-accident actions, by following up slow-development accident exercises with a phase focusing on civil protection;
- involving the Prefects of the defence and security zones in certain exercises.

ASN is also heavily involved in the preparation and performance of other emergency exercises that have a nuclear safety component and are organised by other players such as:
- its counterparts for nuclear security (Defence and Security High Official reporting to the Minister for the Environment) or for defence-related facilities (ASND);
- international bodies (IAEA, European Commission, NEA);
- the Ministries (Health, Interior, etc.).

With regard to defence-related facilities, three exercises run by the ASND were organised during the course of 2016, in accordance with the Interministerial Circular on nuclear and radiological emergency exercises. For one of them, ASN activated its emergency centre to support ASND in accordance with the ASN/ASND protocol of 26th October 2009.

TABLE 2: National civil nuclear and radiological emergency exercises conducted in 2016

NUCLEAR SITE	DATE OF THE EXERCISE	MAIN CHARACTERISTICS
Transport of radioactive substances (Doubs, Landes, Alpes-Maritimes)	8th March 22nd March 31st May	Management of a nuclear emergency by a *département* without BNI, media pressure, interfaces between office of Prefect and national stakeholders
Areva La Hague site (SECNUC)	20th and 21st September	Interaction between the national response plan and the national emergency organisation (CIC); inter-sector problems for existing emergency phase and post-accident management; coordinated governmental communication; international dimension
Paluel NPP	18th October	Decision-making process, media pressure
Blayais NPP	23rd November	Decision-making process, media pressure
Cruas NPP	13th December	Decision-making process

Pursuant to this ASN/ASND protocol, ASN takes part in some of these exercises:
- at the national level, ASN advises the ASND on aspects concerning the impact of releases on the environment and on preparation for post-accident management of the emergency;
- at the local level, a representative of the ASN regional division concerned goes to the office of the Prefect to advise the Prefect pending the arrival of the ASND representative.

The experience acquired during these many exercises enables ASN personnel to respond more effectively in real emergency situations.

3.2 Assessing with a view to improvement

Evaluation meetings are organised immediately after each exercise in each emergency centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:
- the importance of having scenarios that were as realistic as possible, in real meteorological conditions and that were technically complex enough to be able to provide useful experience feedback;
- the importance of communication in an emergency situation, in particular to inform the public and foreign authorities as rapidly as possible and avoid the spread of rumours liable to hamper good emergency management, in France and in other countries;
- the importance of providing the decision-makers with a clear view of the radiological impacts in the form of maps: the tool called Criter developed by IRSN gives a representation of the results of environmental radioactivity measurements.

At the end of 2016, ASN brought all the players together to review best practices to improve the response organisation as a whole.

In 2016, in the light of experience feedback from emergency exercises and actual emergency situations, ASN made it possible for BNIs not concerned by a PPI to trigger its general alert system in the event of an emergency.

4. Outlook

In accordance with the nuclear emergency duties entrusted to it by the Environment Code, ASN makes an active contribution to the review process currently being carried out by the public authorities following the Fukushima Daiichi accident, with the aim of improving the national radiological emergency organisation.

ASN thus participates in the work to implement the major nuclear or radiological accident national response plan and in particular calls on the assistance of the Ministry of the Interior and the offices of the Prefects following the publication of the regional implementation guide. This regional implementation will continue to be tested in 2017 during exercises, in particular in those *départements* in which there is no BNI.

Following the Government's September 2016 adoption of the principle of extending the radius of the PPI perimeter around NPPs from 10 to 20 km, the preparation of immediate evacuation over 5 km and the pre-distribution of stable iodine tablets up to 20 km, ASN will in 2017 contribute to the PPI update work done by the offices of the Prefects and to the new population information and iodine tablets distribution campaign for inhabitants in the zone between 10 and 20 km from the NPPs.

In 2017, ASN will continue to be actively involved in the work on the roadmap for the major nuclear or radiological accident national response plan, in particular with regard to the PPI perimeters for BNIs other than NPPs.

One of the priority actions for 2017 will be to make progress with setting up an on-call duty team at ASN.

The nuclear safety Authorities confirmed the need to continue with international work to improve the coordination of the respective approaches by each country in an emergency situation. In 2017, ASN will continue with the European initiatives taken with a view to harmonisation of actions to protect populations in an emergency situation on either side of a border and to develop a coordinated response by the safety and radiation protection Authorities in the event of a near or remote accident, more specifically as part of the HERCA/WENRA approach. In 2017, ASN will organise an exercise with one or more border countries to test this approach and define joint working documents.

In 2017, in order to prepare the offices of the Prefects for the performance of public protection measures or post-accident actions, certain exercises will be followed up by a phase focusing on civil security objectives.

Finally, in 2017, ASN will complete the drafting of a resolution on the obligations of BNI licensees relative to the preparation for and management of emergency situations and the content of the on-site emergency plan, aiming to clarify the provisions of Title VII of the Order of 7th February 2012 setting the general rules for BNIs.

06

Informing the public and other audiences

Nearly ten years after enacting the Act of 13th June 2006 relative to Transparency and Security in the Nuclear field (TSN Act), the Act of 17th August 2015 relative to Energy Transition for Green Growth (TECV Act) steps up the provisions with regard to transparency. This Act explicitly sets out the role of ASN in producing its annual *report on the state of nuclear safety and radiation protection in France*. The Act also includes a set of provisions relating to the Local Information Committees (CLI) of the Basic Nuclear Installations (BNI), including the organising of a public meeting by the CLIs at least once a year.

In 2016, ASN continued its work to promote the nuclear risk culture during the iodine tablet distribution campaign for populations living near nuclear power plants and by developing the itinerary of the ASN-IRSN road show.

ASN informs the general public, the media, institutional audiences and professionals of its activity. It publishes its resolutions and position statements on its website. Each year it presents its *report on the state of nuclear safety and radiation protection in France* to Parliament.

ASN also encourages the involvement of civil society in nuclear safety and radiation protection and gathers the comments of stakeholders and the public on its draft resolutions, in particular via its website at *www.asn.fr*.

1. Developing relations between ASN and the public

1.1 Opening to the public at large and development of a "risk awareness culture" among citizens

ASN wishes to develop a "nuclear risk awareness culture" by fostering the involvement of citizens in the subjects relating to nuclear safety and radiation protection. ASN uses several means of communication to achieve this.

1.1.1 The website - *www.asn.fr*

ASN's main vector for informing the public is its website at *www.asn.fr*, which gives the various audiences access to information. Links to documents relating to oversight (incident notices, inspection follow-up letters, position statement letters, reactor outage notices) are available alongside the ASN opinions and resolutions, information notices and publications, educational content, as well as public consultations on its draft resolutions. The website also has sections dedicated to professionals (see point 1.2). The creation in 2016 of a section devoted to the irregularities detected in products manufactured in the Creusot Forge plant of Areva NP is noteworthy.

The published information is sometimes accompanied by computer graphics and videos. In 2016, three educational films devoted to radiation protection, the management of radioactive waste and the 5th iodine tablet distribution campaign were added to the *"Let's talk about nuclear safety and radiation protection"* collection, which aims at popularising the technical and/or regulatory aspects of the major nuclear safety and radiation protection issues. ASN has moreover posted on line a film of an inspection in the medical field conducted in a major medical imaging centre of the Paris region.

Developing the image - technical computer graphics, educational videos, video recordings of hearings and press conferences – is more generally part of the strong development of communication to the public via the social networks (see point 1.1.2).

In order to also inform the international audience, ASN publishes information notices, press releases and a variety of specific content (stress tests, the French National Radioactive Material and Waste Management Plan - PNGMDR, etc.) on the English version of its website - *www.french-nuclear-safety.fr*. These publications support ASN's work in large international organisations and foster a concerted global vision of nuclear safety and radiation protection.

Lastly, approximately every two months ASN sends the *Lettre de l'Autorité de sûreté nucléaire* (Nuclear Safety Authority Newsletter) to its on-line subscribers. This publication provides a summary of the most noteworthy topical issues and information relative to ASN resolutions and actions, including on the international front. The ASN newsletter can be consulted and downloaded from *www.asn.fr* and sent by electronic mail by simply registering on *www.asn.fr*.

1.1.2 The social networks

The content of the ASN website is available on mobile equipment (tablets, smartphones, etc.) and on the main social media. In 2016, ASN used the functions offered by Twitter to foster the widest possible dissemination of its news and information about its actions: parliamentary hearings, public meetings during the iodine tablet distribution campaign, road show exhibition on nuclear safety and radiation protection, etc. Its subscribers - 6,600 at present but growing steadily - are also informed of the events in which the Commission and the Director-General's Office participate.

In 2016 ASN performed "live tweets" during parliamentary hearings and press conferences in particular. The publication and dissemination of the ASN Chairman's verbatim report is of particular interest to the press-which is very active on Twitter - and the stakeholders.

Content from other nuclear safety and radiation protection players (IRSN - Institute of Radiation Protection and Nuclear Safety, Anccli - National association of local information committees and commissions, etc.) and ASN's foreign counterparts has been included in ASN's pages in Facebook. ASN also uses Facebook to keep members of associations and populations living near nuclear installations, for example, informed of events (exhibitions, information meetings, etc.) which are relayed by certain CLIs.

Lastly, ASN has continued to develop its network of users on Dailymotion, YouTube and the professional network LinkedIn.

Use of the social networks in emergency response exercises

Since 2011, the use of two of the most popular social media – Twitter and Facebook – has entered into the range of communication tools tested during emergency response exercises including simulated media pressure. The challenge is to train community managers of the various entities involved in the exercise in appropriate and informed use of such tools, given their ever-increasing appropriation by the general public and organisations alike. A publication platform in addition to press releases, therefore allows the dissemination

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Relations with the French Education Authority

ASN renewed its support of the "Radiation protection workshops" organised by the Nuclear Protection Evaluation Centre and the Franche-Comté *département's "Pavillon des sciences"* science centre which brings together French and European high schools to work on educational projects relating to radiation protection. The Dijon, Lille and Nantes divisions of ASN accompanied high school pupils in their studies on the use of radioactivity in the hospital environment.

Within the framework of its partnership with the IFFO-RME (French Institute of Major Risks and Environmental Protection Instructors), ASN received a group of thirty teachers and educational advisors from the Versailles education authority that led to the deployment of interdisciplinary projects.

Hosting teachers from the Versailles education authority, December 2016.

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Information and iodine tablet distribution campaign 2016

In the event of a nuclear accident, radioactive iodine could be released into the atmosphere. Inhalation or ingestion of radioactive iodine could increase the risk of thyroid cancer. Taking stable iodine tablets before any such release saturates the thyroid with stable iodine, preventing it from fixing radioactive iodine and thereby significantly reducing consequences on health.

The fifth stable iodine distribution campaign launched in 2016 around the EDF nuclear power plants replaced the tablets distributed in 2009 and enhanced the protection culture of the populations living within a 10-kilometre radius of the 19 French nuclear power plants.

To organise this campaign, a pluralistic steering committee led by ASN was set up and brought together representatives of the Ministries of National Education, of the Interior and of Health, IRSN, the Regional Health Agencies, the National Order of Pharmacists, the National Order of Medical Physicians, Anccli, the ARCICEN (Association of Representatives of the Municipalities and Urban Communities in which nuclear power plants are installed) and EDF.

Other civil nuclear facilities could release radioactive iodine in the event of an accident (CIS bio international in Saclay (Essonne *département*) and the Laue-Langevin Institute in Grenoble (Isère *département*)). Outside the zone covered by an Off-site Prevention Plan (PPI), tablets are stockpiled to cover the rest of the country. In this respect, the ministries responsible for health and for the interior decided to constitute the stocks of iodine tablets which are put in place and managed by *Santé publique France* (Public Health France). Each Prefect organises the procedures for distribution to the population in their *département*, relying in particular on the mayors for this. This arrangement is described in a Circular of 11th July 2011.

Developing a risk culture

Beyond the distribution of iodine tablets, the aim is also to raise the awareness of local populations to the nuclear risk and the means of protecting themselves against it. The population is at the centre of this approach because as a last resort, in an emergency situation, it will have to take action to protect itself.

A substantial information campaign was deployed, comprising public meetings, a press campaign, a website (*www.distribution-iode.com*), a toll-free telephone number (0 800 96 00 20), information leaflets and posters. It was relayed by the local actors: the prefectures, municipal councils, health professionals, pharmacies, EDF, ASN regional divisions and the CLIs.

Significant progress in the results

The iodine tablet distribution campaign for 2016 concerned 375,000 households, 55,000 companies and facilities open to the public, and 875 schools in over 500 municipalities.

Vouchers for free iodine tablets to be collected from a pharmacy were sent to all those concerned.

The national rates of iodine tablet collection from pharmacies at the end of December 2016 stood at 51% for households, 36% for companies and facilities open to the public, and 85% for schools. 390,000 boxes of tablets were collected from pharmacies compared with less than 320,000 in 2009, which represents a 22% increase. Compared with 2009, the total number of withdrawals from pharmacies increased by 8% for households (190,000 withdrawals in 2016 versus 175,000 in 2009) for private citizens and was multiplied more than three-fold for facilities open to the public and companies (20,000 withdrawals in 2016 versus 6,250 in 2009).

Continuing population awareness-raising over the long term

In 2017, efforts will be concentrated on schools, companies and facilities open to the public. The objective is to increase the collection rate for facilities open to the public and approach 100% coverage for schools.

Beyond the distribution of iodine tablets, the aim is to heighten awareness in the populations living or working near nuclear power plants of the potential risks and the means of protection against them. The citizens are at the core of this action; consequently they will continue to be reminded of the 6 self-protection reflexes in the event of a nuclear alert. This requires the mobilisation of all the actors: public authorities, elected officials, EDF, health professionals, CLIs, etc.

of concise messages using the microblogging model (Twitter) and direct responses to interpellations or questions from exercise participants who play the role of journalists, members of associations or local inhabitants.

The introduction of social networks into the emergency response exercises now concerns everybody involved in the exercise : the licensee, the public authorities (prefecture, ministries concerned in the case of major exercises, the fire brigade or civil protection forces, etc.), ASN and IRSN. The exercise is effectively the most appropriate means of reflecting in real time on the question of the positioning of each entity, so that in an emergency situation, clear, coherent and ordered communication is disseminated to the widest possible audience.

1.1.3 The ASN/IRSN exhibition

ASN and IRSN have created an educational travelling exhibition on the risks associated with radioactivity, intended for the public at large as well as for schools.

Featuring 80 information boards, its purpose is to inform the citizens about the phenomena associated with radioactivity, whether natural or artificial, its use in nuclear power plants, hospitals and industry, and its effects on humans and the environment.

These themes are illustrated by interactive supporting material, videos and workshops, as well as several educational games (interactive models, digital games), providing tangible learning experiences.

The exhibition is placed at the disposal of the hosting organisations free of charge. Requests to host the exhibition are to be addressed to the ASN information centre (*info@asn.fr*).

More than 35 sites hosted the exhibition in 2016. It was deployed in schools and in the sidelines of emergency response exercises and public meetings of the CLIs provided for by the TECV Act (at Chinon, Chooz, Dampierre-en-Burly, Paluel and Penly). It was also presented at seminars, trade fairs and conferences (CLI conference, for example). More than 5,000 people saw the exhibition in 2016. The exhibition as a whole was also promoted during the meetings of the scientific, technical and industrial centres in Nantes in July 2016.

1.1.4 The ASN Information Centre

The role of the ASN Information Centre is to inform the public on nuclear safety and radiation protection. It has more than 3,000 documents relating to nuclear safety and radiation protection (public inquiry files, impact studies and licensees' annual reports) available for consultation. The public has access to all the ASN publications and can also consult French and international publications produced by various actors.

Synthesized educational information is provided on regularly updated sheets covering the broad themes of nuclear safety and radiation protection, such as: *The transport of radioactive substances; Emergency nuclear situations; The French nuclear fuel cycle*.

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The website *www.mesure-radioactivite.fr* gets a facelift

Since its creation in 2010 by ASN and its technical support organisation IRSN, the website *www.mesure-radioactivite.fr* has made accessible to the public the 300,000 radioactivity measurements taken each year in France in the various compartments of the environment (air, water, soils, fauna and flora) and in food products.

In 2016, the website and its presentation were entirely revamped with, among other things, the creation of a guided mode that enables each visitor to have a better idea of the radioactivity in their near environment.

This "general public" mode gives access to a selection of the 15 types of measurement that are most representative of the radiological status of the environment. The results are commented and accompanied by graphic and contextual benchmarks. (see chapter 4, point 4.4.2).

The general public can also send information requests to the information centre's e-mail address: *info@asn.fr*. In 2016 the Centre responded to nearly 1,500 requests from varied audiences on diverse questions (technical questions, requests for administrative documents, information relative to the environment, publications, and documentary searches).

1.2 ASN and the professionals

ASN produces specific publications, organises and takes part in numerous symposia, seminars and meetings to raise the awareness of professionals to the responsibilities and the implications of radiation protection, to make known the regulations and to encourage the notification of significant events and experience feedback.

1.2.1 Making the regulations known and enhancing the safety culture

ASN considers that having clear regulations based on the best safety standards is an important factor in improving the safety of BNIs. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to BNIs.

ASN guides for concrete application of resolutions

The ASN guides give recommendations, present the means ASN considers appropriate for achieving the objectives set by the regulations, and share methods and good practices resulting from experience feedback from significant events. In 2016 some of the ASN guides underwent substantial updating to take into account the most recent regulatory modifications – particularly those introduced by the TECV Act (see chapter 2).

A section dedicated to professionals on www.asn.fr

This section gives professionals access to the regulatory texts and ASN forms concerning their area of activity, along with the possibility of creating a personalised account. The website also provides access to supporting material intended for professionals: sheets, results by sector, presentations of regional seminars, letters on the regulations, etc.

Contrôle magazine

Issued to more than 10,000 subscribers in France and abroad, *Contrôle* magazine provides in-depth examinations of major subjects relating to nuclear safety and radiation protection. Published in April 2016, issue 200 of *Contrôle* magazine reviewed the situation of ASN as an independent administrative Authority, the *"road travelled and the future challenges"* and the major advances in nuclear safety and radiation protection resulting from the TECV Act.

Issue 201 of *Contrôle* magazine published in December was devoted to emergency situations: the lessons learned from the emergency response exercises (for nuclear and non-nuclear risks alike), the analysis of the crisis experienced during the Fukushima Daiichi accident in 2011 and the first assessment of the fifth iodine tablet distribution campaign. The magazine is also available on *www.asn.fr*.

1.2.2 Encouraging the notification of significant events and experience feedback

The notification of significant events is a key factor in strengthening the safety and radiation protection culture.

Since July 2015, the on-line notification portal *www.vigie-radiotherapie.fr*, launched jointly by ASN and the ASNM (French Health Products Safety Agency), can be used to transmit notifications concerning radiation protection and equipment incidents in radiotherapy).

ASN publishes the twice-yearly bulletin *"Healthcare safety – Building momentum for progress"*, co-signed by the SFRO (French Society for Radiation Oncology), the SFPM (French Society for Medical Physics), the AFPPE (the French Association of Radiographers), and the AFQSR (French Association for Quality and Safety in Radiotherapy). Sent to 180 radiotherapy centres in France, the bulletin highlights the progress and experience sharing approach initiated by the radiotherapy centres to enhance health care safety. Two new issues were published in 2016, addressing hypofractionated high-precision irradiation and protraction and fractionation of the delivered dose.

1.2.3 Professional symposia and seminars

The symposia and events organised by the professionals provide opportunities for ASN to develop its relations with this audience.

The ASN regional divisions reaching out to professionals in the small-scale nuclear sector

On 23rd June 2016, the ASN divisions of Lille, Paris and Châlons-en-Champagne organised, in collaboration with the DIRECCTE (Regional Directorate for Enterprises, Competition, Consumption, Labour and Employment) of the Hauts-de France region, an inter-regional seminar on radiation protection in industrial radiography. This seminar was attended by 80 professionals from companies specialised in non-destructive inspections and tests, and ordering customers. This action lies within the framework of the promotion of the regional charter of good practices in industrial radiography.

The ASN divisions of Marseille and Lille also met with the industry players at the forum on *"Decommissioning techniques and methods and radiation protection"* organised by the ATSR (Association for Radiation Protection Techniques and Sciences) in La Grande Motte from

5th to 7th October, and the 7th National conference on technological risks held in Douai on 13th October.

Conferences in the medical and radiation protection sector

ASN met paramedical radiography personnel on its stand at the AFPPE (French Association of Radiographers) congress (31st March - 2nd April), the medical imaging professionals at the French Radiology Days (JFR, 14th to 17th October), and the Person Competent in Radiation protection (PCR) at the PCR days of the SFRP (French Society for Radiation Protection) held on 8th-9th November.

The interchanges with the professionals aim primarily at improving their knowledge of the regulations applicable to them by distributing regulatory sheets and the guide to the regulatory provisions relative to medical and dental radiology, which is updated each year. The professional trade fairs also provide the opportunity to assess the situation of the inspections (in vivo nuclear medicine, computed tomography, teleradiology with computed tomography) and to share lessons learned from the analysis of significant radiation protection events.

The ASN contribution to improving nuclear safety and radiation protection in the world

ASN participated in the sharing of international experience at two benchmark conferences in 2016: the 14th congress of the International Radiation Protection Association (IRPA) in Cape Town (9th to 13th May) and the International Symposium on the Packaging and Transport of Radioactive Materials - PATRAM (18th to 23rd September). At these events it presented, among other things, the French recommendations on the conditions of implementation of new techniques in radiotherapy and the importance of having an organisation to respond to emergency situations in the transport of radioactive substances.

1.3 ASN and the media

ASN maintains regular relations with the regional, national and foreign media throughout the year.

In 2016, topical nuclear safety issues, the manufacturing anomalies affecting the EPR reactor vessel and several steam generators and the irregularities detected in Areva's Creusot Forge plant attracted the interest of the French and international media.

The journalists also focused their attention on the continued operation of existing nuclear reactors, the EPR reactor construction project, the decommissioning of nuclear installations, the situation regarding the safety of the Fessenheim NPP, and the *Cigéo* project.

The ASN Chairman, Pierre-Franck Chevet, was interviewed on several occasions on ASN's positions and on the nuclear safety issues and the resources of the oversight system.

The functioning of the radiotherapy centres, ASN's recommendations in terms of improvement of treatment safety, the optimisation of doses received by patients and practitioners in medical imaging, and the controls in nuclear medicine were the subjects broached most frequently with regard to the radiation protection of patients.

Numerous interviews and coverage in the field with the regional divisions enabled the media to understand the different steps involved in ASN's regulatory work and to inform their audience about the steps taken to ensure the safety of nuclear facilities and the safety of medical treatments.

Throughout the year ASN also received numerous requests from the international media seeking information on its functioning, its news and the events occurring in France.

1.4 ASN's relations with elected officials and institutional bodies

In 2016, ASN was called to regular hearings by Parliament on its activities, on subjects concerning nuclear safety and radiation protection and with regard to the Budget Bill (PLF) for 2017:

- On 1st March, the National Assembly's Commission for sustainable development and regional development heard Pierre-Franck Chevet on the *Cigéo* project.
- On 30th March, ASN was heard at the National Assembly by the group tasked with reviewing the situation of the EDF group.
- On 6th April, ASN took part in the round table *"Reconciling nuclear safety and economic efficiency: how to ensure the necessary level of protection without hindering the action of the economic operators in the nuclear sector?"* organised by the National Assembly's energy studies group chaired by David Habib, vice-president of the National Assembly and member for the Pyrénées-Atlantiques, and Julien Aubert, member for the Vaucluse.
- On 22nd June, Pierre-Franck Chevet was heard by the National Assembly's Commission for economic affairs on the industrial and financial strategy of EDF.
- On 29th June ASN was heard by the sub-committee for information on the technical and financial feasibility of decommissioning nuclear infrastructures of the National Assembly's Commission for sustainable development and regional planning.
- On 12th October, ASN was heard by Jacques Krabal, member of the National Assembly and draftsman of the opinion in the name of the Commission for sustainable development and regional planning for the 2017 Budget Bill.

- On 18th October, ASN was heard by Marc Goua, special rapporteur of the Finance commission, tasked with monitoring programme 174 "Energy, climate and post-mines".
- On 25th October, ASN was heard by the OPECST (Parliamentary Office for the Evaluation of Scientific and Technological Choices) on the oversight of Nuclear Pressure Equipment (NPE) in a hearing open to the press.
- On 8th November ASN was heard by the OPECST on the French National Radioactive Material and Waste Management Plan (PNGMDR).
- On 8th December ASN was heard by Hervé Mariton, special rapporteur of the National Assembly's Finance commission, tasked with monitoring programme 181 "Risk prevention, oversight and safety of nuclear pressure equipment".

ASN presented its 2015 *Report on the State of Nuclear Safety and Radiation Protection in France* to the OPECST on 25th May. This report, which constitutes the reference document on the state of the activities regulated by ASN in France, is submitted each year to the President of the Republic, to the Government and to the Parliament. It

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Press conferences

In 2016 ASN organised twenty national and regional press conferences.

- On 20th January 2016, ASN presented its wishes for the New Year to some thirty journalists from the national and international media. During this event, the ASN Chairman and Director-General presented a review of ASN, its development, its relations with its international counterparts and its strategic priorities for the coming year.
- On 26th May, ASN organised a press conference attended by some forty journalists to present its *Report on the state of nuclear safety and radiation protection in France in 2015*.
- On 5th December, ASN held a press conference with IRSN on the situation of the steam generators whose steel displayed high carbon concentrations.
- The regional divisions of ASN subsequently organised regional conferences to present the results of their activity of the year and inform the regional media of the forthcoming issues at stake. This year, the organisation of these conferences came within the new context of the territorial reform which modified the administrative regions. The local press focused essentially on the regional situation assessments of each division, asking questions concerning the operation and oversight of the nuclear facilities, the incidents that occurred during the year and the environmental impact of the activities overseen.

The ASN barometer

In 2016, in collaboration with the Kantar Public Institute (formerly TNS Sofres), ASN conducted the 12th wave of its annual "barometer" survey of the public's image and knowledge of ASN. This opinion survey was carried out from late October to early December 2016 with a representative sample of the general public and a representative sample of informed and professional audiences (mainly comprising journalists, elected officials, association leaders, heads of administrative authorities, chairmen of CLIs, health professionals and teachers). Moreover, the general public survey included a sample of people living in the PPI (Off-site Emergency Plan) zone near a BNI in order to cover the issues associated with the risk awareness culture.

Designed to measure ASN name awareness and the level of satisfaction of three samples of audiences with regard to its information actions, this barometer enables ASN to adapt its information policy to its various interlocutors.

The overall recognition of ASN by the general public showed a seven percentage point increase this year (37%). This increase results from the current issues relating to nuclear power plant safety, more specifically the reactor outages decided by ASN for inspection purposes, and the discussions about the future of the Fessenheim plant.

Among people living near BNIs, recognition of ASN remains stable at 44% with respect to last year.

Overall recognition of ASN among the informed public remains stable at 88%.

Sixty-two percent of French people who have heard of ASN have a good image of it (stable with respect to the end of 2015) and 75% consider it competent with regard to nuclear safety (+5 percentage points in one year). People living in the vicinity of BNIs perceive it positively: 74% of those who know of ASN have a good image of it, while 85% consider it competent with regard to nuclear safety.

Among the informed public, 86% of those who know ASN have a good image of it, while its competence in nuclear safety and radiation protection respectively is acknowledged by 95% and 92% of the persons questioned.

Efforts regarding public information must be continued with the general public, for whom the value of transparency is recognised by 24% of the persons surveyed.

is also sent out to more than 2,000 addressees: heads of administrative authorities, elected officials, licensees and persons/entities in charge of regulated activities or installations, associations, professional unions, learned societies.

ASN also maintains regular contact with the national and local elected officials and interchanges with its institutional contacts on subjects relating to nuclear safety and radiation protection.

Participation of ASN and IRSN at the 20th Mayors and Local Authorities Exhibition

For the third year running ASN was present at the Mayors and Local Authorities Exhibition which ran from 31st May to 2nd June 2016, sharing a stand with IRSN for the first time.

ASN and IRSN provided elected officials and local authorities with information relating to nuclear safety and radiation protection in their region and answered their questions.

The main subjects of discussion were the 2016 iodine tablet distribution campaign, prevention of the risks associated with radon, environmental monitoring, the service life of nuclear power plants and their oversight.

1.5 International cooperation in the field of communication

ASN invests itself on the international scene to promote experience feedback and the sharing of best practices for informing the public.

In 2016, ASN continued its participation in the communication working group coordinated by Nuclear Energy Agency. It participated from 5th to 8th April in an international workshop organised by its Japanese counterpart (NRA, Nuclear Regulation Authority) along with various other players (medias, NGOs, etc.) to discuss the relations between Asian nuclear authorities and their stakeholders, particularly in the wake of the Fukushima Daiichi accident.

ASN took part in a cooperation mission financed by the European Commission to help the Vietnamese nuclear Authority establish an information policy that complies with the best international standards (see chapter 7).

1.6 ASN staff and information

The main internal information vector available to ASN staff is OASIS, the intranet that gives them access to the documents concerning the life of ASN and its activities.

ASN-IRSN stand at the 20th Mayors and Local Authorities Exhibition, 31st May - 2nd June 2016.

It features the activity report published each year for the staff. This reports highlights information on subjects such as training, the social dialogue, the quality-driven management system, financial resources, etc.

The electronic magazine *Transparence* (Transparency) issued three times a year is also accessible on Oasis.

In-house conferences on subjects associated with ASN's activity, its current news, and nuclear safety and radiation protection risks in France and the world are organised every two months.

Training in communication and media relations

With the aim of issuing high-quality, clear and understandable information, ASN offers its staff training in spoken and written communication and emergency management, tailored to their various responsibilities.

ASN spokespersons prepare themselves for public speaking and communication with the media, notably during emergency exercises with simulated media pressure (see chapter 5).

Training in written communication is provided for all the ASN inspectors.

Emergency situation preparedness

ASN has a duty to inform the public in the event of an emergency situation (Article L. 592-32 of the Environment Code). In order to prepare for this, ASN staff receive specific training and take part in emergency exercises. In 2016, seven emergency exercises included simulated media pressure from journalists, designed to assess and strengthen ASN's reactivity to the media, as well as the consistency and quality of the messages put across by the various stakeholders, licensees and public authorities, both nationally and locally (see chapter 5).

2. Reinforcing the right to information and participation of the public

The legislative and regulatory provisions relative to nuclear activities, which have been gradually reinforced over the last few years, give the general public wide access to information.

ASN applies these measures within its organisation and ensures they are also applied by the licensees subject to its oversight; it endeavours to facilitate interchanges between all the stakeholders.

2.1 Information provided by the licensees

The main licensees of nuclear activities implement a proactive public information policy.

They are also subject to a number of legal obligations, either general, such as the environmental report required by the Commercial Code for joint stock companies, or specific to the nuclear sector. The latter are presented below.

Annual public information report for the Belleville-sur-Loire NPP, June 2016 issue.

2.1.1 The annual public information report drawn up by the BNI licensees

All BNI licensees must establish an annual report concerning more specifically their situation and the steps they take with regard to the prevention of risks for public health and the environment (Article L. 121-15 of the Environment Code). The writing of these reports is covered by ASN recommendations provided in a guide published in 2010. It will shortly be updated to take into account the extension of the report to cover the non-radioactive risks as prescribed by the ordinance of 10th February 2016 introducing various provisions concerning nuclear activities.

The reports are generally available on the licensees' websites and are often presented to the CLIs.

2.1.2 Access to information in the possession of the licensees

Since the TSN Act came into force, the nuclear field has a unique system governing public access to information.

Pursuant to Articles L. 125-10 and L. 125-11 of the Environment Code, in their wording resulting from the ordinance of 10th February 2016 introducing various provisions concerning nuclear activities, licensees must communicate to any person who so requests, the information they hold on the risks their activity presents for public health and the environment and on the measures taken to prevent or mitigate these risks.

There are provisions for protecting public safety and commercial and industrial secrecy.

This right to information concerning the risks is today in force with regard to BNI licensees and to those in charge of radioactive substance transport operations, provided that the quantities exceed thresholds set in the TSN Act. The conditions under which this right will be extended to other nuclear activities that so warrant remain to be defined.

The Commission for Access to Administrative Documents (CADA)

The procedures relative to disputes resulting from a refusal to communicate are similar to those of the general system of access to information concerning the environment: in the event of refusal by a licensee to communicate information, the applicant can refer the matter to the Committee for Access to Administrative Documents (CADA), an independent administrative Authority, which gives an opinion on whether the refusal was justified or not. Should the interested parties not follow the opinion of the CADA, the dispute could be taken before the administrative jurisdiction which would rule on whether or not the information in question can be communicated. ASN is heavily committed to the implementation of this right.

The number of referrals to CADA still remains extremely limited. ASN therefore continues to regularly encourage the public to make use of this right to information.

2.2 Information given to populations living in the vicinity of basic nuclear installations

The TECV Act has instituted an obligation to regularly inform the populations living in the vicinity of a BNI of the nature of the accident risks associated with that installation, the envisaged consequences of such accidents, the planned safety measures and the action to take in the event of an accident. This information is provided at the expense of the licensee (new Article L. 125-16-1 of the Environment Code).

The information and iodine tablet distribution campaign conducted in 2016 (see box on page 188) represented the first implementation of this provision.

2.3 Public consultation about projected resolutions

Article 7 of the Environment Charter embodies the right of participation of any citizen in the framing of public decisions having an impact on the environment (see chapter 3).

This provision is applicable to a large proportion of the resolutions taken by ASN or in which it is involved.

2.3.1 Consultation of the general public on draft statutory resolutions having an impact on the environment

Article L. 123-19 of the Environment Code provides for a procedure of consultation of the public via the Internet on draft regulatory texts having an impact on the environment.

ASN has decided to apply this widely. Consequently, all ASN draft statutory resolutions concerning BNIs, including those relating to Nuclear Pressure Equipment (ESPN), are considered as having an impact on the environment and are therefore subject to public participation. The same approach is applied for the statutory resolutions relative to the transport of radioactive substances that ASN adopts. ASN's statutory resolutions relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a significant hazard for the nearby residents and the surrounding environments in the event of an accident.

Lastly, although they are not of a statutory nature, ASN applies this same procedure to certain guides.

An indicative list of the scheduled consultations on draft statutory resolutions and guides having an impact on the environment is updated every three months on *www.asn.fr*.

The public participation procedure consists in posting the draft statutory resolution on www.asn.fr for at least 21 days in order to give people time to make their comments.

A synthesis of the remarks made, indicating those taken into account and a document setting out the reasons for the resolution are published on *www.asn.fr* at the latest on the date of publication of the resolution. During the year 2016, five draft statutory resolutions and eight draft guides thus underwent the public consultation process.

2.3.2 Consultation of the general public on draft individual resolutions having an impact on the environment

The individual resolutions on nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

The public inquiry

In application of the Environment Code (TSN Act) and Decree 2007-1557 of 2nd November 2007, the BNI creation and decommissioning authorisation procedures form the subject of a public inquiry. Since 1st June 2012, an experiment instituted by Decree 2011-2021 of 29th December 2011, the results of which will be assessed in 2017, involves making available by electronic means the files of projects that are subject to a public inquiry and which could affect the environment. The BNIs, whether for their creation or their decommissioning, are included in this experiment.

In 2016, two public inquiries were conducted on a project to make significant modifications to a BNI, and third public inquiry concerned the introduction of active institutional controls on the site of a former BNI.

The TECV Act provides for a public inquiry for the periodic safety reviews of nuclear reactors which have been in service for more than thirty-five years (Article L. 593-19 of the Environment Code). This inquiry concerns measures proposed by the licensee to increase the safety of its installation and correct any anomalies observed during the safety review. This provision will start to apply in the coming years as the 900 MWe reactors operated by EDF approach their fourth periodic safety reviews. In view of the stakes that these reviews represent, the importance of ensuring a good level of public participation in this process, and the complexity of the process (with a so-called generic phase concerning all the reactors and phases specific to each reactor), the HCTISN (French High Committee for Transparency and Information on Nuclear Security) has set up, further to an ASN proposal, a working group tasked with proposing practical methods of public participation in these various phases, integrating the public inquiry prescribed by the Act but not limited to it.

The posting of projects on the ASN website

The individual resolutions which are not subject to public inquiry and which could have a significant effect on the environment are made available for consultation on the Internet. For the ASN resolutions, these are mainly individual prescriptions applicable to BNIs, the authorisation to commission a BNI or the delicensing of a decommissioned BNI, as well as authorisations for small-scale nuclear activities that could produce effluents or waste.

The consultation concerns the draft resolution and, for resolutions adopted on request, the application file. The consultation is open for at least fifteen days on *www.asn.fr*.

During the year 2016, 105 draft individual resolutions were thus posted for public consultation on *www.asn.fr*.

Disclosure of the files by the licensee

Before setting up the general procedure for consultation via the Internet, a procedure for file disclosure by the licensee was instituted for any project to modify a BNI or its operating conditions that could lead to a significant increase in its water intakes or environmental discharges (while being of insufficient scale to warrant a public inquiry procedure). This procedure is governed by II of Article 26 of the Decree of 2nd November 2007 and by ASN resolution 2013-DC-0352 of 18th June 2013. It now supplements the general consultation procedure via the ASN website.

This procedure was not used in 2016.

2.3.3 Consultation of particular bodies

The BNI authorisation procedures also provide for the opinion of the departmental council, the municipal councils and the CLIs to be obtained (see point 2.3.1). The CLIs also have the possibility of being heard by the ASN Commission before it issues its opinion on the draft authorisation decree submitted to ASN by the Minister responsible for Nuclear Safety.

The CLI and the Departmental Council for the Environment and for Health and Technological Risks are consulted on the draft ASN prescriptions concerning water intakes, effluent discharges into the surrounding environment and the prevention or mitigation of detrimental effects of the installation for the public and the environment.

2.3.4 Progress to be consolidated

ASN ensures that these consultations enable the public and the associations concerned to express their views, in particular by verifying the quality of the licensee's files and by developing the CLI's resources so that they can express an independent opinion on the files (in particular thanks to the possibility of consulting experts other than those of the licensee and ASN).

ASN also endeavours to ensure that the public has information that is as extensive as possible in compliance with the limits on the communication of environmental information provided for in Articles L. 124-1 to L. 124-6 of the Environment Code, in particular to protect public safety or commercial and industrial confidentiality.

The framework of the public consultation has greatly evolved over the last few years. The first efforts consisted in applying the new rules. It is now necessary to examine how to improve the practical conditions of these consultations to make them more effective aids to public participation.

2.4 The other actors in the area of information

2.4.1 The BNI Local Information Committees (CLI)

Operating framework

The CLIs have a general duty of monitoring, information and consultation concerning nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment with regard to the installations of the site(s) that concern them.

The operating framework of the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment

Code and by Decree 2008-251 of 12th March 2008 relative to the CLIs for the BNIs.

The CLIs, whose creation is incumbent upon the President of the *conseil départemental* (departmental council), comprise various categories of members: representatives of departmental councils, of the municipal councils or representative bodies of the groups of municipalities and *conseils régionaux* (regional councils) concerned, members of Parliament elected in the département, representatives of environmental or economic interest protection associations, employee and medical profession union organisations, and qualified personalities. The representatives of Government departments, including ASN, and of the licensee have an automatic right to participate in the work of a CLI, in an advisory capacity. The TECV Act provides for the participation of foreign members in the CLIs of border *départements*. The conditions shall be specified in an amendment to the Decree relative to CLIs.

The CLIs are chaired by the President of the departmental council or by an elected official from the *département* designated by him for this purpose.

The CLIs receive the information they need to function from the licensee, from ASN and from the other Government departments. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

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Seminar on *"Continuing operation of the 900 MWe reactors beyond 40 years, what are the safety implications and who should participate?"*

ASN encourages the involvement of the public in the process for deciding on the conditions of continued operation of the 900 MWe reactors.

On 3rd and 4th October, the Local Information Committee of the large energy facilities of Tricastin (Drôme *département*), Anccli, ASN and IRSN organised a seminar dedicated to continuing operation of French 900 MWe nuclear reactors beyond 40 years.

The French nuclear fleet was commissioned between 1978 and 2002. In accordance with the regulations, EDF performs a periodic safety review of each of its installations every ten years. The law stipulates that the measures proposed by the licensee to enhance the safety of its installation and correct any anomalies observed during the periodic safety reviews after thirty-five years of operation shall form the subject of a public inquiry. The first NPP concerned will be the Tricastin plant in 2019.

One hundred and forty-five people, half of them members of CLIs, participated in the discussion and debate seminar in Valence.

They asked questions about the conditions of involvement of civil society in this essential process of oversight and improvement of the safety of nuclear installations. Three major safety topics also received special scrutiny: external hazards of natural origin, the safety of fuel storage and organisational and human factors.

Seminar on *"Continuing operation of the 900 MWe reactors beyond 40 years, what are the safety implications and who should participate?"*, Valence, October 2016.

The CLIs are financed by the regional authorities and by ASN. ASN devotes about one million euros per year to the financial support of the CLIs and their federation. Within the framework of its reflection on the financing of the oversight of nuclear safety and radiation protection, ASN has again suggested to the Government the application of the provision of the TSN Act to add to the budget of the CLIs with association status (there are about ten of them) with a matching contribution of funds from the BNI Tax; however, this provision has not yet been implemented.

ASN support is not restricted simply to financial aspects. ASN considers that the good functioning of the CLIs contributes to safety. ASN also aims to ensure that the CLIs receive information that is as complete as possible. It also invites CLI representatives to take part in inspections. Within the present framework, only the ASN inspectors have a right of access to facilities that can be enforced upon the licensees, therefore the participation of observers from CLIs is subject to the agreement of the licensees.

ASN encourages BNI licensees to facilitate CLI access - as early as possible - to the procedure files for which the opinion of the CLIs will be required, so that they have sufficient time to develop a well-founded opinion. Similarly, ASN considers that the development of a diversified range of expertise in the nuclear field is essential if the CLIs are to be able to base their opinions, when needed,

FOCUS

28th Conference of Local Information Committees

The 28th Conference of Local Information Committees brought together 244 participants on 16th November 2016 in Paris at the initiative of ASN and in partnership with Anccli.

The conference was attended by some 160 members of CLIs, representatives of departmental councils and prefectures of *départements* with CLIs, national administrations, associations and nuclear installation licensees.

The morning of the conference was devoted to a period of interchanges on the latest news concerning the HCTISN, ASN and Anccli. Jean-Yves Le Déaut, Chairman of the OPECST gave a talk to the conference participants.

The participants also discovered the ASN-IRSN travelling exhibition on the nuclear risk and radiation protection.

In the afternoon, two consecutive round tables were held on the topics of "Current major safety issues" and "Off-site Emergency Plan (PPI): what changes should be made?".

The 29th CLI Conference is scheduled for 15th November 2017.

Contribution of Pierre-Franck Chevet at the 28th CLI conference in November 2016.

on the work of experts other than those called on by the licensee or ASN itself.

All BNI sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*.

This means that there are 35 CLIs coming under the Environment Code. To this total we must add the Bure underground laboratory CLIS (Local Information and Monitoring Committee), created in application of Article L. 542-13 of the Environment Code and whose composition and role are similar to those of a CLI.

The 35 CLIs count more than 3,000 unpaid members, including 1,500 elected officials.

For the nuclear sites concerning defence, which are regulated by the delegate to nuclear safety and radiation protection for defence-related activities and installations, Articles R. 1333-38 and R. 1333-39 of the Defence Code provide for the creation of information committees quite similar to the CLIs but whose members are appointed by the State and not by the President of the departmental council. There are about fifteen such committees. For the Valduc site, in addition to the information committee there is also an associative consultation structure called: the Seiva (Structure for exchanges and information on Valduc).

The CLI activities

The activity of the CLIs essentially consists of plenary meetings and in the functioning of specialised commissions.

The TECV Act obliges each CLI to hold at least one public meeting per year. A little more than half the CLIs applied this provision as of 2016, either by opening one of their normal meetings to the public, or by organising an event designed especially for the public. Levels of public participation varied (an event organised by the Fessenheim CLIs drew nearly 300 members of the public).

Exchanges of good practices should allow these results to be improved upon so that the CLIs can better fulfil one of their primary roles, namely informing the population.

The annual public information report drawn up by the licensee is presented to the CLI. Any significant events are also usually presented to the CLI.

About thirty CLIs have a website or have pages on the website of the local authority that supports them. Some twenty CLIs publish a newsletter (sometimes as inserts in the news bulletin of the municipality).

The CLIs can have special advisers, generally on a part-time basis. They are members of staff of the local authorities or, for those CLIs with association status, employees of the association itself. If these special advisers are in place, this clearly helps the CLIs adopt a more proactive attitude.

ASN informs the CLIs regularly about the files concerning the nuclear facilities. Ten CLIs or so were consulted about licensees' projects in 2016. The CLIs are moreover always informed of the launching of public consultation procedures by ASN. Some ten CLIs (slightly fewer than in 2015) also had appraisals carried out, as allowed by the TSN Act, for example in the form of environmental analysis campaigns.

2.4.2 National Association of Local Information Commissions and Committees (Anccli)

The Environment Code (Article L. 125-32 taken from the TSN Act) provides for the constitution of a federation of CLIs and the Decree of 12th March 2008 details the missions of this federation. The National Association of Local Information Committees and Commissions (Anccli), chaired by Jean-Claude Delalonde, thus groups the 35 CLIs (or equivalent structures) that exist in France.

Anccli comprises numerous internal working bodies (Scientific Committee, Advisory Committees, Officers' club, Cross-border CLI working groups, etc.); it is also heavily involved in the discussion and interchange bodies set up by its partners (HCTISN, ASN, IRSN, etc.).

The audit of the Anccli action programme

In accordance with the agreement that binds it to ASN, Anccli organised an external audit of its action programme. Its conclusions, presented in 2016, are on the whole highly positive and demonstrate the strong involvement of the volunteer members of the CLIs and Anccli.

The Anccli Scientific Committee

Comprising independent unpaid experts from varied horizons, the Scientific Committee conducted several significant actions during 2016: setting up a *"health"* working group, continuing the study on *"Global warming and cooling of the French nuclear power plants"*, appraisal of the seismic regulations at the request of the Fessenheim CLIs, publication in November of a report entitled *"Off-site Emergency Plans (PPI) – Prevention measures, intervention radiuses, preventive distribution of stable iodine tablets"*.

The Anccli Advisory Committees

The aim of these "Advisory Committees", made up of CLI and Anccli members, is to interchange with the CLIs on the major technical implications of the nuclear issues and enable them to develop a regional-scale reflection.

Consequently there is a "Post-Accident and Regions" Advisory Committee (GPPA), a "Materials and Radioactive Waste" Advisory Committee (GPMDR), and a "Decommissioning" Advisory Committee.

In 2016 the work of these advisory committees revolved essentially around the writing and finalising of three white papers intended for CLI members and institutions: *"Planning emergency management and post-accident management"*, "Reversibility and retrievability" and *"Under what conditions can the CLIs and Anccli participate influentially in the regional and national monitoring of decommissioning worksites?"*.

Relations with the CLIs

The Anccli Officers' club

Anccli has created the CLI Officers' club to permit and encourage interchanges with the CLIs and identify the good and bad practices. ASN, IRSN and the licensees are invited from time to time.

National and regional events

Anccli proposes national initiatives to the CLIs (in 2016: two seminars, one presentation of the ASN-IRSN exhibition: *"radioactivity, hundreds of questions, one exhibition"*) or initiatives by geographical area (projects for actions with the CLIs of the Loire and south-east regions).

The "Cross-border CLI" working group

The questions specific to the CLIs in the border areas are examined in a "Cross-border CLIs" working group.

The institutional partners of Anccli

Partnership with ASN

Anccli interchanges with ASN very regularly and participates in several of its permanent or occasional working groups (PNGMDR, Codirpa, RNM - French National Network of Environmental Radioactivity Monitoring, COFSOH - Steering Committee for Social, Organisational and Human Factors, group on infantile leukaemias, steering committee in charge of preparing the 2016 iodine tablet distribution campaign, etc.). In 2016, representatives of Anccli participated in the meetings of the Advisory Committee of Experts on Nuclear Pressure Equipment (GPESPN) addressing the anomalies in the EPR reactor vessel.

Partnership with IRSN

Anccli has set up a very close cooperation with IRSN. The members of the CLIs participate in bodies or working groups (steering and research committee, board of directors, HLW-LL dialogue, action baptised "permanent IRSN representative in the CLIs", "periodic safety review" WG, Opal, etc.).

Likewise, in 2016 Anccli and IRSN organised two seminars, one on the transport of radioactive substances, the other on the 4th ten-yearly outages of the 900 MWe reactors (VD4-900) with the support of ASN and the CLIs of the Drôme *département*.

Partnership with the High Committee for Transparency and Information on Nuclear Security (HCTISN)

Members of Anccli play an active role in the meetings of the HCTISN and in the various working groups it has created.

Technical discussions with the various partners

Anccli, ASN and IRSN organise, with the CLIs, meetings to discuss the important technical files (EPR vessel, general orientations of the fourth ten-yearly outages of the reactors, etc.). They are partners in the production of a medium designed to raise awareness of the regional players to the post-accident problems of a nuclear accident.

Participation in public consultations and parliamentary work

Anccli responds to the public consultations on nuclear issues. It is also invited regularly to hearings or public meetings organised by the parliamentary commissions or offices.

The Budget Act for 2016 planned for the Government to submit a report to Parliament on the financing of the CLIs before 1st July 2016. In Autumn Anccli engaged procedures to obtain this report.

Communication by Anccli

Anccli sends out a newsletter to more than 1,500 addressees by e-mail (two publications in 2016).

It organises press conferences; the press conference of 5th April on the theme *"Nuclear safety: what is the price to pay"* provided the opportunity to present the two appraisals Anccli had ordered from its Scientific Committee and the Association for the oversight of radioactivity in Western France on the off-site emergency plans and on emergency measures in France.

It broadcasts a series of animated presentations on nuclear safety via the Internet: the *"Chronicles of Julie and Martin"*. In 2016, the third episode in this series was devoted to the culture of risk awareness and the distribution of iodine tablets in particular.

European cooperation, the ACN approach and the NTW network

ANCCLI participates in European programmes (PREPARE, BEPPER, etc.) and various international events.

Anccli was the instigator of a consultation process on the conditions of application of the Aarhus convention to the nuclear field ("ACN approach") which comprises a European part and national parts. In this context, a European round table entitled *"Preparedness and response to nuclear accident and post-accident situations"* was held on 29th and 30th November 2016 in Luxembourg, and a national round table entitled *"Public information and participation in the preparation for nuclear emergencies - cross-border aspects"* was held in Metz in June.

Anccli was also behind the creation of the *"European network of citizen vigilance over safety and transparency in the nuclear field"* named Nuclear Transparency Watch (NTW). This network, chaired since 2016 by Nadja Zeleznik (Regional Environmental Centre - REC of Slovenia) organised, jointly with the European Commission, a conference on the theme *"Meeting the requirements of the BSS directive with regard to informing the public about nuclear emergency preparedness and response"*.

2.4.3 High Committee for Transparency and Information on Nuclear Security

The High Committee for Transparency and Information on Nuclear Security (HCTISN) created by the TSN Act is a body that informs, discusses and debates on nuclear activities, their safety and their impact on health and the environment.

The HCTISN comprises 40 members appointed by decree for six years. They include:
- Two members of the National Assembly appointed by the National Assembly and two members of the Senate appointed by the Senate;
- Six representatives of the CLIs;
- Six representatives of environmental protection associations and approved health system users associations;
- Six representatives of persons in charge of nuclear activities;
- Six representatives of representative employee labour organisations;
- Six "qualified personalities" chosen for their scientific, technical, economic or social competence, or for their information and communication expertise, including one appointed by the Government, three appointed by OPECST, one by the Academy of Science and one by the Academy of Moral and Political Sciences;
- The ASN Chairman, an IRSN representative and 4 representatives of the ministries concerned;
- The chair of the HCTISN is appointed by the Prime Minister from among Members of Parliament, members of the CLIs or qualified public figures. Marie-Pierre Comets is currently chair of the HCTISN.

The HCTISN organised four plenary meetings in 2016 during which major topical subjects concerning nuclear activities were detailed and discussed:
- the cost of the *Cigéo* project, with considerable work involved in explaining the options adopted in the various evaluations of these costs and the origin of the differences between the cost proposed by Andra, that proposed by the licensees and that ruled by the Minister of the Environment, Energy and the Sea;
- the quality of the forgings used in the French nuclear power reactor fleet: the irregularities detected on the forgings at Creusot Forge plant of Areva NP ("concealed files") and independently of their place of origin, on forged components in the fleet displaying major carbon segregations;
- the preparation and progress of the national iodine tablet distribution campaign;
- the overview of BNI decommissioning (regulatory part and strategies of the various licensees), which gave rise to a hearing at the National Assembly on 19th October 2016;
- the post-Fukushima situation, as much in Japan, where the HCTISN allowed presentations showing different viewpoints, as in France, with the presentation of the progress of the stress tests;
- the security of nuclear installations in the wake of the terrorist attacks in Paris;
- individual radiosensitivity: the response to exposure to ionising radiation can effectively vary from one person to another;
- presentation of the draft decree "Basic standards relative to protecting health against the risks resulting from exposure to ionising radiation".

The "EPR reactor vessel anomalies" tracking group coordinated by Pierre Pochitalof, which tracks the manufacturing anomalies of the Flamanville EPR reactor vessel domes, met four times with more than 20 participants from all the commissions of the HCTISN. Numerous discussions were held with Areva and EDF, and the HCTISN organised a visit to a test laboratory in Germany and to Areva's Creusot Forge site. The HCTISN was heard by the OPECST on this subject on 25th October 2016. It will make a preliminary report available to the public in the first half of 2017.

A new working group was set up under the aegis of André-Claude Lacoste to look into public participation in the fourth periodic safety reviews of the 900 MWe reactors. Its purpose is to organise transparency in the decision-making process relative to the continuation of reactor operation beyond 40 years; apart from organising public inquiries into the decisions that will be taken reactor by reactor, as prescribed by the TECV Act, the question is more particularly the way in which the public can be involved in the "generic" decisions that will be taken between the start of 2016 and the end of 2018. Its mandate was approved and four meetings were organised in 2016.

Lastly, on 6th December 2016, at the request of Ségolène Royal, Minister of the Environment, Energy and the Sea, the HCTISN broached the subject of the anomalies in the carbon concentration of some EDF reactor steam generators. The same day it issued an opinion that included three categories of recommendations concerning correctly informing the CLIs involved, ensuring international dissemination of information on the issue, and transmission of the documents exchanged between ASN and the licensee to all the stakeholders.

All the HCTISN documents can be consulted on *www.hctisn.fr*.

ASN considers that the HCTISN plays an important national consultation role, which is all the more necessary in the current context associated with the major safety issues in the French nuclear power sector.

2.4.4 IRSN

IRSN implements a policy of information and communication that is consistent with the objectives agreement signed with the Government.

IRSN reports on its activities in its bilingual (French-English) annual report. This document is officially communicated to IRSN's supervisory Ministers, as well as to the HCTISN, the HCSP (French High Public Health Council) and the COCT (Working Conditions Guidance Council). It is also available to the general public via IRSN's website.

Since the TECV Act was introduced, the legislative part of the Environment Code defines the missions of IRSN, French public expert in risks. It also reinforces the informing of the citizens by obliging IRSN to publish the opinions it gives to the authorities who referred the matters to it.

Thus, since March 2016, in accordance with the provisions of Article L. 592-47 of the Environment Code, IRSN publishes on its website the opinions it issues in response to ASN referrals. These opinions are the synthesis of the appraisal carried out by IRSN in response to the ASN's request. Alongside this, as in the previous years, in 2016 IRSN made public the results of its research and development programs, with the exception of those concerning national Defence.

IRSN continued to develop its "multichannel" information policy and its educational approach to nuclear and radiological risks with new files on its website and increased presence on the social networks (professional and general public), not to mention the exhibition on nuclear and radiological risks created by ASN and IRSN for all audiences (see point 1.1.2).

Lastly, throughout 2016 IRSN maintained its readiness to answer questions from the media and the public, an area where demand is growing strongly given the wealth of news concerning the nuclear field.

3. Outlook

In 2017, ASN will continue its action to promote full implementation of the provisions to reinforce nuclear transparency in accordance with the requirements of the TECV Act. It will improve the conditions in which members of the public can express their opinion on the draft regulatory texts on *www.asn.fr*.

ASN will step up its actions to inform the general public in order to make the technical subjects presented to them clearer and more accessible, through increased posting of videos on *www.asn.fr*, among other things. The extension of the reach of the ASN-IRSN road show, the strengthening of ties with schools and the national education authority, the implementation of information initiatives for the populations situated in Off-site Emergency Plan (PPI) zones around nuclear installations are all actions designed to develop the culture of awareness of the risks and issues relating to nuclear safety and radiation protection in the various audiences. The extension of the PPI zones from 10 to 20 kilometres gives ASN a further opportunity to inform the populations of the nuclear risk; it will ensure that the obligations to regularly inform the populations situated in the PPI zone, as instituted by the TECV Act, are correctly implemented.

In 2017, ASN will develop the information it gives to the public on its activities and the areas of competence of its staff. It will examine, among other things, the creation of a "recruitment" space on its website, with the aim of showcasing the full diversity of its activities and competences, and opening its career opportunities to people with different professional profiles.

ASN will interchange with elected officials and stakeholders. After the presidential and legislative elections, it will meet the new members of parliament to present its missions to them. It will participate in the debates on nuclear safety and radiation protection.

ASN will continue to support the activities of the CLIs. This support will more particularly concern, for the CLIs that wish, their actions to involve the population in their work, such as the organisation of meetings for the public, as provided for in the TECV Act.

ASN will contribute among other things to the updating of the regulatory texts relative to these commissions, notably to enable the CLIs of border *départements* to accept people from the neighbouring countries as full members of the CLI. It shall also continue its actions with respect to the Government and Parliament to give the CLIs the means necessary for them to fully accomplish the new missions incumbent on them further to the TECV Act.

07

International relations

ASN's international actions are a decisive factor in ensuring its recognition, because they aim to both promote and share its methodologies and its mode of organisation, more specifically its independence, in the many European and multilateral bodies. It thus makes a decisive contribution to defining and ensuring very high standards in terms of nuclear safety and radiation protection, on behalf of the international community.

Outside the routine operation of nuclear facilities, this process of sharing, harmonisation and improvement of knowledge and practices also includes cooperation regarding any significant nuclear events or accidents (for example Chernobyl and Fukushima Daiichi) in which France has played a key role since 2011.

This action is based on the legislative provisions of the Environment Code, which states that within its scope of competence, ASN proposes France's positions to the Government for international negotiations and must represent France in international and community organisations in this field.

1. ASN objectives in Europe and worldwide

At a European level, the regulatory context has changed in recent years, with the adoption and updating of three European Directives in the fields of nuclear safety, waste legislation and radiation protection.

These Directives set out the requirements and standards to be applied by the Member States of the European Union, with transposition into their legislative and regulatory frameworks. In coordination with the French administrations concerned, ASN thus plays an active role in the transposition work and the implementation of the requirements of these Directives.

In the construction of this legal framework concerning nuclear safety, the European Commission is supported by ENSREG (European Nuclear Safety Regulators Group) which brings together experts from the European Commission and member countries of the European Union[1].

The safety regulators have also set up voluntary associations, such as WENRA (Western European Nuclear Regulators Association) and HERCA (Heads of the European Radiological protection Competent Authorities).

At a multilateral level, cooperation takes place within the framework of the International Atomic Energy Agency (IAEA), a UN agency founded in 1957, and the OECD's Nuclear Energy Agency (NEA), created in 1958. These two agencies are the most important inter-governmental organisations in the field of nuclear safety and radiation protection.

One of the core activities of IAEA is to draft international nuclear safety and radiation protection standards. The NEA is an ideal forum for the exchange of information and experience, leading to identification of the best practices that the Agency wishes to promote. ASN participates actively in the work being carried out within these international organisations.

In the aftermath of the Chernobyl accident (26th April 1986), the International Community negotiated a number of conventions for preventing accidents linked to the use of nuclear power and mitigating their consequences should they occur[2]. These conventions are based on the principle of a voluntary commitment of the Contracting Parties (who alone remain responsible for the facilities based in their territory) and entail no sanctions in the event of any failure to meet their obligations. France is a contracting party to these conventions, with IAEA being the depository and acting as secretary.

Finally, at a bilateral level, ASN cooperates with numerous countries under bilateral agreements, which can be governmental agreements or administrative arrangements. Bilateral relations allow direct exchanges on topical subjects and the rapid implementation of cooperation measures, sometimes on behalf of joint actions within a European or multilateral framework.

1. *The national delegations are made up for one half by heads of safety Regulators and the other half by representatives from Ministries for the Environment or Energy.*

2. *The Convention on Early Notification of a Nuclear Accident (signed in 1986), the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (signed in 1987), the Convention on Nuclear Safety (signed in 1994) and the Joint Convention on the Safety of Spent Fuel management and the Safety of Radioactive Waste Management (signed in 1997).*

They are also essential in the management of emergency situations.

In short, ASN's international actions are organised around four points, presented in the diagram below.

1.1 Giving priority to Europe

Europe is one of the priority areas for ASN's international actions. The aim is to help support and develop actions relating to nuclear safety, the safe management of waste and spent fuels and radiation protection.

With regard to nuclear safety, ASN takes part in two informal organisations working more specifically in favour of European harmonisation: ENSREG and WENRA.

ENSREG was created in 2008 and led to a political consensus on European Directives concerning nuclear safety in June 2009, followed by spent fuel management and waste in July 2011. This institution also took part in a process to revise the Nuclear Safety Directive proposed by the European Commission in 2013, following on from the review further to the Fukushima Daiichi accident. Each safety regulator then provided technical advice to its government responsible for the negotiations in Brussels, until its revision on 8th July 2014.

ENSREG also played a key role in initiating, performing and defining the conclusions of the stress tests. It is now responsible for the follow-up to this unique exercise, in particular for the implementation of the national action plans with a view to application of the recommendations defined in 2012. For performance of the stress tests, ENSREG relied on the specifications drafted by WENRA. It continued its actions during the past year on the topic of the ageing of certain non-replaceable items of power reactors and of research reactors with a power greater than 1 MWe, for which the peer review technical specifications were validated for a review to be held in 2017-2018.

WENRA was created in 1999 and is an association of the heads of nuclear regulatory authorities in Western European countries with power reactors, with the other countries being observers. This voluntary association is based on experience sharing by safety regulators with a view to harmonising safety rules for reactors and waste management facilities.

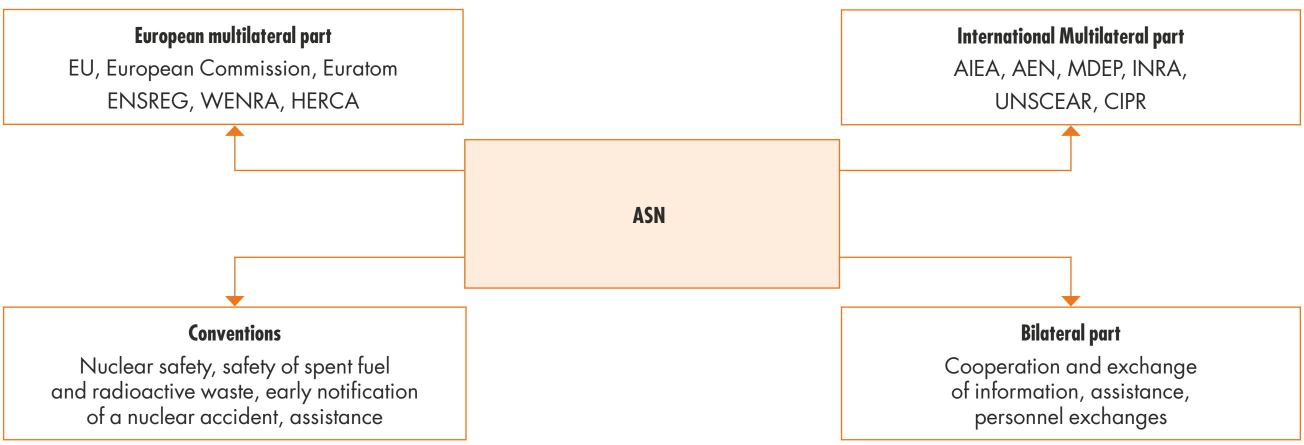
In the field of radiation protection, HERCA, another association, was founded in 2007. In the same way as WENRA, it is an informal grouping of the heads of radiation protection authorities, aiming to reinforce European cooperation in the field of radiation protection and achieve greater harmonisation of regulations and practices. As part of the ongoing work to transpose the Euratom Directive on Radiation Protection Basic Standards, HERCA is more particularly involved in the optimisation and justification of medical exposure to ionising radiation, but also the management of transboundary emergency situations in the event of a nuclear accident, jointly with WENRA. HERCA now comprises 56 Competent Authorities from 32 European countries.

1.2 Cooperation in the fields of nuclear safety and radiation protection worldwide

ASN multiplies its initiatives to share nuclear safety and radiation protection best practices and regulations outside Europe.

Within IAEA, ASN thus actively participates in the work of the Commission on Safety Standards (CSS) which drafts international standards for the safety of

ASN ACTION on the international stage



nuclear installations, waste management, the transport of radioactive substances and radiation protection. Although not legally binding, these standards do constitute an international reference, including in Europe. They are also the documentary reference standards for the international audits overseen by the Agency. They in particular include the Safety Regulator Audit Missions (IRRS, Integrated Regulatory Review Service) the development of which is being supported by ASN, along with OSART (Operational Safety Review Team) audits of nuclear power plants in operation.

ASN also contributes to safety harmonisation work by actively participating in the Multinational Design Evaluation Programme (MDEP) the aim of which is joint evaluation by safety regulators of the design of new reactors, including the EPR. This programme was initiated in 2006 by ASN and the United States Nuclear Regulatory Commission (US-NRC) and currently comprises 15 regulatory bodies. Its aim is harmonisation of the safety objectives, codes and standards associated with the safety evaluation of new reactors.

In the field of radiation protection, ASN is a stakeholder in various international review forums such as UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) or ICRP (International Commission on Radiological Protection). ASN considers that through their publications, these entities contribute to improved understanding of exposure to ionising radiation and of health effects. They issue recommendations helping to improve the protection of exposed persons, whether patients in the medical sector or specific categories of workers.

2. Relations with the European Union

ASN has always considered that a move towards European harmonisation of nuclear safety and radiation protection standards is necessary and must be based on exchanges and discussions between the national safety and radiation protection authorities of the Member States and between these same Authorities and the licensees.

2.1 The EURATOM Treaty

The Treaty creating the European Atomic Energy Community (EURATOM) was signed in 1957 and has led to the harmonised development of a strict oversight system for nuclear safety (see Chapter 7 of the Treaty) and radiation protection (see Chapter 3 of the Treaty). In an Order of 10th December 2002 (Case C-29/99 Commission of European Communities versus EU Council), the EU Court of Justice, ruling that no artificial boundary could be created between radiation protection and nuclear safety, recognised the principle of the existence of Community competence in the field of safety, as in the field of management of radioactive waste and spent fuel.

2.2 European Nuclear Safety Regulators Group (ENSREG)

ASN currently chairs the work of ENSREG, which supports the European Commission's European legislation initiatives. ENSREG is supported by three working groups, devoted to installations safety (WG1), the safe management of radioactive wastes and spent fuels (WG2) and transparency in the nuclear field (WG3) respectively. A fourth group (WG4) dealing with international cooperation was incorporated into the mandate of WG1 and more specifically focuses on the European Commission's Instrument for Nuclear Safety Cooperation (INSC).

On 26th April 2012, one year after the Fukushima Daiichi accident, a joint statement by ENSREG and the European Commission marked the end of the stress tests conducted on the European Nuclear Power Plants (NPP). This statement emphasised the need to implement an overall action plan to make sure that these stress tests are followed by improvements to safety measures, at the national level, and that these measures are implemented in a consistent manner.

This ENSREG overall action led to the nuclear safety regulator of each member country publishing a national action plan by the end of 2012, with each of them being assessed during a seminar in 2013 bringing together the safety regulators concerned.

A further exercise to follow up the recommendations of the stress tests was carried out in 2015.

ENSREG is also participating in preparations for the first peer review of ageing of power reactors and research reactors with a power of greater than 1 MWe. To this end, ENSREG asked WENRA to develop technical specifications for the components and subassemblies concerned by this review.

Finally, in 2016, ENSREG looked to reinforce how the subject of the continued operation of the nuclear power reactors was addressed in its 2016-2019 action programme. On this occasion, ASN shared its experience of the 900 MWe fourth ten-yearly outage inspections.

Peer review of the *Cigéo* project (ASN, 7th to 15th November 2016).

2.3 The European Directive on the Safety of nuclear installations

The Council 2009/71/Euratom Directive of 25th June 2009 aims to establish a Community framework to ensure nuclear safety within the European Atomic Energy Community and to encourage the Member States to guarantee a high level of nuclear safety[3].

Directive 2014 modifies Directive 2009 and more specifically requires additional measures concerning peer reviews, safety reassessments every ten years, greater transparency and safety objectives incorporating the notion of defence in depth.

It makes provision for increased powers and independence of the national safety regulators, sets an ambitious safety objective for the entire Union (based on the baseline safety requirements used by WENRA) and establishes a European system of peer reviews on safety topics (fire risk and flooding for example). It also establishes national periodic safety assessments and provisions concerning preparedness for interventions in an emergency situation. It also reinforces the transparency requirements and provisions concerning education and training.

During the negotiations, ASN endeavoured to promote France's position in favour of these measures, which significantly strengthen the Community's nuclear facilities safety oversight framework. However, European legislation does not yet enshrine in law the institutional independence of the safety regulators. This Directive was extensively transposed into the Energy Transition for Green Growth Act (TECV Act) of 17th August 2015 and the Nuclear Ordinance of 10th February 2016. A number of decrees concerning BNIs are currently being enacted. This legislative and regulatory arrangement will be supplemented by decrees and resolutions to complete this transposition exercise.

3. *On 22nd July 2011, France complied with its obligations to transpose this Directive. As required by the 2009 Directive, France sent the European Commission a first national report on the implementation of the Directive in late July 2014.*
The preparation of this national report was entrusted to ASN but also to the main French administrations concerned. The licensees of the nuclear facilities concerned by the Directive (more specifically NPP reactors, fuel cycle facilities and research reactors) also contributed to the drafting of this report. Under the mandate given by the heads of State and Governments in March 2011, asking the European Commission to look at the necessary changes to the European safety framework following the Fukushima Daiichi accident, it stated that it intended to propose a revision of the 2009 Directive and to involve ENSREG in this process in early 2013.

2.4 The European Directive on the Management of spent fuel and radioactive waste

On 19th July 2011, the Council of the European Union adopted a directive *"establishing a community framework for the responsible and safe management of spent fuel and radioactive waste"* (Directive 2011/70/Euratom). The adoption of this Directive is a major event and one that helps strengthen nuclear safety within the European Union, by making the Member States more accountable for the management of their spent fuel and radioactive wastes.

This Directive is legally binding and covers all aspects of the management of spent fuel and radioactive waste, from production up to long-term disposal. It recalls the prime responsibility of the producers and the ultimate responsibility of each Member State for ensuring the management of the waste produced on its territory, ensuring that the necessary steps are taken to guarantee a high level of safety and to protect the workers and the public from the dangers of ionising radiation.

It clearly defines obligations concerning the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework covering safety issues, stipulating:
- the creation of a competent regulatory authority with a status such as to guarantee its independence from the producers of waste;
- the definition of authorisation procedures involving authorisation requests examined on the basis of the safety cases from the licensees.

The Directive regulates the drafting of the national spent fuel and radioactive waste management policies to be implemented by each Member State. It in particular specifies that each Member State has to adopt a legislative and regulatory framework designed to implement national radioactive waste and spent fuel management programmes.

The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, self-assessment obligations and regular peer reviews. These aspects constitute significant progress in reinforcing the safety and accountability of spent fuel and radioactive waste management in the European Union. In this respect also, the TECV Act and the Nuclear Ordinance also enabled the provisions of the Directive to be transposed.

2.5 The European "Basic Safety Standards" Directive

Directive 2013/59/Euratom of 5th December 2013 updates the basic standards for health protection against the hazards arising from the exposure of individuals to ionising radiation.

The new provisions include the following which are of particular note:
- the introduction of the three exposure situations defined by ICRP: exposure situations linked to the performance of a nuclear activity, emergency exposure situations and exposure situations resulting from radioactive contamination of the environment or of products, or exposure to naturally occurring radiation, including radon;
- the obligation to set up a national radon risks management plan;
- a framework for regulating natural radioactivity in building materials;
- the creation of the position of "radiation protection expert" responsible for advising employers or facility managers with regard to the protection of workers and the public;
- lowering the dose limit for the lens of the eye from 150 mSv to 20 mSv/year.

The Member States must transpose the provisions of this Directive before 6th February 2018.

In November 2013, with the agreement of the Government, ASN took the initiative of setting up the transposition committee for this new Directive, for which it now acts as coordinator and technical secretary. For the legislative part, the provisions were adopted by the Ordinance of 10th February 2016; they will enter into force on a date set by decree of the Council of State and no later than 1st July 2017. Two decrees are also currently being prepared.

2.6 The EURATOM Treaty European working groups

ASN also participates in the work of the EURATOM Treaty committees and working groups:
- Article 31 experts group (Basic Radiation Protection Standards);
- Article 35 experts group (checking and monitoring radioactivity in the environment);
- Article 36 experts group (information concerning regulation of radioactivity in the environment);
- Article 37 experts group (notifications concerning radioactive effluent discharges).

2.7 The Western European Nuclear Regulators Association (WENRA)

WENRA has since its creation pursued objectives that aim:
- to provide the European Union with independent expertise for examining nuclear safety and regulatory issues in the countries applying for European Union membership This first objective was successfully achieved on the occasion of the EU enlargements of 2004 and 2007.
- to develop a common approach to nuclear safety and regulation, in particular within the European Union, then to commit to transposing the jointly decided reference levels into the national regulations. For this second objective, WENRA set up two working groups to harmonise the safety approaches, with a view to ensuring continuous improvement in the fields of:
  - reactor safety (Reactor Harmonisation Working Group - RHWG).
  - radioactive waste, the disposal of spent fuel, decommissioning (WGWD - Working Group on Radioactive Waste and Decommissioning).

In each of these fields, the groups defined the reference levels for each technical topic, based on IAEA's most recent standards and on the most stringent approaches adopted within the European Union.

At the end of 2015, the Canadian Nuclear Safety Commission (CNSC) obtained the status of observer within WENRA. This is the tenth member of WENRA in the group of observers and the first non-European country. Japan and Serbia were also accepted as observers at the last WENRA meeting in October 2016.

In 2016, WENRA organised two plenary meetings in Vienna (13th and 14th April) then Rome (26th to 27th October).

These meetings resulted more particularly in the following:
- In 2016, cooperation between WENRA and HERCA was reinforced in the field of management of transboundary

emergency situations, through the work undertaken by the two associations for implementation of the HERCA/WENRA approach for improved transboundary coordination of protection measures during the first phase of a nuclear accident. A joint seminar was held on 14th and 15th June 2016 (Bled, Slovenia) more specifically to begin discussions with the national and international authorities responsible for civil protection. A number of measures are planned for 2017, including emergency exercises in transboundary zones.
- WENRA also continued its work on extreme phenomena (severe climatic or natural events), as well as on the development of technical specifications for the peer review of the management of the ageing of power and research reactors.
- Investigations also continued into the manufacturing anomalies affecting pressure equipment components (Flamanville, Doel, Tihange and Beznau).

2.8 Association of the Heads of the European Radiological Protection Competent Authorities (HERCA)

HERCA, the Association of the Heads of the European Radiological Protection Competent Authorities, was created in 2007 at the initiative of ASN in order to organise close consultation between the heads of the European authorities with competence for radiation protection.

Five expert groups are currently working on the following topics:
- justification and optimisation of the use of sources in the non-medical field;
- medical applications of ionising radiation;
- preparation and management of emergency situations;
- veterinary applications;
- education and training.

In 2014, HERCA approved an action plan to facilitate the transposition of Euratom Directive 2013/59 on Radiation Protection Basic Standards (see point 2.6). In 2016, HERCA organised five meetings, seminars and workshops for the various stakeholders, such as the European Commission, IAEA, the medical learned societies, manufacturers, etc., as well as the competent national Authorities responsible for the transposition work (see box below on the seminar jointly organised by HERCA and WENRA on the management of emergency situations). These events led to the preparation of joint positions, the last two of which are to be published in mid-2017.

The Board of HERCA met twice in 2016. The documents approved at these meetings were published on the HERCA website (*www.herca.org*).

2.9 ASN participation in the European Horizon 2020 programme

In 2016, ASN continued its involvement in the research sector, with participation in consortiums financed from European funds. ASN is thus one of the partners in the consortium for the European SITEX II (Sustainable Network of Independent Technical Expertise for Radioactive Waste Disposal) project, carried out under the European Horizon 2020 Programme.

The SITEX I (2012-2013) project was carried out under the European Community's seventh framework programme for nuclear research and training. Its aim was to identify the conditions and means necessary for creating an international public expertise network to address the safety and radiological protection issues entailed by the geological disposal of radioactive waste. This work led to the identification of priority topics in terms of R&D, development or harmonisation of technical guides.

FUNDAMENTALS

Establish a relationship of trust between decision-makers to improve the coordination of protection measures in the event of a nuclear accident

On 14th and 15th June 2016, in Bled (Slovenia), the HERCA and WENRA associations jointly organised a seminar on the implementation of the "HERCA/ WENRA" approach for management of radiological emergency situations, published at the end of 2014. Nearly 80 participants from 23 European countries discussed how to set up the reliable communication and information channels that are essential to achieving a harmonised approach during the first hours of an accident. The participants also identified related cooperation subjects, such as protection of the food chain or extension of protection measures beyond the predetermined perimeters, while taking account of the work ongoing or completed by IAEA, the European Commission or the NEA. At a more practical level, the participants identified border areas where NPPs are located and for which the implementation of this approach should be given priority. As of 2017, the countries concerned will simulate transboundary nuclear accidents.

A follow-up to this project was launched in June 2015 for a period of 30 months, under the European Commission's Horizon 2020 Programme, which aims primarily to create a platform of technical experts in the field of geological disposal facilities. It more specifically looks at questions of research, training, examination of files by the safety regulators and experts and the involvement of civil society.

2.10 Assistance programmes under the Instrument for Nuclear Safety Cooperation (INSC)

In 1991, the Commission launched the "nuclear safety" part of the TACIS programme to address the concerns raised by the Chernobyl accident. From 1991 to 2006, more than €1.3 billion were committed to nuclear safety projects. Since 2007, the actions of the European Union with regard to assistance and cooperation in the field of nuclear safety have continued under the Instrument for Nuclear Safety Cooperation (INSC).

Three priority areas for assistance to the countries of Eastern Europe were defined under these programmes, in the field of nuclear safety:
- contribution to improving the operating safety of existing reactors;
- provision of funding for short-term improvements to the least safe reactors;
- improvement in the organisation of safety regulation, making a clear distinction between the responsibilities of the different entities concerned and reinforcing the role and competence of national nuclear regulatory bodies.

Regulation (Euratom) 237/2014 of the European Parliament and the Council, dated 13th December 2013, revised the Instrument for Nuclear Safety Cooperation for the period from 1st January 2014 to 31st December 2020 with a budget envelope of €225.3 million, owing to European budget restrictions. In this context, the Commission also initiated a study in 2016 on the effectiveness of the instrument, to which ASN is contributing via the ENSREG WG1 "Task Group".

Moreover, regulation (EU) 236/2014 of the European Parliament and of the Council, dated 11th March 2014, laid out common rules and procedures for the implementation of the Union's instruments for financing external actions. The objectives of the new instrument include the goals of:
- supporting the promotion and implementation of stricter nuclear safety and radiation protection standards in nuclear facilities and of radiological practices in third-party countries;
- supporting the drafting and implementation of responsible strategies for ultimate disposal of spent fuel, for waste management, for decommissioning of facilities and for cleanout of former nuclear sites;
- in order to improve the implementation of the INSC between now and the end of the 2014-2020 programme, the European Commission now consults ENSREG for the definition of the strategy to be adopted to support the third-party countries.

These actions are supplemented by other international technical assistance programmes, in accordance with resolutions adopted by the G8, or by IAEA, to improve nuclear safety in third party countries, and which are funded by contributions from donor States and the European Union.

The tangible assistance actually provided by ASN via the INSC mainly took the form of aid for the nuclear safety Authorities. Thus, in 2016, ASN took part in regulatory assistance projects on behalf of the safety regulators of China (first phase, closed in October) and Vietnam. It also took part in calls for bids and notably won the second phase of the China project.

3. Multilateral International Relations

3.1 International Atomic Energy Agency (IAEA)

The International Atomic Energy Agency (IAEA) is a United Nations organisation based in Vienna. It comprises 168 Member States (September 2016 data). IAEA's activities are focused on two main areas: on the one hand, the control of nuclear materials and non-proliferation and, on the other, all activities related to the peaceful uses of nuclear energy. In this latter field, two IAEA departments are tasked on the one hand with developing and promoting applications of radioactivity, nuclear energy in particular, and on the other with the safety and security of nuclear facilities and activities.

In September 2011, the IAEA Board of Governors approved an action plan prepared by the Agency's secretariat. The main aim of this plan was to reinforce safety worldwide, taking account of the first lessons learned from the Fukushima Daiichi accident. This plan identified 12 main actions, themselves comprising targeted measures to be implemented by the Agency's secretariat and by the Member States.

IAEA is therefore focusing its work on the following fields:

- **Revision and consolidation of the Safety Standards,** describing the safety principles and practices that the vast majority of Member States use as the basis for their national regulations.

This activity is supervised by the CSS, set up in 1996. The CSS consists of 24 representatives from the highest levels of safety regulator organisations , appointed for four years and has been chaired since early 2012 by the Director General of the Czech regulatory body, Dana Drabova. In 2016, the CSS held its 39th and 40th meetings. An ASN Deputy Director General was the French representative on this Commission.

The CSS coordinates the activities of five committees tasked with supervising the drafting of documents in five areas: NUSSC (Nuclear Safety Standards Committee) for installations safety, RASSC (Radiation Safety Standards Committee) for radiation protection, TRANSSC (Transport Safety Standards Committee) for the safe transport of radioactive materials, WASSC (Waste Safety Standards Committee) for safe radioactive waste management and EPReSC (Emergency Preparedness and Response Safety Standards Committee) for preparation and coordination in the event of a radiological emergency. France, represented by ASN, is present on each of these committees, which meet twice a year. It should be noted that the ASN representative on the NUSSC was appointed chairman of this committee in 2011 and that his three-year mandate was renewed in 2014. Representatives of the relevant French organisations also participate in the work of the technical groups drafting the documents.

In order to improve the incorporation of aspects relative to nuclear safety and security, a specific Nuclear Security Guidance Committee (NSGC) was created, similar to those which already exist for safety, with an official interface being set up between the "safety" and "security" committees. In the longer term, expansion of the scope of the CSS to "security" subjects which overlap the field of safety, is being envisaged.

- **The rise in the number of peer review missions** requested from IAEA by the Member States and their increased effectiveness.

The IRRS and OSART missions belong to this category. These missions are performed using the IAEA Safety Standards as the reference, which confirms the international benchmark status of these standards.

ASN is in favour of holding these peer reviews on a regular basis, with widespread dissemination of their results. It is worth noting that through the provisions of the 2009 European Directive on the safety of nuclear facilities, revised in 2014, the Member States of the European Union are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight arrangements.

The IRRS missions are devoted to analysing all safety aspects of the activities of a regulatory Authority. In 2016, ASN took part in several IRRS missions, in Japan, Kenya, Italy and South Africa respectively. It should be noted that the IRRS mission to Japan (11th-22nd January 2016) was headed by Philippe Jamet, ASN Commissioner. It examined the strengths and weaknesses of the Japanese nuclear safety and radiation protection oversight system by comparison with IAEA standards and assessed the functioning of the new safety Authority, the NRA (Nuclear Regulation Authority) set up in 2012.

Further to the IRRS mission hosted in France in 2014, following which several recommendations and suggestions were made by the team of auditors, ASN developed an action plan to take appropriate measures and change certain practices. The follow-up mission to review the progress achieved should take place in the third quarter of 2017.

The OSART missions are carried out by a team of experts from third party countries who, for two to three weeks, assess the safety organisation of the nuclear power plants in operation. The actual implementation of the recommendations and suggestions put forward by the team of experts is verified during a follow-up mission, 18 months after the visit by the experts. The 29th OSART mission carried out in France (in other words one OSART mission per year) was held at the Golfech NPP in October 2016. As for the previous missions, the report drafted afterwards is published on *www.asn.fr* after validation by the parties. An OSART Corporate EDF follow-up mission (carried out in the head office departments of the industrial licensee) was also held in November 2016 (the OSART Corporate mission took place in 2014).

- **Regional training and assistance missions:** ASN responds to other requests from the IAEA secretariat, in particular to take part in regional radiation protection training and assistance missions. The beneficiaries are generally countries of the French-speaking community. Thus, in 2016, ASN representatives went to Algeria, Democratic Republic of Congo, Madagascar and Morocco in turn. ASN also welcomed interns from Romania and Montenegro.

- **Harmonisation of communication tools.** ASN remains closely involved in the work on the INES (International Nuclear and radiological Event Scale).

In order to contribute to the harmonisation of the use of the INES scale when communicating about an event, IAEA published guidelines in October 2014. These guidelines, which include lessons learned from the Fukushima Daiichi accident, also comprise an appendix which gives advice on how to use the INES scale in the event of an evolving severe accident.

In 2006, at France's request, a working group on the rating of radiation protection events involving patients was set up. This field is one that is not covered by the existing INES scale and in which France, thanks to the experience it has acquired with the ASN-SFRO scale, is closely involved. In 2016, France decided to apply the INES Patients scale to medical imaging but continues to use the ASN-SFRO scale for radiotherapy.

In July 2012, a draft technical document was produced, proposing a method for rating radiation protection events involving patients that is consistent with the INES rating methodology. Starting in February 2013, this method was tested for eighteen months by a small group of countries. In October 2014, the consolidated methodology was presented to all the countries using the INES scale. The documents explaining the proposed methodology were completed in 2015 and submitted to the INES Advisory Committee. They were distributed to all INES national correspondents at the end of 2015.

Generally speaking, ASN is closely involved in the various actions carried out by IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi accident, including the complete report on the accident. For information, this report was presented to the Board of Governors in September 2015 and was published at the end of 2015.

Finally and still under the supervision of IAEA, ASN also participated in the RCF (Regulatory Cooperation Forum) chaired by a deputy Director General of ASN. This forum, created in 2010, aims to bring those safety regulators in countries adopting nuclear energy for the first time into contact with the safety regulators of the major nuclear countries, so that their needs can be identified and the required support can be coordinated, while ensuring that the fundamental nuclear safety objectives can be met (independence of the regulator, appropriate legal and regulatory framework, etc.). This year, in addition to a close examination of the situation of the regulatory authorities in Belorussia, Jordan, Poland and Vietnam, the RCF reinforced its cooperation with the European Union (INSC) and with «regional" forums such as ANNuR (Arab Network of Nuclear Regulators), FNRBA (Forum of Nuclear Regulatory Bodies in Africa) and ANSN (Asian Nuclear Safety Network). Finally, the RCF examined the request from Bangladesh for active assistance, which should be effective in 2017.

3.2 OECD's Nuclear Energy Agency (NEA)

NEA, created in 1958, now counts 34 member countries from Europe, North America and the Asia-Pacific region. Its main role is to assist the member countries in maintaining and developing the scientific, technological and legal bases essential for safe, environmentally-friendly and economic utilisation of nuclear energy.

During the course of 2015, the NEA continued its analysis of experience feedback from the Fukushima Daiichi accident, both through its working groups and at specific seminars. This work led to the NEA publication entitled *"Five years after the Fukushima Daiichi Accident: Nuclear Safety Improvements and Lessons Learnt"*, published in March 2017, which presented the summary of the steps taken by the NEA member countries and defined working priorities on various subjects identified following the accident. ASN made a considerable contribution to this work, notably at the initiative of its Director General, who is also Chair of the Committee on Nuclear Regulatory Activities (CNRA).

Within the NEA, ASN takes part in the work of the CNRA, Chaired between December 2012 and June 2016 by the ASN Director General, in the Committee on Radiation Protection and Public Health (CRPPH), the Radioactive Waste Management Committee (RWMC) and several working groups of the Committee on the Safety of Nuclear Installations (CSNI).

ASN also contributed to France's answers to the questionnaire sent out by the NEA to prepare for the new strategic action plan covering the period 2017-2022 and which will in particular define the main objectives to be reached for the work of the CNRA and the CSNI.

The CNRA supervises the work done by four working groups covering a variety of fields: Working Group on Operating Experience (WGOE), Working Group on Inspection Practices (WGIP), Working Group on Public Communication (WGPC) and the Working Group on the Regulation of New Reactors (WGRNR).

It also set up working groups specifically for the following topics:
- "defence in depth": chaired by a deputy Director-General;
- "safety culture": this group looked at the safety culture characteristics within the safety regulators.

The work by these two groups led to the publication of specific green papers at the beginning of 2016.

Until June 2016, ASN also chaired the Working Group devoted to Inspection Practices (WGIP), which in particular implements a programme of observations of inspections conducted in the various member countries.

Finally, worth noting is the secondment of an ASN staff member to the NEA since 1st September 2016 as assistant to the head of the NEA's nuclear safety division and technical secretary of the CNRA.

More information about NEA/CNRA activities can be found at the following address: *www.oecd-nea.org/nsd/cnra*


Visit by Commissioner Toyoshi Fuketa (NRA) to Flamanville in the margins of the CNRA of December 2016.

3.3 The Multinational Reactor Design Evaluation Program (MDEP)

The MDEP (Multinational Design Evaluation Programme), created in 2006, is an international cooperative initiative to develop innovative approaches for pooling the resources and know-how of the regulatory bodies which have responsibility for regulatory assessment of new reactors. The key goal of this programme is to contribute to the harmonisation and implementation of safety standards.

At the request of the regulatory bodies which are members of the MDEP, the NEA is responsible for the technical secretariat of this programme. An ASN staff member is seconded to NEA to help with this task.

Members of the programme

Since 2015, the MDEP has comprised 15 national regulatory bodies (AERB - India, ASN - France, CCSN - Canada, FANR – United Arab Emirates, HAEA - Hungary, NNR – South Africa, NNSA - China, NRA - Japan, NRC – United States, NSSC – South Korea, ONR – United Kingdom, RTN – Russian Federation, SSM - Sweden, STUK - Finland, TAEK - Turkey).

Organisation

The broad outlines of the work achieved within the MDEP are defined by its Policy Group (PG) and implemented by the Steering Technical Committee (STC). Since February 2015, the STC has been chaired by an ASN Deputy Director General. This work is performed by working groups which meet periodically to deal with specific projects for nuclear reactors - the Design Specific Working Groups (DSWG) and specific technical subjects - the Issue Specific Working Group (ISWG).

The DSWG groups devoted to the EPR reactor (comprising the safety regulators of China, the United States, France, Finland, India, the United Kingdom and Sweden), to the AP1000 reactor (comprising the safety regulators of Canada, China, the United States, the United Kingdom and Sweden) and the APR1400 reactor (comprising the safety regulators of South Korea, the United Arab Emirates, United States and Finland), were supplemented in 2014 by a group devoted to the VVER reactor (in which the safety regulators of Finland, India, Russia and Turkey in particular take part) and a group devoted to the ABWR reactor (safety regulators of the United States, Finland, Japan, the United Kingdom and Sweden).

Three ISWG groups are working on harmonising the multinational inspection of nuclear component manufacturers (Vendor Inspection Cooperation Working Group - VICWG), on standards and codes for pressure vessel components (Codes and Standards Working Group - CSWG), and on design standards for digital I&C (Digital Instrumentation and Control Working Group - DICWG).

Activities

In addition to the periodic meetings by the various working groups, the MDEP began a review of its activities in 2015 in order to reinforce the effectiveness of its actions and optimise its preparations for meeting the forthcoming challenges it will have to face (activities linked to monitoring the start-up process for the EPR and AP1000 reactors, organisation of the working groups, etc.). This review work continued in 2016 and the results of this review were more particularly debated by the heads of the member authorities of the programme during the annual Policy Group meeting in Helsinki on 23rd May 2016, also marked by the celebrations of the 10th anniversary of the MDEP.

A review is also under way into the merging of the activities of the ISWG groups with those of the working groups within the technical committees of the NEA, including the CNRA and CSNI.

This same dynamic process included a first workshop organised jointly by the MDEP and WGRNR – in March 2016 in South Korea – on the generic aspects of new reactor commissioning activities.

The MDEP's 2015-2016 activity report was published in May 2016, providing information about the MDEP's work to the stakeholders, i.e. the Regulatory Authorities not participating in the MDEP, the nuclear sector industry and the general public. This report can be found at the following address: *www.oecd-nea.org/mdep/annual-reports/mdep-annual-report-2015.pdf*.

Finally, the MDEP makes sure that it maintains its interactions with the nuclear industry by organising specific meetings with the designers and the CORDEL group - Cooperation in Reactor Design Evaluation and Licensing - of the World Nuclear Association (WNA).

3.4 International Nuclear Regulators' Association (INRA)

The International Nuclear Regulators' Association (INRA) comprises the regulatory bodies from Germany, Canada, South Korea, Spain, the United States, France, Japan, the United Kingdom and Sweden. This association is a forum for regular and informal discussions concerning nuclear safety issues (each member presents its latest national news and its positions on international issues). It meets twice a year in the country holding the presidency, with each country acting as president for one year in turn (France in 2015 and Spain in 2016, United States in 2017).

3.5 The Association of nuclear Regulators of countries operating French designed nuclear power plants (FRAREG)

The FRAREG (Framatome Regulators) association was created in May 2000. It comprises the nuclear safety regulators of South Africa, Belgium, China, South Korea and France.

Its goal is to facilitate the exchange of operating experience feedback from regulation of the reactors designed or built by the same supplier and to enable the nuclear regulators to compare the methods they use to handle generic problems and evaluate the level of safety of the Framatome type reactors they regulate.

The 8th meeting of the FRAREG association was held in Belgium in November 2015. Each member presented the regulatory changes concerning the nuclear reactors in its country. Each member also reviewed the measures adopted following the Fukushima Daiichi accident. Several countries, including France, presented their experience of steam generator replacement operations. Other subjects, such as the issues involved in extending the operating life of the NPPs, or the anomalies discovered on the reactor vessels in Belgium, were also discussed.

The 9th meeting is to be held in South Korea in 2017.

3.6 The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was created in 1955. It examines all scientific data on radiation sources and the risks this radiation represents for the environment and for health. This activity is supervised by the annual meeting of the national representations of the Member States, comprising experts, including an ASN Commissioner, Margot Tirmarche.

3.7 The International Commission on Radiological Protection (ICRP)

The ICRP is a Non-Governmental Organisation (NGO) created in 1928 for the purpose of assessing the state of knowledge of the effects of radiation in order to identify their implications with regard to the radiological protection rules to be adopted. The ICRP analyses the results of the research work carried out around the world and examines the work of other international organisations, such as in particular that of UNSCEAR.

It issues general recommendations on the protection rules and exposure levels not to be exceeded, intended more particularly for the regulatory bodies.

Margot Tirmarche, ASN Commissioner, is a member of the "Health effects of radiation" C1 Committee of the ICRP and chairs a working group evaluating cancer risks linked to alpha emitters. She also took part in drafting a study on radon dosimetry in professional environments.

4. International agreements

ASN acts as the national point of contact for the two Conventions dealing on the one hand with nuclear safety (the Convention on Nuclear Safety) and on the other with spent fuel and wastes (Joint Convention on the Safety of Spent fuel Management and on the Safety of Radioactive Waste Management). ASN is also the Competent Authority for the two Conventions dedicated to the operational management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 The Convention on Nuclear Safety

The Convention on Nuclear Safety is one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide[4].

The objectives of the Convention on Nuclear Safety are to attain and maintain a high level of nuclear safety worldwide; to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate such consequences should they occur. The areas covered by the Convention have long been part of the French approach to nuclear safety.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience. Since 1999, six review meetings of the Convention on Nuclear Safety have been held, including one chaired by ASN in 2014.

In France, ASN acts as the Competent Authority for the Convention on Nuclear Safety. It coordinates all the preparatory phases prior to the review meetings, in close collaboration with the entities concerned. ASN also devotes considerable resources so that it can participate in the review meetings and be present at the various presentations and discussions.

The Vienna Declaration on Nuclear Safety was adopted by the contracting parties to the Convention on Nuclear Safety, who met on the occasion of the diplomatic conference tasked with reviewing a proposal to amend the Convention on Nuclear Safety, held on 9th February 2015 in Vienna.

In this declaration, the contracting parties to the Convention on Nuclear Safety decided that the agenda of the 7th review meeting of the Convention on Nuclear Safety would comprise a peer review of the incorporation of appropriate technical criteria and standards used by the contracting parties, aiming in each national report to give an overview of the safety improvements identified on existing nuclear facilities.

The 7th review meeting led to the designation of Ramzi Jamal (Canada) as Chair of the 7th Review, with the vice-Chairs being Georg Schwarz (Switzerland) and Geoffrey Emi-Reynolds (Ghana).

Several months before the review meeting is held, each contracting party is required to submit a national report describing how it intends to meet the obligations of the Convention. The French national report was therefore drafted and made public, on 11th August 2016, on the IAEA and ASN websites respectively. This report is then subjected to a peer review ahead of the review meeting, which involves the contracting parties asking questions about foreign national reports and answering questions about their own.

During the review meeting, the contracting parties present their national reports and take part in discussions, which can then raise additional questions. A summary report, drawn up by the meeting chairman and made public, presents the progress achieved and any difficulties that subsist.

After publication of the national report before the deadline, set for 15th August 2016, the next phase begins, involving an analysis by each contracting party of the foreign reports made public. The questions and comments resulting from this analysis by ASN were published and shared on the IAEA website before the deadline of 28th November 2016. This was followed by a new phase to draw up answers to the questions asked of France concerning its national report, which will be transmitted to IAEA before 20th February 2017. France asked 311 questions for the 7th review and received 267 questions from the other contracting parties.

The final phase of the review process for the Convention on Nuclear Safety concerns the holding of the 8th review meeting, scheduled from 27th March to 7th April 2017 in Vienna.

4. *This Convention sets a certain number of nuclear safety objectives and defines measures for achieving them. France signed it on 20th September 1994 and approved it on 13th September 1995. The Convention on Nuclear Safety entered into force on 24th October 1996 and, as at 31st December 2016, there were 79 contracting parties.*

4.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

The "Joint Convention" as it is often called, is the equivalent of the Convention on Nuclear Safety (CNS) for management of the spent fuel and radioactive waste produced by civil nuclear activities. France signed it on 29th September 1997 and it entered into force on 18th June 2001. As at 31st December 2016, there were 73 contracting parties.

The French proposal to set up a mechanism for comparing the review rules for the Joint Convention and those for the Convention on Nuclear Safety to ensure that they are consistent, was adopted and put into practice. Furthermore, at the proposal of the United States, additional meetings designed to ensure follow-up between the review meetings are being organised.

The 5th review meeting of the Joint Convention was held from 11th to 22nd May 2015. An ASN Commissioner acted as Vice-Chair.

The report issued following the Joint Convention review meeting presents an action plan for the coming years, up until the next review meeting in 2018.

A thematic meeting was thus held in September 2016 in Vienna on safety problems and questions of liability with regard to the final disposal of spent fuel or radioactive waste in a country other than that in which it was generated. The legal, regulatory and technical aspects of a multinational repository were discussed during the course of lively debates.

Similarly, on 27th and 28th October 2016, a meeting was organised to look at measures to encourage non-nuclearised countries to join the Joint Convention. Promotional actions could be carried out by IAEA and more extensive consideration of topics of interest to non-nuclear contracting parties is being envisaged.

4.3 The Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident came into force on 27th October 1986, six months after the Chernobyl accident. It had 119 contracting parties as at 31st December 2016.

The contracting parties agree to inform the international community as rapidly as possible of any accident leading to uncontrolled release into the environment of radioactive material likely to affect a neighbouring State. A system of communication between the States is thus coordinated by IAEA. Exercises are periodically organised between the contracting parties.

4.4 The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency came into force on 26th February 1987. As at 31st December 2016, there were 112 contracting parties.

Its purpose is to facilitate cooperation between countries if one of them were to be affected by an accident with radiological consequences. This Convention has already been used on several occasions for irradiation accidents due to abandoned radioactive sources. Within this context, France's specialised services have notably already taken charge of treating victims of such accidents.

4.5 Other Conventions linked to nuclear safety and radiation protection

Other international conventions, the scope of which does not fall within the remit of ASN, may be linked to nuclear safety.

Of particular relevance is the Convention on the Physical Protection of Nuclear Material, the purpose of which is to reinforce protection against malicious acts and against misappropriation of nuclear materials. The Convention came into force on 8th February 1987. It had 105 contracting parties in 2016.

Additional information on these conventions may be obtained from the IAEA website: *www-ns.iaea.org/conventions/*

5. Bilateral relations

ASN collaborates with numerous countries through bilateral agreements, which can take the form of governmental agreements (such as with Germany, Belgium, Luxembourg and Switzerland) or administrative arrangements between ASN and its counterparts (about twenty). ASN is keen to share its best practices and conversely to find out about the methods used by its counterparts in their approach to nuclear safety and radiation protection. The activities of ASN and its counterparts vary according to the safety and radiation protection topics which emerge nationally (legislation, safety topics, incidents, inspection approach, etc.).

5.1 Staff exchanges between ASN and its foreign counterparts

Better understanding how foreign nuclear safety and radiation protection regulators actually function is a way to learn pertinent lessons for the working of ASN itself and enhance staff training. One way to achieve this goal is to develop a staff exchange system.

Provision is made for several types of exchange:
- very short term actions (a few days) are a mean of offering our counterparts a chance to take part in peer-observation of inspections and nuclear and radiological emergency exercises. In 2016, about 30 peer observations of inspections in the field of nuclear safety and radiation protection were organised with Germany, Belgium, Luxembourg, Netherlands, United Kingdom, Russia, Sweden and Switzerland;
- short-term assignments (2 weeks to 6 months) aimed at studying a specific technical topic;
- long-term exchanges (about one to three years) for immersion in the working of foreign nuclear safety and radiation protection regulators. Whenever possible, this type of exchange should be reciprocal.

For many years, ASN and the ONR (Office for Nuclear Regulation – United Kingdom) have engaged in long-term staff exchanges. Since June 2014, an ASN staff member has been seconded to ONR, to join the Sellafield programme for a three-year period. This programme is one with major implications for the ONR in the coming years, in some respects very similar to those being encountered in France with the fuel reprocessing facilities (for example La Hague).

In 2015 and 2016 ASN welcomed two NRC staff members for one year each. These staff members were seconded to the Nuclear Power Plant Department, where they worked on environmental, radiation protection and labour inspectorate questions concerning nuclear power plants. The ASN seconded a staff member to the NRC from 2014 to 2016. He worked more particularly in the field of social, organisational and human factors, as well as on small-scale nuclear activities.

These staff exchanges or secondments are a means of enhancing ASN practices. Experience acquired over more than ten years now indicates that inspector exchange programmes make a significant contribution to stimulating bilateral relations between nuclear safety and radiation protection regulators.

Finally, the appointment of representatives from foreign safety regulators to its Advisory Committees of Experts must be highlighted. ASN employed this practice to enable experts from other countries to take part in these Advisory Committees.

5.2 Bilateral cooperation between ASN and its foreign counterparts

Bilateral relations between ASN and its foreign counterparts are built around an approach that integrates nuclear safety and radiation protection for each of the countries with which ASN maintains relations. The following can be offered as examples

South Africa

In 2016, ASN and its South-African counterpart, the National Nuclear Regulator (NNR), continued their technical exchanges on the topic of steam generator renewal. The NNR is preparing to examine the replacement file for the steam generators in the Koeberg NPP and wishes to draw on ASN's experience in this field. ASN was also contacted on the question of decommissioning, for which cooperation is currently being prepared.

Germany

The 42nd French-German Commission for nuclear facility safety issues (*Die Deutsche-Französische Kommission für Fragen der Sicherheit kerntechnischer Einrichtungen - DFK)* was held in June 2016 in Munich (Germany). This annual meeting enabled the two delegations to present topical points related to nuclear safety and the environment in France and Germany. A large part of the discussions concerned the current situation of border NPPs: Fessenheim and Cattenom for France and Neckarwestheim and Philippsburg for Germany.

The DFK also comprises three working groups meeting once a year and whose work concerns the safety of border NPPs, the management of emergency situations and environmental protection.

Belgium

ASN enjoys long-standing, regular and close relations with its Belgian counterpart, AFCN (Federal Agency for Nuclear Regulation), and Bel V, its technical support organisation, on a variety of subjects (power and research reactors, cyclotrons, radiation protection in particular in the medical field, radon, transport, etc.).

In addition to the periodic meetings on the safety of nuclear facilities (two meetings per year) and transport (one meeting per year), AFCN and ASN are also continuing their exchange of experience of the regulation of facilities such as the Institut national des radioéléments (IRE) in Belgium or CIS bio international in France.

As in previous years, several peer observations of inspections were organised with ASN's Belgian counterparts, whether for NPPs or in the field of small-scale nuclear activities.

Worth noting is the signature in March 2015 of a convention on the rapid exchange of information between ASN's Châlons-en-Champagne, Lille and Strasbourg divisions on the one hand, and AFCN on the other. This convention concerns situations relating to sites holding nuclear or radiological materials close to the Franco-Belgian border. This convention came into effect on 1st March 2015.

The annual meeting of the Franco-Belgian steering committee, co-chaired by Pierre-Franck Chevet and Jan Bens, Director General of AFCN, was held on 12th May 2016 at the AFCN headquarters in France.

Since 2015, internal training has been organised by ASN for the AFCN and Bel V personnel. About ten staff members from these entities can thus benefit from this training annually.

China

ASN and its Chinese counterpart, the NNSA (National Nuclear Safety Administration), renewed their overall nuclear safety and radiation protection cooperation agreement in 2014, expanding the scope of this agreement to include radioactive waste management and fuel cycle facilities. The specific cooperation agreement on the EPR was also extended by five years.

A steering committee meeting of the French and Chinese safety regulators was thus held in Beijing on 20th and 21st July 2015, leading to the drafting of an action plan for cooperation between ASN and NNSA.

An NNSA delegation thus visited ASN to meet the French regulator's teams in charge of communication and public information. ASN and NNSA practices and tools were discussed and debated.

On several occasions in 2016, in the margin of international events organised at IAEA, the senior staff of the two regulators met to discuss topical subjects, in particular concerning the progress of the construction of the EPR reactors in China and France.

Within the framework of the INSC, the consortium set up by ASN, comprising the nuclear safety regulators from Spain (CSN, *Consejo de Seguridad Nuclear*) and Finland (STUK, Säteilyturvakeskus), along with the technical support organisations from France (IRSN), Germany (GRS, *Gesellschaft für Anlagen und Reaktorsicherheit*) and Belgium (Bel V), assisted China with its process to improve the regulatory framework applicable to nuclear safety. This assistance project, which began in December 2013, ended in December 2016.

This programme comprises six areas of work: firstly, the aim is to support NNSA and its technical support organisation the NSC (Nuclear Safety Center) in their NPP reactor authorisation assessment procedures. The second goal is to help them perform these assessments in complete independence from the operator. The other areas for work are: improving the evaluation procedures for new technologies (of particular importance because China is currently building new reactors), flood protection in the NPPs and the development of operating experience feedback analysis. Finally, the aim is to reinforce the safety culture of our counterparts. The final meeting took place in Beijing on 27th October for a presentation of all the results.

Denmark

For the first time, a Danish delegation from the Danish Emergency Management Agency was welcomed in Montrouge on 5th October 2016, on the occasion of a bilateral meeting to present and share information, more specifically concerning emergency situation management (French and Danish procedures).

Spain

The meeting by the steering committee of the two regulators was held on 7th July 2016 in Madrid. The Spanish delegation, led by the CSN Chairman, Fernando Marti Scharfhausen, met the ASN Chairman. The discussions concerning participation in peer inspections, the information exchange protocol in a nuclear emergency situation and the protocol for nuclear facility decommissioning management.

In the same spirit of cooperation between the two entities, ASN received a delegation from the CSN on 23rd November 2016 to discuss spent fuel management.

The next meeting of the steering committee of the safety regulators is scheduled for May 2017 in Paris.

United States

ASN and the NRC, its American counterpart, maintained a high level of cooperation in 2016 on a variety of topics (NPP service life extension, inspections, emergency management).

The two regulators continued with their staff exchanges, with an NRC engineer being seconded to ASN and preparation by ASN for the replacement of its staff member seconded to the NRC from mid-2013 to mid-2016.

In March, ASN took part in the Regulatory Information Conference (RIC) organised by the NRC. The ASN Chairman intervened during a session concerning the service life extension of the NPPs and the Deputy Director General took part in a session on decommissioning. These two subjects led to discussions between ASN and the NRC. On the occasion of the RIC, the ASN delegation met the four NRC commissioners active at that time, including the Commission Chairman, Stephen Burns.

Meeting between the ASN Chairman, Pierre-Franck Chevet and Commissioner Philippe Jamet and the NRC chairman, Stephen Burns, on the occasion of the RIC, March 2016.

ASN and the NRC held two steering committee meetings in 2016: one in March, in Washington, the other in Paris, in October. Each meeting reviewed ongoing cooperation actions and discussed the respective topical issues at ASN and the NRC. The NRC more particularly mentioned the process currently under way in the United States to extend the NPP operating licenses from 40 to 60 years and the commissioning of new reactors, along with the topic of decommissioning. ASN mentioned the irregularities discovered in 2016 in the manufacturing process for certain large components, which was a subject of particular interest for the NRC, which will be verifying this type of deviation on its own reactor fleet.

The subjects raised in 2016 will continue to be monitored in the coming months. More extensive cooperation on the subject of decommissioning is currently being set up. The question of the manufacturing inspection of large components will also be a subject for joint work.

The Russian Federation

Under the terms of the bilateral cooperation between the Russian safety regulator *Rostekhnadzor* (RTN) and ASN, the following actions were carried out in 2016.

- On 9th February 2016, a delegation of staff from RTN took part in a peer inspection of the research reactor in the Institut Laue-Langevin in Grenoble.
- The meeting of the steering committee of the two regulators was held in Montrouge on 10th February 2016. The Russian delegation headed by the Deputy Chairman of Rostechnadzor, Alexei Ferapontov, met the ASN Chairman and their discussions in particular concerned participation in peer inspections, emergency exercises, maintenance and the management of conformity deviations.
- On 5th October 2016, a delegation of ASN staff took apart in a peer inspection of the PNPI research reactor in Gatchina, Orlova Roscha in Saint-Petersburg.

The next meeting of the steering committee of the safety regulators is scheduled for May 2017 in Moscow.

Finland

There has been longstanding cooperation between ASN and its Finnish counterpart STUK, especially in the area of the management of waste and of spent fuel. But cooperation has been significantly enhanced in recent years owing to the construction of an EPR type reactor on the Finnish site of Olkiluoto.

Ireland

In 2016, ASN and its Irish counterpart did not organise any bilateral meetings owing to the prolonged vacancy of the position of Director of the Office for Radiological Protection (ORP). However, ASN did continue its collaboration with its Irish counterpart more indirectly through the HERCA association, on subjects such as management of the radon risk, management of NORM[5] and radioactivity in building materials.

5. *Industries using materials containing natural radionuclides not used for their radioactive properties.*

Visit by Commissioner Philippe Jamet to the Rokkasho site in Japan, September 2016.

Israel

Even if regular exchanges were held in the past between ASN and its Israeli counterpart, the NLSO (Nuclear Licensing and Safety Office), linked to the IAEC (Israel Atomic Energy Commission), 2016 provided an opportunity to consolidate the relations between the two entities, with the signing of a bilateral ASN-NLSO agreement in April 2016. This cooperation primarily concerns the safety of research reactors, nuclear waste management and radiation protection; it would also promote personnel exchanges.

A French delegation, headed by an ASN Deputy Director General, was thus received in Israel in November 2016. A bilateral meeting was organised on this occasion, following a visit to the SARAF accelerator (Soreq Applied Research Accelerator Facility).

Japan

Under the arrangements concluded between ASN and its Japanese counterpart, the NRA (Japan's Nuclear Regulation Authority), a bilateral steering committee meeting was held in Japan on 12th and 13th September 2016. The discussions mainly concerned the measures linked to the restart of the reactors in Japan, the situation on the site of the Fukushima Daiichi NPP and updates regarding the safety of the fuel cycle facilities in the two countries, in particular the reprocessing plants. It should be noted that in-depth discussions on the carbon segregation problems revealed on certain reactor components occupied a good part of the debates. This meeting was supplemented by a visit to the Rokkasho site in the north of the Island of Honshu, which is home to numerous facilities, including the spent fuel reprocessing plant.

Norway

In 2016, ASN and the NRPA (Norwegian Radiation Protection Authority) continued their cooperation, under the terms of the bilateral agreement signed in December 2011. With regard to radiation protection, ASN and the NRPA continued to cooperate within HERCA. With regard to the security of radioactive sources, the two regulators continued their collaboration, in particular under an international initiative which aims to promote the search for alternatives to the use of high-level sources. A meeting was held on this subject in Vienna in June 2016. In the field of emergency situations management, ASN received a Norwegian observer during a French emergency exercise on the subject of transport, in May 2016

United Kingdom

Cooperation between ASN and the British safety regulator (ONR - Office for Nuclear Regulation) has been expanded over the years. In September 2013, a new cooperation and information exchange agreement was signed by ASN and the ONR. This agreement was supplemented in September 2014 by a cooperation protocol, updated in September 2016, to more precisely define the nature of the cooperative work between the two entities and to identify a certain number of working groups for improved oversight of the work performed jointly (see chapter 12, point 2.10.3).

Sweden

Under the terms of the cooperation and information exchange agreement signed between ASN and its Swedish counterpart the SSM *(Strål Säkerhets Myndigheten)* in September 2013, a Swedish delegation took part in a worksite inspection during the reactor 2 outage in the Saint-Laurent-des-Eaux NPP in September 2016.

Switzerland

ASN enjoys long-standing and regular relations with its Swiss counterpart, the IFSN (Federal Nuclear Safety Inspectorate) on a variety of subjects (safety of nuclear facilities, radiation protection in the medical field, preparedness for and management of emergency situations, transport, etc.).

COMPETENCIES of the main civil nuclear activity regulatory Authorities*

COUNTRY/ REGULATORY AUTHORITY	STATUS: ADMINIS-TRATION	STATUS: GOVERNMENT AGENCY	STATUS: INDEPENDENT AGENCY	ACTIVITIES: SAFETY OF CIVIL INSTALLATIONS	ACTIVITIES: RADIATION PROTECTION – LARGE NUCLEAR FACILITIES	ACTIVITIES: RADIATION PROTECTION – OUTSIDE BNIs	ACTIVITIES: RADIATION PROTECTION – PATIENTS	ACTIVITIES: SECURITY (PROTECTION AGAINST MALICIOUS ACTS) – SOURCES	ACTIVITIES: SECURITY (PROTECTION AGAINST MALICIOUS ACTS) – NUCLEAR MATERIALS	ACTIVITIES: SAFETY OF TRANSPORT
EUROPE										
Germany/ BMUB + *Länder*	•			•	•	•	•	•	•	•
Belgium/ AFCN		•		•	•	•	•	•	•	•
Spain/CSN			•	•	•	•	•	•	•	•
Finland/ STUK		•		•	•	•	•	•	•	•
France/ASN			•	•	•	•	•	•***		•
United Kingdom/ ONR		•		•	•			•	•	•
Sweden/SSM		•		•	•	•	•	•	•	•
Switzerland/ENSI			•	•	•				•	•
OTHER COUNTRIES										
Canada/CCSN			•	•	•	•	•	•	•	•
China/NNSA	•			•	•	•		•	•	•
Korea/NSSC		•		•	•	•		•	•	•
United States/ NRC			•	•	•	•	•	•	•	•**
Inda/AERB		•		•	•	•	•	•	•	•
Japan/NRA		•	•	•	•	•	•	•	•	
Russia/ *Rostekhnadzor*	•	•		•	•			•	•	•
Ukraine/ SNRIU	•	•		•	•	•		•	•	•

** Schematic, simplified representation of the main areas of competence of the entities (administrations, independent agencies within government or independent agencies outside government) responsible for regulating nuclear activities in the world's nuclear countries.*
*** National transports only.*
**** Responsibility for source security was given to ASN by the Ordinance of 10th February 2016. This provision will enter into force no later than 1st July 2017.*

Working groups meet periodically to discuss subjects related to transport and to preparedness for emergency situations (experience feedback and exchanges of best practices).

The 27th annual meeting of the Franco-Swiss nuclear safety and radiation protection committee, co-chaired by Pierre-Franck Chevet and Hans Wanner, Director General of the IFSN, took place from 22nd September to 23rd September 2016 in France. The discussions mainly concerned the reactor vessels problem on each side of the border and on the regulation of geological disposal sites. Owing to ASN's role in nuclear safety and radiation protection research as stipulated by the TECV Act, this topic was dealt with for the first time in a bilateral meeting, as Switzerland is at the forefront of research on this subject.

The meeting was preceded by a visit to the IRSN emergency centre and to the Sofia simulator in Fontenay-aux-Roses

5.3 ASN bilateral assistance

In 2015, at their request, ASN had contacts with several safety regulators in countries looking to find out about the safety measures to be implemented (creation of a nuclear safety regulatory and oversight infrastructure).

In line with its policy, ASN responds to these requests as part of its bilateral actions with the safety regulator of the country concerned, in addition to instruments that are either European (EU Instrument for Nuclear Safety Cooperation - INSC) or international (IAEA's - RCF). The purpose of this cooperation is to enable the beneficiary countries to acquire the safety and transparency culture that is essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework and advises the national safety regulator, which must retain full responsibility for its oversight of the nuclear facilities. It pays particular attention to countries acquiring technologies of which it has experience in France.

ASN considers that developing an appropriate safety infrastructure takes at least fifteen years before operation of a nuclear power reactor can begin in good conditions. For these countries, the goal is to set up a legislative framework and an independent and competent safety regulator with the financial and human resources it needs to perform its duties and to develop capacity in terms of safety, safety and regulatory culture and oversight of radiological emergency management.

In 2016, ASN had contacts with the following safety regulators:

Poland

A bilateral meeting was held in Warsaw between ASN and its Polish counterpart, the PAA (*Panstwowa Agencja Atomistyki or* National Atomic Energy Agency) in October 2016. Various safety topics were covered on this occasion: environmental monitoring, the steps in the power reactor operations licensing process (example of the EPR in France), cooperation policy with the safety regulator technical support organisations and the performance indicators used within ASN to improve the effectiveness of its regulation and oversight.

Vietnam

In 2016, ASN oversaw the second assistance programme for Vietnam under the INSC, in order to develop the safety, safety culture and regulatory capabilities of the Vietnamese nuclear regulator, VARANS. This assistance project, which started in May 2016, is scheduled to last for three years.

ASN is also involved in assistance to Vietnam via the RCF, the forum for exchanges between safety regulators, created under the aegis of IAEA. In this context, a meeting was held on 27th and 28th June 2016 in Brussels, with a view to facilitating the sharing of experience between regulators and rationalising the assistance given to those countries looking to develop nuclear energy.

6. Outlook

In 2017, ASN will seek to continue to enhance the European approach to nuclear safety and radiation protection, more particularly through bilateral cooperation agreements, but also and above all by influencing the work of ENSREG which it currently chairs. Particular attention will be given to the performance of the thematic review on the ageing of certain power reactor equipment and certain research reactors, a review that will lead to the production of a national report. ASN will also endeavour to ensure that its policies and positions have influence within multinational frameworks, in particular those linked to IAEA, within which the 7th review of the Convention on Nuclear Safety will be carried out, more specifically to examine the current situation regarding the implementation of the Vienna Declaration.

To this end, ASN:

- will continue bilateral exchanges with foreign safety regulators on regulatory practices and on priority subjects such as monitoring of the manufacture of nuclear pressure equipment;

- will actively take part in the work of HERCA, WENRA, IAEA, the NEA and INRA and will also continue to act as technical secretary for HERCA;
- will support the processes leading to peer reviews within the framework of ENSREG, as well as examination of the work being done on the continued operation of nuclear reactors and on irregularities;
- will oversee the steering committee organising the ENSREG conference on 28th and 29th June 2017;
- will present the French report for the 7th review of the Convention on Nuclear Safety (April 2017) and will prepare the national report for the Joint Convention (2018);
- will contribute to organising a tabletop exercise with safety regulators from other countries, to prepare for the management of transboundary emergency situations (HERCA / WENRA approach);
- will continue its involvement in the European cooperation instruments assisting third party countries in the field of nuclear safety;
- will carry out targeted communication actions in certain border regions where there is considerable demand for information on the part of the general public, jointly with its counterparts.

08

Regional overview of nuclear safety and radiation protection

2016 regional overview of nuclear safety and radiation protection:

Regional overview of nuclear safety and radiation protection

ASN has 11 regional divisions through which it carries out its regulatory responsibilities throughout metropolitan France and in the French overseas *départements* and collectivities.

In 2016, ASN adapted its functioning to the creation of the new regions. It has kept its local facilities which provide the foundation for its field work. Consequently, several ASN regional divisions can be required to coordinate their work in a given administrative region. As at 31st December 2016, the ASN regional divisions totalled 216 employees, including 154 inspectors.

Under the authority of the regional representative(see chapter 2, point 2.3.2), the ASN regional divisions carry out direct inspections on the Basic Nuclear Installations (BNIs), on radioactive substance transport and on small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities in charge of nuclear activity within their regions. They check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment and to Installations Classified on Environmental Protection grounds (ICPEs). They ensure the labour inspection in the nuclear power plants.

In radiological emergency situations, the ASN regional divisions assist the Prefect of the *département,* who is responsible for protection of the population, and check the on-site measures taken by the licensee to make the installation safe. To ensure preparedness for these situations, they help prepare the emergency plans drafted by the Prefects and take part in the periodic exercises.

The ASN regional divisions contribute to the public information duty. They for example take part in the meetings of the Local Information Committees (CLIs) of the BNIs, and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

This chapter presents ASN's overall assessment by broad sector of activity and its assessment of nuclear safety and radiation protection in each region. It also reports on the local issues and procedures that are particularly representative of the regional action of ASN, especially with regard to informing the public and cross-border relations.

The state of nuclear safety and radiation protection in 2016 in the Auvergne-Rhône-Alpes region

The Lyon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Auvergne-Rhône-Alpes region.

The installations and activities to regulate comprise:

- 4 NPPs operated by EDF:
  - Bugey (4 reactors of 900 MWe);
  - Saint-Alban/Saint-Maurice (2 reactors of 1,300 MWe);
  - Cruas-Meysse (4 reactors of 900 MWe);
  - Tricastin (4 reactors of 900 MWe);
- the nuclear fuel fabrication plants of Areva NP in Romans-sur-Isère;
- the nuclear fuel cycle plants operated by Areva and its subsidiaries on the Tricastin industrial platform;
- the Operational Hot Unit at Tricastin (BCOT) operated by EDF;
- the High Flux Reactor operated by the Laue-Langevin Institute in Grenoble;
- the Activated Waste Packaging and Storage Facility (ICEDA) under construction on the Bugey nuclear site and the Bugey Inter-Regional Warehouse (MIR) operated by EDF;
- the Superphénix reactor undergoing decommissioning at Creys-Malville, and its auxiliary installations;
- reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;
- the Ionisos irradiation facility in Dagneux;
- the nuclear fuel fabrication plant and pelletising unit of Areva SICN in Veurey-Voroize, decommissioned and waiting to be delicensed;
- the CEA (French Alternative Energies and Atomic Energy Commission) reactors and plants in Grenoble, decommissioned and waiting to be delicensed;
- the CERN international research centre located on the Swiss-French border;
- small-scale nuclear activities in the medical sector:
  - 22 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 23 nuclear medicine departments;
  - about 200 centres performing interventional procedures;
  - 120 tomography devices;
  - about 10,000 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 700 veterinary structures (practices or clinics);
  - about 30 industrial radiology agencies;
  - about 600 users of ionising radiation in the industrial sector;
  - about 100 research units;
- 22 head offices of ASN-approved organisations:
  - 4 organisations approved for radiation protection technical controls;
  - 6 organisations approved for measuring radon;
  - 12 laboratories approved for measuring environmental radioactivity.

In 2016, ASN carried out 318 inspections in the Auvergne-Rhône-Alpes region, of which 74 were in the nuclear power plants of Bugey, Saint-Alban/Saint-Maurice, Cruas-Meysse and Tricastin, 84 in other nuclear plants and facilities undergoing decommissioning, 145 in small-scale nuclear activities and 11 in the transport of radioactive substances.

ASN also carried out 33 days of labour inspections in the four nuclear power plants and on the Creys-Malville site.

ASN was notified of 33 significant events rated level 1 on the INES scale, of which 30 occurred in BNIs, 1 in the transport of radioactive substances and 2 in small-scale nuclear activities.

In small-scale nuclear activities, 10 significant events concerning radiotherapy patients were rated level 1 or higher on the ASN-SFRO scale. One event in radiotherapy was rated level 2.

1. Assessment by domain

1.1 The nuclear installations

Bugey nuclear power plant

ASN considers that the radiation protection and environmental protection performance of the Bugey NPP is on the whole in line with the general standard of EDF plant performance, but that its nuclear safety performance remains slightly below the norm.

With regard to nuclear safety, ASN notes that in 2016 the Bugey NPP consolidated the progress observed since 2014, but it detected several weaknesses in the periodic tests and monitoring in the control room.

With regard to maintenance, the context of the Bugey NPP is singular, with reactor 5 being kept shut down since the end of August 2015 due to a problem of reactor containment leaktightness. The end of the year was marked by the discovery, during a national inspection campaign, of carbon segregations in the steam generators of reactor 4.

Regarding environmental protection, ASN notes that the operational results concerning discharges are satisfactory.

As far as radiation protection is concerned, ASN notes that the Bugey NPP's results are down with respect to 2015. ASN finds that the radiation protection culture has waned, as witnessed by events that nevertheless concern the basic rules applicable to nuclear workers. ASN also notes too many situations where the personal protection means are inadequate for the work conditions.

Saint-Alban/Saint-Maurice nuclear power plant

ASN considers that the performance of the Saint-Alban/Saint-Maurice NPP with regard to nuclear safety, environmental protection and radiation protection is, on the whole, in line with the general standard of EDF plant performance.

ASN notes that the in-depth actions carried out since 2011 to lastingly redress the site's performance have produced results.

Only one reactor outage was scheduled for maintenance purposes in 2016. The ASN inspection during the outage of reactor 2 revealed that EDF had improved the effectiveness of its maintenance work organisation. ASN does however note that EDF must ensure greater reliability of the circuit breakers on the high-power electrical circuits of the NPP's reactors.

With regard to environmental protection, ASN notes that the operational results for discharges are satisfactory, reflecting EDF's better management of its operational control actions.

With regard to worker protection, ASN notes that the operational results for radiation protection were satisfactory on the whole, particularly during the reactor 2 outage, even though EDF must make further progress in radiological cleanliness.

Cruas-Meysse nuclear power plant

ASN considers that the overall performance of the Cruas-Meysse NPP with regard to nuclear safety, environmental protection and radiation protection is below the general standard of EDF plant performance.

After a relatively good start to 2016, ASN notes that the operating rigour of the Cruas-Meysse NPP with regard to safety remains tenuous when the work load increases due to reactor maintenance outages.

ASN notes that the third ten-yearly outage of reactor 4 on the whole went better than that of reactor 1 in 2015. The outages of reactors 1, 2 and 3 in the second half of the year however did not achieve the performance observed with the third 10-yearly outage of reactor 4.

With regard to environmental protection, ASN remains particularly vigilant in two areas: waste management and containment of liquids.

With regard to radiation protection, 2016 follows the trend of the preceding years: collective dosimetry is properly managed but there are still difficulties in obtaining satisfactory levels of radiological cleanliness during reactor outages.

Tricastin nuclear power plant

ASN considers that the overall performance of the Tricastin NPP with regard to nuclear safety, environmental protection and radiation protection is in line with ASN's general assessment of EDF plant performance and follows the Tricastin NPP's performance trends seen over the last four years.

With regard to maintenance, ASN observes that the Tricastin NPP's performance in reactor outage management remains good on the whole. This being said, all the site's reactors are concerned by the presence of carbon segregations in the steel of the steam generator channel heads, which has led EDF to keep reactors 1 and 3 of its installation shut down. With regard to reactor 2, on 11th January 2017 EDF asked that the checks prescribed by ASN be pushed back two weeks. This request was prompted by the risks for the safety of the electricity network associated with the period of cold weather observed in mid-January. ASN considered this postponement acceptable with regard to the question of safety and set the date of 3rd February 2017 for the checks on this reactor.

With regard to protection of the environment, while the radioactive and chemical discharges are well managed on the whole, ASN notes that waste management and the containment of liquid radioactive substances must be improved without fail.

As far as radiation protection is concerned, although ASN notes some improvements compared with last year, radiological cleanliness displays the same shortcomings as in 2015.

Labour inspection in the nuclear power plants

Eighteen labour inspections were carried out during 2016, along with 15 days of presence in the region's nuclear power plants for meetings, discussions with employees and staff representatives, and participation at the meetings of the Committees for Health, Safety and Working Conditions (CHSCT). These inspections were chiefly carried out on the maintenance worksites set up during reactor outages. Several inspections were also carried out further to serious work accidents.

ASN noted shortcomings in the management of a decommissioning operation which resulted in several employees being exposed to asbestos fibres on the Bugey NPP reactor 1 undergoing decommissioning.

Also to be noted is the handling of two serious and imminent danger reporting procedures by inspectors who had to adopt a position because the management and employee representatives failed to reach a consensus. These serious and imminent danger reports concerned isolated work and the competence of employees called in to replace employees on strike. Lastly, an answer has been given concerning the whistle-blowing right concerning public health and the environment lodged at the end of 2015 with respect to the sulphuric acid and monochloramine installations of the Cruas-Meysse NPP.

Fuel cycle installations

Areva NP nuclear fuel fabrication plants in Romans-sur-Isère

In 2016, Areva NP continued its actions to improve the safety of the facilities in the context of increased ASN scrutiny of the Romans-sur-Isère site since 2014.

The inspections conducted in 2016 confirmed the improvement in safety management. The improvements in operating rigour, particularly in control of the criticality risk, equipment qualification and the performance of periodic checks and tests were also confirmed in 2016.

In terms of environmental protection, ASN considers that Areva NP must improve its control of waste management, particularly with regard to the distinction between nuclear waste and conventional waste. ASN nevertheless notes with approval the repair work on the retention areas and storm-water drainage systems and the creation of storm-water tanks.

The work to bring the BNI 98 installations into conformity and reinforce them is well advanced. The analysis of the periodic review file[1] for this installation, which will be completed in 2017, has already shown that additional substantiations must be provided regarding earthquake and fire resistance and consideration of the risks associated with hazardous substances. On completion of its examination, ASN will declare its decision regarding the conditions

1. *The periodic safety review comprises two parts: the conformity check and the safety reassessment. The periodic safety review allows firstly a detailed examination of the situation of the facility in order to ensure that it does effectively comply with all the rules applicable to it (conformity check) and secondly, it makes it possible to improve its level of safety with regard to the requirements applicable to facilities with more recent safety goals and practices, while taking account of changing knowledge and national and international experience feedback (safety reassessment). The periodic safety review also makes it possible to check that the various ageing phenomena affecting the facilities will be controlled for a further period of at least ten years.*

under which BNI 98 can continue operating and the lifting of increased vigilance. Another phase of reinforcement work on the recycling unit is also expected.

With regard to BNI 63, ASN will be particularly attentive to the execution of the work to improve the containment of radioactive substances and the control of the earthquake and fire risks in the main building, scheduled for 2017. In its examination of the periodic review file provided by the licensee, ASN will assess compliance with its resolution 2015-DC-0485 of 8th January 2015 which requires implementation of the installation reinforcement commitments by the end of 2017. On completion of this examination, ASN will also decide on the continuation of operation of BNI 63 and the release of increased vigilance.

Areva NC nuclear fuel cycle plants situated on the Tricastin industrial platform

The inspections by ASN in 2016 of Areva NC Tricastin site management addressing the themes of deviation management, transport of radioactive substances and emergency management gave satisfactory results. ASN has however noted that the various installations had different understandings of the notion of installation modification and considers that a dedicated quality process - an integral part of the site's integrated management system - should be implemented.

In 2016, Areva NC presented a project to ASN that aims to go further in the mutualisation of the organisation of licensees in order to achieve a fully integrated site organisation in 2017, which would be based on cross-structural functional departments. This modification would lead more specifically to the reorganising of the department responsible for safety and the environment. ASN considered that the submitted file was not admissible because it does not demonstrate how the nuclear licensees, who are responsible for the safety of their installations, will be able to exercise this responsibility.

In 2016, ASN moreover approved all the On-site Emergency Plans (PUI) of the licensees of BNIs operated by Areva NC and its subsidiaries on the Tricastin site, which now allow the deployment of an emergency organisation based on common resources but coordinated by the licensee concerned by the accident, should one occur.

Areva NC's uranium chemistry plants TU5 and W in Pierrelatte

ASN considers that operation of BNI 55 by Areva NC is relatively satisfactory with regard to nuclear safety.

For the TU5 plant, the examination of its periodic safety review continued in 2016. In this context, the classification of the first containment barrier as an Element Important for Protection (EIP), and the measures taken on the systems conveying uranium-bearing materials should enable the number of containment losses, which are still too frequent, to be reduced in the medium term.

With regard to the W plant, ASN's inspections revealed that the licensee must continue to bring the installation into compliance with ASN resolution 2015-DC-0489 of 8th January 2015 setting the prescriptions applicable to it.

The civil engineering work on the W plant's new uranium hexafluoride (UF_6) Emission Unit (EM3), which is scheduled for commissioning in 2018, is finished. This new unit will meet the safety requirements set by ASN following the Fukushima Daiichi nuclear accident. ASN will revise the abovementioned resolution in 2017 setting the prescriptions applicable to the W plant to supervise the functioning of this unit.

More generally speaking, ASN expects the licensee to improve the rigour of operation of the two installations. More specifically, Areva NC must take care to keep the organisational documents and operational documents more up to date and to apply them and fill them out with greater rigour. ASN also expects greater rigour in the execution of operational and maintenance procedures, in the management of anomalies detected further to the periodic checks and tests and in the monitoring of deviations and the resulting actions.

Lastly, the reflections and measures taken to improve zone marking relative to radiation protection and waste respectively must be continued.

Areva NC's uranium fluorination plants in Pierrelatte

ASN considers that the conversion facilities situated within the perimeter of BNI 105 operated by Areva NC require the licensee's continued vigilance. The operating rigour of the Comurhex 1 plant, whose shutdown has been prescribed for 31st December 2017 by ASN, must be maintained.

ASN observed an increase in the number of events in 2016 which, although they had no significant consequences on personnel or the environment, nevertheless led to losses of containment of radioactive or chemical substances. These events have revealed deficiencies in the supervision of work on equipment, operating rigour or the safety culture and the management of alarms and abnormal situations. ASN therefore expects Areva NC to rapidly introduce effective and lasting corrective measures.

In 2016, Areva NC continued the Comurhex 1 plant containment improvement work which began in 2015. It also carried out work on the new building for storing hydrofluoric acid resulting from the Comurhex 2 project, within the framework of the stress tests carried out further to the Fukushima Daiichi nuclear accident.

Construction of the new fluorination unit of the Comurhex 2 project is almost completed. The licensee has started the functional tests of the systems. Commissioning of this new unit is planned for the beginning of 2019.

Alongside this, the licensee continued its programme to prepare for final shutdown of the old installations of BNI 105. It supplemented the final shutdown and decommissioning file for BNI 105 in April 2016. After IRSN (Institute for Radiation Protection and Nuclear Safety) submitted an opinion in May 2016, ASN pursued the examination process by holding administrative consultations, notably the Environmental Authority of the General Council for the Environment and Sustainable Development, which submitted its opinion in September 2016; a public inquiry was held in February 2017.

Eurodif's Georges Bess I enrichment plant in Pierrelatte

ASN considers that operation of BNI 93 by Eurodif is quite satisfactory with regard to nuclear safety.

The gaseous diffusion rinsing of the enrichment cascade equipment was finished at the end of 2015 and achieved the uranium-removal objectives for the circuits and diffusers. In 2016, Eurodif continued the post-operational cleanout and air packaging of these equipment items. The operations of rinsing and pressurising the associated units with air are completed. ASN considers that the safety of conduct of these operations was satisfactory.

For 2016, ASN notes a deterioration in the control of radiation protection and environmental protection, particularly in the areas delegated to the joint services of the Tricastin site, operated by Areva NC. Eurodif must continue to exercise its responsibility as nuclear licensee until the installation is completely decommissioned. ASN will be attentive to ensuring that the licensee has the necessary technical capacities to do this.

The licensee submitted its final shutdown and decommissioning application for the installation in March 2015, and supplemented it at ASN's request on 30th June 2016. This file was subject to a public inquiry in February 2017. The decommissioning challenges concern the volume of waste produced (including 180,000 tonnes of metal waste) and the decommissioning time frame (currently estimated at thirty years).

It is planned to keep the installations under surveillance until the first decommissioning operations are started. ASN has asked Eurodif to continue its operations concerning aspects independent of decommissioning, such as the removal of operational waste and treating residual pollution in the installations.

SET's Georges Bess II enrichment plant in Pierrelatte

The Georges Besse II (GB II) plant operated by *Société d'Enrichissement du Tricastin* (SET), displayed a satisfactory level of safety in 2016. The technologies utilised in the facility enable high targets for safety, radiation protection and environmental protection to be achieved.

Nevertheless, the analysis of event occurrences shows a slight deterioration in operating rigour for which corrective actions must be taken.

The gradual entry into production of the enrichment cascades is almost complete. ASN considers that the internal cascade start-up authorisation commission functioned satisfactorily. Ramping the plant up to full production has been slowed down to maintain the skills currency of the centrifuge installer's teams. It should be completed in 2017.

The year 2016 has enabled the licensee to enhance the operating reliability of the reception, sampling and conditioning unit, in which malfunctions were observed in 2015.

Socatri's maintenance, effluent treatment and waste packaging facilities in Bollène

ASN considers that Socatri's operational safety improved in 2016. The licensee has put in place action plans to better satisfy the requirements concerning management of the criticality risk and to comply with the design requirements of the installation's EIPs.

Implementation of the commitments made by the licensee following the periodic safety review of the installation is progressing. ASN remains vigilant with regard to the successive updates of the safety baseline requirements (safety analysis report and general operating rules) resulting from these commitments.

On the other hand, ASN observed deviations in the field of maintenance in 2016. ASN more specifically expects the licensee to implement tightened checks on the hazardous substances retention systems.

Lastly, the Creation Authorisation Decree for BNI 138, authorising more specifically creation of the new waste treatment facility «Trident» (French acronym derived from its purpose, namely «integrated treatment of Tricastin's nuclear waste), is currently being prepared. The public inquiry was held from 6th June to 5th August 2016 and the licensee's file received a favourable opinion from the inquiry commission.

Atlas laboratories in Pierrelatte

Atlas constitutes BNI 176, a new installation of laboratories authorised by Decree 2015-1210 of 30th September 2015.

ASN inspected the development worksite in 2016 and defined the prescriptions governing discharges, the intakes and the monitoring of the environment around this installation. The installation commissioning conditions are set out in ASN resolution CODEP-CLG-2016-051122.

Installations undergoing decommissioning

EDF Superphénix reactor at Creys-Malville

ASN considers that the safety of the Superphénix reactor decommissioning operations and of operation of the APEC (Fuel Storage Facility) is ensured satisfactorily. However, several events resulted from inadequately prepared periodic tests or maintenance operations.

With regard to environmental protection, in 2015 ASN asked EDF to set up an organisation enabling it to remove hazardous substances that could build up in the retention areas. The year 2016 showed that EDF had taken this request into account but additional measures were necessary to improve the leak tightness checks of the retention systems and to deal with defects identified during these checks.

EDF performed the periodic safety review on the site's two installations. ASN has started the technical examination of the submitted files and once completed it will specify the upgrading work to perform on the installations.

EDF Bugey nuclear power plant reactor 1 undergoing decommissioning

ASN considers that the decommissioning of the Bugey NPP reactor 1 is proceeding with satisfactory levels of safety. The licensee has a robust organisation and monitors the decommissioning equipment and work with rigour.

In 2016, EDF presented a project to ASN to modify the decommissioning strategy for the gas-cooled reactors which would result in the Bugey 1 installation decommissioning schedule being pushed back by several decades. In 2017, ASN will examine the files it has requested to justify this change of strategy and its compatibility with the principle of immediate dismantling defined by the environment code. If this new strategy and the corresponding time frame were implemented, the decree governing the reactor decommissioning would have to be revised.

ASN will also examine the periodic safety review guidance file provided by EDF for the Bugey NPP reactor 1. The safety review conclusion report is to be submitted by EDF before the end of 2018.

CEA Grenoble reactors and plants undergoing decommissioning

The LAMA (Active Materials Analysis Laboratory) and the STED (Effluent and Solid Waste Treatment Station) decommissioning operations are now completed. ASN considers that these operations were carried out under satisfactory conditions with regard to safety and protection of the environment and the workers.

As the post-operational cleanout objectives for the LAMA have been achieved, ASN has started the procedures to inform and consult the stakeholders on the draft resolution for delicensing the installation.

The technical discussions between ASN and CEA concerning remediation of the soil of the STED (Effluent and Solid Waste Treatment Plant) continued in 2016. The installation delicensing application file will be sent to ASN in 2017.

The other installations on the site - the experimental reactors Siloé, Siloette and Melusine - have been cleaned out and delicensed.

The other industrial and research facilities

High Flux Reactor of the Laue-Langevin Institute in Grenoble

ASN considers that the safety of the High Flux Reactor (RHF) which constitutes BNI 67 is managed satisfactorily for the technical subjects identified as priorities by the Laue-Langevin Institute (ILL), but it wants ILL's organisation regarding the requirements of the regulations to be reinforced.

Consequently, in the light of lessons learned from the Fukushima Daiichi accident, the ILL proposed applying substantial reinforcements with an ambitious schedule, and this work continued satisfactorily in 2016.

Nevertheless, ASN expects the ILL to analyse and make greater use of experience feedback to improve its organisation and its practices, particularly on the basis of notified significant events, observations and requests formulated by ASN following inspections, or in the context of the annual assessments relative to safety, the environment and radiation protection.

After having authorised a modification of the site's safety organisation in order to meet regulatory requirements, ASN asked the ILL in 2016 to evaluate the need to allocate additional resources to safety. This is because ASN noted that the licensee's current organisation does not enable it to meet all the requirements concerning the management of deviations, the detection of events and the Integrated Management System (IMS) as specified in the Order of 7th February 2012. ASN wants to see the effective implementation of an ISM and will perform inspections on this subject in 2017.

Lastly, the ILL must transmit the periodic safety review file for the installation to ASN in 2017. On completion of its examination, ASN will rule on the continuation of operation of the installation.

The EDF Activated Waste Packaging and Interim storage Installation (Iceda) at Bugey

The purpose of the Iceda facility (BNI 173) will be to process and store activated wastes from operation of the EDF installations and from the decommissioning of the first-generation reactors and the Creys-Malville NPP.

The construction work on the facility continued in 2016. Suspension of the worksite further to administrative proceedings led to a delay of at least three years in the commissioning of the facility, which EDF had initially planned for early 2014.

The Iceda commissioning authorisation application file was submitted to ASN in July 2016 with commissioning planned for 2017. ASN plans to perform several inspections prior to facility commissioning to check qualification of the EIPs and the AIPs (Activities Important for Protection) and to monitor the equipment and system tests.

The EDF Inter-Regional fuel Warehouse at Bugey

The Inter-Regional Warehouse (MIR - BNI 102) operated by EDF at Bugey is a storage facility for fresh nuclear fuel intended for the nuclear power plant fleet in operation.

The level of safety of MIR was satisfactory in 2016. ASN nevertheless considers that the licensee must be more rigorous in the scheduling of periodic tests.

The periodic safety review of the facility is in progress, as are the stress tests required by ASN in the wake of the Fukushima Daiichi nuclear accident. The facility has more specifically been modified to improve control of the risk of flooding.

After completing examination of the periodic safety review file submitted by the licensee, ASN will rule on the conditions for continued operation of the facility.

Ionisos irradiator in Dagneux

The Dagneux irradiator – BNI 68 – operated by the company Ionisos, displayed a satisfactory level of safety in 2016.

Ionisos has undertaken to send a periodic safety review conclusions report for the facility by 31st October 2017, which must take into account the lessons learned from the periodic reviews of the Ionisos sites of Pouzauges (Vendée) and Sablé-sur-Sarthe (Sarthe).

ASN considers that the decommissioning of pools D1 and 2 in final shutdown status must begin. ASN has asked Ionisos to update its decommissioning strategy. Ionisos responded by submitting a decommissioning plan for the pools, which ASN is currently examining.

Tricastin Operational Hot Unit (BCOT) in Bollène

On completion of its inspections, ASN considers that level of safety of the Tricastin Operational Hot Unit (BCOT) is satisfactory on the whole. It nevertheless considers that the licensee must improve the operational rigour of the periodic checks and tests. The on-site emergency plan approved by ASN at the end of 2016 must moreover be implemented rapidly.

Following a first campaign of cutting up used rod cluster control guide tubes from the EDF pressurised water reactors, for which the feedback report demonstrated satisfactory conditions of safety, the operations were continued and should end in 2017.

CERN accelerators and research centre (Geneva)

Following the signing of an international agreement between France, Switzerland and CERN on 15th November 2010, ASN and the OFSP (Swiss Federal Office of Public Health) - the Swiss radiation protection oversight body - are contributing to the verification of the safety and radiation protection requirements applied by CERN. The joint actions concern transport, waste and radiation protection.

In 2016, ASN and the OFSP thus continued examining the safety rules submitted by CERN to demonstrate the safety of the new facilities, and more specifically the new linear accelerator Linac 4 and a waste storage and sorting facility.

The French and Swiss authorities made a joint visit in 2016 on the theme of environmental monitoring.

1.2 Radiation protection in the medical field

Radiotherapy

In 2016, ASN conducted inspections in 9 of the 22 radiotherapy centres of the Auvergne-Rhône-Alpes region and two inspections in brachytherapy centres.

ASN's inspections focused in particular on the management of treatment safety and quality, preparation of treatments, control of patient positioning during treatment and implementation of the professional practices evaluation process. Particular attention was also devoted to centres that implement innovative treatment technologies, those whose staffing levels are considered potentially vulnerable, and those that are behind schedule with implementation of the quality assurance system.

The results of these inspections show that all centres have taken organisational steps since 2009 to implement a quality assurance approach to improve the delivery of treatments to patients. These quality assurance systems are now increasingly used on a daily basis by all the personnel in the centres as part of a process for continuous improvement of quality of medical care.

The radiotherapy centres have all put in place a system for detecting significant events. In the majority of cases, these events concern a patient over one or a few treatment sessions and have no expected clinical consequences. ASN was notified of 17 events in 2016 and is making sure that the centres concerned draw the appropriate lessons from these events. Of these 17 significant events, one was provisionally rated level 2 and nine were rated level 1 on the ASN-SFRO scale, which comprises eight levels from 0 to 7.

One of the ASN inspections was carried out further to the occurrence of an event provisionally rated level 2 on the ASN-SFRO scale: the event involved exposure of a patient to a higher-than-prescribed dose.

Interventional practices

In the light of the 26 inspections carried out in 2016, ASN considers that patient and worker radiation protection practices have improved slightly over the last three years, but they must be further optimised in the area of interventional practices. Large disparities have been observed between interventional services and improvements are required in operating theatres, where ASN has in particular observed deficiencies in personnel training and the wearing of dosimeters.

With regard to interventional practices, the optimisation of doses delivered to patients and medical personnel is not yet sufficiently developed. The time medical physicists devote to this activity is still insufficient. Furthermore, the training of practitioners in good patient and staff radiation protection practices, and in the use of certain devices, must be continued.

Nuclear medicine

The 6 inspections carried out in 2016 reveal that radiation protection of workers, patients and the public is on the whole taken into account in the nuclear medicine facilities in the Auvergne-Rhône-Alpes region.

Improvements are nonetheless required in performing in-house technical radiation protection controls, in assessing the risk of worker internal contamination, in the management of radioactive effluents and the analysis of significant events.

Computed tomography

ASN conducted six inspections in computed tomography facilities in the Auvergne-Rhône-Alpes region in 2016. ASN mainly verified that the inspected centres had initiated a patient dose optimisation approach when performing computed tomography procedures. This process must be continued and developed, particularly by generalising the involvement of medical physicists in this area.

1.3 Radiation protection in the industrial, research and veterinary sectors

Industrial radiography

In the industrial radiography sector, ASN considers that radiation protection is ensured relatively satisfactorily, be it in the agencies or during worksite operations. The inspections carried out in 2016 indicate that the main regulatory requirements concerning radiation protection of workers and the public are satisfied. Nevertheless, improvements are required in the delineation of the worksite work zones (installation of signs and markings) and their consistency with the risk analyses, and in the exhaustiveness of the radiation protection controls carried out within the agencies.

Veterinary

During summer 2016, ASN conducted an inspection campaign in Auvergne involving 21 veterinary practices and clinics specialised in pet care. This campaign was carried out in several stages as indicated below.
- A self-assessment questionnaire was sent to all the veterinary practices and clinics in Auvergne in autumn 2015. This questionnaire provided an initial estimation of the degree of regulatory compliance along with information on the activities and organisation of the practices/clinics. Analysis of the questionnaire also enabled those practices/clinics presenting deviations to be encouraged to take measures to ensure compliance with the regulations in force and target those on which ASN would continue its inspections.
- ASN then conducted a more detailed remote documentary verification in early 2016 on 25 veterinary practices/clinics. They were chosen according to their level of regulatory compliance, estimated from the self-assessment questionnaire.
- Lastly, a field inspection campaign was carried out on 21 veterinary practices/clinics during summer 2016.

These inspections revealed that the main regulatory radiation protection provisions were applied relatively satisfactorily.

1.4 Radiation protection of the public and the environment

Radon

In 2016, ASN continued its inspections to verify compliance with the regulations relating to management of the radon risk in facilities open to the public in the Auvergne-Rhône-Alpes region, particularly in schools, detention centres and spas.

The results of the remote inspection campaign on the limitation of radon exposure risks in state-run schools (nursery and primary) carried out by ASN jointly with the eight prefectures and the two Regional Health Agencies (ARS) concerned, were analysed. This campaign targeted the largest municipalities in the *départements* classified with priority status for the radon risk. It reveals a situation that is generally satisfactory, even if the radon screening periodicity of ten years is not always respected. This investigation complemented the meetings with the regional authorities responsible for state-run lower and upper secondary schools.

ASN began a series of inspections in private educational institutions concerned by the radon exposure risk. These inspections should continue in 2017.

Furthermore, after meeting the inter-regional directorate of prison authorities, responsible for the large majority of detention centres in AuvergneRhône-Alpes, ASN had meetings with non-state-owned detention centres to verify that the radon risk was duly taken into account in these establishments.

Likewise, ASN conducted inspections in spas.

***Former mining site of Saint-Priest-la-Prugne (Loire* département)**

In 2015, Areva withdrew its file for the redevelopment of the Saint-Priest-la-Prugne site. This project planned to make the site safe over the long term by eliminating the dam behind which the mine tailings are stored and replacing the hydraulic cover with a solid cover. ASN considers that, although the site is safe in the short and medium term, given the nature of the radionuclides stored there, Areva must find a solution to improve its security over the long term.

In 2016, ASN participated in meetings organised by the Roanne sub-prefecture concerning the situation of the site and of the mine tailings found around the former Saint-Priest-la-Prugne mine. An unannounced visit was made jointly with the Regional Directorate for the Environment, Planning and Housing (Dreal) in October 2016 to observe the mine tailings removal work.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out 11 inspections in the field of radioactive substance transport in the Auvergne-Rhône-Alpes region in 2016, including two inspections of nuclear medicine departments, three unannounced inspections of radioactive package carriers and one unannounced inspection of on-site transport and shipping on the Areva platform at Tricastin.

During these inspections, ASN checked the organisation put in place by the licensees and carriers to comply with the regulations relative to the transport of radioactive substances and for the operations relating to the shipping and reception of packages in these installations.

The inspections on the transport of radioactive substances carried out by ASN in the Auvergne-Rhône-Alpes region in 2016 revealed no situations giving cause for concern. With regard more specifically to the inspections in the nuclear medicine departments, although they revealed satisfactory application of the regulations, improvements are required in several areas, notably the establishing of a security protocol, the monitoring of personnel training in radioactive substance transport and the robustness of the quality assurance systems.

With regard to the tightened inspection conducted on the Areva platform at Tricastin, the inspectors found the management of on-site and off-site transport operations to be satisfactory on the whole. Numerous minor deviations were nevertheless noted.

2. Additional information

2.1 Informing the public

Work with the Local Information Committees (CLIs)

All nuclear facilities in the Rhône-Alpes region apart from the Ionisos irradiator in Dagneux (Ain *département*) have a CLI.

These CLIs, whose activity has developed considerably since 2009 through the coordination and realisation of diverse assessments, held regular meetings in 2016. Only the CLIs of Creys-Malville and of the Société Industrielle de Combustible Nucléaire - SICN (both in the Isère *département*) did not meet in 2016.

ASN took part in 16 CLI meetings in 2016. The subjects addressed concerned the ongoing issues in the nuclear installations, such as the anomalies affecting primary system components, or the revisions of installation water intake and discharge authorisations. The iodine tablet distribution campaign was presented in each of the four CLIs concerned (Bugey, Saint-Alban/Saint-Maurice, Cruas-Meysse and Tricastin). Lastly, the tightened vigilance applied to the Areva NP site of Romans-sur-Isère and the progress of the licensee's safety improvement plan are always presented at each meeting of the CLI.

A number of CLI members attended ASN inspections on the EDF and Areva sites at Tricastin as observers, which was a first for an Areva site.

In application of the new provisions of the Energy Transition for Green Growth Act (TECV), the CLIs of Bugey, Saint-Alban/Saint-Maurice, Cruas-Meysse, Romans-sur-Isère and Tricastin organised public information meetings on nuclear activities and on their work.

Information and preventive distribution of iodine tablets campaign around French nuclear power plants

This campaign aimed at both replacing the iodine tablets distributed in 2009, which reached their expiry date in 2016, and developing the radiation protection culture of the people living or working in the vicinity of the 19 French nuclear power plants and the ILL (Laue-Langevin Institute).

This campaign concerned 375,000 households and facilities open to the public (companies, shops, schools, etc.) in 500 municipalities in France.

The campaign was organised by the Ministries responsible for Education, the Interior and Health, jointly with ASN and EDF. It was coordinated at regional level by the Prefects assisted by the Regional Health Agencies (ARS), mayors, CLIs, dispensing pharmacists and private practitioners of the areas concerned.

ASN took part in 17 public meetings organised around the four NPPs plants in the Auvergne-Rhône-Alpes region.

2.2 International action

The Lyon division continued its bilateral exchanges with the Japanese and Chinese nuclear safety authorities concerning inspection practices and measures implemented further to the Fukushima Daiichi accident.

In this context, a delegation of inspectors from the Lyon division was received by the NRA (Japan's Nuclear Regulation Authority). The exchanges focused on equipment qualification and putting the reactors in Japan back into service. A visit to the Fukushima site was organised.

Three inspectors from the NNSA (National Nuclear Security Administration), the Chinese safety authority, were received in Lyon for information exchanges on technical anomalies and significant events having occurred in France and China. ASN gave them a presentation of the hardened safety core approach put in place in France after the Fukushima Daiichi accident and organised a visit to the Cruas-Meysse reactor reinforcement worksites.

The Lyon division also contributed to a cross-inspection campaign with inspectors from Rostechnadzor, the Russian Safety Authority. Three Russian inspectors participated in an inspection of the ILL reactor in Grenoble, and three French inspectors participated in an inspection of the PIK reactor situated near Saint-Petersburg. The two Authorities discussed inspection practices on the sidelines of these inspections.

The Lyon division also continued joint inspection actions with the Swiss OFSP.

To conclude, the Lyon division participated in the 13th international seminar organised by the inspection practices working group of the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD).

As a general rule, these exchanges allowed the sharing of best practices in the methods for overseeing those responsible for nuclear facilities.

The state of nuclear safety and radiation protection in 2016 in the Bourgogne-Franche-Comté region

The Dijon division regulates radiation protection and the transport of radioactive substances in the 8 *départements* of the Bourgogne-Franche-Comté region.

The activities and installations to regulate comprise:
- small-scale nuclear activities in the medical sector:
  - 8 external-beam radiotherapy departments (19 accelerators, 2 contact radiotherapy devices);
  - 4 brachytherapy departments;
  - 14 nuclear medicine departments, 3 of which practice internal radiotherapy;
  - 41 centres performing interventional procedures;
  - 49 computed tomography scanners;
  - about 800 medical diagnostic radiology devices;
  - about 2,000 dental diagnostic radiology devices;
- small-scale nuclear activities in the veterinary, industrial and research sectors:
  - 186 veterinary practices;
  - 317 industrial and research establishments, including 30 companies exercising an industrial radiography activity, 167 users of devices for detecting lead in paint, 1 cyclotron accelerator for research and the production of medical imaging drugs and 2 industrial accelerators for radiography and polymer cross-linking;
- approved laboratories and organisations:
  - 3 organisations approved for radiation protection controls, with 6 agencies;
  - 5 organisations approved for radon monitoring and 1 laboratory approved for measuring radioactivity in the environment.

ASN conducted 55 inspections in the Bourgogne-Franche-Comté region in 2016, comprising 26 inspections in the medical sector, 10 inspections in the industrial research and veterinary sectors, 7 inspections concerning radon exposure, 7 oversight inspections of the activity of approved organisations and laboratories, 4 inspections on the transport of radioactive substances and 1 inspection of a site contaminated by radioactive substances.

Among the significant events notified and analysed to draw lessons from them, 7 events concerning radiotherapy patients were rated level 1 on the ASN-SFRO scale, and one event concerning workers was rated level 1 on the INES scale.

The manufacturing plants of Areva NP situated in the Bourgogne-Franche-Comté region were also the subject of particular scrutiny on the part of ASN following the discovery of irregularities in components manufactured by Creusot Forge. The steps taken by ASN in this respect are described in point 3.4 of chapter 12.

1. Assessment by domain

1.1 Radiation protection in the medical field

Radiotherapy and brachytherapy

In 2016, half of the radiotherapy or brachytherapy departments in the Bourgogne and Franche-Comté regions had their licenses renewed or modified, two-thirds of them on account of significant organisational changes. The five inspections carried out in these departments showed that they have now all on the whole complied with the ASN resolution requiring a specific organisation to ensure treatment safety and quality. The implementation of this organisation nevertheless varies from one centre to another. Studies of the risks to which patients are exposed must be taken further and more specifically take account of the lessons learned from past incidents.

ASN placed the University Hospital of Besançon (CHRUB) under tightened monitoring in the second quarter of 2015 on account of substantial changes in its organisation and being significantly behind schedule in radiation protection in the areas of radiotherapy and interventional practices.

In February 2016, seven ASN inspectors conducted a three-day inspection to assess the progress made. The inspections confirmed a collective realisation of the radiation protection risks involved and the effective involvement of the players concerned. Significant progress has been observed in radiation protection in interventional practices. The improvement is less marked in radiotherapy due to occasional difficulties relating to human resources and the relocation of the department. The ASN inspections more specifically revealed a lack of harmonisation in the medical protocols used by the radiation oncologists; this situation has been corrected. In 2017, ASN will decide whether to continue tightened monitoring of the CHRUB or not.

In 2016, eight significant radiation protection events concerning radiotherapy patients were reported further to errors in the performance of examinations, seven of which were rated level 1 on the ASN-SFRO scale. Half of the events concern one and the same department which will be subject to particular scrutiny in 2017. ASN considers that radiotherapy centres must be more attentive to updating their procedures when material or organisational changes take place, and take full account of lessons learned from adverse events.

Interventional practices

ASN focused particular attention in 2016 on centres that use image intensifiers in the operating theatre, carrying out seven inspections in this field, five of them in public hospital centres and two in private clinics in the Bourgogne-Franche-Comté region.

With regard to patient radiation protection, all the inspected centres have initiated a process to optimise doses delivered to patients, making use of the skills of medical physicists, often assisted by external service providers. The dosimetric data are currently being collected in order to establish internal reference levels. The obligation to control the quality of the images delivered by the devices is well respected. Progress nevertheless remains to be made in generalising the training of physicians in the use of imaging devices and in indicating the delivered radiation doses on the medical procedure reports.

The situation with respect to radiation protection of health professionals gives more cause for concern. The assessment of the resources necessary for radiation protection could be improved in many cases and the corresponding organisation is poorly formalised. The Person Competent in Radiation protection (PCR) does not always have the time necessary to carry out the assigned duties. Although significant progress has been noted in the wearing of dosimeters and personal protective equipment, the working environment studies are usually incomplete and radiation protection training is often not provided at the required frequency.

In 2016, no significant events relating to interventional practices in the region were notified to ASN. One inspection nevertheless detected an event that should have been notified in 2015. ASN considers that failure to notify significant events in interventional practices is likely and it is particularly attentive to the handling of adverse situations during its inspections.

Nuclear medicine

ASN delivered eight licenses in nuclear medicine in 2016, of which three were further to modifications to facilities or new facilities in nuclear medicine departments in the Bourgogne-Franche-Comté region.

The six inspections performed show that patient and personnel radiation protection is satisfactory, although progress is still required on specific points.

With regard to radiation protection of personnel and health professionals, a good level of involvement of PCRs was noted. The inspections nevertheless revealed areas for progress, primarily in the performance of radiation protection technical controls and the coordination and organisation of radiation protection with the practitioners from the private sector and subcontractor companies conducting work.

As far as patient radiation protection is concerned, the diagnostic reference levels are by and large respected and in the majority of centres, like the quality controls, they are verified by a medical physicist. The main areas for progress concern putting in place procedures to prevent errors in the preparation or administration of radiopharmaceuticals and in bringing nuclear medicine premises into compliance with the layout rules set by ASN resolution 2014-DC-0463 of 23rd October 2014.

ASN was notified of ten significant events in this area, which represents about 36% of the events in the medical field notified in the Bourgogne-Franche-Comté region. Errors in the preparation of performance of examinations are still the primary cause of these events. This highlights the importance of putting in place an organisation for treatment quality and safety in nuclear medicine departments.

Computed tomography

ASN carried out six inspections in computed tomography in 2016, four of them in private centres and two in public centres.

These inspections showed that significant progress has been made in patient radiation protection since the last inspections performed in 2014 and the standard of radiation protection in the inspected centres seems higher than the national average. The inspectors observed in particular more frequent prior examination of the justification for using computed tomography. In addition, radiation doses delivered to patients are falling due to the purchase of devices with more sophisticated software and the engaging of an exposure optimisation approach driven by medical physicists. In the inspected centres, the delivered radiation doses were mentioned in the procedure reports thanks to an automated interface between the machine and the patient's file. The obligation to control the quality of the images of the devices used was also well respected. The training of health professionals in patient radiation protection can nevertheless be further improved.

With regard to worker radiation protection, the inspections have shown a high degree of PCR involvement and correct performance of the mandatory technical controls on the facilities. On the other hand, training in worker radiation protection, working environment studies and the wearing of passive dosimetry devices can still be improved.

Six events relating to computed tomography procedures were notified to ASN in 2016, of which three concerned errors in carrying out the examination and two the accidental exposure of the health professional during the examination. One single event concerned the exposure of a woman who was unaware of her pregnancy, compared with four in 2015.

1.2 Radiation protection in the industrial and research sectors

Industrial radiography

ASN performed five inspections concerning industrial radiography activities in 2016. The inspectors endeavoured to examine radiography conditions in protected bunkers and in worksite conditions on an industrial site. ASN moreover renewed 13 licences to exercise this activity, one of which included a deadline for bringing facilities into compliance.

ASN observed that on the whole the inspected organisations know and comply with the radiation protection requirements. The main lines for improvement concern worker classification, which must match the true level of risk, the regular updating of the documents required by the regulations (analysis of working practices and conditions, radiological zoning) and compliance of fixed radiography facilities with standards.

Universities, laboratories or research centres

ASN did not conduct any inspections in the area of research in the Bourgogne-Franche-Comté region in 2016, but continued its oversight of the management of legacy radioactive waste at the Franche-Comté University, as a follow-up to the conclusions of the inspections carried out in 2015.

ASN was notified of one significant event in research rated level 1 on the INES scale. This event concerned three researchers who exceeded a quarter of the annual dose limit further to an error in the operation of an X-ray fluorescence analysis device.

Installations Classified on Environmental Protection Grounds (ICPEs)

ASN performed four inspections in 2016 on sites with ICPE status situated in the Bourgogne-Franche-Comté region. The four companies inspected use radioactive sources to check physical parameters; one of them also exercises industrial radiography activities. These inspections showed that the ICPEs concerned have a good work safety culture but must improve the way specific aspects of the radiation protection regulations are taken into account. The radiation protection technical controls represent a priority area for progress.

1.3 Monitoring approved organisations and laboratories

ASN carried out seven oversight inspections of the activity of approved organisations and laboratories in 2016. Six of these inspections concerned the activity of organisations approved for radiation protection controls or radon screening, while the seventh concerned the activity of a laboratory approved for environmental monitoring. ASN observed that these organisations and laboratories carry out their controls in accordance with the reference system that was approved when they received their accreditation. Areas for progress have nevertheless been identified, namely in personnel radiation protection and the correct utilisation of measuring devices.

1.4 Radiation protection of the public and the environment

Exposure to radon

In 2016, ASN conducted inspections of the regional council and the departmental councils - the administrators of the state-run lower and upper secondary schools - of the five *départements* with priority status for management of the radon risk. The aim is to take stock of the actions taken in the lower and upper secondary schools to measure the level of exposure to radon and, if necessary, initiate remediation actions. ASN also inspected a spa. This approach will be continued in 2017 with inspections targeting the administrators of private educational institutions and the other spas in the region.

ASN continued its collaboration with the ARS and the Dreal for the management of situations of exposure to a high level of radon in certain places open to the public and in dwellings close to former mining sites.

ASN also participated in the pluralistic actions carried out in Bourgogne and Franche-Comté to raise awareness of regional authorities, construction professionals and the general public to the risks caused by exposure to radon. It will contribute to the Franco-Swiss project JURAD-BAT which began in September 2016 and aims at establishing a cross-border platform to improve management of the radon exposure risk in buildings situated in the Jura Arc.

Contaminated sites and soils

In 2016, ASN issued an opinion to the CNAR (French National Funding Commission for Radioactive Matters) on the envisaged scenarios for completing the clean-out of a former clock-making factory in the Haut-Doubs in which traces of radium and tritium have been evidenced. The CNAR adopted the scenario permitting the most extensive clean-out of the site, in accordance with the opinion expressed by ASN.

Mining sites

In 2009, the State put in place a national action plan for the management of former uranium mines, which provides for Areva to list the sites in which mining waste rock has been reused, and then clean out the areas in which the radiological anomalies are incompatible with the land use. In this context, at the end of 2014 Areva identified, through aerial surveys followed by ground verifications, 59 sites in municipalities of the Nièvre and Saône-et-Loire *départements* where mining waste rock has been deposited. This inventory was supplemented in 2015 by a radon measurement campaign in the buildings of the municipalities concerned. In 2016, Areva proposed solutions to the State services for remedying the radiological anomalies resulting from the reuse of mining waste rock on two sites in Saône-et-Loire. In June 2016 the Dreal asked ASN to help assess these proposals. ASN will issue an opinion on this subject in 2017.

ASN is particularly attentive to the monitoring of two other sites situated in Saône-et-Loire on the municipalities of Gueugnon and Issy l'Evêque, because they contain radioactive substances which are not mining waste rock. In Issy l'Evêque, waste from nuclear installations and tailings from the treatment of uranium-bearing ores have been stored in a former uranium mine (Bauzot site). In 2016, the prefectural authority asked Areva to supplement the assessment of radioactive substances present on the site and the monitoring of the site environment. ASN will contribute to the assessment of the proposals made by Areva.

In Gueugnon, waste from a uranium ore processing plant which operated there between 1955 et 1980 is stored in an ICPE. In 2015, during the process to inventory mining waste rock, Areva discovered near this ICPE five plots of land with radiological contamination from ore treatment residues. In June 2016 the Dreal asked ASN to assess the risks presented by this radiological contamination and to participate in the assessment of Areva's future remediation proposals. In September 2016 Areva began the remediation of a first site accommodating a residential house. ASN is monitoring remediation work progress, assisted by IRSN.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

Four inspections of radiopharmaceutical transport operations were carried out in 2016. These inspections showed that radioactive substance transport operations are on the whole conducted in compliance with regulatory requirements. Progress can nevertheless still be made with regard to pre-shipment verifications and the securing of packages.

2. Additional information

2.1 Informing the public

Press conference

On 7th June 2016, ASN held a press conference in Dijon on the state of nuclear safety and radiation protection in the Bourgogne-Franche-Comté region.

Local Information Committee near Valduc

In 1996, the Prefect of the Côte-d'Or set up an exchange and information structure on the CEA Valduc centre (Seiva). This is an association which, although it does not have CLI status, functions in the same manner as the CLIs which the Environment Code has rendered mandatory for civil nuclear installations. Seiva thus informs the public of the impact of the Valduc centre's activities, insofar as the subjects addressed do not concern confidential aspects covered by its classification as a secret basic nuclear installation. Seiva takes radioactive measurements in the environmental compartments and records them on an environmental monitoring dashboard spanning several years. Seiva's main sources of funding to date are the Departmental Council of the Côte-d'Or and ASN. ASN attends the annual general meeting of Seiva.

2.2 The other notable events

On 8th March 2016, the Dijon division took part in the national emergency exercise simulating a radioactive substance transport accident in Doubs *département* on the A36 motorway. The aim of this exercise was to verify the response of a non-nuclearised *département* in the event of such an emergency and to test the prefecture's response to media pressure and its interfaces with the national level of radiological emergency situation management. The exercise revealed areas for improvement concerning more specifically transmission of the alert and consideration of the toxicity risk of the transported substances.

The state of nuclear safety and radiation protection in 2016 in the Bretagne region

The Nantes division regulates radiation protection and the transport of radioactive substances in the 4 *départements* of the Bretagne region. The Caen division regulates the nuclear safety of the Monts d'Arrée NPP, currently undergoing decommissioning.

The pool of installations and activities comprises:
- the Monts d'Arrée site NPP undergoing decommissioning, regulated by the Caen division;
- small-scale nuclear activities in the medical sector:
  - 8 radiotherapy centres;
  - 5 brachytherapy units;
  - 11 nuclear medicine departments;
  - 37 centres performing interventional procedures;
  - 54 tomography devices;
  - some 2,500 medical and dental radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 20 industrial radiography companies (including 3 gamma radiography contractors);
  - about 450 industrial and research equipment licences (including 325 users of devices for detecting lead in paint);
- organisations approved by ASN:
  - 6 agencies for radiation protection technical controls;
  - 7 organisations for radon monitoring and 4 head offices of laboratories approved for measuring radioactivity in the environment.

In 2016, ASN carried out 44 inspections: 2 at the Monts d'Arrée NPP undergoing decommissioning, 39 in small-scale nuclear activities and 3 in the transport of radioactive substances.

Among the notified events, none was rated level 1 or higher on the INES scale and 10 events in radiotherapy were rated level 1 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Brennilis nuclear power plant

During 2016 EDF continued the reactor containment restoration operations (cleaning traffic lanes, expert appraisals, repair of equipment necessary for normal operation of the facility, etc.) following the fire that broke out on the heat exchanger decommissioning worksite in September 2015, and the decommissioning operations on the Effluent Treatment Station (STE) authorised by Decree 2011-886 of 27th July 2011.

ASN verified compliance with the licensee's commitments following the reactive inspection of September 2015 following the fire on the heat exchanger decommissioning worksite. ASN considers that before resuming decommissioning activites on the worksite, EDF must take all necessary measures to ensure appropriate monitoring of the drafting of hot work permits by outside contractors and to check practical implementation of the fire risk control measures.

In addition, the STE decommissioning schedule was revised in view of several technical difficulties. The STE superstructure demolition operations were completed in April 2016 and the base mat demolition operations began in August 2016.

EDF submitted a decommissioning decree modification application to set a new deadline for the operations. The draft modification decree was submitted to the Prime Minister for signing following public consultation and obtaining the opinion of ASN. The Decree was published in the *Official Journal* of 17th November 2016. It stipulates that EDF must submit a new complete decommissioning file within two years.

ASN is also examining the management plan for the land subjacent to the STE.

The site's main activities in 2017 relate to the finalising of the heat exchanger and STE decommissioning operations. ASN will start examining the periodic safety review guidance file, which is to be submitted at the end of 2016, and will review the supervision of the reactor block sampling operations.

1.2 Radiation protection in the medical field

Radiotherapy

A single change of radiotherapy accelerator was registered for Bretagne in 2016. However, several projected changes are currently being examined and will take effect in 2017. The change in equipment is accompanied by the development of new techniques (primarily stereotaxy) which lead to new risks. Three of the eight radiotherapy centres in Bretagne were inspected in 2016. Management of the risks and anticipation of the needs created by the new techniques were verified in detail.

Following a phase of consolidation of the quality approach, all the inspected centres are now resolutely engaged in a phase of quality management and continuous improvement. Although the "quality" objectives are regularly updated by the centres' respective governing bodies, their monitoring and assessment can still be improved in some cases.

The state of progress in the a priori risk management approach varies from one centre to another, even though the methodologies used are relatively similar. The risks induced by the new techniques are integrated in the a priori risks analysis with the putting in place of new requirements or defence barriers. However, deadlines and the people responsible for their implementation are not always specified.

The organisation for detecting and analysing adverse events is effective on the whole and contributes to the development of the risk analysis. A total of 11 significant patient radiation protection events were notified to ASN in 2016, and 10 of them were rated level 1 on the ASN-SFRO scale. 2016 stands out on account of the large variability of causes behind these events, with the discovery of new risks such as the impact of the density of the treatment table on dosimetry. After analysing the events, improvement measures have been implemented but their effectiveness is still insufficiently assessed in some centres.

Finally, the efforts made in the last few years to recruit medical physicists, dosimetrists and physical measurement technicians enable all the centres to ensure the presence of at least one medical physicist during the treatment periods each day while freeing time for the deployment of new treatment techniques. Nevertheless, the evaluation of needs in medical physics could be better finalised in most of the centres.

Interventional practices

Oversight of interventional practices has figured among the priority objectives of the Nantes division since 2014[1].

The effort made over the last few years in terms of volume and prioritisation of inspections has allowed the inspection in 2016, as in 2015, of the majority of the centres performing the largest number of procedures with major implications for patient radiation protection and the monitoring of the identified areas for progress to be reinforced.

Nine centres were inspected in Bretagne in 2016.

With regard to the centres inspected for the first time in 2016, the findings remain quite similar to those of the preceding years, with considerable room for improvement in worker and patient radiation protection.

As far as the centres representing major implications for radiation protection are concerned, which are inspected more frequently, a significant improvement has been observed in the majority of them, particularly in terms of training in worker and patient radiation protection. Dose optimisation and patient monitoring in long or iterative medical procedures are becoming increasingly common practices, especially in large centres employing a medical physicist. With regard to occupational radiation protection, continued efforts are required in the quantification of doses and protection of the lens of the eye and the extremities of health professionals. For practitioners, particularly from the private sector, there is significant room for progress in

1. *Twenty-four sites inspected out of a total of 39 sites (37 centres) over the 2014-2016 period.*

occupational radiation protection training and medical monitoring.

Nuclear medicine

The nine nuclear medicine centres are continuing to modernise their technical platforms, enabling them to have at least one gamma camera coupled to a computed tomography scanner and, in the case of six of them, to also have a positron emitting tomography scanner.

Three nuclear medicine departments were inspected in Bretagne in 2016. The inspections focused in particular on the management of waste and effluents, targeted internal radiotherapy and the measures taken to ensure the safety of patient treatment and of radiopharmaceutical handling.

Worker radiation protection can be further improved in a few areas, such as the coordination of radiation protection means during operations by outside contractors and the conditions and means of worker protection when transporting sources outside the department.

Patient radiation protection is taken into account to variable extents. Practices for detecting pregnancy are rarely formalised and scanner utilisation protocols are not fully optimised.

The management of waste and effluents is considered satisfactory. Periodic checks are carried out at the centre's discharge outlet at least once a year; the results of these checks should be better assessed and communicated to the sewage network manager.

The organisation for detecting and analysing adverse events is formalised. A drop in the number of significant radiation protection event notifications with respect to 2015 is to be underlined.

Lastly, with regard to the analysis of conformity of the facilities with ASN resolution 2013-DC-0463 applicable since 1st July 2015, it emerges that compliance with ventilation requirements must be confirmed by specific checks.

Computed tomography

The inspections of the two centres inspected in 2016 focused more specifically on patient radiation protection, which is well implemented on the whole, particularly through compliance with the required quality control frequencies and the optimisation of delivered doses. Nevertheless, other aspects such as tracking patient radiation protection training for health professionals and sending IRSN the dosimetric evaluations in view of the diagnostic reference levels, can be improved upon.

Furthermore, drafting the working conditions and environment studies and training in worker radiation protection remain two areas for improvement in worker radiation protection.

1.3 Radiation protection in the industrial sector

Industrial radiography

ASN carried out two inspections in industrial radiography in Bretagne in 2016. They show that the worksite industrial radiography operations are carried out under satisfactory conditions, particularly as regards operator training and monitoring, the general conduct of industrial radiography work and work zone signalling.

Progress nevertheless remains to be made in defining and deploying signalling plans, operator knowledge of dosimeter alarm thresholds and the availability of certain items of equipment, such as the Sentinelle beacons controlled by radiation detectors and radiation meters.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In 2016, ASN carried out 3 inspections focusing specifically on radioactive substance transport operations, two of them in companies specialised in the transport of radiopharmaceuticals and one in a hospital which carries out radioactive source reception and shipping operations.

The radiopharmaceutical transport companies on the whole comply with the main provisions of the regulations. The identified areas for improvement concern the methods of securing the packages in the vehicle and increasing the radiological protection of the driver's cab.

With regard to the hospital, there are shortcomings in the knowledge and formalisation of the obligations relating to the shipping of the radioactive sources used in brachytherapy, particularly with regard to organisation and the quality management system.

1.5 Radiation protection of the public and the environment

Radon

The Nantes division participated in the working group on the 3rd Regional Health and Environment Plan (PRSE 3) in order to be a source of proposals and to coordinate the radon-related actions alongside the ARS and Dreal. "Reducing exposure of the Breton population to radon" is one of the initiatives of the "Develop and build to promote a healthy living environment" objective of the PRSE3 project.

In 2016, ASN checked compliance with the radiation protection requirements relating to radon in state-run lower and upper secondary schools[2].

An initial radon measurement campaign was carried out in 2001 in all the state-run lower and upper secondary schools. However, the ten-yearly renewal of radon measurements in schools has not been carried out in the upper secondary schools in Bretagne or in the recently-built lower secondary schools for which no initial measurements were made.

The random check of the schools also revealed that in several lower or upper secondary schools, exceeding of the initial action-triggering threshold of 400 Bq/m^3 had not always been addressed by simple measures such as regular airing of the premises and conducting diagnostics, or work to reduce the radon volume concentrations within two years. Furthermore, the effectiveness of these actions has not been verified systematically by taking new radon measurements.

Mining sites

ASN is keeping a watchful eye on the progress of the actions carried out by Areva to inventory radiologically marked areas around the former mining sites and sites in the public domain where uranium mining waste rock has been reused. The 12 work sheets associated with places in which mining waste rock has been reused have thus been analysed jointly by the services of Dreal and ASN. The resulting redevelopment work should start in 2017.

Moreover, ASN has actively participated in the information and consultation meetings organised on this subject by the Morbihan prefecture. At the meeting of November 2016, ASN reminded Areva to submit complementary studies to ASN and the Dreal for the other places where mining waste rock had been reused to enable them to validate them, or even impose further redevelopment work.

With regard to sites of mining waste rock reuse situated near living areas or dwellings, Areva, at the request of the State, conducted a first radon screening campaign by sending radon dosimeters to all the property owners concerned. Despite a return rate of less than 50%, this campaign did reveal two dwellings in which the radon concentrations exceed 2,500 Bq/m^3. Complementary analyses in the dwellings determined that the uranium-bearing mining waste rock was not the source of the radon. ASN also asked that the distribution of dosimeters to the populations concerned be taken up again.

Lastly, ASN issued a favourable opinion on the project to use the former mine of Prat Mérien as a disposal site for the mining waste rock from the 12 reuse sites in Bretagne for which work sheets were issued.

2. Additional information

2.1 Informing the public

Press conference

In 2016, ASN held a press conference in Rennes on the situation of nuclear safety and radiation protection.

Work with the Local Information Committees (CLIs)

During 2016 ASN participated in two meetings of the CLI for the Brennilis NPP; it presented the results of its oversight actions for the year 2015 at the meeting of 5th July 2016.

In accordance with the provisions of the TECV Act, the Brennilis CLI organised a public meeting on 30th November 2016 and proposed two round tables: ASN took part in the round table devoted to the decommissioning of the NPP. The second round table in which ACRO (Association for Monitoring Radioactivity in the West) participated addressed environmental monitoring around the NPP undergoing decommissioning. This meeting also gave the public the opportunity to see the ASN and IRSN exhibition on radioactivity.

2. *The lower secondary schools are attached to the departmental councils of Finistère, the Côtes d'Armor and the Morbihan, while the upper secondary schools are attached to the Bretagne regional council.*

The state of nuclear safety and radiation protection in 2016 in the Centre-Val de Loire region

The Orléans division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 6 *départements* of the Centre-Val de Loire region.

The activities and installations to regulate comprise:

- BNIs:
  - the Belleville-sur-Loire NPP (2 reactors of 1,300 MWe);
  - the Dampierre-en-Burly NPP (4 reactors of 900 MWe);
  - the Saint-Laurent-des-Eaux site: the NPP (2 reactors of 900 MWe) in operation, the 2 Gas-Cooled Reactors (GCR) undergoing decommissioning and the irradiated graphite sleeve storage silos;
  - the Chinon site: the NPP in operation (4 reactors of 900 MWe), the 3 GCRs undergoing decommissioning, the Irradiated Material Facility (AMI) and the Inter-Regional Fuel Warehouse (MIR);
- small-scale nuclear activities in the medical sector:
  - 8 radiotherapy centres;
  - 3 brachytherapy departments;
  - 10 nuclear medicine departments;
  - 35 centres performing interventional procedures;
  - 43 tomography devices;
  - some 2,700 medical and dental radiology devices;
- small-scale nuclear activities and facilities in the industrial and research sectors:
  - 10 industrial radiography companies including 4 gamma radiography contractors;
  - about 280 industrial devices subject to the licensing system;
  - 30 research institutions holding a license;
  - 8 veterinary practices holding a license;
  - more than 90 industrial, veterinary and research devices subject to the notification system;
- 2 head offices of organisations approved for radiation protection controls.

In 2016, ASN carried out 148 inspections in the areas of nuclear safety and radiation protection: 89 inspections of the nuclear installations on the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux (of which 4 concerned transport), and 59 inspections in small-scale nuclear activities in the Centre-Val de Loire region. ASN carried out 55 days of labour inspections in the nuclear power plants.

Twenty-three significant events rated level 1 on the INES scale were notified by the licensees of the EDF nuclear installations in the Centre-Val de Loire region in 2016. In small-scale nuclear activities, 4 significant events of level 1 on the ASN-SFRO scale and 2 significant events of level 1 on the INES scale were notified in the Centre-Val de Loire region.

The ASN inspectors drew up two violation reports which were submitted to the competent public prosecutors' departments.

1. Assessment by domain

1.1 The nuclear installations

Belleville-sur-Loire nuclear power plant

ASN considers that the performance of the Belleville-sur-Loire NPP is on the whole in line with the general assessment of EDF in the areas of radiation protection and environmental protection, but its nuclear safety performance is below average.

With regard to nuclear safety, ASN considers that the Belleville-sur-Loire NPP lacked rigour in the scheduling, preparation and performance of certain maintenance and periodic test activities. Several significant events notified in 2016 were caused by the lack of a questioning attitude and surveillance deficiencies on the part of the operating teams. ASN notes difficulties in managing unexpected situations and considers that greater rigour in individual behaviour is required.

In the areas of security and worker radiation protection, ASN observes good control of radiological cleanliness in the facilities in 2016. Weaknesses were nevertheless detected in the optimisation of radiological exposure of workers and the control of radiological work zone marking. Improvements are therefore expected on these points.

The site's performance in the prevention of pollution and control of the impact and nuisance factors for the public and the environment has remained stable. The Belleville-sur-Loire NPP now has a robust organisation in this respect. Several events have nevertheless highlighted difficulties in keeping some of the site's equipment items compliant with environmental regulations.

Chinon site

ASN considers that the nuclear safety and environmental protection performance of the Chinon NPP on the whole is in line with ASN's general assessment of EDF, and that the radiation protection performance stands out positively.

ASN considers that the site has continued to make improvements in nuclear safety. Progress has been observed in the general organisation of the periodic tests and in the integration of reliability-enhancing practices. Lack of rigour nevertheless remains the cause of a large proportion of significant events. The inspections carried out in 2016 moreover revealed deficiencies in taking the hydrogen risk into account and in filling out the work record files during inspection and maintenance operations.

The radiation protection organisation is deemed satisfactory. Despite longer outage periods than initially planned, radiological exposure of the personnel remained within projected limits. With regard to control of radiological cleanliness, the ambitious goals the site had set itself were achieved during the outages, except for reactor 3. Several Significant Radiation protection Events (ESR) were notified in 2016, mainly linked to individual behaviours and a lack of radiation protection culture in outside contractor companies. The site must therefore continue the ongoing efforts to increase outside contractors' awareness of the radiological risk.

Performance in environmental protection seems to be satisfactory on the whole, as much for the management of liquid and gaseous effluent discharges as for pollution prevention. This being said, on-site management and monitoring of waste must be improved. Deviations have been observed in the preparation of the waste production forecast and in the storage conditions in the building dedicated to waste packaging.

ASN considers that the level of safety of the nuclear facilities of the former Chinon NPP is satisfactory. Greater rigour is nevertheless required in the management of periodic tests.

Decommissioning of the Chinon A3 reactor heat exchangers began in 2013. The operations have been temporarily stopped however, due to the discovery of asbestos in certain parts of the heat exchangers. Removal of the components of the previously removed Chinon A2 reactor systems is under preparation following the first tests.

ASN will monitor the depollution operations that EDF will be carrying out on the chemically polluted soils on the Chinon site. Furthermore, ground water monitoring and complementary gaseous discharges characterisation reinforcement actions are in progress, in accordance with the regulatory provisions.

In a context of organisational changes, ASN will be attentive to the execution, within controlled time frames, of ongoing or recently started actions, to the rigour of operation of the installations and the monitoring of outside contractors.

In March 2016, during a hearing before ASN devoted to the decommissioning of its first-generation reactors, EDF announced a complete change of strategy due to difficulties relative to the decommissioning techniques initially envisaged for its GCR reactors, which include the reactors of the old Chinon NPP. Completion of the Chinon A decommissioning operations would be pushed back by several decades. In this new context, the Chinon A2 reactor would become the "first in series" for the decommissioning of these reactors. This new strategy, which has been submitted to ASN, was presented to the Chinon CLI in 2016.

Operation of the AMI was marred in 2016 by deficiencies in the monitoring of outside contractors and in operation management. The integration of experience feedback and the assessment of deviations must be improved. With the organisation of the facility due to change significantly in 2017, ASN will be particularly attentive to the licensee's compliance with the facility's baseline requirements and to operating rigour.

The expert appraisal activities to which the facility was dedicated ceased definitively at the end of 2015 when they were entirely transferred to a new facility on the Chinon site; the transfer went smoothly. With a view to decommissioning the facility, for which the file will be subject to a public inquiry in 2017, the AMI's activities will essentially consist in decommissioning preparation and monitoring operations.

As part of the decommissioning preparation operations, specific provisions are implemented for the packaging and storage of a certain wastes. The waste in question is legacy waste for which appropriate management routes are not yet available. ASN will be attentive to the legacy waste retrieval and packaging operations, given the way they have fallen behind schedule over the last few years.

ASN considers that the MIR operating organisation is more robust and allows closer monitoring of the commitments made further to the inspections and significant events. Several physical improvements have thus been made for protection against the risks of fire and flooding.

Dampierre-en-Burly nuclear power plant

ASN considers that the performance of the Dampierre-en-Burly NPP is on the whole in line with the general assessment of EDF in the areas of nuclear safety, and environmental protection. It considers that the radiation protection performance is below the national average.

The site's nuclear safety organisation is deemed satisfactory. ASN does nevertheless note that several inspections revealed deficiencies in EDF's preparation, performance and monitoring of maintenance operations. ASN considers that particular attention must be paid to the rigour of operations and the monitoring of outside contractors performing activities considered important for safety.

2016 shows a downturn in the site's performance in worker radiation protection. ASN has more specifically noted shortcomings in radiological cleanliness and in the control of contamination dispersion on several worksites during reactor outages. The site must maintain the efforts deployed in this area during 2016, and in 2017 it must reinforce its organisation and its verifications to remedy these deviations.

As regards environmental protection, the site's performance is found to be below ASN's assessment of the preceding years. ASN has observed organisational deficiencies in coordinating and monitoring the management of regulatory compliance in environmental matters. Actions have been defined by NPP management. ASN will evaluate the effectiveness of the measures taken in this respect.

Saint-Laurent-des-Eaux site

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP with regard to nuclear safety, radiation protection and the environment is, on the whole, in line with the general assessment of the EDF plants.

With regard to nuclear safety, ASN considers that the main inspection and maintenance activities run satisfactorily. However, deficiencies in the management of periodic tests and the monitoring of the maintenance programmes caused several significant events in 2016. The site's efforts to prevent the introduction of foreign bodies into the primary system must be continued, as the tightened action plan put in place is not yet giving full satisfaction in view of the reactor outage results.

ASN considers that the radioprotection organisation of the Saint-Laurent-des-Eaux NPP is satisfactory. The radiation protection rules are generally well taken into account in the preparation and performance of work in controlled areas. Certain failures to comply with simple rules concerning radiological work zone marking nevertheless show that worker radiation protection practices must be further improved. Progress must also be made in the way interfaces between activities and the coordination of departments are taken into consideration.

The performance of Saint-Laurent-des-Eaux with regard to the environment seems satisfactory on the whole. ASN underlines the reliability of the organisation and the robustness of the measures taken to manage activities involving high environmental risks. On the other hand, despite a number of improvements in 2016, the site must further improve its management of waste storage and monitoring. Improvements can be made in the constituting of regulatory files.

ASN considers that the level of safety of the nuclear installations of the former Saint-Laurent-des-Eaux NPP is satisfactory. Several liquid and solid waste removal operations were carried out in 2016 as part of the decommissioning of the reactors of Saint-Laurent-des-Eaux A.

However, all the worksites (emptying of tanks, characterisation of sludge, removal of the source term from the Saint-Laurent-des-Eaux A2 pool) were halted following the discovery of internal contamination of persons who had worked on worksites presenting a risk of contamination by alpha emitters. EDF identified the possible causes of the internal contaminations and defined corrective measures to prevent this type of event from recurring. During the next inspections ASN shall check that these measures have been implemented with rigour. ASN shall verify in particular EDF's monitoring of outside contractors, as a deficiency in this respect was a contributing cause of the event.

The complete change in EDF's strategy for its GCR reactors concerns the Saint-Laurent-des-Eaux A reactors as it does the Chinon A reactors. Under this new strategy submitted to ASN, EDF has announced its decision to start the operations to remove the graphite from the silos without waiting for a disposal route for this waste to become available. To this end, EDF proposes creating a new facility for storing graphite sleeves on the Saint-Laurent-des-Eaux site and submitting a decommissioning file to ASN in 2019 with a view to starting removal of the sleeves in 2027.

The file concerning the Saint-Laurent-des-Eaux A stress tests transmitted at the end of 2015 and focusing essentially on the absence of a cliff-edge effect, is currently being examined by ASN.

Lastly, ASN will keep track of the examination of the periodic safety review[1] of the Saint-Laurent-des-Eaux A1 and A2 reactors, for which the conclusions report is expected by the end of 2017.

Labour inspection in the nuclear power plants

In 2016, the ASN labour inspectors conducted worksite inspections on all the nuclear power plants of the Centre-Val de Loire region in the areas of health and safety at work, particularly during periods of intense activity, such as maintenance outages. Furthermore, specific inspections were conducted on taking into account electrical risks, lifting operations and the conformity of work equipment. Specific inspections were also carried out on the construction worksites of the ultimate backup diesel generator sets further to the lessons learned from the Fukushima Daiichi accident. In addition to this, regular meetings with the personnel representative bodies take place during the meetings of the CHSCT (Committee for Health Safety and Working Conditions) and when the personnel representatives make ad hoc requests concerning labour standards.

The labour inspectorate remained attentive with respect to compliance with the regulations relative to the mandatory public holiday on 1st May. In this respect, two NPPs were inspected to verify that no activity other than that relating to electricity production was carried on 1st May.

1. *See note on page 231.*

1.2 Radiation protection in the medical field

Radiotherapy and brachytherapy

The Centre-Val de Loire region counts eight radiotherapy centres. The two regional centres of the hospitals of Tours and Orléans implement advanced treatment techniques such as tomotherapy and stereotactic treatments. Other techniques can be grafted onto the existing equipment to ensure a better targeted treatment. Further to the action to raise radiotherapy department awareness of the implications associated with good preparation of the organisation for integrating these new techniques, the inspections carried out in 2016 focused on this aspect in particular.

It emerges from ASN's inspections that the requirements in terms of organisation and defining stages in the treatment of the patient required by ASN resolution 2008-DC-0103 with a view to guaranteeing treatment quality and safety, are well applied by the radiotherapy centres. On the other hand, the organisation intended to reassess the risks by analysing incidents is not always appropriately or fully set up in some centres, mainly when the teams do not consider this to be a priority issue.

Further patient positioning errors have been observed, leading to over-irradiation of organs at risk, but without confirmed clinical consequences, given the speed of detection and the corrections made. Among the significant events notified in 2016 concerning patient positioning errors, dose fractionation and, in one case, interchanging of patients, four were rated level 1 on the ASN-SFRO scale.

The Centre-Val de Loire region has three brachytherapy departments. This treatment method differs from external-beam radiotherapy in the type of radiation sources used and by the fact that the sources are placed in the immediate proximity of the area or organ to treat.

The requirements in terms of organisation and defining stages in the treatment of the patient required by ASN resolution 2008-DC-0103 are found to be correctly applied by the brachytherapy centres.

One significant event was notified in 2016. Sources (small seeds of iodine-131) were disposed of using the conventional waste route and were introduced into an incineration plant. A study was carried out to assess the consequences of this incident; it confirmed that it had no impact on health or the environment.

Interventional practices

In the light of the six inspections concerning interventional practices in the Centre-Val de Loire region, ASN considers that worker radiation protection is tending to improve in this area and that the regulatory radiation protection controls are performed satisfactorily. Passive and active dosimetry resources are made available to the personnel in the centres concerned. The shortcomings in worker radiation protection noted by ASN, particularly the random way in which personal protective equipment and dosimeters are used, seem to stem from a lack of radiation protection culture in the operating theatres and a lack of time that can be dedicated to the PCRs.

ASN considers that the technical training of practitioners in the use of the devices remains insufficient, as are the efforts made to optimise doses delivered to patients.

No significant radiation protection event concerning interventional imaging was notified in the Centre-Val de Loire region. In view of the number of centres or departments using these techniques, the absence of event notifications reveals the necessity to continue putting in place tools to identify and analyse abnormal situations.

Nuclear medicine

ASN inspected four of the ten centres practising nuclear medicine in the Centre-Val de Loire region. The organisation in place to ensure safe administration of radiopharmaceuticals was examined. The overall findings are positive with regard to the measures taken in response to this challenge. The waste treatment route, management of waste during decay and of the condition of the pipes carrying the radioactive effluents from these departments require particular vigilance.

An initiative to raise awareness of the recurrent incidents involving the administration of radiopharmaceuticals was directed at all the nuclear medicine departments through a review of the events analysed by ASN since 2007 and the resulting recommendations.

The significant event notifications received by ASN in 2016 concerned more specifically blocked pipes, injection errors and equipment failures making it necessary to repeat examinations and reinject the radiopharmaceuticals.

These incidents had no clinical consequence on the patients or personnel, but they demonstrate the absolute necessity for rigour in the organisation and management of the abovementioned functions.

Computed tomography

ASN conducted five inspections in computed tomography departments in 2016. The inspections focused on patient radiation protection measures, particularly with regard to justification of the procedures and exposure limitation during the examinations. The inspectors note with particular emphasis the good level of awareness of these important issues in young physicians.

The significant events in computed tomography notified in 2016 chiefly concerned examinations performed on pregnant women who were unaware of their pregnancy, which had no expected consequences on health.

Conventional radiology

ASN conducted an inspection campaign in 2016 in dental surgeries equipped with a 3D radiography device. These devices are used primarily in dental implantology, but also in orthodontics. This type of equipment has a X-ray emission remote control situated remotely outside the room.

Fifty dental surgeries identified as having this type of equipment were sent a questionnaire. Sixteen of these surgeries were then inspected, ten situated in the Centre-Val de Loire region and six in Nouvelle-Aquitaine.

The inspections revealed satisfactory application of worker radiation protection regulations on the whole, most often based on the outsourcing of the PCR function to specialised consultants. The inspectors also noted positively the initiatives taken with regard to the wearing of passive dosimeters by the para-medical and non-medical personnel.

With regard to patient radiation protection, although the Order of 24th October 2011 on the diagnostic reference levels does not apply to these devices, the practitioners use acquisition protocols adapted to the morphology of the patient which enable the delivered doses to be optimised.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out five inspections in companies using X-rays for the Non-Destructive Testing (NDT) of industrial parts, particularly in the weapons industry. Worker radiation protection is found to be satisfactory despite findings showing the absence of reports demonstrating compliance of the facilities with the standards in effect. The personnel assigned to NDT tasks are trained and have an appropriate understanding of the radiation protection issues.

Three worksite inspections, two of them in a nuclear power plant, again highlight the risks of this activity, particular when using high-activity sealed sources. These sources are stowed in a device called a gamma ray projector, which both protects the surrounding external environment from the effects of the radiation and enables the source to be projected in a controlled manner to irradiate the inspected metal part. One incident with no radiological consequences was reported, concerning the operation to retract the source into its location inside the gamma ray projector. The guide tube was partially pulled out further to seizure of the retraction device. The manufacturer examined the device.

Veterinary

In 2016, ASN inspected two veterinary practices equipped with a computed tomography scanner. The utilisation if this equipment which comes from the medical sector was judged satisfactory with regard to worker radiation protection.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In the area of radioactive substance transport, in 2016 ASN conducted four inspections in BNIs, one inspection in a nuclear medicine centre, one inspection of an industrial company and one inspection of a road transport carrier.

The verifications focused primarily on the management systems, the operational measures applied, compliance with the package approvals, particularly for spent fuel transport operations, and emergency situation preparedness. Transport operations within BNI sites were also inspected.

The inspections show that the regulations pertaining to road and rail transport are correctly applied on the whole. The main areas where improvements are expected concern the management of deviations, the rigour of pre-shipment verifications, the completeness of the management systems, audits and training, the packaging conformity certificates and the radiation protection measures. Relatively few significant events were notified in 2016. The event analyses concluded they had no consequences on the environment. They mainly concerned non-conformance of the transported contents with the package specifications and marking and labelling anomalies.

1.5 Monitoring of approved organisations

Two organisations approved for radiation protection controls (out of 42 in France) have their head office in the Centre-Val de Loire region. ASN maintained its oversight action in 2016 with the audit of one organisation with a view to renewing its approval, one check of an agency and two supervisory checks.

The main findings of these oversight actions, for which the conclusions are on the whole satisfactory, concerned the conditions of supervision of the inspectors and the ionising radiation measurement conditions when performing the radiation protection controls. Some of the organisations would appear not to communicate their projected control schedules as a matter of course.

2. Additional information

2.1 Informing the public

Press conference

ASN held a press conference in Orléans on 9th June 2016 to present the situation of nuclear safety and radiation protection in the Centre-Val de Loire region.

Work with the Local Information Committees (CLIs)

The ASN Orléans division supported the work of the Centre-Val de Loire CLIs by participating in their plenary meetings. It also participated in the public meetings organised in 2016 in accordance with the provisions introduced by the TECV Act.

Iodine tablet distribution campaign around the nuclear power plants

The division took part in the public meetings organised at the beginning of 2016 around the nuclear power plants of the Centre-Val de Loire region, as part of the campaign to distribute replacement iodine tablets in the zones covered by the Off-site Emergency Plans (PPI). In addition to this, it organised a meeting to raise nuclear awareness in the teaching staff of the Saint-François-de-Sales upper secondary school in Gien, situated within the perimeter of the Dampierre-en-Burly NPP off-site emergency plan.

2.2 International action

In 2016, a further meeting took place between ASN's Orléans division and the Swedish safety authority SSM (*Strål Säkerhets Myndigheten*), to discuss oversight practices. On this occasion a team of inspectors from the SSM participated in an ASN inspection of the Saint-Laurent-des-Eaux NPP.

The state of nuclear safety and radiation protection in 2016 in the Corse region

The Marseille division regulates radiation protection and the transport of radioactive substances in the 2 *départements* of the Corse region.

The activities and installations to regulate comprise:

- numerous small-scale nuclear activities in the medical sector:
  - 1 external-beam radiotherapy department;
  - 2 nuclear medicine departments;
  - 9 centres performing interventional procedures;
  - 7 tomography devices;
  - about 330 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial sector:
  - 6 industrial establishments licensed to hold or use sources of ionising radiation;
  - 22 users of lead detectors;
  - some 20 veterinary surgeons using diagnostic radiology devices.

In 2016, ASN's carried out 5 inspections in Corse, of which 4 concerned small-scale nuclear activities and 1 concerned the transport of radioactive substances.

Among the significant events notified, one was rated level 1 on the INES scale; it concerned the exposure of a member of the public to ionising radiation.

1. Assessment by domain

1.1 Radiation protection in the medical field

ASN performed one inspection in external-beam radiotherapy in the Corse region in 2016. ASN considers that the work conducted by the team at the inspected centre on treatment quality and safety and the control of risks is relevant. The cohesion of the team was also noted. Nevertheless, the low staffing level leads to vulnerabilities in treatment quality and safety. ASN also noted the need to supplement the medical physics organisation plan of the centre, particularly as regards task quantification and prioritisation.

In 2016, ASN inspected two centres in Corse that perform interventional procedures. ASN considers that both centres must continue their efforts in worker and patient radiation protection by putting all the related procedures into practice with the involvement of the personnel concerned. ASN underlines the high level of involvement of the PCRs. The providing and wearing of dosimeters remain weak points however. Furthermore, a number of actions relating to dose optimisation must be engaged or continued.

1.2 Radiation protection in the industrial and research sectors

ASN carried out an inspection in a department that uses a gamma ray densitometer and another inspection in this same department but in the area of radioactive substance transport. ASN noted good daily involvement of the PCR in disseminating a radiation protection culture to the worksite operators. The department takes due account of the radiation protection issues although formalisation of the actions taken is lacking. ASN considers moreover that the regulations relative to radioactive substance transport are correctly applied.

The state of nuclear safety and radiation protection in 2016 in the Grand Est region

The Châlons-en-Champagne and Strasbourg divisions are jointly responsible for regulating nuclear safety, radiation protection and the transport of radioactive substances in the 10 *départements* of the Grand Est region.

The activities and installations to regulate comprise:

- BNIs:
  - the Cattenom NPP (4 reactors of 1,300 MWe);
  - the Chooz A NPP (currently being decommissioned);
  - the Chooz B NPP (2 reactors of 1,450 MWe);
  - the Fessenheim NPP (2 reactors of 900 MWe);
  - the Nogent-sur-Seine NPP (2 reactors of 1,300 MWe);
  - the low and intermediate-level short-lived radioactive waste repository (CSA) located at Soulaines-Dhuys in the Aube *département*;
  - Andra's underground research laboratory in Bure, in preparation for the creation of a geological repository for high-and medium-level long-lived radioactive waste;
- small-scale nuclear activities in the medical sector:
  - 14 radiotherapy centres;
  - 5 brachytherapy centres;
  - 19 nuclear medicine centres;
  - 93 tomography devices;
  - about 76 centres carrying out interventional procedures;
  - about 2,100 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - about 85 veterinary clinics;
  - about 500 licensed industrial activities, with more than half of the licenses being for possession of devices to detect lead in paint;
  - about 50 research laboratories situated primarily in the universities of the region;
- 5 head offices of organisations approved in radiation protection.

In 2016, ASN carried out 166 inspections, of which 62 were in nuclear power plants (NPPs), 7 in radioactive waste disposal facilities, 87 in small-scale nuclear activities and 10 in the transport of radioactive substances.

ASN also carried out 8 days of labour inspections in the NPPs.

During 2016, eleven significant events rated level 1 on the INES scale were notified by nuclear installation licensees. In small-scale nuclear activities, 12 significant events were rated level 1 on the ASN/SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Cattenom nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Cattenom NPP is, on the whole, in line with ASN's general assessment of EDF's performance.

With regard to operation of the reactors, ASN considers that the site's performance is satisfactory on the whole. However, some events point to insufficient monitoring of outside contractors or inappropriate choices of procedures applied in operating or test operations, which illustrates a slight downturn with respect to the preceding years and the need for greater vigilance during reactor operating operations. The site's organisation for taking Social Organisational and Human Factors (SOHF) into consideration is of a good standard. The year 2016, which was marked by a very large amount of maintenance work, went well on the whole and showed the robustness of the organisation in place and the satisfactory scaling of the human resources.

With regard to protection of the environment, ASN considers that the efforts undertaken must be continued. The progress observed in waste management was confirmed in 2016. Aqueous discharges are controlled but remain a special issue given the sensitivity of the receiving environment (Moselle River). Lastly, several events linked to a lack of proficiency in the management and containment of chemical products show the need for increased vigilance.

With respect to worker radiation protection, ASN observed determined efforts and mobilisation at senior management level, resulting in significant progress in a context of major work intervention programmes in 2016. This progress nevertheless remains to be confirmed given the rise in deviations detected at the end of the year and the change in the main radiation protection service provider.

Chooz nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Chooz B NPP is, on the whole, in line with its general assessment of EDF's performance.

ASN notes an increase in the number of significant safety events linked to management of the reactors. A lack of rigour in certain individual behaviours and the effects of the renewal of the personnel responsible for operation, factors which have been identified for several years, emerge as the main causes. The year was also marked by several errors in the implementation of equipment periodic test rules.

From the maintenance aspect, the refuelling shutdown of reactor 2 went smoothly. ASN nevertheless underlines that insufficient rigour or lack of a questioning attitude was the cause of a large number of significant events. Monitoring outside contractors and reinforcing the preparation phases by providing appropriate documentation for example, are also identified lines of progress.

ASN considers that the radiation protection performance of the site is stable. 2016 saw the deployment of the "Everest" initiative concerning entry into the nuclear zones of the installation in standard working overalls. In this context, the attention paid to maintaining radiological cleanliness and educating the personnel in radiation protection actions must remain a priority.

Lastly, ASN considers that the site's organisation for environmental protection is satisfactory. It nevertheless notes a significant increase in the number of failures of measuring equipment involved in environmental and discharge monitoring.

Fessenheim nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Fessenheim plant are above the average of the plants operated by EDF and that the radiation protection performance is in line with the general assessment for EDF.

The year 2016 was marked by the exceptionally short operating time of the reactors, in view of the two outages involving major work programmes, and the identification of irregularities and technical anomalies affecting certain Nuclear Pressure Equipment (NPE) items. The discovery of a nonconformity affecting the manufacture of a steam generator of reactor 2 led to the early shutdown of this reactor on 13th June 2016. The suspension by ASN of the certificate of conformity of the steam generator in question means that the reactor will remain shut down until the suspension is lifted. EDF is continuing a procedure to prove that steam generator in question is in conformity with the regulations. Moreover, an additional outage of reactor 1 in December 2016 was necessary to carry out further inspections on steam generator channel heads forged in Japan displaying significant carbon-rich segregate zones. A number of significant events during operation of the reactors connected with enhancing the reliability of interventions and operational control, and the performance of periodic tests, are to be noted.

ASN considers that personnel training is of a good standard and did not observe any demotivation of the teams in spite of the prolonged shutdown of reactor 2. The particular context regarding the prospects of closure of the site nevertheless requires EDF to be particularly attentive to the SOHFs.

The maintenance operations carried out in 2016 were scheduled and managed satisfactorily, which ASN views positively given the heavy work schedule and the context mentioned above. Moreover, the audit of the site's users' inspection department gave positive results with regard to pressure equipment and more generally for application of the regulations governing Nuclear Pressure Equipment (NPE).

The site's organisation for environmental protection is satisfactory and the personnel are environmentally aware. The site has put into practice the new prescriptions regulating its discharges, which has led to an increase in event notifications, in a context of overall progress and significant tightening of requirements.

Worker radiation protection displayed occasional deficiencies, particularly during the outage of reactor 2, and necessitated increased coordination by the site's senior management in the middle of the year. EDF must maintain its vigilance to ensure long-term control of the worker radiation protection issues.

Nogent-sur-Seine nuclear power plant

ASN considers that the nuclear safety, radiation protection and environmental protection performance of the Nogent-sur-Seine NPP is, on the whole, in line with its general assessment of EDF's performance.

With regard to the operational control of the reactors and operating rigour, ASN considers that the licensee's performance has been satisfactory apart from the maintenance shutdown and restarting phases during which several deviations from the general operating rules were noted. As in 2015, the cause of the deviations lies most often in a lack of preparation of the activity and of communication between the persons involved.

With regard to maintenance, ASN considers that the scheduled maintenance outage of reactor 1 was managed satisfactorily. ASN nevertheless notes shortcomings in the preparation and performance of unscheduled maintenance activities and in the organisational capacity to take decisions based on an overall view of the issues at stake.

With regard to radiation protection, ASN considers that the site has not corrected the shortcomings in radiation protection culture already seen in 2015 during the scheduled maintenance work on reactor 1. In view of the deficiencies observed in the use of inspection equipment or radiological zone marking equipment, the licensee must significantly reinforce the radiation protection education of all the personnel, including that of outside contractors.

As far as environmental protection is concerned, ASN considers that the site must improve its performance. The organisation and means deployed to anticipate and manage the bypassing of normal wastewater discharge routes show that the site is not always sufficiently responsive in this area.

Labour inspection in the nuclear power plants

ASN continued its oversight of health and safety conditions, particularly during reactor outages.

The health and safety measures taken by the licensee are found to be satisfactory in the majority of cases. Nevertheless, ASN observes, as in the preceding years, that some risk analyses prior to maintenance operations are insufficient and that the working conditions do not always minimise the risks for the personnel.

ASN also continued its oversight actions with specific inspections on the themes of chemical risks, lifting, and the inspection of working facilities and equipment. Cases of noncompliance with regulatory requirements have been observed, particularly when checking the serviceability of certain collective protection systems (aeration systems and radioactivity measurement equipment), as well as lateness in integrating regulatory changes concerning measurements of the limit professional exposure values for workers.

With regard to radiation protection, the inspectors continued to check implementation of the Everest initiative on the Chooz site, an initiative that significantly changes the conditions of access to controlled areas and must still undergo operational adaptations.

The Soulaines-Dhuys waste repository and the Bure laboratory

ASN considers that operation of the CSA repository is satisfactory, in line with the previous years.

In 2016, the French National Radioactive Waste Management Agency (Andra), continued deployment of the package inspection facility designed to provide the CSA site with more powerful means of checking the quality of the packages it receives. ASN is currently examining the commissioning authorisation application for this facility. Construction of the disposal structures of section 9, for which ASN has given its agreement, continued in 2016.

In 2016, ASN also authorised the CSA to accept ten non-standard packages originating from the decommissioning of the Creys-Malville installations.

Andra sent ASN the periodic safety review file for the CSA in August 2016. The examination of this file will focus in particular on evaluating the safety of the facility with regard to the planned development of its activities over the next ten years. It will also enable the strategy for decommissioning, closing and monitoring the facility once it has stopped receiving waste to be detailed.

ASN considers that experiments and scientific work conducted by Andra in the underground laboratory at Bure continued in 2016 with a good standard of quality, comparable with that of the preceding years. The tunnelling work to create new drifts however gave rise to a serious work accident on 26th January 2016. Andra has sent ASN a safety options dossier for the *Cigéo* deep geological repository project. ASN will give an opinion once it has finished examining this dossier. Andra will be able to take the opinion into account when drawing up the facility creation authorisation application, which it plans to present in 2018.

Chooz A reactor undergoing decommissioning

The preparatory work for the decommissioning of the Chooz A reactor vessel continued in 2016. These activities constitute an important step for decommissioning the reactor vessel as from 2017.

With regard to the environment and nuclear safety, ASN considers that the decommissioning operations are being carried out satisfactorily. The site must maintain an adequate level of vigilance in the preparation of the activities, the management of waste, prevention of the fire risk and the management and monitoring of lifting equipment.

Lastly, in 2017 ASN will start examining the reactor safety report which it expects to receive in September 2017.

1.2 Radiation protection in the medical field

Radiotherapy

ASN inspected six radiotherapy centres in 2016. These inspections showed that the centres now have treatment quality and safety management systems which are well established and evolving, encouraging the development of internal audits and the defining of formalised protocols. These inspections nevertheless also revealed the need to continue improving the studies of risks run by patients and taking experience feedback into account. The management system upgrades must also take better account of the development of new techniques and the replacement of equipment.

Interventional practices

ASN carried out nine inspections of operating theatres in the region in 2016. These inspections revealed great disparities between the inspected centres. On the whole, the centres performing the most complex procedures with high risks have good and appropriate practices in place. The findings notified over the past years concerning training the personnel in patient and worker radiation protection and the technical controls of the devices are often still pertinent, indicating that the centres have difficulty in giving a rapid follow-up to ASN's demands, often due to a lack of human and material resources. The improvements that are also expected in the monitoring and analysis of doses delivered to patients seem to be limited by the means available to the medical physics teams.

Nuclear medicine

ASN inspected seven nuclear medicine centres in 2016. These inspections confirmed a good overall level of application of the radiation protection requirements for both patients and the personnel. More specifically, optimising doses delivered to patients and establishing protocols, particularly for the most common examinations, have become the rule. Likewise, improvements have been observed in the management of the sealed sources used for equipment calibration, in the in-house radiation protection controls and in the monitoring of workers. The measures taken by the nuclear medicine centre having undergone an SOHF study conducted by IRSN under the aegis of ASN, with the participation of the Regional Health Agency (ARS) of Champagne-Ardenne, were examined and showed that the first organisation measures have been taken into account. Lastly, the regular updating of the licenses issued by ASN should be better anticipated by the centres.

Computed tomography

ASN carried out seven inspections in computed tomography (CT) in 2016, maintaining its focus on the examination of the patient radiation protection measures taken by the centres. The reason for this is that CT examinations represent a significant source of exposure to ionising radiation in the French population. In this respect ASN has observed that the effective optimisation of procedures and defining of examination protocols have become widespread practices. Moreover, some centres with advanced technologies and performing examinations involving risks are developing particularly effective optimisation practices.

Dental radiology

In 2016, ASN inspected three dental surgeries situated near Reims further to the oversight campaign carried out in 2015 by letter. The radiation protection technical controls and the external quality controls were the main areas justifying the putting in place of corrective actions.

1.3 Radiation protection in the industrial, research and veterinary sectors

Industrial radiography

ASN inspected 13 industrial radiography and gamma radiography activities in 2016 and found extremely varied situations. Some companies rigorously apply the radiation protection rules, while for others ASN has been obliged to put in place tightened monitoring. The major deviations observed concerned signalling and the delineation of work areas. Control of these areas by the operators will remain a priority line of oversight in 2017.

Research

The seven inspections ASN carried out in the research centres of the region show that these centres usually have very high level skills and are fully conversant with the radiation protection issues from the operational viewpoint. Shortcomings are however regularly observed in the rigour with which the regulations are applied. More specifically, the substantial efforts initiated by the regions' major university research centres to bring the administrative situation of all their entities into compliance must be continued.

Veterinary

ASN conducted a remote oversight operation involving about twenty veterinary surgeries in the Aube *département*. The main findings resulting from this concerned the conformity of the premises in which the radiological equipment is used and the taking into account of the results of the in-house radiological controls

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

Continuing in line with the preceding years, ASN contributed – along with decentralised government services and Andra – to dealing with the legacy radioactive contamination resulting from operation of the former Orflam-Plast plant in Pargny-sur-Saulx (Marne *département*). A public presentation of the rehabilitation developments and the monitoring of the site of the former plant was organised on 15th October 2016. Complementary investigations on plots of land situated outside the industrial site were continued in 2016.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN performed four inspections focusing on the on-site transport of radioactive substances on the sites of Cattenom, Chooz, Fessenheim and Nogent; they showed in general the need to more clearly define the internal organisation of the sites and the interfaces between the various actors, with the exception of the Fessenheim site which stands out for its very good performance in the area of transport, and particularly as regards the traceability and management of files.

Six inspections were carried out in small-scale nuclear activities. These inspections focused more specifically on work radiation protection, conformity of the transport documents with the regulations, and management of the storage of packages and equipment.

2. Additional information

2.1 Informing the public

Press conferences

ASN held a press conference in Châlons-en-Champagne on 31st May 2015, in Metz on 29th June and in Strasbourg on 30th June 2016, on the status of nuclear safety and radiation protection in the Grand Est region.

Work with the Local Information Committees (CLIs)

ASN took part in meetings of the Cattenom, Chooz, Fessenheim, Nogent-sur-Seine and Soulaines CLIs. During these meetings ASN presented its assessment of the safety of these nuclear installations and its action on these sites, the follow-ups at national and local level to the Fukushima Daiichi accident, the stable iodine distribution campaign and the ASN resolutions concerning the management of radioactive waste in view of the preparation of the PNGMDR (French National Radioactive Material and Waste Management Plan) 2016-2018. Detailed presentations of topical files concerning the irregularities and technical anomalies affecting the NPE were also given to the stakeholders represented in the CLIs and to the public, to whom these meetings were open pursuant to the provisions introduced by the TECV Act.

The meetings of the Fessenheim and Cattenom CLIs also provided the opportunity for in-depth exchanges with representatives of Luxembourg and German stakeholders.

The Cattenom CLI was involved in the national work of the National Association of Local Information Committees and Commissions (Anccli), and more specifically the subjects associated with emergency situation preparedness and the extension of the Off-site Emergency Plan (PPI) perimeters to 20 km.

The Fessenheim CLI organised a public meeting on 27th June 2016 which was attended by 300 people from France, Germany and Switzerland. Apart from the subjects addressed as a matter of course at CLI meetings (annual results, significant events, etc.), the risks associated with the technical irregularities and anomalies affecting the NPE and their impact on the Fessenheim NPP were presented.

The Chooz CLI organised a presentation of the ASN-IRSN exhibition devoted to the functioning of reactors and accident situations in two municipalities in the region of Chooz (Vireux-Wallerand and Givet) in April and May 2016; school pupils and teachers could thus visit the exhibition during this period. A delegation from Anccli visited the Chooz A reactor decommissioning worksite on 20th October 2016.

The Nogent CLI continued the experimental process of periodically examining EDF's replies to the follow-up letters sent by ASN further to its on-site inspections.

ASN also regularly attended the annual general meetings and meetings of the board of the Bure CLIS (Local Information and Monitoring Committee) where it made its contribution with a view to informing the local populations.

Lastly, ASN participated in the meeting of the regional network of PCRs of the Grand Est region.

2.2 International action

The Châlons-en-Champagne division continued to maintain regular relations with the Belgian nuclear regulator, the AFCN. The cross-inspections continued in the areas of small-scale nuclear activities and nuclear industry facilities on the sites of Chooz and Tihange (Belgium). The division took part in the Franco-Belgian management committee meetings and the Franco-Belgian working group on nuclear safety.

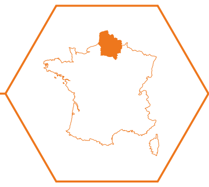
The Strasbourg division was deeply involved in the bilateral relations with its German counter parts, particularly the work of the Franco-German Commission (DFK) in the plenary sessions and within working group No.1 dedicated to reactor safety. The division moreover invited representatives of the Ministry of the Environment and Nuclear Safety of the Land of Bade-Wurtemberg and of the approved organisation TÜV to a cross-inspection on the Fessenheim site.

A cross-inspection in the area of small-scale nuclear activities was organised with representatives of the Luxembourg Ministry of Health in the regional hospital centre of Metz-Thionville.

2.3 The other notable events

With respect to major risk prevention, ASN assisted the prefectures of the Aube, Ardennes, Haut-Rhin and Moselle *départements* in the preparation and monitoring of the stable iodine tablet replacement campaign in the areas around the Nogent, Chooz, Fessenheim and Cattenom NPPs.

The Châlons-en-Champagne division took part in the emergency exercise organised on 18th May 2016 on the Saint-Dizier air base (Haute-Marne *département*) by making its contribution to the functioning of the operations decision centre set up in the Haute-Marne prefecture.



The state of nuclear safety and radiation protection in 2016 in the Hauts-de-France region

The Châlons-en-Champagne and Lille divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Hauts-de-France region.

The activities and installations to regulate comprise:
- BNIs:
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
  - the Somanu (*Société de maintenance nucléaire*) site operated by Areva in Maubeuge (Nord *département*);
- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments;
  - 3 brachytherapy departments;
  - 27 nuclear medicine units;
  - 92 centres performing interventional procedures;
  - 126 tomography devices;
  - about 4,600 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 1 organisation using blood product ionisers;
  - 2 cyclotrons producing fluorine-18;
  - about 330 veterinary diagnostic radiology devices;
  - 31 industrial radiography companies;
  - about 1,900 industrial devices;
  - 38 research units;
- organisations approved by ASN:
  - 4 agencies of approved organisations in the area of small-scale nuclear activities.

In 2016, ASN carried out 135 inspections in the Hauts-de-France region, comprising 21 inspections in the Gravelines Nuclear Power Plant (NPP), 3 at Somanu in Maubeuge, 102 in small-scale nuclear activities and 9 in the transport of radioactive substances. ASN also carried out 14 days of labour inspection in the Gravelines NPP.

During 2016, 6 significant events rated level 1 on the INES scale were notified by the Gravelines NPP. One significant event in the transport of radioactive substances notified by the Gravelines NPP was rated level 1 on the INES scale. In small-scale nuclear activities 5 events were rated level 1 on the INES scale (loss or theft of devices for detecting lead in paint and irradiation by computed tomography (CT) scanners), plus 7 events involving radiotherapy treatments rated level 1 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Gravelines nuclear power plant

ASN considers that performance of the Gravelines NPP with regard to nuclear safety and radiation protection are on the whole in line with the general assessment of EDF, while its performance in environmental protection is substandard.

Performance with regard to operation of the reactors improved in 2016. The site must nevertheless pursue its continuous improvement actions, particularly with regard to operating rigour, performance of operations, rapid detection of deviations and application of instructions.

With regard to maintenance, ASN considers that general condition of certain items of equipment has improved. Efforts must be continued on other equipment such as the pipes which are sensitive to corrosion due to their situation by the sea. The site must remain vigilant in the preparation and quality of the technical controls performed during maintenance operations, even if the number of quality deviations has fallen compared with 2015.

With regard to environmental protection, the work to restore conformance of the storage tanks for effluents from the primary and secondary systems of the reactors is continuing. The site must be particularly attentive to the conformance of its facilities with respect to the modification files it submits and to the authorisations issued by ASN.

With regard to management of emergency situations and the fire risk, ASN considers that the site must improve the management of fire loads and fire sectorisation, particularly during reactor maintenance operations.

With regard to radiation protection, ASN notes recurrent shortcomings in the control of access to some areas presenting risks of radiological exposure. Improvements are also expected in the monitoring of workers at exits from controlled areas and in the management of worksites where there is a risk of radioactive substance dispersion. The site must improve the provision of radiation protection training for exposed workers by involving the Persons Competent in Radiation protection (PCR) and the occupational physicians to a greater extent. Two significant events rated level 1 were notified in this area.

On 30th August 2016, ASN issued a resolution imposing prescriptions relative to the continued operation of reactor 1. One of these prescriptions required that bottom-mounted instrumentation penetration No. 4 (the reactor vessel has 50 of them) be definitively repaired before 31st December 2016. This operation was carried out during the maintenance and refuelling outage which began on 13th August. The repair was carried out without any particular problems. On 18th November 2016 ASN gave its consent for EDF to proceed with the criticality research and then the reactor divergence operations.

Labour inspection in the Gravelines nuclear power plant

Among the 14 days of labour inspection, ASN carried out three joint inspections with the common law labour inspectorate. Particular emphasis was placed on the safety of lifting operations, particularly on account of the planned steam generator replacement operations on reactor 5. ASN remains attentive to worker compliance with the safety rules. There were no serious work accidents.

Société de Maintenance Nucléaire (Somanu) in Maubeuge

ASN considers that operation of Somanu's facilities is satisfactory on the whole. The operating performance of Somanu improved during the year 2016. However, given the many technical and organisational challenges facing Somanu in the years to come, the ongoing efforts will have to be maintained over the long term.

The performance in radiation protection was maintained at the level of the previous year. ASN asks that the efforts be maintained, particularly regarding the trend in doses received by the personnel of Somanu and of outside contractors.

In the context of its oversight missions, ASN identified a number of weaknesses in the identification and handling of deviations in 2016. ASN remains attentive to the way licensees take its demands into account and to the monitoring of their commitments.

The actions relating to the periodic safety review[1] of the facility are continuing and will require Somanu to maintain its efforts in this respect in the coming years. Examination of the Creation Authorisation Decree (DAC) modification file and the modification request concerning the associated discharge resolutions led to several technical discussions between the licensee, ASN and its technical advisor IRSN, which concluded that it was necessary to amend the existing file with further measurements and studies. The lateness in this matter identified in 2015 was not caught up in 2016. It should be noted in this respect that the examination of the DAC modification by the Minister responsible for the Environment was suspended pending reception of these additional elements.

1. *See note on page 231.*

1.2 Radiation protection in the medical field

Radiotherapy

The Hauts-de-France region counts 19 radiotherapy centres under ASN oversight. These centres operate 44 accelerators, most of them recent and some of which use innovative techniques, and more specifically two contactherapy devices, one GammaKnife® (device with sources), a robotic radiosurgery system called CyberKnife® (X-ray generator), put into service in 2016 at the new university hospital centre in Amiens and one tomotherapy machine in the Saint-Quentin hospital centre which was also commissioned in 2016.

ASN carried out fourteen inspections in these radiotherapy centres to check the radiation protection of patients and workers. The inspections were turned towards examining the quality policy and management, through processes such as a priori risk management, management of experience feedback from adverse events or the implementation of new techniques and change management.

ASN had noted over the last few years that the centres were engaged in the process of continuous improvement of practices. 2016 was marked by more mixed findings regarding the durability of the systems in place. In effect, further to human or organisational changes, several centres have to upgrade their quality management system and the associated coordination tools. ASN notes disparities between the centres in the region and a lack of consistency over time. This situation moreover entailed the decision to issue a formal compliance notice for one centre and tightened monitoring (inspection frequency higher than the national average) for six others, of which two have difficulties with radiation oncologist resources and two others have management difficulties further to restructuring operations.

The procedure for recording and analysing adverse events is now in place in all the centres. ASN nevertheless again observes a loss of momentum in the recording and analysis of adverse and precursory events. The number of notifications of significant radiation protection events, both within the centres and to ASN, remains relatively low and involves the personnel to different extents. Furthermore, monitoring of the action plans resulting from these analyses can be improved in some cases.

The initiative of making the patient treatment process be subject to strict quality assurance procedures, after having progressed strongly in the past years, must now be maintained over time through lasting and resilient systems which can withstand environment and organisation changes in a context of rapidly evolving techniques.

Radiotherapy is effectively a field that increasingly calls upon innovative technologies which bring, among other things, greater precision in treatments. ASN asks that in-depth reflection be carried out on the appropriation of these technologies by teams of the centres on a project management basis and with the support of adequate human and technical resources. ASN will continue to give priority to good integration of these prerequisites.

Interventional practices

ASN's inspections in interventional practices are based on a study carried out in 2013 with centres in the region performing procedures in operating theatres and dedicated rooms. ASN observes that interventional practices are being used more and more and that they have considerably evolved over the last few years. This study served to increase knowledge about interventional practices and provide a better grasp of the serious radiation protection implications for the practitioner, the medical team and the patients, particularly during long or repeated procedures.

In 2016, ASN carried out 14 inspections in the area of interventional practices, particularly in operating theatres, including procedures in cardiology. These inspections show there is considerable room for progress in taking these risks into account, particularly through the need to optimise the machine parameters by adapting the suppliers' standard protocols, which would enable the exposure of patients and staff to be reduced. Furthermore, difficulties are identified in the management of practices from when there are complex structures involving different entities or external practices working with their own personnel. ASN has noted progress in the wearing of personal protective equipment by the workers and in the designation of PCRs for interventional radiology. Efforts nevertheless remain to be made in implementing commitments made during preceding inspections. Likewise, improvements are still expected in the effective wearing of dosimeters, especially among the practitioners, and in training in worker and patient radiation protection.

Nuclear medicine

ASN conducted seven inspections in nuclear medicine in 2016. These inspections reveal a slow improvement in the application of radiation protection rules. The involvement of PCRs is conspicuous among the improvements. It nevertheless remains that progress is expected essentially in giving a more precise definition of radiological zone marking and in the completeness of the working environment analyses. The management of liquid effluents can also be improved, as can the application of the facility layout rules, including basic points such as applying the correct level of negative pressure in the radioelement handling hoods. ASN nevertheless notes positively that the centres are committed to a patient dose monitoring and optimisation approach. Lastly, 2016 was marked by the development of the nuclear medicine activity in the region, with the commissioning of a new positron emission tomography facility in Bois-Bernard (Pas-de-Calais *département)* and work on a new nuclear medicine department - also equipped with a positron emission tomography facility - in Dunkerque Hospital (Nord *département)* and whose clinical operations are planned to start in early 2017. Licensing applications concerning the use of radioelements which are new for the region, such as lutecium-177 (treatment of endocrine tumours) and ytrium-190 in microspheres (treatment of hepatic tumours), can also be underlined.

Computed tomography

ASN's inspections in computed tomography facilities in 2016 concerned nine centres in the Hauts-de-France region. The relatively satisfactory situation in this area has changed little since 2015. During its inspections, ASN highlighted that although the occupational radiation protection rules are on the whole applied satisfactorily, improvements must still be made, more specifically by formalising the technical radiation protection controls to a greater extent, by giving the PCRs sufficient time to accomplish their duties, by better informing outside contractors' personnel, and by reminding physicians of the need to comply with radiation protection rules. Greater traceability of application of the principle of procedure justification is also required. Lastly, ASN considers that progress has been made in the optimisation of doses delivered to patients and that these efforts must be continued, particularly with the paediatric protocols.

1.3 Radiation protection in the industrial, research and veterinary sectors

Industrial radiography

In 2016, 12 inspections were carried out in industrial radiography. ASN observes continued improvement in the organisation of radiation protection and the monitoring of workers in the companies. ASN's oversight continues to consist primarily of unannounced night-time worksite inspections, where it still notes deficiencies in compliance with radiation protection rules, particularly in delimiting, signalling and controlling the work areas. These inspections also revealed insufficient checks when retracting sources into the gamma ray projectors, despite several reminder campaigns. With regard to the inspections of the NDT agencies, ASN focused its attention in particular on the compliance of the exposure bunkers with the standards in effect.

Since 2009, ASN, in partnership with DIRECCTE (Regional Directorate for Enterprises, Competition, Consumption, Work and Employment) and CARSAT (Retirement and Occupational Health Insurance Fund), has instituted a charter of good practices in industrial radiography for the Hauts-de-France region. The aim of this charter is to optimise the use of ionising radiation in this area of activity; at present it has been signed by 19 companies. In 2016, ASN organised, in relation with the charter signatories, an awareness-raising seminar for the ordering customers, the contractors and their radiographers, focusing on the planned regulatory changes in industrial radiography and the security of the sources. This seminar was attended by some 80 participants at the *Palais de l'univers et des sciences* in Cappelle-la-Grande.

Universities and laboratories or research centres

ASN regulates the 36 research units in the Hauts-de-France region. These units use a wide variety of ionising radiation sources (sealed sources, unsealed sources, X-ray generators). ASN's oversight duties led to the performance of five inspections in 2016, particularly on the subjects of occupational radiation protection and the management of radioactive sources and waste. ASN considers that over the last few years these research units have improved their application of radiation protection rules. Nevertheless, the discovery and management of radioactive sources and the removal of sources and radioactive waste stored in some universities remain topical issues.

Veterinary

Following on from the campaigns to assess the regulatory situation of veterinary clinics in the *départements* of Aisne and Pas-de-Calais, ASN carried out an ad hoc operation of inspections in 23 veterinary practices out of the total of 180 in these *départements*. In view of the low radiological risks, this activity is not subject to systematic and periodic field inspections.

Compared with the situation found during the inspections of 2010 and 2011, these inspections revealed a better level of administrative compliance of the facilities, a distinct improvement in the risk assessment carried out by the practices, and progress in the performance of the third-party radiation protection technical controls by approved organisations. From this point of view, it is worth pointing out that the announcement of the inspections had a positive effect on the mobilisation of the heads of the veterinary practices concerned. ASN nevertheless identified some failings concerning the document certifying the conformity of the radiology facilities with standard NF C 15-160, compliance with the interval between two third-party radiation protection controls, and the three-yearly renewal frequency of training in occupational radiation protection for the exposed personnel. The work environment studies frequently fail to include exposure of the extremities and the lens of the eye.

Devices for detecting lead in paint

An information campaign directed at holders of devices for detecting lead in paint (X-ray fluorescence using a sealed source of radioactive material) was renewed in the Aisne and Oise *départements* in 2016. Based on a documentary survey, this type of action aims more specifically at detecting any deviations and improving compliance with the obligations associated with cessation of activity which requires the sources to be taken back by the suppliers. Given the five-year validity of their license, 80 companies were listed and underwent this survey in 2016. Their situation is compliant or in the process of becoming so.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

ASN conducted nine inspections in the transport of radioactive substances in 2016. These inspections revealed no major deviations from the regulations, although ASN found a certain lack of knowledge among the workers on the ground, BNI personnel excepted, with regard to their radiological exposure.

The inspections in small-scale nuclear activities were carried out in two nuclear medicine departments and one technical control company.

2. Additional information

2.1 Informing the public

Press conferences

In 2016, ASN held two press conferences on the status of nuclear safety and radiation protection, one in Lille, the other in Dunkerque.

Work with the Local Information Committees (CLIs)

ASN regularly presented files in progress in the Somanu facility in Maubeuge and in the Gravelines NPP to their CLIs. More specifically, the Gravelines CLI was informed of the high carbon concentration anomalies affecting the steam generators of reactors 2 and 4 and the manufacturing irregularities affecting one of the new steam generators that were to be installed on reactor 5.

In accordance with the provisions introduced by the TECV Act, the Gravelines and Somanu CLIs each organised a public meeting in December 2016 focusing respectively on emergency organisation and population protection measures.

Other public information initiatives

ASN contributed to the information seminar on the subject of decommissioning held on 11th October 2016 at Lille University and organised by the association *"Environnement et développement alternatif"* (Environment and alterative development). It also took part in the 7th *Assises nationales des risques technologiques* (National conference on technological risks) held in Douai on 13th October 2016.

Professional gathering

On 23rd June 2016, ASN organised a seminar for industrial radiography professionals of the Hauts-de-France and neighbouring regions. The presentations and discussions provided the opportunity to address various subjects ensuring a better guarantee of protection of the populations and workers through, for example:
- changes in the regulations of the Labour Code and the Public Health Code, including new measures concerning the security of sources;
- the search for alternative non-destructive testing methods;
- occupational medicine actions;
- the dissemination of good practices;
- a reflection on the dialogue that is necessary between ordering customers and contractors.

2.2 International action

Within the framework of the international exchanges, eight joint inspections were carried out with AFCN, the Belgian nuclear safety authority and its technical advisor (BEL V), with the ONR (Office for Nuclear Regulation), the United Kingdom's nuclear safety authority, and with ANVS, the Dutch Safety Authority. These inspections, six of which were carried out in the Gravelines NPP concerned the themes of radiation protection, fire, transport and waste.

2.3 The other notable events

The Lille division participated in the adaptation of the national response plan to a nuclear or major radiological accident. Six meetings were organised in 2016 to adapt the national sheets to the zonal level (70% of the sheets adapted).

With respect to the prevention of major risks, ASN assisted the prefecture of the Nord *département* in the preparation and monitoring of the iodine tablet distribution campaign in the 14 municipalities of the Nord and Pas-de-Calais *départements* concerned by the Off-site Emergency Plan (PPI) of the Gravelines NPP.

Lastly, the division assisted the Prefect in the updating of this PPI with a first work meeting held in December 2016.

The state of nuclear safety and radiation protection in 2016 in the Ile-de-France region

The Orléans and Paris divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 8 *départements* of the Ile-de-France region.

The activities and installations to regulate comprise:

- the BNIs regulated by the Orléans division:
  - the 8 BNIs of the CEA Saclay centre, including in particular the experimental reactor Orphée;
  - the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay;
  - the 2 BNIs undergoing decommissioning in CEA's Fontenay-aux- Roses centre;
- small-scale nuclear activities in the medical sector regulated by the Paris division:
  - 26 external-beam radiotherapy departments (nearly 90 accelerators);
  - 13 brachytherapy departments;
  - 63 nuclear medicine departments;
  - about 170 centres performing interventional procedures;
  - more than 200 computed tomography devices;
  - about 850 medical diagnostic radiology centres;
  - about 8,000 dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - about 650 users of veterinary diagnostic radiology devices;
  - 9 industrial radiography companies using gamma radiography devices;
  - more than 200 licenses concerning research activities involving unsealed radioactive sources;
- organisations approved by ASN:
  - 13 organisations approved for radiation protection controls.

The inspections carried out in Ile-de-France in 2016 comprised 27 inspections in the field of nuclear safety, 157 inspections in small-scale nuclear activities and 38 inspections in the transport of radioactive substances.

Two significant events notified in Ile-de-France and relating to safety in BNIs were rated level 1 on the INES scale. In small-scale nuclear activities, 11 Significant Radiation protection Events (ESR) were rated level 1 on the INES scale. In addition to these, 17 events involving radiotherapy patients were rated level 1 and one event rated level 2 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

CEA's Saclay Centre

ASN considers that the safety of operation of the CEA Saclay Centre BNIs is satisfactory. However, the planned organisation for the management of decommissioning projects, such as it was understood during the in-depth inspection on decommissioning management, does not enable decommissioning - soil remediation included - to be carried out within controlled times while at the same time ensuring the requisite conditions of safety and radiation protection. ASN considers that the CEA's announcement at the end of 2016 that it was pushing back the submission of the Osiris decommissioning file by more than two years, with a new deadline set for March 2019, can only consolidate this judgement.

The in-depth inspection which concerned the CEA Saclay and Fontenay-aux-Roses Centre BNIs, which are undergoing decommissioning, has shown that the rigour of operation of the waste storage areas, particularly with regard to compliance with operating instructions and keeping the waste inventory up to date, was unsatisfactory, despite the progress made in this area since 2015.

Given the major organisational changes planned in 2017, which include reorganising the decommissioning within CEA and merging CEA's Saclay and Fontenay-aux-Roses Centres, ASN considers, without prejudice to their long-term impact, that CEA must take care to guarantee the necessary conditions for ensuring safety and radiation protection in the Saclay BNIs while this new organisation is being set up and consolidated. ASN is also attentive to trends in the management of liquid effluents in the BNIs in the current context of lockout/tagout of the premises housing the front-end tanks of BNI 35 and the robustness of the provisions for managing the solid waste produced by the BNIs of the centre with a view to final shutdown of BNI 72.

Alongside this, ASN observes the successful deployment of the action plan to check compliance with the regulatory procedures, particularly with regard to modification management. The internal authorisation process for minor modifications is managed correctly but the observance of a few deviations shows that CEA must remain vigilant in this area.

ASN is in favour of defining an action plan to prevent obsolescence of the ionising radiation control panels of several BNIs and will be attentive to its implementation. It emerges from the inspections that the analysis of the necessity to notify certain deviations as significant events or to classify them as notable events must be carried out more systematically and in greater depth; the monitoring of commitments is ensured with the expected rigour. The BNIs must increase their vigilance in monitoring the maintaining of fire protection measures over time.

The review of the post-Fukushima stress tests performed by CEA led ASN to prescribe, on 12th January 2016, the implementation of an emergency management hardened safety core. Like the prescriptions issued earlier for the Cadarache and Marcoule Centres' general resources, this resolution establishes complementary prescriptions specifying the requirements applicable to the management of emergency situations at the Saclay Centre. CEA met the first deadlines of this resolution by submitting the complementary studies and additional proof of its ability to deploy its emergency organisation in extreme situations. These elements are currently being examined by ASN.

Lastly, CEA must continue structuring the process for monitoring outside contractors, which includes reinforcing the presence of its personnel in the field.

CEA's Fontenay-aux-Roses Centre

Despite the efforts of the CEA teams in place, ASN considers that the level of safety of the Fontenay-aux-Roses BNIs is not entirely satisfactory.

ASN's assessment of the organisation for managing the decommissioning projects on the Fontenay site converges with that for the Saclay site. Furthermore, the in-depth inspection of the BNIs undergoing decommissioning in the CEA Saclay and Fontenay-aux-Roses Centres showed that the operating rigour of the waste storage areas was not satisfactory, although progress has been made since 2015.

In 2013, a new organisation was put in place for the BNIs operated by CEA on the Fontenay site. Significant changes are once again planned in 2017. They are associated with the reorganising of decommissioning within CEA and the merging of the CEA Saclay and Fontenay-aux-Roses Centres. In this context, ASN considers that CEA must take care to guarantee the conditions necessary to ensure safety and radiation protection in the Fontenay-aux-Roses BNIs while this new organisation is being set up and consolidated. This new organisation and the improvement plan requested by ASN must take into account the results of the in-depth diagnosis of organisational and human factors in the Centre carried out by CEA in 2016

With regard to internal organisation, ASN considers that CEA has realised the extent of recurrent deviations linked to the multi-technical contract by planning the redistribution of the services by activity. ASN will be particularly attentive to the monitoring of outside contractors once these future contracts have been put in place. The CEA must increase the field presence of its personnel in this respect.

The year 2016 was marked by a significant number of prolonged failures of the ventilation systems ensuring dynamic containment on BNI 165 and losses of alarm or measurement transfers. These events are all related to the electrical power supplies. ASN considers that the difficulties in diagnosing and remedying these situations should lead CEA to step up the technical control of its facilities.

ASN also considers that control of the fire risk remains an issue, as witnessed by the two events linked to the heating of electrical components in 2016.

ASN also noted in 2016 that the system for internal authorisation of minor modifications is well managed by the centre.

2016 also saw substantial progress in the On-site Emergency Plan (PUI) after several years of examination. ASN authorised the modification of the operational part of this plan. Likewise, progress in the updating of the prescriptions governing discharges, effluent transfers and environmental monitoring around the CEA Fontenay-aux-Roses BNIs makes it possible to envisage their completion in 2017.

ASN draws CEA's attention to the close deadlines, set by decrees, for the decommissioning of BNIs 165 and 166. With this in mind, it is important for CEA to be attentive to the quality of the decommissioning files which aim to push back these deadlines significantly. The first versions of these files submitted in 2016 were not considered admissible.

The CIS bio international plant in Saclay

ASN considers that the nuclear safety performance of CIS bio international must be significantly improved.

Despite CIS bio international's efforts to reinforce its integrated management system and its human resources, and despite some observed improvements, the organisation is still not effective enough in obtaining lasting results. ASN considers that operating rigour, operations conformity checks, the cross-functional operation of the organisation, compliance with the baseline requirements of the facility and the decisions and regulations for the implementation of modifications must be improved.

Following the failure to comply with the ASN prescriptions issued after completing the periodic safety review and the administrative police enforcement measures applied by ASN in 2014 and 2015, automatic fire extinguishing devices have been put into service. ASN once again applied an administrative police measure further to noncompliance with a prescription concerning the removal of radioactive substances. These materials have been removed. On account of the large number of commitments made by CIS bio international following the safety review and which have not been met, ASN has prescribed deadlines for their completion.

A large amount of work contributing to improving safety, some of which has been in progress for several years, is not completed. Generally speaking, the large-scale actions initiated by CIS bio international are not completed within reasonable time frames.

Setting up production on Saturdays and Sundays required a specific organisation and additional training in emergency management which ASN inspected with particular attention. The first inspection resulted in an administrative police measure relating more specifically to compliance with the applicable prescriptions regarding the management of fire loads, which the licensee satisfied.

Complementary studies concerning the consequences of accident situations are currently being appraised.

CIS bio international must improve its compliance with the deadlines set for accomplishing the actions defined further to inspections and events. The deviations observed during inspections and the predominance of Social, Organisational and Human Factors (SOHF) in the causes of events reveal persistent weaknesses in operating rigour and in correcting deviations. The management of waste in particular must be significantly improved.

ASN will be attentive to CIS bio international's compliance with prescriptions and the meeting of its commitments, to the improvement in safety in operation and the progress of ongoing work. Consequently, it will keep the facility under tightened surveillance in 2017.

1.2 Radiation protection in the medical field

Radiotherapy

ASN performed 17 inspections in external-beam radiotherapy and brachytherapy departments in 2016. One inspection further to a Significant Radiation protection Event (ESR) in 2015 involving a laterality (wrong-side) error and rated level 2 on the ASN-SFRO scale was carried out with the support of IRSN. This inspection resulted in a better understanding of the chain of events that led to the occurrence of the ESR: the radiation oncologist prescribed the treatment on the healthy side and the error was not detected during the pre-treatment verifications or during the weekly follow-up consultations, the majority of them having been cancelled. The inspection also allowed an examination of the quality of the analysis, the appropriateness of the corrective actions implemented and the methods of assessing these actions. On 6th April 2016, ASN and the ARS of Ile-de-France sent a letter to all the radiotherapy centres in Ile-de-France to alert them to this type of event.

ASN considers that the centres have on the whole progressed. Most of them now have a documentary baseline describing their work methods and the organisation adopted to continuously improve treatment quality and safety. The centre identified as being significantly behind schedule and displaying organisational weaknesses in 2016 is now on schedule. The inspections in 2016 focused mainly on the practical implementation of these procedures and the involvement of all the players in the culture of risk management, in relation more specifically with the above-mentioned event. Further progress is required in taking SOHFs into account, particularly through experience feedback from adverse events. Furthermore, the renewal of machines and the implementation of new treatment techniques create tensions in the organisational setups, which can foster the occurrence of errors.

In brachytherapy, the two sites displaying failings in the application of the regulations in 2015 are now compliant. In 2016, ASN favoured long inspections in the brachytherapy centres in order to have a complete view of the way worker and patient radiation protection is applied and of the safety of transport operations in the largest centres.

Interventional practices

ASN performed 38 inspections in the area of interventional practices in Ile-de-France in 2016. One inspection further to an ESR involving overexposure of a patient during a peripheral arterial embolisation procedure was carried out with the assistance of a medical physicist from ASN's Ionising Radiation Department (DRI) and an expert radiologist designated by the Professional college of French radiology (G4). This inspection more particularly provided a better appreciation of the optimisation measures taken by the centre during the operation and the opportunity to question representatives of the manufacturer of the imaging device concerned by the ESR, for which the centre made a medical devices vigilance notification to the ANSM (French Health Products Safety Agency).

The inspections performed in 2016 confirmed the major radiation protection implications for patients and workers during interventions involving ionising radiation. ASN noted that the way radiation protection is integrated in this sector varied greatly according to the departments and specialities. Radiation protection is better integrated in the medical specialities of interventional cardiology and neuroradiology, where procedures are carried out in dedicated rooms with professionals who are more aware of the radiation protection issues than in specialities in which the practitioners carry out interventional procedures in operating theatres.

ASN was notified of five significant radiation protection events occurring during interventional practices; they all concerned patients.

Nuclear medicine

ASN carried out 18 inspections in nuclear medicine departments in Ile-de-France in 2016, of which one was a new facility commissioning inspection. The number of items of equipment in service in Ile-de-France continues to grow.

ASN observed that the layout and the ventilation systems of several departments were not in conformity with the new requirements of ASN resolution 2014-DC-0463 of 23rd October 2014 relative to the minimum technical rules for design, operation and maintenance with which *in vivo* nuclear medicine facilities must comply.

Seventeen ESRs were notified by nuclear medicine departments. One event concerned the radiological overexposure of a female patient during selective radioembolisation of hepatic metastases. Eight events involved errors in the preparation or administration of radionuclides to the patient, leading to either administration of the wrong radiopharmaceutical or an error in the administered dose. Two events concerned leaks in the system for recovering contaminated liquid effluents placed in a tank to decay prior to discharge. One of these two events, rated level 1 on the INES scale, resulted in the centre discharging the contaminated liquid effluents from the storage tank into the sewage network even though their activity concentration was slightly above the regulatory limit.

Computed tomography

ASN carried out nine inspections in computed tomography in 2016 in Ile-de-France, in order more specifically to verify application of the principle of optimisation of doses delivered to patients. The efforts made to control the dose delivered to patients must be continued, particularly through greater involvement of the medical physicists on the ground. Some centres must continue to improve the monitoring of training in worker radiation protection and the justification of the procedures performed.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN continued its oversight of industrial radiography activities and users of gamma radiography in particular, performing 8 inspections in Ile-de-France in 2016.

The inspections and license renewals were specifically monitored with regard to the regularisation of the old pool of exposure bunkers, particularly as concerns their conformity with applicable standards. Five unannounced inspections were carried out in worksite conditions.

Universities, laboratories and research centres

ASN performed 25 inspections in research facilities in the Ile-de-France region in 2016, with each inspection most often including several laboratories in a given establishment. Particular attention was paid to cessations of activity in the laboratories, as some have still not regularised their situation many years after ceasing to use radioactive sources.

Five significant events were notified in this area in 2016, of which three concerning lost sources were rated level 1 on the INES scale.

1.4 Monitoring of organisations approved for radiation protection controls

In 2016, ASN carried out six approval-renewal audits and three unannounced supervisory inspections as part of the monitoring of organisations approved for radiation protection controls in Ile-de-France. These turned out to be satisfactory on the whole. However, some audited organisations with an analysis laboratory were found to be in breach of requirements concerning laboratory analysis means. Their shortcomings included, for example, an inadequate grasp of the quality management system, failure to assess suppliers which can affect the quality of tests and calibrations, and failure to monitor the radiological contamination in the laboratory environment. These deviations were dealt with during the approval renewal procedures.

1.5 Radiation protection of the public and the environment

Contaminated sites and soils

In the context of its public information and radiation protection oversight duties with regard to the management of contaminated sites and soils, ASN continued its oversight of sites and soils contaminated by radioactive substances, such as the Curie Institute site (Paris), the CEA Fontenay-aux-Roses site (Hauts-de-Seine *département)*, the CEA Saclay site (Essonne *département)*, the site of the former Satchi factory of Ile-Saint-Denis (Seine-Saint-Denis *département)*, the site of the former Curie laboratories in Arcueil (Val-de-Marne *département)*, the former CEA Fort de Vaujours site (Seine-et-Marne and Seine-Saint-Denis *départements)*, the Marie-Curie school site in Nogent-sur-Marne (Val-de-Marne *département)*, the site of the former company Electro-luminescence in Colombes (Hauts-de-Seine *département)*, and a large number of sites managed under the Diagnostic Radium operation.

2016 was marked by the resuming of radiological diagnoses and studies on several sites in preparation for future clean-out and remediation operations. These sites with legacy contamination belong to local authorities, private companies or public developers.

ASN also participated in the development of Soil Information Sectors (SIS) relating to radiologically contaminated sites. This initiative, introduced by the "access to housing and renovated urban planning" act, aims at a better dissemination of information on polluted sites, whatever the nature of the pollution, and to govern their clean-out and remediation or their reuse.

The former CEA site of Fort de Vaujours, on which experiments involving natural and depleted uranium were carried out, was purchased by the Placoplatre Company with the aim of operating an open pit gypsum quarry. Following on from the oversight actions conducted at the request of the Prefects of Seine-et-Marne and Seine-Saint-Denis, ASN issued an opinion on 3rd June 2016 relative to the radiation protection measures taken for the removal of buried pipes situated in the municipality of Vaujours (Seine-Saint-Denis *département),* excluding the central Fort. ASN moreover organised an examination of the site by a third-party expert. It drew up specifications for the verifications to be carried out and gave an opinion on the technical proposals received from the various laboratories interested. A grouping comprising the Centre of Nuclear Studies of Bordeaux Gradignan and the Institute of Nuclear Physics of Lyon was designated third-party expert by the Prefects of Seine-et-Marne and of Seine-Saint-Denis, after receiving a favourable opinion from the Fort de Vaujours site monitoring committee. The grouping carried out a first measurement campaign in June 2016 under the conditions set by ASN. All the actions taken were presented at meetings of the site monitoring committee.

Finally, the Diagnostic Radium operation which began on 21st September 2010 is continuing in Ile-de-France. The State has decided to perform the diagnoses free of charge in order to detect and, where applicable, to treat any radium contamination inherited from the past. This operation, which is placed under the responsibility of the Prefect of the Ile-de-France region, the Prefect of Paris, and is coordinated by ASN, concerns 84 sites in Ile-de-France.

Thirty-six sites had been examined by the end of 2016. Eight of these 36 sites were able to be excluded outright because the buildings are too recent with respect to the period of potential manipulation of radium to be able to have any radioactive contamination. On the remaining 28 sites, more than 430 diagnoses were carried out; in effect, the majority of the sites comprise just one building with many apartments, or to several individual plots. Twenty-one diagnoses revealed traces of radium in premises that are undergoing rehabilitation. The levels measured are low and the exposure does not present any health risk for the occupants.

For the occupants and owners of the contaminated premises, personalised assistance is being provided to apply the necessary protection measures and start the rehabilitation work, paid for by the State. The rehabilitation work has been completed on 14 sites, is in progress on two sites and under preparation on five others.

1.6 Nuclear safety and radiation protection in the transport of radioactive substances

Thirteen inspections concerned road transport carriers, two concerned carriers working in the freight zone of the Charles de Gaulle airport, one concerned a radiopharmaceutical consignor and 22 concerned nuclear licensees who are consignees (recipients) or consignors (dispatchers) of radioactive substances.

The inspections relative to the transport of radiopharmaceutical products reveal that the regulatory obligations concerning the training of the personnel performing the transport operations, the receiving inspections and the shipping of the packages are still insufficiently well known in the nuclear medicine centres. Furthermore, progress in aspects relating to driver radiation protection is expected of the radiopharmaceutical transport carriers.

The inspections of transport carriers working in the freight zone of the Charles de Gaulle airport show that shortcomings persist in the implementation of the quality management system required by the regulations.

In 2016, the Paris division continued the partnership initiated in 2014 with the Department of Public Order and Traffic of the Prefecture of Police of Paris and the Transport Safety Service of the Regional and Interdepartmental Directorate of Infrastructure and Regional Planning in order to carry out unannounced roadside inspections. The inspections took place in the municipality of Lisses (Essonne *département)*.

2. Additional information

2.1 Informing the public

ASN held a press conference in Paris division on 21st June 2016 to present the results of its regional action. It took part in the meeting of the monitoring committee of the Curie site in Arcueil and the three meetings of the Fort de Vaujours monitoring committee.

The state of nuclear safety and radiation protection in 2016 in the Normandie region

The Caen division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Normandie region.

The activities and installations to regulate comprise:
- BNIs:
  - the NPPs of Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe) operated by EDF;
  - the Flamanville 3 EPR reactor construction site;
  - the Areva NC spent nuclear fuel reprocessing plant at La Hague;
  - the Andra Manche repository;
  - the Ganil (National Large Heavy Ion Accelerator) in Caen;
- small-scale nuclear activities in the medical sector:
  - 8 radiotherapy centres (21 machines);
  - 1 protontherapy centre currently being set up;
  - 3 brachytherapy departments;
  - 11 nuclear medicine departments;
  - 35 centres performing interventional procedures;
  - 62 computed tomography departments;
  - about 2,100 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 18 establishments using industrial radiography devices;
  - 1 cyclotron producing radioisotopes;
  - 150 users of lead detectors;
  - about 350 veterinary practices using diagnostic radiology devices;
  - 21 laboratories and universities using ionising radiation;
- ASN-approved laboratories and organisations, including:
  - 9 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 3 head offices of organisations approved for radiation protection controls.

In 2016, ASN carried out 194 inspections in Normandie, comprising 57 inspections in the Nuclear Power Plants (NPP) of Flamanville, Paluel and Penly, 20 inspections on the construction site of the Flamanville 3 EPR reactor, 58 inspections on fuel cycle facilities, research facilities and facilities undergoing decommissioning, 52 inspections in small-scale nuclear activities and 7 in the transport of radioactive substances.

In addition to this, 44 days of labour inspection were carried out on the NPP sites and the Flamanville 3 worksite.

During 2016, 13 significant events rated level 1 on the INES scale were notified to ASN. In addition, 9 events rated level 1 on the ASN-SFRO scale were notified by the heads of radiotherapy departments in the Normandie region.

1. Assessment by domain

1.1 The nuclear installations

Areva NC plant at La Hague

ASN considers that the situation of plants operated by Areva NC in La Hague is relatively satisfactory with regard to nuclear safety, control of personnel exposure to ionising radiation and compliance with the environmental discharge limits. It notes moreover that Areva NC must, without delay, take all necessary measures to comply with the provisions of the BNI Order of 7th February 2012 concerning the defining of Elements Important for Protection (EIP) of the interests and the monitoring of outside contractors.

The corrosion of the fission product concentration evaporators of the La Hague R2 and T2 facilities at a faster rate than initially predicted at the design stage, led ASN to issue a resolution on 23rd June 2016 to regulate the continued operation of these items of equipment (see chapter 13, point 1.2.2).

During the inspections carried out in 2016, ASN observed deviations with respect to the waste storage rules and the rules relative to the waste management instructions modification process. At the request of ASN, Areva NC notified two safety-related significant events for the deviations noted during a targeted inspection on waste management in the installations undergoing decommissioning. Areva NC defined an action plan for dealing with them, on completion of which ASN inspected the facilities in question and found no notable deviations. ASN does however note that one-off deviations from the waste storage rules are observed regularly. It draws Areva NC's attention to the required rigour in the management of waste and the monitoring of outside contractors in this area.

ASN also noted that combustible and even flammable materials were sometimes stored near potential sources of ignition, particularly of electrical origin. It reminds the licensee that it must take all necessary measures to prevent any risk of electrical fire outbreak and measures to control the fire risk to prevent flammable liquids or gases from being able to start a fire or foster its propagation in accordance with resolution 2014-DC-0417 relative to the control of fire-related risks. Furthermore, ASN noted that the firefighting resources were not always kept rigorously accessible, limiting the effectiveness of an intervention in the event of an accident.

ASN conducted a reactive inspection further to a significant event for safety concerning the loss of negative pressure in the calcining equipment of one of the vitrification lines in the R7 facility which occurred on 4th September 2016. ASN noted several deficiencies in Areva NC's organisation regarding compliance with the operating instruction for that facility and the management of EIP maintenance. Areva NC must draw all the relevant lessons from the technical, organisational and human aspects from these deficiencies. ASN considers that the occurrence of this significant event gives cause for concern, as it reveals malfunctions in Areva NC's integrated management system. ASN notes from another significant event for safety that occurred in 2016 that the management of failures of EIPs requires greater vigilance on the part of Areva NC when compensatory measures are required by the general operating rules.

In 2016, ASN examined and then authorised through a resolution of 12th October 2016, a noteworthy modification in the operating organisation of the La Hague site having led to the grouping of the operating activities within three operational units. ASN will verify during its oversight actions that in practice this modification has no negative impacts on the safety of the installations.

With regard to radiation protection, ASN notes that Areva NC has renewed some of the contamination monitoring equipment. Despite this, ASN nevertheless observes that monitoring equipment used at the exit from controlled areas is often out of service. The repeated observation of such situations brings ASN to wonder about the conditions of performance and the reliability of the radiation protection checks at zone exits. ASN considers that Areva NC must step up its contamination monitoring equipment servicing or replacement actions. ASN notes positively the implementation - as of the second half of 2016 - of a more precise procedure applicable to the entire site, for the radiological monitoring of persons and equipment at the exit of controlled areas.

ASN notes that during 2016, Areva NC continued the decommissioning operations on the UP2-400 industrial plant authorised in November 2013. Areva NC has more specifically finished the removal of the dry process glove boxes of the MAPu facility and implemented a plan of action to meet the regulatory deadline for retrieval of the fissile material still present in room 107 of this facility. Areva NC has also begun preparatory work for the decommissioning of units 501 (reagents) and 531 (chemical treatment) and of cell 959 (formerly filtration before discharging into sea) of the STE2 facility (BNI 38) and cell 900 of the ELAN IIB facility (BNI 47). ASN notes that the difficulties encountered on the decommissioning worksites are essentially linked to uncertainties regarding the initial state of the site and the presence of asbestos. ASN notes that Areva NC is endeavouring to define action plans to control the schedule delays that could result from these difficulties.

With regard to the retrieval and packaging of legacy waste, which represents a major safety risk, ASN carried out several inspections including an in-depth inspection in October 2016. This inspection examined the industrial organisation put in place by Areva NC in October 2015 and the progress of the top priority projects as defined by ASN resolution 2014-DC-0472. ASN has noted that although efforts have been made to contain or even reduce the back-log in certain legacy waste retrieval operations, blocking points could severely hinder the progress of other operations such as the retrieval of sludge from the STE2 facility. ASN will be particularly attentive to Areva NC's analysis of the situations of the various projects in order to identify lines for improvement that allow the prescribed deadlines to be met.

Flamanville nuclear power plant

ASN considers that the performance of the Flamanville NPP with regard to nuclear safety, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance.

With regard to operation, performance of periodic tests and reactor management, ASN considers that the site's performance remains satisfactory on the whole. The inspection ASN carried out in 2016 on the maintenance of the electrical systems nevertheless showed that the assessments established by the maintenance services were not always representative of the reliability and the actual condition of the equipment. The complete deployment of EDF's new information system on the site took place in November 2016.

With regard to the reloading outage of reactor 1, ASN considers that the conditions of the maintenance operations were satisfactory, but that an effort must be made in the management of working conditions in areas where there is a risk of introducing foreign bodies into the equipment or systems. ASN also considers that the coordination of lifting operations has to be improved.

In the area of fire risk management, ASN considers that the issuing and monitoring of hot work permits and fire detection system disabling permits must be improved during reactor outages.

With regard to radiation protection, ASN notes that during the reactor 1 outage, the overall radiological exposure of the workers was satisfactorily controlled. ASN nevertheless considers that work monitoring must be reinforced to better control the contamination risks.

ASN considers that the site's organisation for managing waste must be improved, particularly the management of waste in the storage areas and the tracking of the monitoring programme for the overall worksite assistance service. ASN considers also that the search for the causes of several significant events concerning the environment should be continued with a view to consolidate the corrective actions taken accordingly.

Paluel nuclear power plant

ASN considers that the performance of the Paluel NPP with regard to nuclear safety, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance.

The continuation in 2016 of the 10-yearly outage of reactor 2 was marked on 31st March 2016 by the fall of a worn steam generator when handling it in the reactor building during operations to replace the four steam generators mounted on this reactor. This was the first operation of this type carried out on the 1,300 MWe plant unit reactors, and during the handling of the third worn steam generator, a failure occurred on the lifting device which consisted of slings connected to a lifting beam, which in turn was connected to a machine mounted on the polar crane of the reactor building.

ASN checked the measures taken by EDF with a view, first of all, to making secure the steam generator which had fallen to the ground, and the measures envisaged for its subsequent removal using specific means. ASN will examine reports of the expert appraisals requested of EDF to draw the lessons from this event and check that the reactor equipment is in satisfactory condition.

With regard to operation, the performance of periodic tests and reactor management, ASN considers that the site must improve its performance in certain areas. ASN notes in particular that the operations relating to the preparation and retrospective verification of operating and maintenance activities are still carried out with insufficient rigour, particularly for reactor operational control. ASN notes an increase in the proportion of significant events, several of which are linked to the use of incomplete or inappropriate operational documentation.

During 2016, ASN inspected the10-yearly outage of reactor 1 which underwent major maintenance operations and system modifications aiming in particular at improving the safety of the reactor. The main primary system of reactor 1 was tested at 206 bars relative pressure as part of its complete requalification. ASN also inspected a reactor maintenance outage on reactor 4 and the continuation in 2016 of the 10-yearly outage of reactor 2. ASN considers that the operations of the reactor outages started in 2016 went satisfactorily. ASN nevertheless considers that the analyses concerning the fire risk must take into account the particularities of each activity.

In the area of radiation protection, ASN notes that the site's organisation would benefit from being stepped up, particularly with regard to the traceability of activities and the monitoring of outside contractors. ASN considers that the site has room for progress in dose optimisation and the control of contamination risks.

With regard to environmental protection, ASN considers that the site must reinforce its organisation to guarantee the leak tightness of the cooling units. In addition to this, in 2017 ASN will continue its examination of the file submitted by EDF to request modifications in the site's discharge prescriptions.

Penly nuclear power plant

ASN considers that the performance of the Penly NPP with regard to nuclear safety, radiation protection and environmental protection is, on the whole, in line with the general assessment of EDF plant performance.

With regard to operation, the performance of periodic tests and reactor operational control, ASN considers that the site is maintaining a satisfactory level but without having made any progress in operating rigour with respect to the previous years. ASN considers that the site can make improvements in the performance of the periodic tests and that it should be more rigorous in the preparation and performance of operational control operations.

As concerns the reloading outage of reactor 1 and the maintenance outage of reactor 2, ASN considers that the overall organisation of these two reactor outages proved on the whole to be satisfactory. During 2016, ASN noted a drop in the number of significant event notifications stemming from maintenance operations.

With regard to radiation protection, ASN observes that several significant events result from substandard application of worker radiation protection. The lack of rigour in defining and managing the controlled areas presenting a radiological risk and failure to take account of the associated warning signs are spotlighted as the predominant causes of these events. ASN considers that the site must maintain its efforts to improve its radiation protection culture.

As far as environmental protection is concerned, ASN considers that the organisation in place enables the associated requirements to be satisfied on the whole. ASN notes in particular the progress the site has made in limiting cooling fluid discharges.

Labour inspection in the nuclear power plants

ASN conducted oversight actions concerning the conditions of health and safety during maintenance and construction operations and the management of subcontracting in the nuclear power plants.

ASN examined the conditions under which a worn steam generator fell during its handling in reactor building No. 2 of the Paluel NPP. ASN more specifically prescribed conformity checks by a third-party organisation of the handling devices designed and used specifically for this operation. ASN checked the measures taken by EDF to secure the steam generator which had fallen to the ground, and then to remove it using specific handling means.

Construction of the Flamanville 3 EPR reactor

After issue of the authorisation decree and the building permit, construction work began on the Flamanville 3 reactor in September 2007.

A predominant part of the activities in 2016 concerned mechanical assemblies, notably the systems connected to the primary and secondary systems of the nuclear steam supply system, the auxiliary systems and the mechanical penetrations of the reactor containment, including the transfer tube. The assemblies also concerned the reactor vessel head, the spent fuel pool storage racks and equipment necessary for the operation of the emergency diesel generator sets. In addition to this, a major modification was made to the reactor instrumentation and control and electrical assembly work was stepped with a view to continuing the start-up tests. The civil engineering finishing work continued. ASN carried out a specific inspection of these operations, and examined worker radiation protection, protection of the environment and preparation for reactor operation.

ASN considers that EDF's organisational setup is satisfactory but it must be improved in certain areas such as environmental protection, equipment preservation, management of foreign material exclusion and the handling of deviations detected during EDF's monitoring of outside contractors. Alongside this, the rigour of performance of the first inspections of the main primary system welds for the complete initial inspection had to be improved following an ASN inspection.

The electro-mechanical assemblies continued in 2016 applying worksite cleanliness and upkeep practices similar to those applied in operation. The spent fuel rack assembly operations enabled EDF to put in place a dedicated organisation for managing the risk of introducing foreign objects into the systems. ASN considers that this organisation must be further improved and be applied more widely to ensure a level of cleanliness compatible with the arrival of the fresh fuel on the site. ASN also considers that EDF must be rigorous in its handling of deviations detected during the monitoring of outside contractors, particularly in the welding activities, and must make sure that any associated protective measures are documented. Lastly, ASN examined the execution of the first inspections of the main primary system welds for the complete initial inspection and noted serious shortcomings in the way the inspections were conducted. After establishing a major action plan implemented by EDF, these activities were resumed and ASN verified the effectiveness of the actions.

In view of the time frames announced by EDF for reactor commissioning and further to the deviations encountered in the preservation of new heat exchangers, ASN considers that EDF must remain vigilant with regard to the preservation of the equipment already installed, taking into account the impact of filling the systems with water for the hydraulic tests and the start-up tests, as well as the worksite conditions and the ongoing concomitant activities.

Further to the inspections focusing on environmental protection, ASN examined the corrective actions implemented by EDF. These actions reinforced the rigour of the periodic checks and the completeness of the in-house baseline requirements for the equipment intended to protect the environment.

One tightened radiation protection inspection was carried out on the worksite. The organisation established and implemented on the site for personnel radiation protection was found on the whole to be satisfactory.

ASN continued its oversight of the start-up tests, and the reactor heat sink equipment in particular. ASN considers that the organisation put in place for the preparation and performance of the start-up tests is satisfactory on the whole. ASN will be attentive to the smooth functioning of a dedicated organisation for the overall tests which will follow on from the preliminary tests of the systems.

ASN was attentive to the organisation put in place by the teams responsible for future operation of the Flamanville 3 reactor, particularly for the production of the operating documentation, emergency situation preparedness and consideration of social, organisational and human factors. ASN considers that progress must be made in the organisation deployed by EDF for the approval of the operating documents, which is carried out during the start-up tests, and the appropriation of the future local emergency resources.

ASN ensures the labour inspection missions on the Flamanville 3 worksite. Regular inspections were carried out to ensure compliance with the applicable safety rules; in this area ASN drew the attention of EDF to the efforts that must be kept up to maintain good protection against the risk of a fall from height and to the impact of the start-up tests which entail the powering up of systems or the pressurising of equipment. Lastly, ASN continued several oversight operations concerning the transnational secondment of workers.

Andra's Manche repository

ASN considers that the condition and the organisation of operation of the Manche repository (CSM) facilities are on the whole satisfactory. Andra must continue its efforts to reinforce the stability of the cover and to eliminate storm water infiltrations into the repository via the edge of its sealing membrane. In this respect ASN notes that a drainage trench was put in place in 2016 with the aim of reducing the stormwater infiltrations upstream of drainage chamber No. 11 and considers that Andra must keep a close watch over the performance of this compensatory measure while continuing to try to find corrective measures.

In accordance with the commitment made during the last periodic safety review[1] of the facility, Andra sent ASN an interim review of the work carried out on the repository cover. ASN requested additional technical information, particularly concerning the dimensioning of the long-term cover. This information will also be studied in the future examination of the periodic safety review guidance file submitted by Andra in July 2016.

In 2015, the TECV Act amended the provisions applicable to the decommissioning of BNIs. Pursuant to the Decree of 28th June 2016, the CSM is now considered from an administrative point of view to be in the decommissioning phase and no longer in the monitoring phase. ASN asked Andra to indicate the duration of the long-term cover installation operations before the CSM is closed and enters the monitoring phase. On the basis of this information, ASN will issue a resolution setting the date before which a closure and entry-into-monitoring-phase application file must be submitted, and the duration of the CSM monitoring phase.

In 2016, Andra continued taking tritium activity measurements in the ground waters at the CSM. The measurements reveal a reduction in the average level of tritium marking of the ground waters, consistent with the radioactive half-life of tritium. ASN considers that the regulatory monitoring plan for the CSM is appropriate for monitoring the tritium contamination of the ground and surface waters. ASN takes note of Andra's intention to continue measuring the tritium activity in the chosen piezometers of the monitoring network every five years and at different depths.

Ganil (National Large Heavy Ion Accelerator)

Further to the failure to comply with two prescriptions of ASN Decision of 11th June 2015 concluding the examination of the periodic safety review of BNI 113, ASN, through a resolution of 12th May 2016, gave the licensee formal notice to comply with these prescriptions before the end of 2016. In September 2016 the licensee informed ASN that the implementation of several prescriptions of resolution 2015-DC-0516 relative to the monitoring of discharges into the environment had fallen behind schedule. ASN will ensure that the prescribed conditions of environmental discharge monitoring to guarantee protection of the interests mentioned in Article L. 593-1 of the Environment Code are satisfied.

During an inspection carried out in 2016, ASN highlighted shortcomings in the organisation dedicated to ensuring compliance with the licensee's commitments. Since then, the licensee has stated that it has corrected the deviations noted during the inspection and has reinforced its organisation to prevent them from recurring. ASN considers that the licensee's compliance with the commitments it has made should be subject to effective monitoring.

ASN will continue its examination of the commissioning application for phase 1 of the Spiral2 project submitted in

1. *See note on page 231.*

October 2013, for which the last complementary elements requested were handed over at the end of May 2016.

ASN notes that in 2016, the Ganil modified its organisation by integrating the Spiral 2 project resources into the operating organisation for safety, the environment and radiation protection.

1.2 Radiation protection in the medical field

Radiotherapy

In 2016, ASN began a new multi-year inspection cycle covering all the radiotherapy departments in Normandie; an annual inspection is maintained for departments with identified points requiring particular vigilance. The inspections conducted in 2016 revealed the maintaining of a real process to improve the rigour, organisation and traceability of interventions and the implementation of management systems to ensure treatment quality and safety. Nevertheless, despite the increased staffing in the majority of centres, a small number of the radiotherapy centres in Normandie still suffer staff shortages or instability, particularly as regards medical physics and physicians. These difficulties hinder the progress initiatives and led ASN in 2013 to ask one of the centres concerned to take immediate corrective action. This centre was subject to tightened monitoring by ASN in 2014, 2015 and 2016, which enabled a significant improvement in the situation to be observed. The inspections in 2016 also showed that the majority of the centres do not analyse the malfunctions they detect in sufficient detail.

Interventional practices

ASN maintained tightened oversight in the centres performing interventional procedures. The activities in these facilities entail risks for both patients and workers, and these risks must be duly controlled. The inspections revealed contrasting situations and many areas for improvement, such as the training and qualification of personnel using the devices, performing device quality controls, personal protection of the personnel, medical monitoring of private practice workers, or the optimisation of practices in this sector. ASN notes that radiation protection is generally better integrated in the rooms dedicated to interventional practices than in the operating theatres.

Nuclear medicine

In 2016, ASN inspected a quarter of the nuclear medicine departments in Normandie. The inspections revealed a satisfactory situation which nevertheless displays some room for improvement in the coordination of prevention measures for outside contractors and taking account of radiation exposure of workers' extremities (hands).

Computed tomography

ASN continued its inspections of computed tomography departments in 2016. In the light of these inspections, occupational radiation protection is found to be satisfactory on the whole. ASN considers that patient radiation protection measures are still variable and are often based on the use of the optimisation procedures specified by the machine manufacturers. The level of involvement of medical physicists varies considerably from one department to another; increasing their involvement could help to optimise practices. The use of Magnetic Resonance Imaging (MRI) techniques when indicated as an alternative remains limited due to the low availability of MRI scanners.

1.3 Radiation protection in the industrial sector

Industrial radiography

The oversight of industrial radiography remains a priority for ASN, which carried out unannounced night-time inspections on worksites in 2016. Depending on the companies, these inspections brought to light a widely contrasting picture of the way the risk of worker exposure to ionising radiation is taken into account. Although work conditions are improving on the whole, ASN observes that some companies must still make significant progress while others must remain vigilant to maintain their standard of radiation protection.

In parallel with this and in collaboration with the DIRECCTE (Regional Directorate for Enterprises, Competition, Consumption, Work and Employment) and CARSAT (Retirement and Occupational Health Insurance Fund) of Normandie, ASN continued the promotion of good practices with the signatories of the industrial radiography charter in HauteNormandie. Prospective work was carried out in 2016 with a view to extending the charter to the whole of Normandie and to the nuclear industry and naval construction sectors. Some thirty companies, ordering customers and industrial radiography companies have signed this charter to date.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

In March 2013 work was undertaken jointly by Andra as part of its public service remit (see chapter 16) and the EPF (Public Land-management Corporation) of Normandie to complete the decontamination and to rehabilitate the industrial site of Etablissements Bayard, situated in Saint-Nicolas d'Aliermont in the

Seine-Maritime *département*. Etablissements Bayard was specialised in the production of pendulum clocks and alarm clocks between 1867 and 1989. From 1949 until the workshops closed in 1989, the site produced and used luminescent paint based first on radium, then on tritium. The traces of contamination that remained after the initial decontamination work carried out in the 1990's do not represent a risk for public health or the environment.

ASN continued to support the Dreal of Normandie in the monitoring of these operations and more specifically aspects relating to the redevelopment of the site. An inspection to verify compliance with the clean-out objectives was carried out on a random check basis in July 2016 by two ASN inspectors accompanied by experts from IRSN. ASN considers that the clean-out work was carried out satisfactorily. Demonstration of compliance with the clean-out thresholds and the putting in place of institutional controls remain prerequisites before handing over the land for rehabilitation as an open-air public space with car-parking areas.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN considers that the regional consignors involved in the transport of radioactive substances maintained a level of safety in 2016 that was on the whole satisfactory.

With regard to shipments of radioactive substances from BNIs in Normandie, ASN considers that the requirements specific to these operations are satisfied on the whole. ASN considers that the licensees are rigorous in the shipping of packages that are subject to ASN approval, which present the greatest safety risks. During its inspections on the nuclear power plants, ASN noted some progress in the preparation of shipments of packages that are not subject to approval.

In 2016, ASN continued checking the implementation in the BNIs of the new regulatory requirements applicable to on-site transport operations.

2. Additional information

2.1 Informing the public

Press conferences

In 2016, ASN held three press conferences on the situation of nuclear safety and radiation protection, in Caen, Rouen and Rennes – the latter was organised jointly with the Nantes division.

Work with the Local Information Committees (CLIs)

ASN participated in the various general meetings of the CLIs of Normandie. ASN presented, among other things, its assessment of the safety of the nuclear installations concerned, the corrosion of the fission product concentration evaporators of the La Hague R2 and T2 facilities at a faster rate than initially predicted and the ASN resolution of June 2016 that governs the continued operation of these equipment items, and the fall of a worn steam generator while being handled in the reactor 2 building of the Paluel NPP.

In accordance with the provisions introduced by the TECV Act, the CLIs of Areva La Hague, Flamanville and the CSM held "standard" public meetings. The CLI of Paluel-Penly organised a public meeting addressing three topics, namely the third 10-yearly outages of the 1,300 MWe plant series, the *"grand carénage"* major overhaul programme, and the role of ASN in the periodic safety reviews.

Public information

ASN took part in the public information initiatives organised as part of the campaign to distribute replacement iodine tablets in the Off-site Emergency Plan (PPI) zones around the Flamanville, Paluel and Penly NPPs. Public meetings were held in Paluel, Saint-Martin-en-Campagne (Seine-Maritime *département*) and Les Pieux (Manche *département*). These information meetings provided the opportunity to remind people what to do in the event of an accident in a nuclear installation.

2.2 International action

Given that EPR reactors are being built on the sites of Olkiluoto in Finland and Flamanville in France, the ASN Caen division is participating in the close cooperation between ASN and STUK, the Finnish nuclear regulator. The ASN inspectors went to Finland in March 2016 to discuss the progress of the construction work and the experience feedback received. A joint trip was made to the Olkiluoto EPR worksite.

The Caen division also participated in a seminar organised by the NEA (Nuclear Energy Agency) in South Korea to share the approaches applied internationally with regard to the regulation and oversight of the start-up tests of new nuclear reactors.

The state of nuclear safety and radiation protection in 2016 in the Nouvelle-Aquitaine region

The Bordeaux and Orléans divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Nouvelle-Aquitaine region.

The activities and installations to regulate comprise:
- BNIs:
  - the Blayais NPP (4 reactors of 900 MWe);
  - the Civaux NPP (2 reactors of 1,450 MWe);
- small-scale nuclear activities in the medical sector:
  - 19 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 21 nuclear medicine departments;
  - 96 centres performing interventional procedures;
  - 93 tomography devices;
  - about 5,700 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 37 companies exercising industrial radiology activities;
  - 26 gamma densitometry devices;
  - about 190 diverse industrial companies;
  - about 300 devices for detecting lead in paint;
  - 1 cyclotron producing radioisotopes;
  - 31 veterinary practices performing equine radiology procedures;
  - about 400 veterinary practices performing radiology procedures on small animals;
  - 72 research laboratories and universities using ionising radiation;
- ASN-approved laboratories and organisations:
  - 4 organisations approved for radiation protection technical controls
  - 1 organisation approved for measuring radon;
  - 4 laboratories approved for taking environmental radioactivity measurements.

In 2016, ASN carried out 115 inspections in the Nouvelle-Aquitaine region, comprising 33 inspections in the area of nuclear safety in the Blayais and Civaux Nuclear Power Plants (NPPs), 6 inspections concerning the transport of radioactive substances and 76 inspections of small-scale nuclear activities. ASN carried out 28 days of labour inspections in the NPPs.

During 2016, three significant events rated level 1 on the INES scale were notified by the NPP licensees of Nouvelle-Aquitaine.

In small-scale nuclear activities, 2 significant events rated level 1 on the INES scale were notified to ASN. In addition to this come the significant events concerning radiotherapy patients, 14 of which were rated level 1 on the ASN-SFRO scale.

1. Assessment by domain

1.1 The nuclear installations

Blayais nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Blayais NPP site on the whole matches ASN's general assessment of EDF and that its radiation protection performance stands out positively.

With regard to safety, ASN has noted that the reactor outages for maintenance and refuelling proceeded smoothly on the whole. ASN noted that the site was continuing its efforts in maintenance, focusing in particular on improving the quality of the operational documentation. ASN nevertheless observed that the site had difficulties in the preparation and performance of the periodic tests required by the general operating rules.

Reactors 1, 3 and 4 of the Blayais NPP are concerned by the irregularities affecting the Nuclear Pressure Equipment (NPE) manufactured by Areva. Reactor 1 is also concerned by the high carbon concentrations in the channel heads of the steam generators manufactured by the Areva NP's Creusot Forge plant (see chapter 12 point 3.4).

With regard to radiation protection, ASN noted progress in radiation protection management on worksites during reactor outages, thanks in particular to the integration of lessons learned from previous reactor outages.

ASN considers however that the site's environmental protection measures must be stepped up, in particular to ensure more effective management of the nuclear waste produced in the installations during reactor outages and to speed up the search for the causes and the treatment of legacy contamination.

Civaux nuclear power plant

ASN considers that the nuclear safety and environmental protection performance of the Civaux NPP on the whole matches ASN's general assessment of EDF and that its radiation protection performance stands out positively.

With regard to safety, ASN noted that the two scheduled outages for the reloading of the two reactors went smoothly on the whole. They were marked more specifically by the replacement of the hydraulic sections of the reactor coolant pump sets and the performance of inspections on the steam generator channel heads. Reactors 1 and 2 are effectively concerned by the high carbon concentrations in the steam generator channel heads produced by Japan Casting & Forge Corporation. ASN notes progress in the quality of maintenance activities. With regard to operating activities, ASN considers that the measures implemented to improve the rigour of performance of reactor operations must be continued.

Reactor 2 is moreover concerned by the irregularities affecting the NPE manufactured by Areva NP's Creusot Forge plant (see chapter 12 point 3.4).

ASN observes that radiation protection is integrated satisfactorily in work preparation and performance. ASN has noted significant progress in radiological cleanliness but considers that the site must continue its efforts in this area in order to further improve the results obtained.

With regard to the environment, ASN observes that the site has implemented an efficient process for controlling discharges, but the way environmental protection is taken into consideration in the management of certain unexpected situations must be improved.

Labour inspection in the nuclear power plants

ASN continued its oversight actions on the activities involving a risk of exposure to asbestos, particularly during reactor outages for maintenance. Several failures to meet regulatory obligations were again observed in 2016. The personnel responsible for labour inspection also carried out inspections on the construction sites of the buildings intended to house the future ultimate backup diesel generator sets. They also verified compliance with the rules governing the secondment of foreign employees and continued the actions in progress since 2013 on the risks of work at height and the conformity of work equipment. Work equipment has been the subject of resolutions requiring the verification of their conformity by an approved organisation. Lastly, specific investigations were carried out following work accidents and in response to specific requests concerning employees of outside companies.

1.2 Radiation protection in the medical field

Radiotherapy and brachytherapy

During 2016 ASN conducted seven inspections in radiotherapy departments in the NouvelleAquitaine region, one of which was devoted to the commissioning of a new accelerator, and two inspections of brachytherapy departments. The oversight of radiotherapy and brachytherapy departments aims at examining the ability of the centres to manage the risks in order to ensure the radiation protection of patients and workers. The inspections focused in particular on the risk analyses, skills management, the medical physics situation and the implementation of new techniques in radiotherapy.

ASN considers that the inspected radiotherapy and brachytherapy centres have satisfactory treatment quality and safety management systems. ASN observes however that the analyses of the risks run by patients are often incomplete and do not allow the identification of the defence barriers necessary to ensure patient radiation protection.

ASN considers that the means devoted to medical physics are satisfactory. The medical physics organisation plans must nevertheless evolve to describe staffing requirements, particularly for the management of projects involving new techniques or new radiotherapy equipment.

ASN notes the effective performance of quality controls in radiotherapy; the centres must nevertheless continue their efforts to respond to the observations resulting from in-house and third-party quality controls.

ASN considers moreover that the occupational radiation protection measures are correctly applied in the radiotherapy and brachytherapy departments.

Lastly ASN notes that a large proportion of the significant events notified in radiotherapy are associated with a location error or a dose error.

Interventional practices

ASN continued its inspections in centres performing interventional procedures both in operating theatres and in facilities dedicated to cardiology, neuroradiology and vascular radiology. Twelve centres were inspected on this theme in 2016.

With regard to patient radiation protection, ASN made a point of checking the dispensing to health professionals of training in patient radiation protection, the optimisation of exposures by qualified personnel (radiographers), the involvement of medical physicists and the performance of quality controls on the devices used.

ASN observes that little use is made of the skills of radiographers in the operating theatres or of medical physicists in the sectors dedicated to cardiology, neuroradiology and vascular radiology, which hinders progress in the optimisation of doses delivered to patients.

With regard to occupational radiation protection, ASN systematically examined the designation of Persons Competent in Radiation protection (PCR), means of worker dosimetric monitoring, performance of the technical radiation protection controls, performance of the work environment analyses and the appropriateness of the zone marking in the premises.

ASN notes the persistence of the lack of radiation protection culture in the operating theatre. More specifically, compliance with regulatory provisions regarding worker dosimetric monitoring is low among medical practitioners. Furthermore, the use of collective protective equipment must be improved. Lastly, no significant radiation protection events concerning patients or workers performing interventional procedures were notified in Nouvelle-Aquitaine in 2016.

Implementation by the centres of the provisions of ASN resolution 2013-DC-0349 setting design rules for the premises in which X-ray generators are used was verified systematically. ASN considers that the situation is satisfactory on the whole.

Nuclear medicine

ASN performed 7 inspections in nuclear medicine departments in the Nouvelle-Aquitaine region in 2016.

ASN verified compliance with its resolution 2014-DC-0463 relative to the design and operation of nuclear medicine facilities. More specifically, ASN checked that the provisions of the resolution are applied from the design stage in new nuclear medicine premises.

ASN considers that patient and worker radiation protection is on the whole ensured in a satisfactory manner in nuclear medicine departments.

With regard to protection of the population and the environment, ASN generally notes significant improvements in the management of contaminated effluents. ASN nevertheless considers that the centres must continue to be particularly vigilant with regard to the monitoring and maintenance of the pipes that carry these effluents.

Lastly, ASN notes that the majority of the notified significant events result from an error in the preparation of radiopharmaceuticals injected into the patients.

Computed tomography

ASN carried out three inspections in computed tomography in the Nouvelle-Aquitaine region in 2016.

In the area of patient radiation protection, ASN made a point of checking the dispensing to health professionals of training in patient radiation protection, the involvement of medical physicists, the performance of the scanner quality controls and the evaluation of the doses delivered to patients with respect to the diagnostic reference levels. ASN observes that medical physicists are rarely called upon to optimise doses delivered to patients.

With regard to worker radiation protection, ASN systematically examined the dosimetric and medical monitoring of exposed workers, compliance with the frequency of training in worker radiation protection and performance of the technical radiation protection controls, performance of the work place analyses and the appropriateness of the zone marking of the premises. ASN notes a lack of tightened medical monitoring of personnel exposed to ionising radiation and shortcomings in the coordination of prevention measures relative to ionising radiation.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN continued its oversight of industrial radiography activities in exposure bunkers and on worksites in 2016.

During the 12 inspections it carried out, ASN observed progress in the areas of scheduling and performance of the technical radiation protection controls, the maintenance of industrial radiography devices and the conformity of protected bunkers dedicated to industrial radiography.

The general organisation of radiation protection, the training and the dosimetric and medical monitoring of the personnel exposed to ionising radiation remain satisfactory, even though a few deviations are observed from time to time in these areas.

On several occasions however ASN has observed failures to mark out and signal the work zone on industrial radiography worksites. It considers that the companies concerned must make progress in this respect.

ASN observes that five industrial radiography bunkers have been commissioned in Nouvelle-Aquitaine over the last few years. ASN considers this to be a positive development which means that certain ordering customers will no longer have to use services under worksite conditions.

Universities and laboratories or research centres

Following the discovery of two radioactive sources in a room of the Carreire campus in 2015 (event rated level 2 on the INES scale on account of the doses received by the unintentionally exposed workers), Bordeaux University implemented a plan of action to seek out any other sources that might be present on its premises. ASN approves of this initiative, which led to the discovery of a sealed source with very low activity in a laboratory in 2016.

Broadly speaking, ASN observes that the research laboratories on the whole comply with the radiation protection requirements concerning training and the dosimetric and medical monitoring of personnel exposed to ionising radiation.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

During 2016 ASN assisted the Dreal in the management of various sites and soils contaminated by radioactive substances in the Nouvelle-Aquitaine region.

More specifically, ASN monitored actions taken by the Bordeaux city council in response to the prefectural order issued in 2015 to regulate the decontamination activities on a site contaminated with radium.

Former uranium mines

ASN continued to assist the Dreal in the management of mining waste rock and of the former uranium mine in the three *départements* of the former Limousin region.

In application of the Circular of 22nd July 2009, Areva has inventoried the sites in which mining waste rock has been reused in the Limousin region, as they are highly diverse: dwellings, platforms accommodating buildings for business activities, paths, recreational grounds, campsites, green zones in residential areas. The maps were presented to the Limousin's three site monitoring committees in 2012.

The cleaning out of the sites of mining waste rock reuse by removing these materials reduces the exposure of persons in accordance with the objectives set in the abovementioned Circular. This work has been carried out on seven sites in Haute-Vienne.

The projected work has been made available to the public. The impact of the work has given rise to expert appraisals by IRSN and the Bureau of Geological and Mining Research. These appraisals were presented to the Corrèze site monitoring committee in December 2016.

In November 2016, work was carried out on the La Védrenne site in Egletons (Corrèze *département*), a former uranium mine, with the aim of reducing public exposure to ionising radiation by covering the radiologically contaminated zones with inert material.

ASN asked Areva for complementary information when evaluating the risks of transfer of radionuclides from the site of the former uranium mines to human foodstuffs *via* livestock grazing on these areas.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out six inspections concerning the transport of radioactive substances in the Nouvelle-Aquitaine region in 2016.

On completion of the inspections conducted during the shipment of spent fuels by the Blayais and Civaux NPPs, ASN considers that the workers in charge of the operations are competent and that the process is well mastered on the whole.

Moreover, when ASN conducts inspections on industrial radiography worksites it verifies compliance with the regulatory requirements for transport at the same time.

ASN considers that these requirements are satisfied on the whole.

2. Additional information

2.1 Informing the public

Press conference

ASN held a press conference in Bordeaux on 9th June 2016 to present the situation of nuclear safety and radiation protection in the Nouvelle-Aquitaine region.

Work with the Local Information Committees (CLIs)

The Bordeaux division supported the work of the two CLIs in the Nouvelle-Aquitaine region by participating in their general meetings and several technical committee meetings.

In accordance with the provisions introduced by the TECV Act, the CLIs of Blayais and Civaux each organised a public meeting. These meetings, in which ASN took part, were devoted in particular to the monitoring of the environment around the nuclear power plants.

The Civaux CLI sent observers to attend several inspections conducted by ASN on the themes of maintenance and deviation management.

Other public information actions

ASN took part in the initiatives to raise awareness to the risk culture organised as part of the campaign to distribute replacement iodine tablets in the Off-site Emergency Plan (PPI) zones around the Civaux and Blayais NPPs. Three public meetings were organised to inform the populations living or working in the vicinity of these installations.

The state of nuclear safety and radiation protection in 2016 in the Occitanie

The Bordeaux and Marseille divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 13 *départements* of the Occitanie region.

The activities and installations to regulate comprise:
- BNIs:
  in Golfech (Tarn-et-Garonne *département*):
  - the Golfech NPP (2 reactors of 1,300 MWe);

  in Marcoule (Gard *département*):
  - the Mélox MOX nuclear fuel production facility;
  - the CEA Marcoule research centre, which includes the civil BNIs Atalante and Phénix and the Diadem waste storage facility construction site;
  - the Centraco facility for processing low-activity waste;
  - the Gammatec industrial ioniser;

  in Narbonne (Aude *département*):
  - facility for storing Écrin waste on the Malvési site;
- small-scale nuclear activities in the medical sector:
  - 14 external-beam radiotherapy departments;
  - 6 brachytherapy departments;
  - 20 nuclear medicine departments;
  - 96 centres performing interventional procedures;
  - 102 tomography devices;
  - about 5,000 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 26 establishments using industrial radiography devices;
  - 4 cyclotrons producing radioisotopes;
  - 310 users of lead detectors;
  - about 450 veterinary practices using diagnostic radiology devices;
  - 158 laboratories and universities using ionising radiation;
- ASN-approved laboratories and organisations, including:
  - 3 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 6 head offices of organisations approved for radiation protection controls.

In 2016, ASN carried out 130 inspections in the Occitanie region, of which 36 were in BNIs, 83 in small-scale nuclear activities and 11 in the transport of radioactive substances.

During 2016, two significant events rated level 1 on the INES scale were notified by nuclear installation licensees in Occitanie.

In the small-scale nuclear activities, 1 significant event rated level 1 on the INES scale was notified to ASN. Two events involving radiotherapy patients were rated level 1 on the ASN-SFRO scale.

In the execution of its oversight duties in Occitanie, ASN served formal notice on the head of radiotherapy at the Rodez hospital to comply with ASN resolution 2008-DC-0103 setting quality assurance obligations for radiotherapy.

1. Assessment by domain

1.1 The nuclear installations

Golfech nuclear power plant

ASN considers that the nuclear safety performance of the Golfech site is below ASN's general assessment of EDF, that its performance in environmental performance is on the whole in line with the general assessment and that its radiation protection performance stands out positively.

In the area of nuclear safety, the scheduled reloading outage of reactor 1 went well on the whole. ASN considers that the operational control teams managed several unexpected situations competently. Nevertheless, as in 2014 and 2015, ASN considers that the site's ability to record the deviations affecting its facilities, to determine their possible impact on safety, to correct them with appropriate speed and to draw lessons from them is not up to standard. ASN notes that several significant safety-related events notified by EDF are linked to inadequate preparation of activities. Progress is required in the quality of the documentation necessary for operation of the installations and in the rigour of application of instructions.

ASN observes deterioration in environmental protection control, as shown by several significant events involving unplanned releases into the environment due to shortcomings in the operation of the installations. The reactors in service were moreover marked in 2016 by the appearance of leaks in the fuel assembly cladding which constitutes the first containment barrier; these defects led to a limited increase in the concentration of radioactive substances in the water of the main primary cooling system.

With regard to radiation protection, the site maintains satisfactory results in collective dosimetry and the radiological cleanliness of the installations.

Labour inspection in the nuclear power plants

In 2016, the personnel in charge of labour inspection continued their oversight actions on the work presenting a risk of exposure to asbestos at the Golfech NPP, particularly in periods of maintenance during reactor outages. They also verified compliance with the rules governing the secondment of foreign employees and continued the actions in progress since 2013 on the risks of work at height and the conformity of work equipment. Work equipment has been the subject of resolutions requiring the verification of their conformity by an approved organisation. The labour inspectors also verified the implementation of the licensee's corrective action plans for the lifting equipment. In addition, particular attention was focused on compliance with the labour regulations during construction of the buildings intended to accommodate the future ultimate backup diesel generator sets.

Marcoule platform

Seven resolutions relative to water intake and consumption sampling and the discharge of liquid and gaseous effluents from Mélox, Centraco, Atalante and Gammatec came into effect on 1st March 2016. These resolutions take into account the way the installations have evolved, with a significant drop in the overall discharge limits, and they define a common environmental monitoring plan. ASN is currently carrying out a similar examination concerning decommissioning of the Phénix plant.

Mélox plant

ASN carried out seven inspections at the Mélox plant in 2016 and considers that the level of nuclear safety and radiation protection remains satisfactory on the whole.

The containment barriers on which a large part of the safety case is based appear effective. The radiation protection issues are addressed with rigour and the licensee seems to be lastingly committed to carrying out, year after year, operations that bring substantial gains in radiological exposure by taking into account the ageing of the facilities and the necessary optimisation of work stations. ASN nevertheless notes ten or so low level events in these areas, indicating that the licensee must maintain its vigilance.

Taking account of the criticality risk is still one of the major challenges in this facility and it continues to be ensured satisfactorily. Few events were recorded in this sector but events of this type are often caused by human-related factors.

With regard to the follow-ups to the periodic safety review[1] of the BNI carried out in 2011, although the actions associated with the commitments made by the licensee and the prescriptions enacted by ASN in 2014 are in most cases correctly carried out or monitored, ASN notes delays in the performance of the work to reinforce the control of fire risks and in meeting commitments regarding the monitoring of outside contractors.

CEA Marcoule Centre

ASN carried out ten inspections at the CEA Marcoule Centre in 2016: three inspections of the Centre, of which two were conducted jointly with ASND, the Defence Nuclear Safety Authority, three inspections in the Phénix NPP, three inspections of the Atalante facility and one inspection of the Diadem storage facility

1. *See note on page 231.*

construction site. ASN considers that the level of nuclear safety and radiation protection at the Centre is satisfactory.

The Centre's cross-functional organisation for waste management was found to be satisfactory. The quality of the numerous packages produced and shipped by the Centre is correctly monitored; the facilities' waste representatives hold regular meetings and the baseline requirements for waste management are revised periodically to take ASN and ASND resolutions into account. With regard to protection against the fire risk, on the other hand, ASN considers that the instructions and procedures in effect on the site should be harmonised and that the Centre's body of descriptive and prescriptive documents should be expanded.

ASN considers that the Atalante facility is duly preparing for the arrival within its walls of some of the activities of the LEFCA (Laboratory for Research and Experimental Fabrication of Advanced nuclear Fuels) in Cadarache Centre. Nevertheless, aware of the diversity of the Atalante personnel profiles, ASN remains attentive to the support activities which are essential for safe continuation of the experiments conducted on the facility. ASN has authorised the facility to store organic liquids for subsequent treatment by hydrothermal oxidation. Alongside the scientific activities and standard operational activities, the licensee is continuing the periodic safety review of the facility, for which the conclusions report was submitted to ASN at the end of 2016.

As far as the Phénix NPP is concerned, 2016 saw the publishing of Decree 2016-739 of 2nd June 2016 instructing CEA to proceed with the NPP decommissioning operations. This Decree was supplemented by ASN resolution 2016-DC-0564 of 7th July 2016 which indicates the prescriptions relative to the decommissioning and the periodic safety review of the BNI. ASN also approved the general operating rules by a resolution of 18th November 2016, thereby marking entry into effect of the decommissioning decree. The inspections carried out by ASN in 2016, which focused chiefly on the monitoring of outside contractors, the meeting of commitments and construction of the NOAH building (for transforming the sodium from the Phénix installation and other CEA installations into sodium hydroxide) did not reveal any deviations that could call into question the continuation of decommissioning of the NPP.

With regard to the Diadem facility, 2016 was marked by the publication of Decree 2016-793 of 14th June 2016 authorising CEA to create this facility. This facility will more specifically be used for storing decommissioning waste from the Phénix NPP. Inspection of the facility construction site revealed a good standard of worksite monitoring, good construction work on the structure and compliance with the commitments CEA made during the technical examination of the installation creation authorisation application.

Centraco plant

ASN conducted four inspections on the Centraco facility in 2016 and considers that the level of nuclear safety and radiation protection is satisfactory. During two inspections - one reactive - ASN examined the licensee's handling of the notified significant events and gave a favourable assessment.

ASN authorised modifications to the facility which enable Socodéi to increase the annual processing capacity for incinerable liquid waste and the temporary pre-dispatch storage capacities.

The solid and liquid waste incineration unit functions slightly below the maximum possible rate because the waste producers have optimised their management practices such that the Centraco plant does not accumulate waste waiting to be treated.

The melting unit functioned in duly safe conditions. The unit has nevertheless not yet reached its maximum treatment capacity. The greasy metal parts whose melting gave rise to a significant event notification in 2015 were cleaned then melted.

ASN considers that the current plant organisation ensures satisfactory functioning of the facilities on the whole with regard to safety, and has therefore put an end to the tightened monitoring applied since 2009.

Gammatec ioniser

ASN conducted an inspection of the Gammatec ioniser in 2016 and considers the level of nuclear safety to be satisfactory. Following the licensee's detection of a weakness in the source holder module, the module was reinforced taking into consideration the company's international feedback, which ASN judges satisfactory. Improvements are nevertheless expected in the traceability and formalisation of the periodic checks and tests. ASN also remains vigilant regarding the management of modifications to the facility.

Écrin facility

Further to the regularisation of the Écrin facility by the Decree of 20th July 2015, ASN's prescriptions for setting the conditions of liquid effluent transfer and facility environment monitoring were made available for public consultation and were presented to the Aude Departmental Council for the Environment, Health and Technological Risks (CODERST) and to the CLI of the Écrin facility. These prescriptions will be adopted in 2017 prior to the facility commissioning authorisation which will consist in development work to limit the environmental impact of the facility.

1.2 Radiation protection in the medical field

External radiotherapy and brachytherapy

ASN carried out eight inspections in external-beam radiotherapy departments and three inspections of brachytherapy departments in 2016.

The resources devoted to medical physics are deemed satisfactory. Nevertheless, the medical physics organisation plans do not always take into account the staffing levels necessary to put in place new techniques or new radiotherapy equipment.

ASN considers that the treatment quality and safety management systems of the inspected radiotherapy and brachytherapy centres are satisfactory. ASN observes however that the a priori risk analysis procedure, which should result in appropriate barriers for preventing adverse patient radiation protection events, is not carried out in sufficient depth.

ASN considers moreover that the occupational radiation protection measures are correctly applied in the radiotherapy and brachytherapy departments.

Further to organisational difficulties, the radiotherapy centre of the Rodez hospital was subject to tightened monitoring in 2016. A first inspection at the beginning of the year addressing social, organisational and human factors led ASN to issue formal notice requiring the centre to take corrective action in order to comply with the prescriptions of ASN resolution 2008-DC-0103 setting quality assurance obligations in radiotherapy and to validate its medical physics organisation plan. A second inspection carried out in May 2016 confirmed that a plan of action had been implemented by hospital management. Working closely with the Regional Health Agency (ARS) of Occitanie, ASN remains attentive to ensure that the necessary recruitment and investment measures are taken.

Interventional practices

In 2016 in the Occitanie region ASN inspected 15 centres performing interventional procedures both in operating theatres and in facilities dedicated to cardiology, neuroradiology and vascular radiology. ASN notes the persistence of the lack of radiation protection culture in the operating theatre.

With regard to patient radiation protection, ASN observes that the principle of patient dose optimisation is insufficiently applied due firstly to the absence of radiographers in the operating theatres, and secondly the reluctance to call upon medical physicists.

With regard to occupational radiation protection, compliance with regulatory provisions relative to worker dosimetric monitoring is low among medical practitioners.

Furthermore, the use of collective protective equipment must be improved.

Lastly, ASN verified implementation in the centres of the provisions of ASN resolution 2013-DC-0349 setting the design rules for premises in which X-ray generators are used. It considers that the situation is satisfactory on the whole.

Nuclear medicine

ASN performed four inspections in nuclear medicine departments in the Occitanie region in 2016.

ASN verified compliance with its resolution 2014-DC-0463 relative to the design and operation of nuclear medicine facilities, particularly from the design stage where new premises are concerned. In this context, further to an inspection carried out in December 2015, ASN asked the Cancer Institute of Montpellier (ICM Val d'Aurelle) to revise the layout of its nuclear medicine department.

ASN considers that patient and worker radiation protection is on the whole ensured correctly in the nuclear medicine departments. With regard to protection of the public and the environment, ASN notes improvements in the condition of the contaminated waste collection and treatment equipment. Nevertheless, the departments could make their waste management plan more comprehensive and improve its updating.

Lastly, ASN notes that the majority of the notified significant events result from an error in the preparation of radiopharmaceuticals injected into the patients.

Several preparation errors of this type were notified by the nuclear medicine department of the Rodez hospital centre in 2015. Following these notifications, ASN conducted an inspection in the centre which resulted in the head of the nuclear activity being served formal notice to comply with good practices in drug preparation to ensure patient radiation protection. The implementation of appropriate corrective actions by the centre was verified during a follow-up inspection by ASN in May 2016.

Computed tomography

ASN carried out five inspections in computed tomography in 2016.

As far as patient radiation protection is concerned, ASN considers that on the whole it is duly taken into account in the computed tomography departments.

With regard to occupational radiation protection, ASN notes a lack of medical monitoring of personnel exposed to ionising radiation and shortcomings in the coordination of prevention measures. Defining and performing technical radiation protection controls must also be improved.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out six inspections of industrial radiography activities in bunkers or on worksites in 2016. ASN observes progress in the scheduling and performance of the technical radiation protection controls, the maintenance of industrial radiography devices and the conformity of protected bunkers.

The general organisation of radiation protection, the training and the dosimetric and medical monitoring of the personnel exposed to ionising radiation remain satisfactory on the whole.

ASN does however consider that the delineation and signalling of work zones on industrial radiography worksites must be improved. Likewise, the implementation of optimisation practices must be continued.

Universities and laboratories or research centres

Two joint inspections by ASN's Bordeaux and Marseille divisions and its Department of transport and sources were conducted in Montpellier University and the Institute of Systems Electronics in 2016. These inspections more specifically examined compliance with the regulatory provisions before commissioning a gamma ray projector in a bunker built for this purpose.

ASN also checked the implementation of the plan of action defined by the Paul-Sabatier University in Toulouse for the removal of the expired sources and contaminated waste present in its waste bunker. During 2016, the university characterised the various radionuclides in the bunker in order to determine appropriate disposal routes.

ASN considers that the research laboratories on the whole comply with the requirements concerning training and dosimetric and medical monitoring of personnel exposed to ionising radiation.

Installations Classified on Environmental Protection grounds (ICPEs)

In application of Decree 2014-996 of 2nd September 2014 amending the ICPE nomenclature, an inspection was carried out jointly with the Dreal (Regional Directorate for the Environment, Planning and Housing) of Occitanie on the Areva Malvési site in Narbonne on the theme of significant events concerning radiation protection. Coordinated requests were made.

The discussions between ASN and the Dreal will continue in 2017, focusing in particular on the other sites in Occitanie concerned by the abovementioned decree.

1.4 Radiation protection of the public and the environment

Radon

In 2016, ASN carried out three inspections focusing on radon in buildings open to the public in the Lozère *département*. These inspections, conducted jointly by ASN and the ARS, targeted buildings in which radon concentrations exceeding the regulatory action triggering thresholds had been evidenced in 2004.

This inspection campaign demonstrated that measures had been taken to ventilate the buildings and modify their leak-tightness. However, the buildings concerned have not yet all managed to get below the regulatory threshold of 400 Bq/m^3. The setting up of additional actions will be monitored in 2017 and verified by an approved organisation.

Mining sites

In 2016, ASN assisted the Dreal in monitoring the former uranium mining sites which are situated more particularly in the Hérault and Lozère *départements*.

This gave rise to in-depth discussions with the ARS, the Dreal and the company Areva Mines concerning the monitoring of the Lodévois sites (Hérault *département)* and resulted in the two matters being referred by the Dreal, firstly the analysis of the conditions defined by Areva for the management of the legacy mining waste rock used in the public domain, and secondly the conditions for the demolition of the buildings situated on the land of the former Bosc mining site which is intended to accommodate the future Michel-Chevalier regional business park.

ASN will respond to these two referrals from the Dreal in 2017. Possible restrictions on the use of the site will be examined.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

In 2016, ASN carried out 11 inspections concerning the transport of radioactive substances by BNIs and small-scale nuclear activity licensees in 2016.

On completion of the inspection carried out at the Golfech NPP, ASN considered that the site's organisation for the shipment of packages not subject to approval is satisfactory on the whole. Application of the utilisation instructions for this type of package must nevertheless be improved. Further to the inspections conducted on the Mélox plant and the Centraco facility, ASN also considers that the measures taken by the licensees of these two BNIs with regard to the shipment and reception of radioactive substances are satisfactory.

ASN carried out a series of unannounced inspections of the consignments of a radiopharmaceutical package producer. These inspections showed that on the whole the regulatory requirements concerning the securing of packages, placarding and display of orange signs on vehicles, on-board documents and equipment and driver training are satisfied. As regards the consignor, no particular comments were made regarding the records necessary for carriage of the packages and which are given to the carriers.

ASN also continued its multi-year programme of inspections of nuclear medicine and brachytherapy departments. ASN observes that the measures put in place for managing radioactive substance transport operations in these departments must be improved with regard to the verification of packages on dispatch and reception, the security protocols, the training of the personnel involved and the quality management system.

Lastly, ASN verified compliance with regulatory requirements in radioactive substance transport during industrial radiography worksite inspections. ASN considers that these requirements are satisfied on the whole, even if as a general rule the quality management systems need to be improved and the regulatory pre-dispatch checks of the packages are not always carried out.

2. Additional information

2.1 Informing the public

Press conferences

ASN held two press conferences in June 2016, one in Toulouse, the other in Montpellier, addressing the situation of nuclear safety and radiation protection in the Occitanie region, and which provided the opportunity to address the restarting of the Centraco melting furnace and the deficiencies in radiation protection culture observed in the operating theatre.

Work with the Local Information Committees (CLIs)

ASN accompanied the work of the Golfech CLI by participating at the general meetings and several technical commission meetings. The CLI moreover designated observers who attended several inspections conducted by the ASN Bordeaux division at the Golfech NPP.

ASN participated in the activities of the Marcoule-Gard CLI, more specifically by presenting the results of the oversight actions carried out in 2015 and the regulatory approach with regard to effluent discharges and environmental monitoring. ASN underlines the commitment of the members of the Marcoule-Gard CLI regarding questions relating to BNI decommissioning and post-accident management.

ASN also gave the CLI of the Écrin facility a presentation of the planned prescriptions concerning the conditions of liquid effluent transfer and environmental monitoring at the facility.

In accordance with the provisions introduced by the TECV Act, the Golfech and Marcoule-Gard CLIs each organised a public meeting, held on the 1st and 6th of December 2016 respectively, in which ASN participated. The public meeting organised by the Golfech CLI was devoted to environmental monitoring around the nuclear power plant and integration of the lessons learned from the Fukushima Daiichi accident. The public meeting organised by the Marcoule-Gard CLI was more particularly devoted to the prospect of certain municipalities situated within the Off-site Emergency Plan (PPI) zone of the Marcoule platform being concerned by the extension of the perimeter of the Tricastin site's PPI.

Other public information actions

ASN took part in the initiatives to raise awareness in the risk culture organised as part of the campaign to distribute replacement iodine tablets in the PPI zone of the Golfech NPP. Several public information meetings were held in this context. Beyond the information on the iodine tablet distribution campaign, these meetings provided the opportunity to remind people of the population protection measures to implement should an accident occur in a nuclear facility.

ASN also participated in the 5th European Radiation Protection Forum organised by the ATSR (Association of Techniques and Sciences of Radiation Protection) in La Grande-Motte, where it gave a talk on the subject of decommissioning regulations.

The state of nuclear safety and radiation protection in 2016 in the Pays de la Loire region

The Nantes division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Pays de la Loire region.

The activities and installations to regulate comprise:
- the Ionisos irradiator in Sablé-sur-Sarthe;
- the Ionisos irradiator in Pouzauges;
- the facilities and activities using ionising radiation in the medical, industrial and research sectors:
  medical services:
  - 6 radiotherapy centres;
  - 4 brachytherapy units;
  - 11 nuclear medicine departments;
  - 38 centres performing interventional procedures;
  - 52 tomography devices;
  - some 2,500 medical and dental radiology devices;

  industrial and research uses:
  - 34 industrial radiography companies (including 7 gamma radiography contractors);
  - about 400 industrial and research equipment licences (including 220 users of devices for detecting lead in paint);
- 5 radiation protection technical control agencies, one radon screening agency and one head office of laboratories approved for taking environmental radioactivity measurements.

In 2016, ASN carried out 35 inspections, of which 1 was in BNIs, 33 in small-scale nuclear activities and 1 in the transport of radioactive substances.

Among the notified events, none was rated level 1 or higher on the INES scale and 5 events in radiotherapy were rated level 1 on the ASN-SFRO scale.

The ASN inspectors issued a violation report against an industrial radiography company for not having a license.

1. Assessment by domain

1.1 The nuclear installations

Industrial irradiators operated by the company Ionisos

Ionisos operates two industrial irradiators in the Pays de la Loire region, using them essentially for two applications: product sterilisation (mainly medical devices and, to a lesser extent, foodstuffs) and the treatment of plastic materials to improve their mechanical characteristics. ASN considers that these operations are carried out with due attention to nuclear safety and radiation protection.

In June 2015, as agreed, Ionisos submitted a summary file for the first periodic safety review[1] of the irradiator in Sablé-sur-Sarthe. ASN requested IRSN's opinion on this file, asking it to examine more particularly the relevance of the licensee's proposed action plan and the corresponding implementation schedule. This periodic safety review is also used to study the additional measures to be put in place concerning accesses to the irradiation cell, further to the incident of June 2009 involving the untimely opening of the irradiation cell access door on the Pouzauges site.

An inspection carried out on the Sablé-sur-Sarthe site in 2016 assessed the method used by Ionisos to draw up its first periodic safety review file. The general organisation put in place is robust and good practices were noted, but a few areas for improvement were also identified to supplement the integrated management system and the methodology associated with the monitoring of elements and activities important for protection.

Ionisos will carry out the first periodic safety review of the Pouzauges site in 2017, for which the licensee must integrate the lessons identified by ASN during the examination of the periodic safety review of the Sablé-sur-Sarthe site.

1.2 Radiation protection in the medical field

Radiotherapy

Two radiotherapy accelerator changes were registered in the Pays de la Loire region in 2016. The change in equipment is accompanied by the development of new techniques (primarily stereotaxy) which lead to new risks. Four of the six radiotherapy centres were inspected in 2016. Management of the risks and anticipation of the needs created by the new techniques were verified in detail.

Following a phase of consolidation of the quality approach, all the inspected centres are now resolutely engaged in a phase of quality management and continuous improvement. Although the "quality" objectives are regularly updated by their respective governing bodies, their monitoring and assessment can still be improved in some cases.

The state of progress in the a priori risk management approach varies from one centre to another, even though the methodologies used are relatively similar. The risks induced by the new techniques are integrated in the a priori risk analysis with the putting in place of new requirements or defence barriers. However, deadlines and the people responsible for their implementation are not always specified.

The organisation for detecting and analysing adverse events is effective on the whole and contributes to the development of the risk analysis. Six significant patient radiation protection events were notified to ASN in 2016, mainly involving positioning errors; five were rated level 1 on the ASN-SFRO scale. After analysing the events, improvement measures have been implemented but their effectiveness is still insufficiently assessed in some centres. Furthermore, the question of the need to renew training in the identification of adverse events must be looked into, in view of the drop in the number of events notified.

Lastly, the efforts made in the last few years to recruit medical physicists, dosimetrists and physical measurement technicians enable all the centres to ensure the presence of at least one medical physicist during the treatment periods each day while at the same time freeing up medical physicist time for the deployment of new treatment techniques. Nevertheless, the evaluation of needs in medical physics could be better finalised in most of the centres.

Interventional practices

Oversight of interventional practices has figured among the priority objectives of the Nantes division since 2014.[2]

The efforts made over the last few years in terms of volume and prioritisation of inspections enabled three centres performing a large number of procedures with major implications for patient radiation protection to be reinspected in 2016 and the monitoring of the identified areas for progress to be reinforced.

A significant improvement over previous years has been observed in these centres where radiation protection is

1. *See note on page 231.*

2. *Fifty sites inspected out of a total of 79 sites (75 centres) over the 2014-2016 period.*

a key issue. Dose optimisation and patient monitoring in long or iterative medical procedures are becoming increasingly common practices, especially in large centres employing a medical physicist. With regard to occupational radiation protection, continued efforts are required in the quantification of doses and protection of the lens of the eye and the extremities of health professionals.

For practitioners, particularly from the private sector, there is significant room for progress in occupational radiation protection training and medical monitoring.

Nuclear medicine

The 11 nuclear medicine centres are continuing to modernise their technical platforms, enabling 80% of them to have at least one gamma camera coupled to a computed tomography scanner. Six of the centres also have a positron emitting tomography scanner.

Three nuclear medicine units were inspected in 2016. The inspections focused in particular on the management of waste and effluents, targeted internal radiotherapy and the measures taken to ensure the safety of patient treatment and of radiopharmaceutical handling.

Worker radiation protection can be further improved in a few areas, such as the coordination of radiation protection means during operations by outside contractors and the conditions and means of worker protection when transporting sources outside the department.

Patient radiation protection is taken into account to varying extents. Practices for detecting pregnancy are rarely formalised and scanner utilisation protocols are not fully optimised.

The management of waste and effluents is considered satisfactory. Periodic checks are carried out at the centre's discharge outlet at least once a year; the results of these checks should be better assessed and communicated to the sewage network manager.

The organisation for detecting and analysing adverse events is formalised. 75% of the significant radiation protection events in the Pays de la Loire region processed by the division were notified by nuclear medicine centres, primarily in the hospital centres.

Lastly, with regard to the analysis of conformity of the facilities with ASN resolution 2013-DC-0463 applicable since 1st July 2015, it emerges that compliance with ventilation requirements must be confirmed by specific checks.

Computed tomography

Three centres were inspected in 2016. The inspections focused particularly on patient radiation protection, which is generally well implemented in these centres. The patient radiation protection training has been correctly implemented, the facility quality controls have been carried out and patient dose optimisation protocols have been established.

Nevertheless, the medical monitoring of workers, the coordination of the resources of private practitioners and outside companies and, with the exception of one centre, the periodic refreshing of occupational radiation protection training, still constitute the three areas for improvement in occupational radiation protection.

1.3 Radiation protection in the industrial sector

Industrial radiography

ASN carried out four inspections of industrial radiography activities in 2016, two of which were on gamma radiography worksites.

The findings are relatively similar to those of 2015. ASN notices that on the whole, regulatory requirements are duly satisfied with regard to the organisation of radiation protection, operator training and monitoring and equipment maintenance. Progress nevertheless remains to be made in the performance of the internal and third-party technical radiation protection controls, particularly following reception of the devices, and in the analysis of doses received by workers, bringing exposure bunkers into conformity, defining and implementing operation zones on work sites and transmission of the projected worksite schedules.

1.4 Nuclear safety and radiation protection in the transport of radioactive substances

In 2016, ASN conducted three inspections concerning the transport of radioactive substances. Two of them were carried out during radiation protection inspections on gamma densitometry and gamma radiography worksites. The identified areas for improvement primarily relate to vehicle signalling and the updating of on-board documents.

1.5 Radiation protection of the public and the environment

Radon

ASN has participated since 2009 in the campaigns for radon measurement in private homes organised by the city of Nantes. Two public meetings were held during each campaign: the first ending with the issuing of dosimeters to the inhabitants of the districts concerned by the campaign, and the second during which the measurement results are detailed and remediation actions are proposed.

Other radon measurement campaigns were conducted by municipalities in the Pays de la Loire region in 2016, and ASN took the floor during the corresponding information meetings in Orvault, Savenay and Sucé-sur-Erdre.

On 4th November 2016, ASN, the Dreal and the ARS organised a press conference to inform the public of the health risks associated with radon. This was accompanied by an information leaflet intended for the public, which was distributed to information relays such as town halls, health professionals, notaries and solicitors.

In addition, ASN contributed to the preparation of the Pays de la Loire's 3rd Regional Health and Environment Plan (PRSE 3), coordinated by the Dreal and the ARS, and sat on several steering committees.

Mining sites

ASN keeps a close watch on the progress of Areva's actions around the sites in the public domain where uranium mining waste rock has been reused. One inspection was carried out during redevelopment work. Three new works sheets relating to waste rock reuse sites were analysed jointly by the Dreal and ASN in 2016, bringing the number of cases studied to 13. The resulting redevelopment work began in early 2016 and will continue in 2017.

ASN also took an active part in the information and discussion meetings organised by the prefectures of the Loire-Atlantique and Vendée *départements* on the subject of the former uranium mines. During these meetings, ASN reminded Areva to submit complementary studies to ASN and the Dreal for the other places where mining waste rock had been reused, to enable them to validate them or even impose further redevelopment work.

With regard to mining waste rock reuse sites accommodating living areas or residential buildings presenting a radon problem, Areva carried out an initial radon screening campaign at the request of the State. Despite a return rate of less than 50%, this campaign led to the identification of eight places with radon concentrations exceeding 2,500 Bq/m^3. For some buildings, the Dreal and ASN asked IRSN to perform a third-party appraisal to determine whether the radon was of natural or anthropogenic origin. In situations where anthropogenic origin was confirmed, Areva was asked to carry out work in 2016 to reduce the radon concentrations. ASN also asked for a second dosimeter distribution operation targeting the populations concerned. Furthermore at the end of 2016, ASN, the Dreal and the ARS began working on measures to take for residential buildings displaying radon concentrations between 300 Bq/m^3 and 2,500 Bq/m^3.

Lastly, ASN issued favourable opinions on the projects for disposal of the radiologically contaminated sludge and sediment from the former mining sites in Bretagne and disposal of the waste rock from the 13 sites in Pays de la Loire for which works sheets have been drawn up.

2. Additional information

2.1 Informing the public

Press conferences

ASN held two press conferences in Nantes in 2016, the first in June on the situation of nuclear safety and radiation protection, the second in November on exposure of populations to radon.

Work with the Local Information Committees (CLIs)

ASN took part in the meeting of the Sablé-sur-Sarthe CLI on June 14th 2016 and that of the Pouzauges CLI on 27th October 2016, during which Ionisos presented its annual reports.

2.2 International action

The Nantes division participated - prior to the organisation by the International Atomic Energy Agency (IAEA) of Integrated Regulatory Review Service (IRRS) missions - in advisory missions proposed by the IAEA to the authorities of Madagascar (National Authority for Radiological Protection and Safety – ANPSR) and Morocco (Moroccan Authority for Nuclear and Radiological Safety and Security – AMSSNouR).

The Nantes division also contributed to the review of Croatia's report on the implementation of the obligations of the Convention on Nuclear Safety.

To conclude, the Nantes division also participated in a cross-inspection in the United Kingdom on the subject of patient radiation protection in medical imaging.

The state of nuclear safety and radiation protection in 2016 in the Provence-Alpes-Côte-d'Azur region

The Marseille division regulates nuclear safety, radiation protection and the transport of nuclear substances in the 6 *départements* of the Provence-Alpes-Côte-d'Azur (PACA) region.

The activities and installations to regulate comprise:
- BNIs:
  in Cadarache:
  - the CEA Cadarache research Centre which counts 21 BNI's, including the Jules Horowitz Reactor currently under construction;
  - the ITER installation construction site, adjacent to the CEA Cadarache Centre;

  In Marseille:
  - the Gammaster industrial ioniser;
- small-scale nuclear activities in the medical sector:
  - 12 external-beam radiotherapy departments;
  - 4 brachytherapy departments;
  - 19 nuclear medicine departments;
  - 51 centres performing interventional procedures;
  - 98 tomography devices;
  - about 8,200 medical and dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - 13 head offices and 8 branch offices of industrial radiography companies;
  - 183 industrial establishments licensed to hold or use sources of ionising radiation;
  - 267 users of lead detectors;
  - some 260 veterinary surgeons using diagnostic radiology devices;
  - some 130 laboratories and universities using ionising radiation;
- ASN-approved laboratories and organisations:
  - 3 head offices of laboratories approved for taking environmental radioactivity measurements;
  - 5 organisations approved for radiation protection controls.

In 2016, ASN carried out 122 inspections in the PACA region, of which 45 were in BNIs, 73 in small-scale nuclear activities and 4 in the transport of radioactive substances.

Among the significant events notified for the BNIs, 6 were rated level 1 on the INES scale. Among the events notified in small-scale nuclear activities, none was rated level 1 or higher on the INES scale by ASN. Among the significant events concerning radiotherapy patients, one was provisionally rated level 2 on the ASN-SFRO scale and one was rated level 1.

In the execution of its oversight missions in the PACA region, ASN served two compliance notices on CEA, one concerning the management of deviations on its STD and STE facilities, the other concerning delays in the implementation of ASN resolution 2014-DC-0431 of 13th May 2014 on the STAR facility.

1. Assessment by domain

1.1 The nuclear installations

Cadarache site

Cadarache

ASN performed 41 inspections concerning BNIs in the CEA Cadarache Centre in 2016. Although ASN considers that the level of safety remains satisfactory on the whole, it still notes persistent disparities between the installations of the Centre and points out that it used its power of enforcement to obtain compliance with certain safety requirements. More specifically, further to shortcomings noted since 2012 in operating rigour and in the meeting of commitments on the STD and the STE, ASN gave CEA formal notice to improve the management of deviations with respect to safety requirements on these two BNIs.

ASN underlines that several large-scale projects of diverse nature and representing varied risks for safety are conducted concomitantly at the Centre. With regard to the decommissioning and radioactive waste retrieval and packaging work, whether at the radioactive wastes storage yard (BNI 56), the spent fuel storage pool on the Pégase installation or the experimental reactor Pégase, now shut down, ASN notes that the milestones for removal of legacy waste and fuel are duly followed. In view of the progress of the Areva NC-coordinated work to remove the glove boxes from the Plutonium Technology facility (ATPu) and from the Chemical Purification Laboratory (LPC) and to clean up the cells, plus the measures taken by CEA in preparation for the withdrawal of Areva NC, ASN has noted that CEA will be taking over operational responsibility for these two BNIs at the beginning of 2017. With regard to the BNI construction or redevelopment work, ASN considers that construction of the Jules Horowitz Reactor (JHR) is proceeding with the required rigour. The start-up tests of the newly-configured Cabri reactor are also continuing with due rigour. Furthermore, more than half the BNIs in the Centre are concerned by a periodic safety review[1] which has either been recently examined, is currently being examined or is to be submitted in 2017, and which can lead to substantial renovation work given the age of several BNIs (see chapter 14). This is the case with the STD for example, for which a renovation programme has been prescribed by ASN Chairman's resolution CODEP-CLG-2016-015866 of 18th April 2016.

ASN considers that the measures taken in the Centre with regard to the management of nuclear safety and radiation protection are on the whole satisfactory, despite difficulties inherent to the complexity of CEA's organisation. With regard to the monitoring of outside contractors, ASN notes the widespread implementation of monitoring plans for work performed by outside contractors on elements important for protection. As regards experience feedback, the implementing of expert appraisals by the Centre following significant events which are strongly linked to social, organisational and human factors is also viewed positively. The coordination of these analyses to draw lessons from significant events that could be of interest to several BNIs at the Centre is now operational.

ASN considers that CEA must continue its efforts in the planning and performance of periodic inspections and tests and protection against the fire risk.

As far as radiation protection is concerned, ASN considers that the Centre's organisation is still robust. Nevertheless, further to a confirmed case of exceeding one quarter of the regulatory annual radiological dose limit which was rated level 1 on the INES scale, ASN has asked for the effectiveness of the radiological contamination checks to be improved on the ATPu and the LPC.

In the area of waste management, ASN has noted shortcomings in the inspection of packages on acceptance, the handling of packages and compliance with waste storage conditions. Three significant events concerning the Cedra facility and rated level 1 on the INES scale led CEA to again reflect upon the conditions of acceptance of packages at the facility. As for the management of disused sources, ASN considers that the measures taken by CEA to set up an effective organisation for their disposal under appropriate conditions must be continued.

ASN considers that CEA's organisation of the management of liquid and gaseous effluents is satisfactory. However, further to significant events notified by the licensee over the last few years and installation modifications, whether completed or planned for in the coming years, ASN is undertaking a revision - which it started in 2014 - of the applicable prescriptions in this respect. This revision, which should be completed in 2017, will take better account of the actual operating situation of the Centre's BNIs and will govern the updating of the impact studies of some of the BNIs.

ITER

ASN performed five inspections of ITER in 2016. ASN notes the continued efforts in the organisation of this international project. The facility construction work has continued and significant progress has been made with the tokamak complex. ASN considers that the work on the cryostat is carried out to a satisfactory standard.

The setting out of the safety requirements in the design and construction of the building can nevertheless be improved. Deficiencies have been observed in the transmission of requirements, as much with regard to deadlines as to the content. Improvements are also still required in the detection of deviations and outside contractor compliance with procedures. The licensee's monitoring measures nevertheless proved effective in the detection of deviations

1. *See note on page 231.*

that should have been identified prior to construction. However, in view of the identified shortcomings, ASN has asked the licensee to tighten its monitoring of certain work packages under the responsibility of Fusion for Energy (F4E), the European Domestic Agency for ITER[2].

Gammaster ioniser

ASN carried out on inspection of Gammaster in 2016 and considers that the level of nuclear safety and radiation protection is satisfactory. The source loading and unloading rules have been changed to integrate experience feedback from these delicate operations. Improvements are nevertheless expected in the management of deviations and the application of new regulations.

1.2 Radiation protection in the medical field

External radiotherapy and brachytherapy

ASN carried out three inspections in external-beam radiotherapy and one in brachytherapy in centres in the PACA region.

ASN saw the continued efforts made by the radiotherapy centres to effectively implement a treatment quality and safety management system. Nevertheless, proper implementation of management reviews that take into account experience feedback, internal and external audits, patient satisfaction analyses and continuous improvement loops is required.

ASN emphasises the need to establish medical physics organisation plans based on the actual needs and not simply considering the number of medical physicists present. This applies equally well to the centres using innovative techniques as to those using more conventional ones. In the case of centres using innovative treatment techniques and new equipment, progress must be made in the identification of specific training and documentation needs before the techniques and devices are put into service.

Interventional practices

ASN carried out ten inspections of centres performing interventional procedures in the PACA region in 2016. ASN notes that the medical personnel working in operating theatres sometimes lacks radiation protection culture.

The regulatory provisions relative to dosimetric monitoring are poorly applied and the use of collective protective equipment, the provision and wearing of dosimeters and the performance of radiation protection technical controls remain weak points.

With regard to patient radiation protection, the weaknesses observed concern such aspects as the generally insufficient number of medical physicists and radiographers, the technical training of practitioners in the use of the machines, the drawing up of protocols for the most common procedures and the indication of the dosimetric information in the procedure reports.

Nuclear medicine

ASN carried out four inspections in nuclear medicine in the PACA region in 2016. The generally positive dynamics regarding the integration of radiation protection within the inspected services is maintained.

The inspected departments have increasingly modern premises and equipment at their disposal further to the relocating of departments and the replacement of old equipment. The improvements in the management of radioactive waste and effluents in 2015 continued in 2016. ASN notes in particular a substantial increase in the number of authorisations to discharge radionuclides into the public sewage networks, as provided for by the Public Health Code. The management plans on the other hand, are most often either incomplete or require updating.

Computed tomography

ASN performed three inspections in computed tomography in 2016 and considers that due account is taken of the radiation protection issues. With regard to patient radiation protection, ASN considers it necessary to improve the robustness of the patient identity monitoring process, the verification of the justification of the examinations performed and the completeness of the medical physics organisation plans. As for occupational radiation protection, progress is still required in the medical monitoring of exposed workers, particularly private-sector physicians. ASN moreover notes that the replacement of CT scanners in some departments gave rise over a short period to the use of mobile CT scanners installed in vehicles with sub-optimal provisions for radiation protection.

1.3 Radiation protection in the industrial and research sectors

Industrial radiography

ASN carried out 11 inspections of industrial radiography activities in bunkers or on worksites in 2016. The inspections on the whole revealed satisfactory situations. ASN notes, for example, an improvement in the submission of projected work schedules, albeit gradual and tenuous.

2. Each of the seven countries or group of ITER member countries (China, the European Union, India, Japan, South Korea, Russia, the United States) has created a "Domestic Agency" responsible for providing the nuclear operator with the elements of the installation for which it has been entrusted the manufacture.

Universities and laboratories or research centres

In 2016 ASN carried out three inspections of universities, laboratories and research centres using ionising radiation.

The progress observed in 2015 in the management of radioactive sources has been maintained. On the other hand, these inspections revealed the persistence of shortcomings in radiological zone marking, in radiation protection controls and in the verification of measuring devices. The management of radioactive effluents also remains a point to improve.

1.4 Radiation protection of the public and the environment

Contaminated sites and soils

In 2016, ASN continued its initiative to identify - and make safe - sites contaminated by radioactive substances. This initiative resulted more specifically in support from the Dreal during the work conducted by Andra in 2016 on the Ganagobie site contaminated with carbon-14 and tritium further to the activities of the Isotopchim Company between 1987 and 2000. Waste stored on the site was removed in December 2016. ASN does however note that significant quantities of waste will be kept on the site pending identification of a management route for it.

On the same subject, following significant events at the CEA Cadarache Centre, ASN asked for details on the measures taken regarding the management of contaminated sites and soils. While it appears that the monitoring measures are satisfactory, additional elements are to be provided in 2017 to guarantee that the licensee's management measures are appropriate for the risks.

Technologically enhanced naturally occurring radioactivity

ASN assisted the Dreal, particularly through the analysis of the studies relative to the assessment of the radiological impact of the Mange-Garri site (Bouches-du-Rhône *département*). This analysis will continue in 2017.

1.5 Nuclear safety and radiation protection in the transport of radioactive substances

ASN carried out four inspections in the area of radioactive substance transport addressing diverse players: BNIs, hospital centres and the industrial sector of small-scale nuclear activities.

In the BNIs and the small-scale industrial nuclear activities, ASN considers that the regulations are correctly applied and notes that significant event notifications essentially concern malfunctions relating to package tie-down. In the medical field and in nuclear medicine departments in particular, the risks associated with transport operations are still insufficiently taken into account. The management system upgrading work is still topical. Reception and dispatch verifications are not performed exhaustively. The second-level check of contractor carriers is not always carried out, even though ASN did observe an improvement in this latter point this year.

2. Additional information

2.1 Informing the public

Press conferences

ASN organised two press conferences on the situation of nuclear safety and radiation protection held in Marseille and Nice on the 9th and 28th June 2016 respectively. They allowed subjects such as decommissioning and - as far as CEA Cadarache is concerned - the numerous forthcoming periodic safety reviews, to be raised.

Work with the Local Information Committees (CLIs)

ASN continued to provide its support to the Cadarache CLI by participating in some ten meetings in 2016. In accordance with the provisions introduced by the TECV Act, the CLI organised three public meetings addressing respectively the risks of the Gammaster installation, the progress of the ITER project and monitoring of the environment around the Cadarache site. ASN underlines the dynamism of this CLI and the level of investment of its members on the national scale.

2.2 International action

In 2016, ASN took part in a meeting with its German counterpart on the Cadarache site addressing emergency situation management. ASN also made a trip to Israel on the invitation of its Israeli counterpart, to discuss, among other things, oversight of the JHR currently under construction on the Cadarache site.

2.3 The other notable events

ASN was mobilised during two emergency exercises, one on the Toulon naval base (Var *département*), the other in the Alpes-Maritimes *département*, staging a radioactive substance transport accident in a valley of the Alps. The first feedback on the lessons drawn from these exercises is satisfactory as far as both the licensees and the public authorities are concerned.

The state of nuclear safety and radiation protection in 2016 in the Overseas *Départements* and Regions (DROM) and the Overseas Communities (COM)

The regulation of radiation protection and the transport of radioactive substances in the 6 overseas *départements* and regions (Guadeloupe, Guyane, La Réunion, Martinique, Mayotte, Saint-Pierre-et-Miquelon) is ensured by the Paris division. It also fulfils duties as expert to the competent authorities of French Polynesia and New Caledonia.

The activities to regulate comprise:

- small-scale nuclear activities in the medical sector:
  - 4 external-beam radiotherapy departments (some 10 accelerators);
  - 3 brachytherapy departments;
  - 4 nuclear medicine departments;
  - 26 centres performing interventional procedures;
  - more than 40 computed tomography devices;
  - about 100 medical diagnostic radiology centres;
  - about 1,000 dental diagnostic radiology devices;
- small-scale nuclear activities in the industrial and research sectors:
  - about 70 users of veterinary diagnostic radiology devices;
  - 2 industrial radiography companies using gamma radiography devices.

In 2016, ASN carried out 20 inspections during two campaigns in small-scale nuclear activities in the DROM in 2016.

One event involving a brachytherapy patient was rated level 2+ on the ASN-SFRO scale and gave rise to an incident notification. One event involving an external-beam radiotherapy patient was rated level 1 on the ASN-SFRO scale. No events were rated on the INES scale.

1. Assessment by domain

1.1 Radiation protection in the medical field

The inspections revealed the DROM to be somewhat behind in the application of patient radiation protection measures. Firstly, there are still difficulties in deploying the radiotherapy risks management process as required. Moreover, the involvement of medical physicists in interventional imaging is insufficient, and even totally inexistent in some centres. This situation led ASN to serve one centre with a compliance notice. Tightened oversight will be exercised in 2017.

A significant event rated level 2+ on the ASN-SFRO scale was notified in brachytherapy further to the reversal of batches of seeds containing radioactive iodine used as permanent implants in prostate brachytherapy. This error resulted in two patients being administered an activity higher than that prescribed. The centre concerned was inspected by ASN.

1.2 Radiation protection in the industrial sector

ASN's oversight actions identified one industrial radiography company with a manifest lack of radiation protection culture. The application of radiation protection measures in the other facilities appears to be satisfactory on the whole, but specific difficulties, inherent to the remoteness and the absence of certain types of permanent service providers, have been identified.

2. ASN's action in New Caledonia and French Polynesia

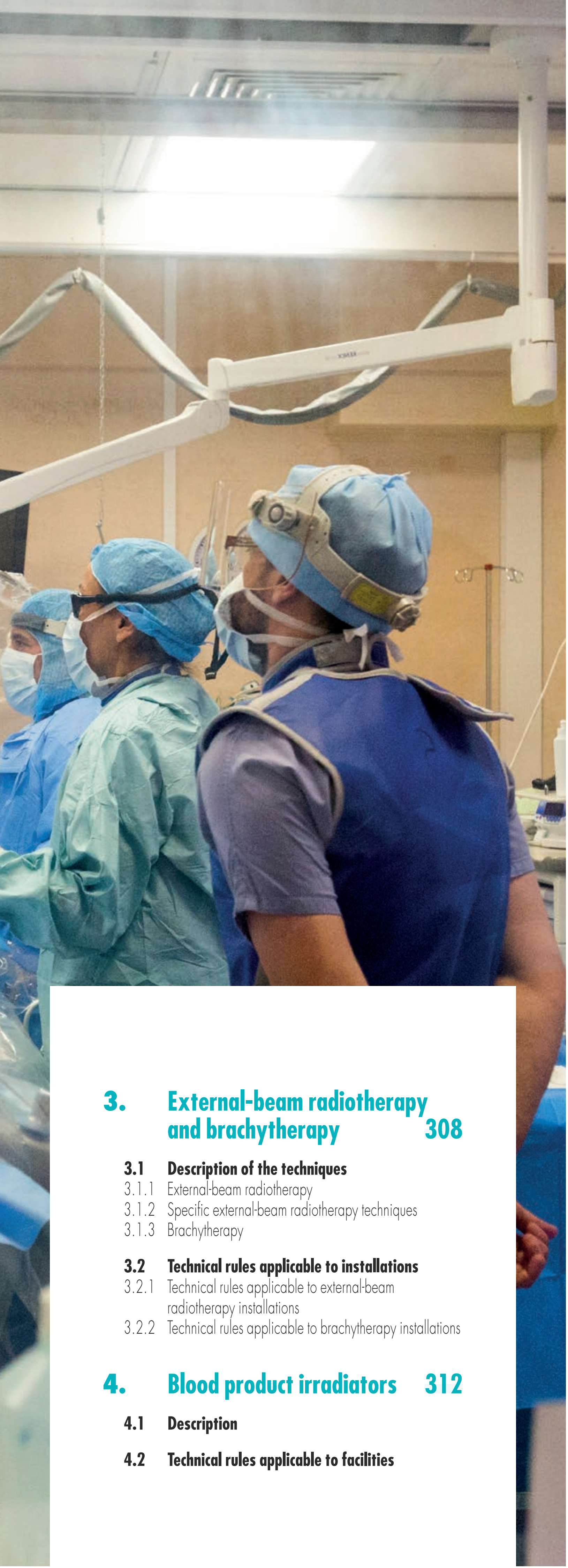
During 2016 ASN continued its cooperation work with French Polynesia and New Caledonia as part of their operations to regulate activities involving ionising radiation and to update the regulatory framework governing nuclear activities in these territories. This cooperation is governed by multi-year agreements signed between the overseas communities and ASN.

ASN conducted a mission in French Polynesia in 2016 further to the opening of the hospital centre's isotope medicine department. This mission also provides the opportunity to conduct inspections in the radiotherapy and interventional imaging department of the hospital centre, and on the industrial site in which orphan sources were discovered in 2015. These inspections were carried out on the basis of the regulatory baseline requirements applicable in metropolitan France. Discussions and actions to raise the stakeholders' awareness on the subjects of waste management and the transport of radioactive substances also took place.

In 2016, for the fourth year running, ASN carried out another mission in New Caledonia. Six inspections, one focusing on the entry into service of the new radiotherapy centre, were carried out with the local authorities in the medical and industrial sectors on the basis of the regulatory baseline requirements applicable in metropolitan France. The discussions and training measures for the local authorities in charge of licenses and oversight were continued. ASN also contributed its expertise in the ongoing reflection in New Caledonia concerning the creation of a unit dedicated to radiation protection and ultimately tasked, among other things, with examining license applications and oversight and management of emergency situations. Meetings were organised with Government representatives and the High Commission in order to present the cooperation initiatives and the radiation protection challenges in New Caledonia, insisting on the benefits of rapidly adopting regulatory baseline requirements similar to those in effect in metropolitan France, on the basis of draft texts produced in 2015 by ASN in collaboration with the local authorities.

09

Medical uses of ionising radiation



For more than a century now, for both diagnostic and therapeutic purposes, medicine has made use of ionising radiation produced either by electric generators or by radionuclides in sealed or unsealed sources. The benefits and usefulness of these techniques have long been proven, but they nevertheless contribute significantly to the exposure of the population to ionising radiation. They effectively represent the second source of exposure for the population (behind exposure to natural ionising radiation) and the leading source of artificial exposure (see chapter 1).

Protection of the staff working in facilities using ionising radiation for medical purposes is regulated by the provisions of the Labour Code. The medical facilities and devices emitting ionising radiation, including sealed and unsealed sources, must satisfy technical rules and procedures defined in the Public Health Code (see chapter 3).

The protection of patients undergoing medical imaging examinations or receiving therapeutic treatments involving ionising radiation is regulated by specific provisions of the Public Health Code. The principles of justification of procedures and optimisation of the doses delivered are the basis of these regulations. However, contrary to the other applications of ionising radiation, the principle of dose limitation does not apply to patients due to the need to adapt the dose delivered to each individual patient according to the therapeutic objective or to obtain an image of adequate quality to make the diagnosis.

1. Medical and dental radiodiagnosis installations

1.1 Presentation of the equipment and inventory

Medical diagnostic radiology is based on the principle of differential attenuation of X-rays by the organs and tissues of the human body. The information is most often collected on digital media allowing computer processing of the resulting images, and their transfer and filing.

Diagnostic X-ray imaging is one of the oldest medical applications of ionising radiation; it encompasses all the methods of morphological exploration of the human body using X-rays produced by electric generators. It occupies an important place in the field of medical imaging and comprises various techniques (conventional radiology, radiology associated with interventional practices, computed tomography, mammography) and a very wide variety of examinations (radiography of the thorax, chest-abdomen-pelvis computed tomography scan, etc.).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the patient's known medical history, the question posed, the expected benefit for the patient, the exposure level and the possibilities offered by other non-irradiating investigative techniques. A guide intended for medical doctors *(Guide to good medical imaging examination practices)* updated in 2013 indicates the most appropriate examinations to request according to the clinical situations (see box).

1.1.1 Medical radiodiagnosis

Conventional radiology

Conventional radiology (producing radiographic images, or radiographs), if considered by the number of procedures, represents the large majority of radiological examinations performed.

The examinations mainly concern the bones, the thorax and the abdomen. Conventional radiology can be carried out in fixed facilities reserved for diagnostic radiology or, in certain cases, using portable devices if justified by the clinical situation of the patient.

Angiography

This technique, used for exploring blood vessels, involves injecting a radio-opaque contrast agent into the vessels which enables the arterial (arteriography) or venous (venography) tree to be visualised. Angiography techniques benefit from computerised image processing (such as digital subtraction angiography).

Mammography

Given the composition of the mammary gland and the fineness of the details that must be seen in order to diagnose mammary pathologies, specific devices (mammography units) are used. They operate at low voltage and provide high resolution and high contrast. They are used in particular in the national breast cancer screening programme.

The use of a new three-dimensional imaging technique called "tomosynthesis", which reconstructs the breast from a series of slice images is growing in Europe. The evaluation of this technique, currently in progress in several European countries, should enable its advantages compared with the traditional planar technique to be determined. At present, this technique is not recognised for use in organised breast cancer screening.

Computed Tomography

Computed Tomography (CT) scanners use a beam of X-rays emitted by a tube which moves in a spiral around the body of the patient (spiral or helical CT scanner). Based on a computerised image acquisition and processing system, these scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. The number of rows of detectors (multi-detector-row CT scanner) has been increased in recent machines, enabling thinner slices to be produced.

This technique can, like Magnetic Resonance Imaging (MRI), be associated with functional imaging provided by nuclear medicine in order to obtain fusion images combining functional information with structural information.

FUNDAMENTALS

Medical imaging: several imaging techniques can be used for a given organ

Complementary examinations (medical imaging, biological analysis, samples, etc.) supplement the physician's diagnostic approach based on the history of the illness and the clinical examination of the patient.

There are four broad medical imaging techniques. They use X-rays (radiology), gamma rays (nuclear medicine), ultrasounds (ultrasonography) and magnetic fields (MRI - Magnetic Resonance Imaging). These techniques enable the morphology of an organ to be analysed or its function to be studied; the intrinsic qualities and the medical interpretation of the resulting images are fundamentally dependent on the physical principle used:

- Radiology reveals differences in density in a tissue (due to the presence of a tumour, for example) or between different organs. Radiology, mammography and X-ray computed tomography are radiological examinations. The scanner enables an organ to be reconstructed in 3D and slices of an organ to be created (slice imaging or tomography).
- Nuclear medicine analyses the distribution of a radiopharmaceutical (drug consisting of a vector marked by a radioactive isotope or isolated radionuclide) injected into the human body. This is functional imaging which enables the physiopathological processes to be studied and provides important information on the normal or pathological functioning of a tissue or organ. The radiopharmaceutical is chosen according to the target and the studied organ.
- Ultrasonography uses the properties of ultrasounds to echo (reflect) off interfaces, whether these interfaces are the anatomical boundaries of organs or heterogeneous areas within an organ or tissue. The recorded echoes allow the reconstruction of an image of the explored area. By combining this with the Doppler effect it is also possible to measure the rate of blood flow in the vessels.
- MRI uses the magnetic properties of hydrogen nuclei placed in a strong and stable magnetic field. The proton (H^+) is the main constituent of the molecule of water, an element that is present to a greater or lesser extent in all the tissues of the human body. After excitation by radiofrequency waves, the signals from the protons in the water of the human body are picked up by dedicated antennas and analysed by computer in order to reconstruct a slice image.

Radiology and nuclear medicine that use ionising radiation are regulated by ASN. Ultrasonography and MRI do not use ionising radiation.

The Guide to good medical imaging examination practices, produced by the French Society of Radiology (SFR) and the French Society of Nuclear Medicine and Molecular Imaging (SFMN), helps physicians to choose the most appropriate examination according to the symptomatology, the suggested diagnoses and the patient's medical history. It takes into account the proof of the level of diagnostic performance of the examinations in each of the situations (analysis of international publications), whether the examination involves radiation or not, and if so, the corresponding doses. No technique is universal; a technique that gives good results for one organ or function of that organ may be less effective for another organ, and vice versa.

The technological developments over the last few years have made examinations easier and faster to perform, and led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications[1]. The commercialisation of mobile CT equipment for intraoperative use is to be noted.

On the other hand, these technological developments have led to an increase in the number of examinations, resulting in an increase in the doses delivered to patients and thus reinforcing the need for strict application of the principles of justification and optimisation (see chapter 1).

As at 31st December 2016, the French pool of radiological devices included slightly more than 1,000 computed tomography facilities covered by an ASN license.

Teleradiology

Teleradiology provides the possibility of guiding the performance and interpreting the results of radiology examinations carried out in another location. The interchanges must be carried out in strict application of the regulations (relating to radiation protection and the quality of image production and transfer in particular) and professional ethics.

Essentially two methods of interchange are used:
- Telediagnosis, which enables a doctor on the scene (ex: an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the images to a radiologist in order to obtain an interpretation. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it.
- Tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other - the «expert radiologist» (teleradiologist) - for a remote confirmation or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination.

The data transmissions are protected and preserve medical secrecy and image quality.

Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure to the teleradiologist. The teleradiology procedure is a medical procedure in its own right, like all other imaging procedures, and cannot be reduced to a simple interpretation of images. Teleradiology therefore fits into the general healthcare organisation governed by the Public Health Code and obeys the rules of professional ethics in effect (see the good practices recommendations issued by the professionals).

1.1.2 Interventional practices using ionising radiation

Interventional practices using ionising radiation comprise *"all invasive diagnostic and/or therapeutic medical procedures, as well as surgical procedures that use ionising radiation for guidance, including monitoring"*[2].

The machines used are either fixed machines installed in rooms dedicated to this activity, chiefly vascular (neurology, cardiology, gastroenterology, etc.), in which case one talks of interventional radiology, or mobile radiology machines used in operating theatres in several medical specialities, notably digestive surgery, orthopaedics and urology. They involve techniques that use fluoroscopy with an image intensifier or digital images (flat panel detector) which require special equipment.

Interventional techniques using computed tomography are on the increase, mainly thanks to recent technical developments (acquisition speed, miniaturisation, mobile CT scanners, etc.). These techniques are used during diagnostic interventions (coronarography or examination of coronary arteries, etc.) or for therapeutic purposes (dilation of coronary arteries, angioplasty, vascular embolization, etc.) as well as during surgical procedures using ionising radiation to guide or monitor the surgeon's actions. They can require long-duration exposure of the patients at high dose rates which can, in some cases, lead to deterministic effects on tissues due to the ionising radiation (cutaneous lesions, etc.).

The staff usually work in the immediate vicinity of the patient and are also exposed to higher dose levels than during other radiological practices. In these conditions, given the exposure risks for both the operator and the patient, practices must be optimised to reduce doses and ensure the radiation protection of operators and patients alike.

ASN does not know exactly how many facilities are used for interventional procedures, mainly due to a rapid increase in interventional practices in medical specialities as a whole in recent years. Only the numbers of rhythmology, interventional cardiology and interventional neuroradiology units are known with precision since these healthcare activities require an authorisation from the Regional Health Agency. The regional divisions of ASN make increasing use of the data on hospital activities to have better insight into

1. *The term indication means a clinical sign, an illness or a situation affecting a patient which justifies the value of a medical treatment or a medical examination.*

2. *Definition from the GPMED Advisory Committee for Radiation Protection for the Medical and Forensic Applications of Ionising Radiation (reporting to ASN).*

the activities and the risks associated with medical imaging. More than 1,000 centres (lower bracket) practising interventional radiology and fluoroscopy-guided procedures have thus been inventoried in France.

1.1.3 Dental radiodiagnosis

Intra-oral radiography

Intra-oral radiography generators, which are usually mounted on an articulated arm, are used to take localised planar images of the teeth (the radiological detector is placed in the patient's mouth). They operate with low voltage and current and a very short exposure time, of about a few hundredths of a second. This technique is most often associated with digital systems for processing and filing the radiographic images.

Panoramic dental radiography

Panoramic radiography (orthopantomography) gives a single picture showing both jaws in full, by rotating the radiation generating tube around the patient's head for a few seconds.

Cone-beam computed tomography

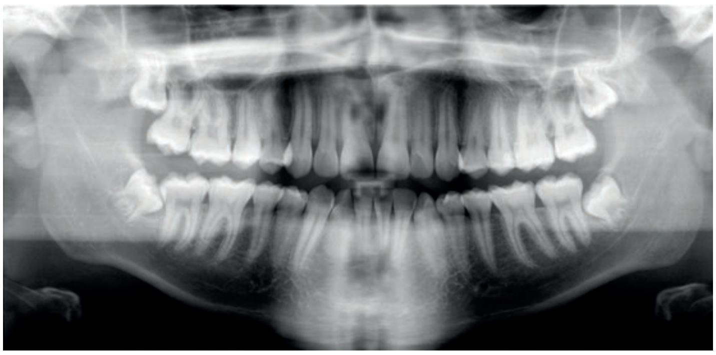
Cone-beam computed tomography (3D) is developing very rapidly in all areas of dental radiology, due to the exceptional quality of the images produced (spatial resolution of about 100 microns). The trade-off for this better diagnostic performance is that these devices deliver significantly higher doses than in conventional dental radiology.

Portable X-ray generating devices

ASN and the Dental Radiation Protection Commission (CRD) published an information notice in May 2016[3] reiterating the rules associated with the possession and utilisation of portable X-ray generating devices. They draw attention to the fact that *"the performance of radiological examinations outside a room fitted out for that purpose must remain the exception and be justified by vital medical needs, limited to intraoperative examinations or for patients who cannot be moved. Routine radiology practice in a dental surgery equipped with a compliant facility shall not carried out using mobile or portable devices"*.

This position is supported by that of HERCA (Heads of the European Radiological protection Competent Authorities), for which the use of such devices should be reserved for incapacitated patients, forensic medicine and military field operations.

3. *www.asn.fr/Informer/Actualites/Appareils-electriques-portables-rappel-de-l-ASN-et-de-la-Commission-Radioprotection-Dentaire*



Panoramic dental radiography.

1.2 Technical rules for fitting out radiology and tomography installations

Radiology installations

A conventional radiological facility usually comprises a generator (high-voltage unit, X-ray tube), associated with a support (the stand) for moving the tube, a control unit and an examination table or chair.

The mobile facilities that are commonly used in the same room, such as the X-ray generators used in operating theatres, are to be considered as fixed facilities.

As of 2013, radiological facilities must be installed in accordance with the provisions of the new ASN technical resolution 2013-DC-0349 of 4th June 2013 (see chapter 3). This resolution requires that the layout and access to the facilities comply with the radiation protection rules set by French Standard NFC 15-160 in its March 2011 version.

The new standard NFC 15-160 common to all medical radiology facilities, including computed tomography and dental radiology, introduces a method of calculating the required thickness of the protection screens in all facilities that use X-ray generators.

This resolution came into effect on 1st January 2014, and it is progressively applicable in accordance with the calendar appended to it, with compliance required by 31st December 2016 at the latest. It should however be noted that this resolution is currently being revised (see chapter 3).

2. Nuclear medicine

2.1 Presentation of nuclear medicine activities

Nuclear medicine includes all uses of unsealed radioactive sources for diagnostic or therapeutic purposes. Diagnostic uses can be divided into *in vivo* techniques, based on administration of radionuclides to a patient, and exclusively *in vitro* applications (medical biology). Functional exploration examinations can combine *in vitro* and *in vivo* techniques.

About 1,340,000 procedures were carried out in 2015[4], including 340,000 Positron Emission Tomography (PET) examinations. Nuclear medicine comprises about 700 specialist practitioners, along with another 1,000 physicians from other specialities working together in nuclear medicine units (interns, cardiologists, endocrinologists, etc.)

At the end of 2016, this sector of activity comprised 232 nuclear medicine units accommodating the associated *in vivo* and *in vitro* facilities. At the end of 2014 the number of *in vitro* diagnostic laboratories stood at less than 60 (of which 40 were independent of the nuclear medicine departments), and this number is tending to fall due to the gradual cessation of this activity.

At the end of 2016 the inventory stood at about 145 Positron Emission Tomography cameras coupled with a Computed Tomography scanner (PET-CT) and about 450 Single-Photon Emission Tomography (SPECT) cameras (including about 250 hybrid cameras, that is to say combining a CT scanner with the SPECT. Three PET cameras combined with an MRI scanner are installed and two or three installation projects are in progress.

Forty-five nuclear medicine units accommodate a total of 157 Targeted Internal Radiotherapy (TIR) rooms.[5] Nearly 160 automated or semi-automated devices for preparing radiopharmaceuticals marked with fluorine-18 and as many injection devices are used.

2.1.1 *In vivo* diagnosis

This technique consists in examining an organ or a function of the organism with a specific radioactive substance – called a radiopharmaceutical – administered to a patient. The nature of the radiopharmaceutical depends on the studied organ or function. The radionuclide can be used directly or fixed to a carrier (molecule, hormone, antibody, etc.). For example, Table 1 presents some of the main radionuclides used in various investigations.

The administered radioactive substance – often technetium-99m – is localised in the organism using a specific detector and scintigraphy techniques. This detector, called a scintillation camera or gamma camera, consists of a crystal of sodium iodide (in the majority of cameras) coupled to a computerised acquisition and analysis system. This equipment produces images of the functioning of the explored tissues or organs. The physiological or physiopathological processes can be quantified.

The majority of gamma cameras allow tomographic acquisitions, cross-sectional imaging and a three-dimensional reconstruction of the organs (Single-Photon Emission Tomography - SPECT).

Fluorine-18, a positron-emitting radionuclide, is commonly used today, frequently in the form of a marked sugar, fluorodeoxyglucose, particularly in oncology. Its utilisation necessitates the use of a special camera (Positron Emission Tomography – PET camera). The principle of operation of PET cameras is the detection

TABLE 1: Some of the main radionuclides used in the various *in vivo* nuclear medicine examinations

TYPE OF EXAMINATION	RADIONUCLIDES USED
Thyroid metabolism	Iodine-123, Technetium-99m
Myocardial perfusion	Thallium-201, Technetium-99m, Rubidium-82
Lung perfusion	Technetium-99m
Lung ventilation	Technetium-99m, Krypton-81m
Osteo-articular process	Technetium-99m, Fluorine-18
Renal exploration	Technetium-99m
Oncology - search for metastasis	Technetium-99m, Fluorine-18, Gallium-68
Neurology	Technetium-99m, Fluorine-18

4. *Dashboard of the SFMN (French Society of Nuclear Medicine and Molecular Imaging) www.sfmn.org/images/pdf/InformationsProfessionnelles/2015_NATIONAL.pdf*

5. *Source: Review of nuclear medicine department inspections (2016).*

of the coincidence of the two photons emitted when the positron is annihilated in the matter near its point of emission. Other radiopharmaceuticals marked with other positron emitters, notably gallium-68, are starting to be used.

Nuclear medicine enables functional images to be produced. It is therefore complementary to the purely morphological images obtained using the other imaging techniques. In order to make it easier to merge functional and morphological images, hybrid appliances have been developed: Positron-Emitting Tomography (PET) scanners are now systematically coupled with a CT scanner (PET-CT) and gamma-cameras are equipped with a CT scanner (SPECT-CT).

2.1.2 *In vitro* diagnosis

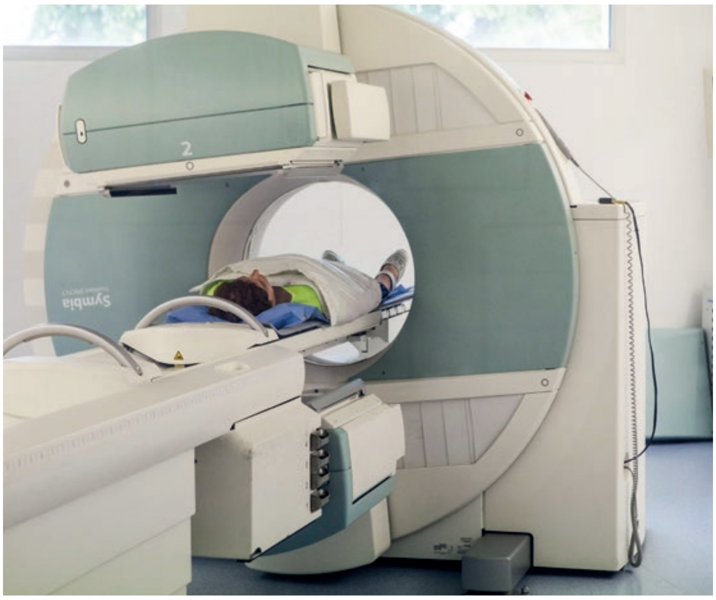
This is a medical biology technique for assaying certain compounds contained in biological fluid samples taken from the patient, such as hormones, tumour markers, etc., and it does not involve administering radionuclides to the patients. The technique uses assay methods based on immunological reactions (antigen-antibody reactions labelled with iodine-125), hence the name RIA (Radioimmunology Assay). The activities contained in the analysis kits designed for a series of assays do not exceed a few thousand becquerels (kBq). Radioimmunology is currently challenged by techniques which make no use of radioactivity, such as immuno-enzymology and chemiluminescence. A few techniques use other radionuclides such as tritium or carbon-14. Here again the activity levels involved are of the order of the kBq.

2.1.3 Targeted internal radiotherapy

Targeted Internal Radiotherapy (TIR) aims to administer radiopharmaceutical emitting ionising radiation, which will deliver a high dose to a target organ for curative or remedial purposes. Two areas of therapeutic application of nuclear medicine can be identified: oncology and non-oncological conditions (treatment of hyperthyroidism, synoviorthesis).

Several types of cancer treatment can be identified:
- systemic treatments (thyroid cancer by iodine-131, non-Hodgkin lymphoma by monoclonal antibodies marked with yttrium-90, prostate cancer with bone metastases by radium-223, etc.);
- treatments administered by selective routes (treatment of liver cancers by administering microspheres marked with yttrium-90 through a catheter placed in a hepatic artery).

Some treatments require patients to be hospitalised for several days in specially fitted-out rooms in the nuclear medicine unit to ensure the radiation protection of the personnel, of people visiting the patients and of



ASN inspection of the nuclear medicine unit of the Eugène-Marquis regional cancer centre in Rennes, July 2015.

the environment. The radiological protection of these rooms is adapted to the nature of the radiation emitted by the radionuclides, and the contaminated urine of the patients is collected in tanks. This is particularly the case with the post-surgical treatment of certain thyroid cancers. The treatments are performed by administering varying activities of iodine-131 (1.1 GBq, 4 GBq, 5.5 GBq).

Other treatments can be on an out-patient basis. Examples include administering iodine-131 to treat hyperthyroidism, strontium-89 or samarium-153 for painful bone metastases, and radium-223 for prostate cancer with bone metastases. Joints can also be treated using colloids labelled with yttrium-90, erbium-169 or rhenium-186. Finally, radioimmunotherapy can be used to treat certain lymphomas using yttrium-90 labelled antibodies.

2.1.4 Research in nuclear medicine involving humans

Research on humans in nuclear medicine has been particularly dynamic in the last few years: protocols are regularly developed for new radionuclides and vectors. These innovations mainly concern:
- PET with fluorine-18, gallium-68 and rubidium-82;
- Targeted Internal Radiotherapy with radium-223, microspheres labelled with yttrium-90, vectors labelled with yttrium-90 or lutetium-177;
- the use of lutetium-177 for the treatment of multiple endocrine neoplasia.

The use of new radiopharmaceuticals means that the radiation protection requirements associated with their use must be integrated as early as possible in the process. Indeed, given the activity levels involved, the characteristics of certain radionuclides and the preparations to produce, appropriate measures must be implemented with regard to operator exposure and environmental impact.

2.2 Layout rules for nuclear medicine facilities

Given the radiation protection constraints involved in the use of unsealed radioactive sources, nuclear medicine units are designed and organised so that they can receive, store, prepare and then administer unsealed radioactive sources to patients or handle them in laboratories (radioimmunology for instance). Provision is also made for the collection, storage and disposal of radioactive wastes and effluents produced in the facility, particularly the radionuclides contained in patients' urine.

From the radiological viewpoint, the personnel are subjected to a risk of external exposure, in particular on the fingers, due to the handling of certain radionuclides (case with fluorine-18, iodine-131 or yttrium-90), and a risk of internal exposure through accidental intake of radioactive substances. Given these conditions, nuclear medicine units must satisfy the rules prescribed by ASN resolution 2014-DC-0463 of 23rd October 2014 relative to the minimum technical rules of design, operation and maintenance that *in vivo* nuclear medicine facilities must satisfy, approved by the Order of 16th January 2015.

This resolution more specifically introduces new rules for the ventilation of nuclear medicine units (cancellation of the negative pressure requirements and hourly air renewal rates figuring in the Order of 30th October 1981) and of the rooms accommodating patients being treated for thyroid cancer with iodine-131 in particular (new negative pressure requirement). It is to be noted in addition that facilities equipped with a CT scanner coupled with a gamma camera or a PET camera must comply with the provisions of ASN resolution 2013-DC-0349 of 4th June 2013 (see chapter 3).

3. External-beam radiotherapy and brachytherapy

3.1 Description of the techniques

Alongside surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. Some 180,000 patients are treated each year, which represents nearly 4 million radiation sessions. Radiotherapy uses ionising radiation to destroy malignant cells (and non-malignant cells in a small number of cases). The ionising radiation necessary for treatment is either produced by an electric generator or emitted by radionuclides in the form of a sealed source. There are thus two ways of delivering the radiation: external-beam radiotherapy, where the source of radiation produced by a particle accelerator or radioactive sources (Gamma knife® for example) is external to the patient, and brachytherapy, where the source is placed in direct contact with the patient, within or as close as possible to the area to treat.

In December 2016, ASN counted 172 radiotherapy centres holding an ASN license, half with public status and half in private practice. At the end of 2016, external beam radiotherapy installations comprised 476 treatment devices, including 461 conventional linear accelerators. Seven hundred and fifty radiation oncologists were listed in the directory of the French Society for Radiation Oncology (SFRO) in 2016. Lastly, 63 radiotherapy centres held an ASN license to perform brachytherapy treatments.

3.1.1 External-beam radiotherapy

The irradiation sessions are always preceded by preparation of a treatment plan which defines the dose to be delivered, the target volume(s) to be treated, the irradiation beam setting and the estimated dose distribution (dosimetry) for each patient. Preparation of this plan, which aims to set conditions for achieving a high dose in the target volume while preserving surrounding healthy tissues, requires close cooperation between the radiation oncologist, the medical physicist and, when applicable, the dosimetrists.

In the vast majority of treatments, irradiation is ensured using linear particle accelerators with an isocentric arm emitting beams of photons produced at a voltage varying from 4 to 25 megavolts (MV) or electrons with an energy level of between 4 and 25 megaelectronvolts (MeV) and delivering dose-rates that can vary from 2 to 6 grays per minute (Gy)/min, although some latest-generation linear accelerators can deliver much higher dose-rates of up to 25 Gy/min (in the case of photon beams).

For certain specific therapeutic indications, several centres propose treatments that are made possible thanks in particular to the use of:
- a linear accelerator equipped with specific functions (micro multileaf collimator, additional imaging systems, robotic arm and/or table, etc.);
- a gammatherapy device equipped with more than 200 sources of cobalt-60;
- a cyclotron producing proton beams.

Stereotactic radiotherapy techniques

Stereotactic radiotherapy is a fast-growing treatment method which aims to offer millimetre-precise, high-dose irradiation using multiple mini-beams converging in the centre of the target, for intra- or extra-cranial lesions. In stereotactic radiotherapy treatments, the total dose is delivered either in a single session or in a hypofractionated manner, depending on the disease being treated. The term radiosurgery is used to designate treatments carried out in a single session.

Cyberknife.

This technique firstly requires great precision in defining the target volume to irradiate, and secondly that the treatment be as conformal as possible, that is to say that the irradiation beams follow the shape of the tumour as closely as possible.

It was originally developed to treat surgically-inaccessible non-cancerous diseases in neurosurgery (artery or vein malformations, benign tumours) and uses specific positioning techniques to ensure very precise localisation of the lesion.

It is more and more frequently used to treat cerebral metastases, but also for extra-cranial tumours.

This therapeutic technique essentially uses three types of equipment:
- specific systems such as Gamma Knife® which directs the emissions from more than 200 cobalt-60 sources towards a single focal spot (4 units are currently in service in three establishments in France), and CyberKnife® which consists of a miniaturised linear accelerator mounted on a robotic arm;
- “conventional” linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

3.1.2 Specific external-beam radiotherapy techniques

Helical radiotherapy

Helical radiotherapy, marketed under the name TomoTherapy®, enables radiation treatment to be delivered by combining the continuous rotation of an accelerator with the longitudinal movement of the patient during the treatment. The technique employed is similar to the principle of helical image acquisitions obtained with computed tomography. A photon beam, emitted at a voltage of 6 MV and a dose-rate of 8 Gy/min, shaped by a multileaf collimator enabling the intensity of the radiation to be modulated, allows the irradiation of large volumes of complex shape as well as extremely localised lesions, which may be in anatomically independent regions. It is also possible to acquire images in treatment conditions and compare them with reference computed tomography images, in order to improve the quality of patient positioning.

As at the end of 2015, 32 systems of this type were installed in France (Radiotherapy observatory INCa 2016).

Intensity Modulated Arc Therapy

Intensity Modulated Arc Therapy, an extension of Intensity Modulated Radiation Therapy[6] (IMRT), is now used in France. This technique consists in irradiating a target volume by continuous irradiation rotating around the patient. Several parameters can vary during the irradiation, including the shape of the multileaf collimator aperture, the dose-rate, the rotation speed of the arm or the orientation of the multileaf collimator.

This technique, designated under different terms (VMAT®, RapidArc®) depending on the manufacturer, is achieved using isocentric linear accelerators equipped with this technological option.

6. *The collimator leaves move during irradiation, which modulates the delivered dose in a complex manner.*

Robotic stereotactic radiotherapy

Stereotactic radiotherapy with a robotic arm consists in using a small particle accelerator producing 6 MV photons, placed on an industrial type robotic arm with six degrees of freedom, marketed under the name CyberKnife®. Furthermore, the treatment table is also positioned on a robot of the same type. By combining the movement possibilities of the two robots, it is possible to use multiple, non-coplanar beams to irradiate small tumours that are difficult to access using surgery and conventional radiotherapy. This technique enables irradiation to be carried out under stereotactic conditions, and with respiratory tracking.

Given the movement capabilities of the robot and its arm, the usual standards do not apply to the radiation protection of the treatment room and a specific study is therefore required.

As at the end of 2016, 12 sites in France were equipped with this type of radiotherapy device.

Intraoperative radiotherapy

Intraoperative radiotherapy combines surgery and radiotherapy, performed concomitantly in the operating theatre environment. The dose of radiation is delivered to the tumour bed during surgical intervention.

In March 2011, the French National Cancer Institute (INCa) launched a call for proposals to support the installation of intraoperative radiotherapy equipment for the treatment of breast cancer patients. One of the objectives of this call for proposals was to carry out a medico-economic evaluation of radiotherapy treatments involving a small number of sessions compared with standard breast cancer treatments. Seven projects deploying an INTRABEAM® accelerator producing X-rays with a voltage of 50 kV were selected and launched between 2011 and 2012.

In April 2016, the French National Authority for Health (HAS) published the results of its assessment[7]. According to the HAS, current knowledge is insufficient to demonstrate the benefits of intraoperative radiotherapy in the adjuvant treatment of breast cancer compared with standard external-beam radiotherapy. The HAS concludes that at present, the elements necessary to propose that it be covered by the health insurance scheme are not yet established and considers that the clinical and medico-economic studies must be continued in order to acquire clinical data over the longer term. At the end of this assessment, the HAS does however recommend continuing the assessment of intraoperative radiotherapy for clinical research purposes.

7. *www.has-sante.fr/portail/jcms/c_2562276/fr/evaluation-de-la-radiotherapie-peroperatoire-rtpo-dans-le-cancer-du-sein*

Hadron therapy

Hadron therapy is a treatment technique based on the use of beams of charged particles - protons and carbon nuclei - whose particular physical properties ensure highly localised dose distribution during treatment (Bragg's peak). Compared with existing techniques, the dose delivered around the tumour to be irradiated is lower, therefore the volume of healthy tissue irradiated is drastically reduced. Hadron therapy allows the specific treatment of tumours.

Hadron therapy with protons is currently practised in two centres in France - the Curie Institute in Orsay (equipment renewed in 2010) and the Antoine Lacassagne Centre in Nice (new equipment installed in 2016).

According to its advocates, hadron therapy with carbon nuclei is more appropriate for the treatment of the most radiation-resistant tumours and could bring several hundred additional cured cancer cases per year. The claimed biological advantage is reportedly due to the very high ionisation of these particles at the end of their path, combined with a reduced effect on the tissues they pass through before reaching the target volume.

3.1.3 Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours, particularly in the head and neck, the skin, the breast, the genitals and the bronchial tubes.

This technique consists in implanting radionuclides, exclusively in the form of sealed sources, either in contact with or inside the solid tumours to be treated.

The main radionuclides used in brachytherapy are caesium-137, iridium-192 and iodine-125.

Brachytherapy techniques involve three types of applications:

a- Low Dose-Rate (LDR) brachytherapy:
- delivering dose-rates of between 0.4 and 2 Gy/h;
- using iodine-125 sources in the form of seeds implanted permanently.

For the treatment of prostate cancers, iodine-125 sources are used. These sources (seeds), 4.5 mm long and 0.8 mm in diameter, are positioned permanently inside the patient's prostate gland. Their unit activity is between 10 and 30 MBq and treatment requires about a hundred seeds representing a total activity of 1 to 2 gigabecquerels (GBq).

b- Pulsed Dose-Rate (PDR) brachytherapy:
- delivering dose-rates of between 2 and 12 Gy/h;
- using iridium-192 sources in the form of a source 3.5 mm long, 1 mm in diameter and with maximum activity of 18.5 GBq, implemented with a specific source afterloader.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate for the maximum activity of the radioactive source used. It is based on the use of a single radioactive source which moves in steps, and stops in predetermined positions for predetermined times.

The doses delivered are identical to those of low dose-rate brachytherapy, but are delivered in sequences of 5 to 20 minutes, or sometimes even 50 minutes, every hour for the duration of the planned treatment, hence the name pulsed dose-rate brachytherapy.

Pulsed dose-rate brachytherapy offers a number of radiation protection advantages:
- no handling of sources;
- no continuous irradiation, which enables the patient to receive medical care without irradiating the staff or having to interrupt the treatment.

However, it is necessary to make provisions for accident situations related to the operation of the source afterloader and to the high dose-rate delivered by the sources used.

HDR afterloader.

c - High Dose-Rate (HDR) brachytherapy:
- delivering dose-rates in excess of 12 Gy/h;
- using iridium-192 sources in the form of a source 3.5 mm long, 1 mm in diameter and with maximum activity of 370 GBq, implemented with a specific source afterloader. Some afterloaders use a high-activity (91 GBq) cobalt-60 source.

This technique does not require patient hospitalisation in a room with radiological protection and is performed on an outpatient basis in a room with a configuration comparable to that of an external- beam radiotherapy room. The treatment is performed with an afterloader containing the source and involves one or more sessions of a few minutes, spread over several days.

High dose-rate brachytherapy is used mainly for gynaecological cancers. This technique can also be used to treat prostate cancers, usually combined with an external beam radiotherapy treatment.

3.2 Technical rules applicable to installations

3.2.1 Technical rules applicable to external-beam radiotherapy installations

The devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable bunkers (wall thickness can vary from 1 m to 2.5 m of ordinary concrete). A radiotherapy installation comprises a treatment room including a technical area containing the treatment device, a control station outside the room and, for some accelerators, auxiliary technical premises.

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. A specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the Person Competent in Radiation Protection (PCR).

This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below the treatment room. This study should be included in the file presented to support the application for a license to use a radiotherapy installation, examined by ASN.

In addition, safety systems must indicate machine status (operating or not) and must switch off the beam in an emergency or if the door to the irradiation room is opened.

3.2.2 Technical rules applicable to brachytherapy installations

The rules for radioactive source management in brachytherapy are comparable to those defined for all sealed sources, regardless of their use.

Low Dose-Rate brachytherapy

In cases where permanent implant techniques are used (seeds of iodine-125 in particular for treating prostate cancer), the applications are carried out in the operating theatre with ultrasonography monitoring, and do not require hospitalisation in a room with radiation protection.

Pulsed Dose-Rate brachytherapy

This technique uses source afterloaders (generally 18.5 GBq of iridium-192). The treatment takes place in hospital rooms with radiological protection appropriate for the maximum activity of the radioactive source used.

High Dose-Rate brachytherapy

As the maximum activity used is high (370 GBq of iridium-192 or 91 GBq of cobalt-60), irradiation can only be carried out in a room with a configuration comparable to that of an external beam radiotherapy room.

4. Blood product irradiators

4.1 Description

The irradiation of blood products is used to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with an average dose of about 20 to 25 grays.

Since 2009, source irradiators have been gradually replaced by X-ray generators. As at 1st November 2016, the irradiator fleet comprises 30 devices equipped with X-ray generators.

In accordance with ASN resolution 2015-DC-0531 of 10th November 2015, X-ray generators used for the purpose of irradiating products from the human body are now subject to declaration. This change of administrative system does not apply to the licenses issued until now which are considered equivalent to a declaration with indefinite validity.

4.2 Technical rules applicable to facilities

A blood product irradiator must be installed in a dedicated room designed to provide physical protection (fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, must be limited to authorised persons only.

The layout of irradiators equipped with X-ray generators shall comply with the provisions of ASN's technical resolution 2013-DC-0349 of 4th June 2013, currently being revised (see chapter 3).

5. The state of radiation protection in the medical sector

Radiation protection in the medical sector concerns patients receiving treatment or undergoing diagnostic examinations, health professionals (physicians, medical physicists, radiographers, nurses, nursing auxiliaries, etc.) who are required to use or participate in the use of ionising radiation, and also the population, such as members of the public who may be present within a health facility, or population groups that could be exposed to waste or effluents from nuclear medicine units.

Since 2008, ASN has periodically produced documents presenting a national synthesis of the main lessons learned from inspections, based on indicators that determine compliance with the regulatory radiation protection requirements. These syntheses enable the state of radiation protection in the different areas (radiotherapy, nuclear medicine, interventional radiology, etc.) to be assessed for publication in the annual report. The syntheses are based on the findings established during the year preceding their publication. ASN also publishes annual or several-year national appraisals of inspection results; these are available at *www.asn.fr*.

2016 saw the publishing of one computed tomography review (inspections of 2015), one radiotherapy review (inspections of 2014) and two nuclear medicine reviews, one covering three years (inspections of 2012 to 2014) and one covering the inspections carried out in 2015.

5.1 Exposure situations in the medical sector

5.1.1 Exposure of health professionals

The risks for health professionals arising from the use of ionising radiation are above all the risks of external exposure generated by the medical devices (devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed and unsealed sources (particularly after administering radiopharmaceuticals). When using unsealed sources, the risk of contamination must be taken into consideration in the risk assessment (particularly in nuclear medicine).

The prevention of risks of exposure of health professionals to ionising radiation is required by provisions of the Labour Code concerning occupational radiation protection.

5.1.2 Exposure of patients

The exposure of patients to ionising radiation must be distinguished from the exposure of workers and the public insofar as it is subject to no dose limits whatsoever. The only principles applicable remain those of justification and optimisation (see introduction to this chapter).

The patient's exposure situation differs depending on whether diagnostic or therapeutic medical applications are being considered. In the first case, it is necessary to optimise the exposure to ionising radiation in order to deliver the minimum dose required to obtain the appropriate diagnostic information or to perform the planned interventional procedure; in the second case, it is necessary to deliver the highest possible dose needed to destroy the targeted cells while at the same time preserving the healthy neighbouring tissues to the best possible extent.

Whatever the case however, control of the doses delivered during imaging examinations and treatments is a vital requirement that depends not only on the skills of the patient radiation protection professionals but also on the procedures for optimising and maintaining equipment performance.

The steps undertaken by ASN since 2011 in collaboration with the health Authorities and medical imaging professionals are designed to progressively ensure fully effective control over the doses delivered to patients. Many measures have been taken in this respect, including the updating and reinforcement of training in patient radiation protection for interventional practitioners in particular, the development of a quality assurance baseline in the radiology departments and centres provided for in Cancer Plan 3, the development of access to MRI and the defining of reference levels for the most highly irradiating interventional procedures.

5.1.3 Exposure of persons providing support and comfort to patients

The persons close to patients having been treated with radiopharmaceuticals (e.g. treatment of thyroid cancer or hyperthyroidism with iodine-131) can be exposed to ionising radiation for a few days due to the residual activity in the patient. In 2016, ASN asked IRSN (Institute of Radiation Protection and Nuclear Safety) to issue recommendations for setting dose limitations for persons providing support or comfort to patients during their medical diagnosis or treatment. The Advisory Committee of Experts for Medical Exposure (GPMED) has given an opinion on these recommendations which will be published in 2017.

5.1.4 Exposure of the general public and environmental impact

With the exception of incident situations, the potential impact of medical applications of ionising radiation is likely to concern:
- members of the public who are close to facilities that emit ionising radiation but do not have the required protection;
- persons close to patients having received a treatment or a nuclear medicine examination, particularly those using radionuclides such as iodine-131, or a brachytherapy with iodine-125;
- the specific professional categories (e.g. sewage workers) liable to be exposed to effluents or waste produced by nuclear medicine units.

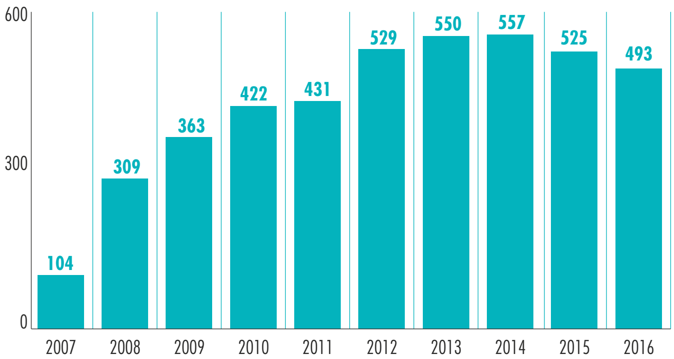
The available information concerning radiological monitoring of the environment carried out by IRSN, in particular the measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the variations in the background radiation. On the other hand, radioactivity measurements in major rivers or wastewater treatment plants in the larger towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (e.g. iodine-131) exceeding the measurement thresholds. The available data on the impact of these discharges indicate doses of a few tens of microsieverts per year for the most exposed individuals, in particular people working in the sewerage networks and wastewater treatment plants (source: IRSN studies, 2005 and 2014). Furthermore, no trace of these radionuclides has ever been measured in water intended for human consumption (see chapter 1).

5.2 Some general indicators

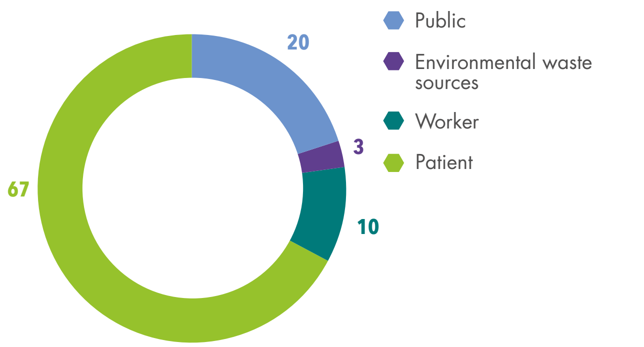
5.2.1 Licenses and declarations

In 2016, ASN issued:
- 8,860 acknowledgements of receipt of declarations of medical and dental diagnostic radiology devices, of which nearly 73% concerned dental radiology devices;
- 883 licenses (for entry into service, renewal or cancellation), of which 58% were in computed tomography, 22% in nuclear medicine, 15% in external-beam radiotherapy, 4% in brachytherapy and 1% for blood product irradiators.

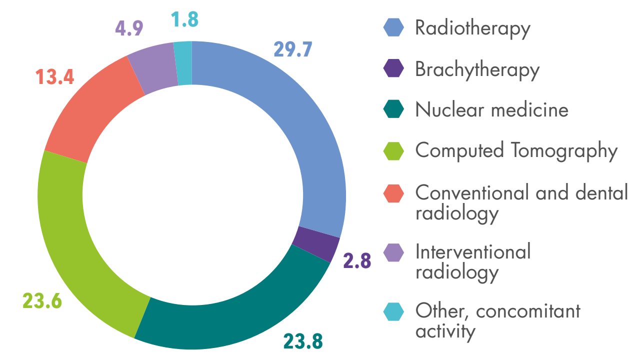
MEDICAL ESRS



NOTIFICATION CRITERIA FOR ESRS in the medical field notified to ASN in 2016 (%)



ESRS IN THE MEDICAL FIELD notified to ASN in 2016 (%)



5.2.2 Dosimetry of health professionals

According to the data collected in 2015 by IRSN, 228,371 people working in sectors using ionising radiation for medical and veterinary purposes were subject to dosimetric monitoring of their exposure. Medical radiology (52%) and dental care (22%) alone account for nearly 74% of the medical personnel exposed.

More than 99% of the health professionals monitored in 2015 received an annual effective dose below 1 millisievert (mSv). One case of exceeding the annual effective dose limit of 20 mSv was recorded (in radiotherapy) and one of exceeding the annual dose limit at the extremities (500 mSv) was reported in interventional radiology. The average dose for persons whose dosimetry exceeded the detection threshold is 0.34 mSv/year.

Of the 2,031 persons monitored for an internal exposure risk, 28 (1%) were detected positively due to the incorporation of radionuclides. An effective dose calculation was carried out for three workers and in the three cases the effective dose engaged remained below 1 mSv.

5.2.3 Report on Significant Radiation protection Events

Significant Radiation protection Events (ESR) have been notified to ASN since 2007. These notifications provide professionals with increasingly valuable experience feedback, helping to improve radiation protection in the medical field. In 2016, ASN issued two circular letters, one for nuclear medicine departments and the other for radiotherapy departments, and it published a bulletin on the safety of radiotherapy patients (see points 5.3.3 and 5.5.5). It also participated in the publication of an article for the Congress on risk control and operating safety organised by the Institute for risk control entitled *"Organisational analysis assisting the CREX (experience feedback analysis committees), an experiment in nuclear medicine"*.

Since July 2015, radiotherapy departments can notify significant radiation protection events on line. This portal falls within the framework of the single vigilance portal created by the Ministry of Health. It will be extended to cover the entire medical sector early 2017.

Since 2012, the number of ESRs stands at about 500 per year. In 2016, the number of ESRs notified to ASN in the medical field stood at 493 (525 in 2015). The incident notices are published on *www.asn.fr*.

The graphs opposite illustrate the breakdown of the number of ESRs in 2016 by area and how they have evolved since 2007, along with the breakdown of events by notification criterion.

Eighty percent of the notified events originate from radiotherapy (32%), nuclear medicine (24%) and computed tomography (23%) departments. These events chiefly concern exposure of patients (67%) and foetuses in pregnant women unaware of their pregnancy (20%).

The events notified to ASN in 2016 show that the consequences with the most significance in radiation protection terms concern:
- for workers: nuclear medicine (contamination of workers, external exposure) and interventional radiology (external exposure of operators and, in particular, exposure of the extremities) although it is difficult to have exhaustive knowledge of these situations because the wearing of dosimeters is not common among interventional practitioners;
- for the patients: interventional practices with deterministic effects observed in patients having undergone long and complex procedures, radiotherapy with dose fractionation errors and wrong-side errors and, lastly, nuclear medicine, with radiopharmaceutical administration errors;
- for the public and the environment: nuclear medicine, with leaks from radioactive effluent pipes and containments.

Information detailed by area is provided on the following points.

In 2016, as part of the transposition of Euratom Directive 2013, the HERCA working group tasked with medical applications of ionising radiation organised two seminars in Montrouge, one of which focused on accidental and unintentional exposures (Article 63 of the Directive). This seminar was attended by 44 participants representing European and international medical societies (ESR, ESTRO, EFOMP, EFRS, ISRRT), European and international organisations (European Commission, IAEA, COCIR) and radiation protection and health authorities (*www.herca.org*).

5.3 Radiation protection situation in external-beam radiotherapy

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007. 2015 saw the completion of the four-yearly inspection programme for the 2012-2015 period, intended to verify that the procedures (formally written practices) were correctly implemented. The systematic check points focused on the treatment quality and safety management system, the management of malfunctions and the organisation of medical physics. In 2014 and 2015 the inspections focused more specifically on management of the skills of personnel assigned to dosimetry and the radiographers assigned to treatment preparation, checking correct implementation of the treatment preparation procedures and verifying positioning during treatments and the obligations regarding maintenance and quality control of medical devices.

Four broad inspection themes have been selected for the 2016-2019 period: risk management, skills management, the implementation of new techniques or practices and the control of equipment. All radiotherapy departments were informed of these new lines of inspection in early 2016.

5.3.1 Radiation protection of radiotherapy professionals

When the facilities are correctly designed, the radiation protection risks for the professionals in radiotherapy are limited due to the protection provided by the walls of the irradiation room.

In 2015 the inspectors inspected the methods of verification and maintenance of the radiotherapy and associated computed tomography facilities. These methods are formalised in 76% of the inspected centres. The external quality control of the scanners (used during treatment preparation) is carried out in accordance with the regulatory annual frequency in 90% of the inspected centres.

Performance of the internal quality control and external quality control of external-beam radiotherapy facilities must be audited by an organisation approved by the French Health Products Safety Agency (ANSM). In 2015, 17% of the centres inspected had not carried out this audit.

5.3.2 Radiation protection of radiotherapy patients

In 2015, ASN carried out 109 inspections in 104 radiotherapy centres, representing 60% of the centres. The positive trend, that started in 2008 with regard to the increased human resources deployed in medical radiation physics, is continuing. Furthermore, a campaign of unannounced inspections confirmed the presence of a medical physicist throughout the duration of treatments during the summer vacation period.

Implementation of a quality management system

ASN has observed continuous improvement in the implementation of the quality and safety management requirements in radiotherapy departments since 2008; and considers that the findings established at the end of 2015 confirm this analysis. Nevertheless, disparities between centres persist, and failures to meet the regulatory deadlines set by ASN technical resolution

2008-DC-0103 of 1st July 2008 continue to be observed. These essentially concern the continuous improvement of the documentary system relative to the safety and quality of treatments, the defining of treatment safety and quality objectives and the performance of study of the risks run by the patients.

The results of the inspections performed in 2015 show in particular that:
- 4% of the inspected centres had not designated an operational quality manager; however, 7% of the centres inspected have designated operational quality managers but have not defined their missions, objectives or the means at their disposal.
- 96% of the centres inspected have formalised the mapping of the processes.
- 88% of the centres inspected have defined treatment quality and safety objectives, but 25% do not follow them entirely or do not update them.
- 53% of the centres perform internal audits and process reviews but 30% of them only conduct a management review.
- The study of the risks run by the patients has been carried out in 100% of the centres inspected in 2015 but the analysis is updated in only 68% of the centres, even though this updating is essential, especially when new techniques are introduced.

Control of treatment procedures

Based on the analysis of the events notified to ASN, inspections have targeted certain treatment steps in order to verify the existence of procedures formalising the practices and their effective implementation. In 2015 (as in 2014), treatment preparation (computed tomography and dosimetry) and the verification of patient positioning during treatment were examined. The findings are similar to those made in 2014. It was observed that:
- 96% of the inspected centres have devised a procedure for setting up the patient under the scanner for the principal locations treated.
- 95% of the inspected centres have devised a treatment preparation procedure for the principal locations.
- 100% of the inspected centres have the dosimetric treatment plan approved by the medical physicist and the radiation oncologist before delivering the treatment.
- 93% of the inspected centres check the position by imaging at least once per week. This imaging is approved by the radiation oncologist in 90% of the centres. Progress is nevertheless required with regard to the methods of performing and supervising the positioning verifications, as only 77% of the centres have formalised the criteria for determining when a medical opinion must be requested.

Management of risks and addressing malfunctions

An internal record of malfunctions has been put in place in virtually all the centres, given that 99% of the centres inspected in 2015 have such a record, but 9% of the centres use it rarely or not at all.

ASN observed that 100% of the inspected centres have an organisational set-up enabling them to regularly bring together multidisciplinary skills to analyse significant radiation protection events. However, although 96% of the centres have identified improvement actions after analysing these events, 32% implement them only partially or not at all. The involvement of medical institution management and the medical profession is vital for the success of these experience feedback analysis procedures.

Hypofractionated treatments

The analysis of events notified to ASN has underlined the high potential risks of hypofractionated treatments. ASN focused its inspections on this type of treatment in 2016, and on the robustness of the defence barriers in particular. One-off inspections were carried out on, among other things, the application of the principle of dose optimisation for organs and tissues at risk.

Accident-inducing situations

Several inspections carried out in 2016 further to complaints, to the deployment of a new technique or in the context of investigations further to the notification of an ESR revealed situations that could lead to accidents. Thus, an uncontrolled increase in activity (number of treatments, complexity of treatments, deployment of a new technique), the shortage - sometimes chronic - of radiation oncologists, differences in practices, particularly

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The new techniques in radiotherapy

The GPMED's recommendations on the conditions of implementation of new techniques in radiotherapy and the associated practices issued on 10th February 2015 are now monitored by the radiotherapy monitoring committee coordinated by the INCa. ASN remains highly attentive to the monitoring of these actions, especially those concerning adaptation of the means necessary for deploying these new techniques or practices and the implementation of clinical audit procedures. The investigations carried out further to significant event notifications support ASN's concerns by demonstrating firstly that the impact of the deployment of new techniques and practices on the activity of the personnel was not sufficiently analysed and that secondly these periods of intense activity could render the safety barriers less effective.

in case of a merger or collaboration between several centres, weaken the safety measures in place, leading in one case to an ESR rated level 2 on the ASN-SFRO scale, which comprises eight levels from 0 to 7.

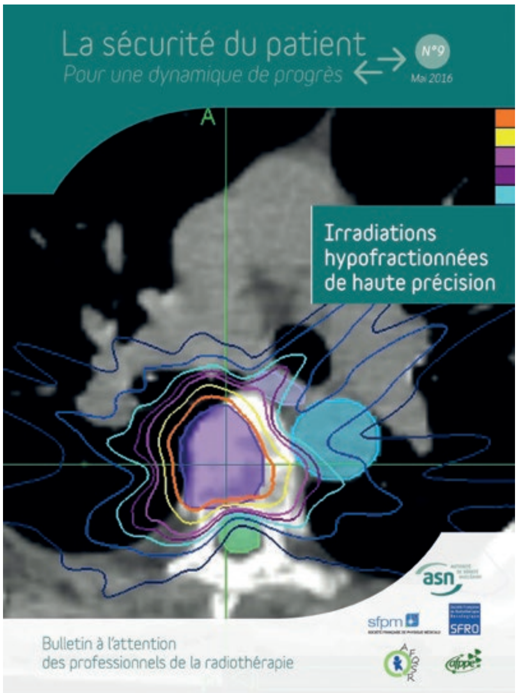
Consequently, ASN is concerned that technical, organisational or human changes are not sufficiently analysed to determine the impact on the activity of the operators and, when risks are identified in the *a priori* risk analysis, they do not result in the strengthening of the required safety barriers. ASN will take these findings particularly into account in future inspections.

5.3.3 Notified events in external-beam radiotherapy

148 significant events in radiotherapy were notified in 2016. ASN observes a significant reduction in the ESRs notified by radiotherapy departments. Indeed, since 2008, some 240 ESRs per year were being notified. While the drop in the number of notifications could be partly due to a loss of momentum in the experience feedback initiatives, which ASN has observed through its inspections, a more detailed analysis must be carried out with the radiotherapy professionals to understand the reasons for this drop.

The majority of events concerning patients notified in 2016 occurred in radiotherapy departments (83%). The large majority of ESRs (97%) had no clinical consequences for the patients.

Seventy percent of the events were rated level 1 on the ASN-SFRO scale in 2016. Two events notified in 2015 by the same centre were rated in 2016 as level 1+ on the ASN-SFRO scale. Further to these errors, ASN asked IRSN to examine the conditions of determining the absorbed dose for beams used in radiotherapy. IRSN's appraisal (opinion of March 2016) confirmed the evaluations made by the radiotherapy centre and revealed a lack of metrological rigour when making modifications to procedures and in the use of reference protocols for measuring the dose. In May 2016, ASN sent a letter drawing up the lessons learned from the events to all radiotherapy departments.



Bulletin No. 9, *Patient safety*.

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Dose protraction or fractionation errors

Given the regular notification of dose protraction or fractionation errors, ASN conducted investigations in order to feed back information to the radiotherapy departments. Thus, between January 2013 and June 2015, ASN was notified of 17 significant radiation protection events linked to a problem of fractionation (11) or protraction (6) of the dose to deliver during external-beam radiotherapy treatments.

The implications for protection raised by these data are all the greater given that the number of hypofractionated stereotactic treatments is bound to increase in the coming years (see *Patient safety* bulletin No. 9). Consequently, in July 2015 ASN mandated IRSN to carry out a technical, organisational and human analysis of the causes of these malfunctions. In this context IRSN issued recommendations* for users and suppliers.

These recommendations were discussed in a meeting organised by ASN in the presence of two RIS/R&V** manufacturers (Varian and Elekta), the AFQSR (French Association for Quality and Safety in Radiotherapy), the AFPPE (French Association of Radiographers, the SFPM (French Society of Medical Physicists), the ANSM (French Health Products Safety Agency) and IRSN. The main conclusions of this study and the reflections of the multidisciplinary working group dedicated to giving experience feedback to the radiotherapy professionals, have enabled ASN to issue recommendations to the radiotherapy centres through *Patient safety* bulletin No. 10 published in January 2017.

** IRSN Opinion published in July 2016 (www.irsn.fr)*

*** RIS/R&V = Radiotherapy Information System / Record and Verify*

In addition, three ESRs rated level 2 were notified in radiotherapy in 2016. One was a dose error further to incorrect manual entry of the number of radiotherapy sessions when the treatment planning software was changed, one was a laterality error and the third a computer blockage that resulted in a modification of the volumes of two cerebral metastases to treat. In addition, two ESRs notified in 2015 were rated level 2 in 2016. These ESRs were associated with a laterality error and a fractionation error during manual transcription of the prescription.

As in preceding years, these events highlight the organisational weaknesses in managing the movements of patients' files, in validation steps that are not sufficiently explicit and in the upkeep of patients' files to ensure an overall view and access to the necessary information at the right time. Variations in practices within the same centre, frequent task interruptions, a heavy and uncontrolled workload with an impact on treatment amplitudes, or the deployment of a new technique or practice, are all risk factors.

5.3.4 Summary and outlook

To conclude, ASN considers that treatment quality and safety management are now integrated in the functioning of radiotherapy centres, even if disparities between centres are observed. ASN does however observe that the risk management procedures (risk analyses and feedback from significant radiation protection events) are insufficiently used and taken into account to further enhance treatment safety.

The progress made by the centres, the findings from inspections, the lessons learned from the ESRs, the new risks associated with the deployment of new techniques and practices mean that ASN has to constantly adapt its oversight. New themes have been defined for the inspections carried out during the 2016-2019 period. ASN continues its graduated approach by reducing inspection frequency which, as from 2016, will be once every 3 years (instead of every 2 years previously). Nevertheless, in view of the diversity of situations encountered, the centres displaying weaknesses or particular risks shall be inspected more frequently at intervals determined by the ASN regional divisions.

ASN oversight, focusing in the last few years on the technical barriers (performance of equipment quality checks, double calculation of monitor units, implementation of *in vivo* dosimetry, etc.) plus the implementation of quality assurance procedures should:
- allow the centre's risk management capability to be examined by highlighting the ways in which training, material resources, the working environment or organisation, allow or prevent the performance of procedures in complete safety with regard to patient radiation protection;
- question more extensively the actual functioning of the organisation and the work practices, the constraints on the operators and the variations in practices with regard to the quality baseline requirements;
- take account of the lessons learned from the analysis of the events notified to ASN and the risks generated in certain periods of the life cycle of the centres (implementation of new techniques or practices, collaboration between centres).

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Mermoz medical imaging centre - Jean Mermoz private hospital - Lyon

On 19th August 2016, ASN was informed of a significant radiation protection event in radiotherapy during which a patient received a higher dose than prescribed, and provisionally rated this event at level 2 on the ASN-SFRO scale.

The treatment was delivered in sessions of 2.8 Gy instead of 2 Gy. The error was detected fortuitously after the 31st session in a treatment comprising 35 sessions, in the step of provisional calculation of the dose distribution. The number of sessions entered manually (25 instead of 35) in the Treatment Planning System (TPS) was incorrect, leading finally to the calculation and delivery of higher-than-planned dose per session.

The information gathered during the inspection shows that the event was caused by several factors, particularly organisational factors. The event occurred in a context of change of TPS and high work load for the medical radiation physics team due to the implementation of a new treatment technique. Furthermore, the software environment modification affected the means of monitoring certain treatment parameters, including fractionation and control of the transfer of data from the TPS into the treatment parameters of the record and verify system.

The centre took immediate measures to tighten the verifications of the treatment parameters and to optimise conditions of involvement of the radiation physics team. Other measures are currently being deployed to improve the means for double-checking treatment data. ASN will monitor the measures taken by the centre and the ongoing actions.

5.4 Radiation protection situation in brachytherapy

Twenty brachytherapy centres were inspected in 2015 (31% of the centres).

5.4.1 Worker radiation protection

The occupational radiation protection measures deployed in 2015 by the brachytherapy departments were considered satisfactory, but various points can be improved:
- All the centres inspected in 2015 have designated a Competent in Radiation Protection (PCR) specifically for this activity, but in 11% of the centres the PCR's missions have not been defined and in 22% of the centres the resources are still insufficient.
- All the inspected centres monitor the personnel using passive dosimetry and 95% monitor personnel working in controlled areas using active dosimetry.
- All the inspected centres have carried out working environment analyses but in 28% of the centres they do not cover all the jobs.
- The assessment of risks is carried out in 94% of the centres but in 22% of them the assessment is not consistent with the delimitation of regulated areas.
- 89% of the centres have drawn up the technical programme of internal and external radiation protection verifications. These verifications are carried out in 94% of the inspected centres, but in 39% of them the internal technical verifications are not exhaustive or are not carried out at the required frequency.

5.4.2 Radiation protection of patients

The treatment quality and safety management system

The results of the inspections carried out in 2015 show that the majority of the brachytherapy departments implemented a quality approach. Despite being supported by the external-beam radiotherapy departments, shortcomings remain in the implementation of the approach:
- All the centres inspected have designated an operational quality manager, but 17% have not formalised this, nor have they defined the person's missions, objectives or the means at their disposal.
- 89% of the centres inspected have formalised the mapping of the processes.
- 88% of the centres inspected have defined treatment quality and safety objectives, but 11% do not follow them entirely or do not update them.
- The study of the risks run by the patients in brachytherapy is carried out in 89 % of the centres inspected in 2015 but 33% do not update it.
- 89% of the centres have put in place a management review and 61% also conduct internal audits and process reviews.

Training and information

Training in patient radiation protection has been carried out in 89% of the centres inspected in 2015.

Maintenance and quality controls

In 2015, the majority of the centres had an inventory of medical devices and a register for recording maintenance operations and quality controls. In the absence of an ANSM decision defining the quality controls for brachytherapy devices, the nature of the quality controls results from past practices and is based on recommendations provided by device manufacturers or professionals.

Maintenance of the HDR and PDR afterloaders is ensured by the manufacturers. More specifically, the manufacturers perform the afterloader operating verifications when the sources are replaced. The brachytherapy units rely on these verifications to guarantee correct operation of the devices. The source activity is verified at each delivery and source removal verifications are also carried out.

5.4.3 Management of sources

Management of the brachytherapy sources is satisfactory. All the centres inspected in 2015 record the tracking of source movements, transmit the source inventory to IRSN and store the sources waiting to be loaded or collected in a suitable place. 39% of the centres inspected in 2015 had expired sealed sources in storage.

5.4.4 Emergency situations and the management of malfunctions

The majority of the centres have put in place appropriate measures for:
- internal recording of events that are precursors of malfunctions or undesirable situations;
- an organisation allowing the multidisciplinary analysis of the causes of internal malfunctions or ESRs;
- the implementation of an events management procedure;
- seeking improvement actions for the analysed events.

In 2016, the jamming of an iridium-192 source in a PDR afterloader led to the exposure of a worker and a patient. Another event of this type had occurred in 2013 with an HDR afterloader. These events emphasise the importance of training the personnel in emergency measures. This training must focus in particular on the emergency measures to implement in the event of possible loss of control of the high-activity source (jamming of the source, for example). Instructions on the risk of source jamming are provided in the brachytherapy units. However, exercises to prepare for and assess intervention methods are still very rare.

Compliance with the requirements relative to advanced training in worker radiation protection when using high-activity sealed sources is still unsatisfactory (50% of the centres have carried out this training).

5.4.5 Notified events in brachytherapy

13 ESRs were notified in brachytherapy in 2016.

One event was rated level 2+ on the ASN-SFRO scale. A mix-up between batches of permanent iodine-125 seed implants used for prostate brachytherapy led to an activity error of about 8% in the treatment of two patients. This event revealed iodine seed management deficiencies in the verifications carried out on reception of the seeds.

Further notified events concerned the jamming of an iridium-192 source in a PDR afterloader which led to the exposure of a worker and a patient, and the premature interruption of a PDR treatment by a resident due to misinterpretation of the machine's data.

Lastly, errors in the target volume to treat occurred due to incorrect positioning of permanent implants of iodine-125 and an iridium-192 source in the catheter, the use of an afterloader of a different size to that planned, and the accidental movement of brachytherapy afterloader during treatment.

The analysis of these events underlines that the control of risks in brachytherapy must be based on appropriate quality controls and the implementation of organisational measures to better manage the sources and emergency situations.

5.4.6 Summary

Despite encouraging findings from the inspections carried out in the last few years, ASN considers that efforts must be made to reinforce the radiation protection training of workers when holding high-activity sources and in the performance of the radiation protection internal technical verifications.

5.5 Radiation protection situation in nuclear medicine

As at the end of 2016, 232 *in vivo* nuclear medicine facilities were licensed in France and the overseas *départements*.

About 23% of the *in vivo* nuclear medicine departments (metropolitan France and overseas *départements*) have been inspected, which represents 53 departments. Stepping up the graduated approach to oversight has resulted, as of 2013, in changes in inspection frequencies by distinguishing:
- facilities performing only diagnostics, which are now inspected once every 5 years instead of every 3 years;
- departments performing therapies, for which a 3-year inspection frequency is maintained.

The departments inspected had on average two gamma cameras and about half of them were equipped with a PET scanner. Of the departments equipped with a PET scanner:
- 84% have an automatic or semi-automatic syringe-filling device;
- 32% have an automatic or semi-automatic injection device;

In addition, 39 departments (73% of the departments inspected) were equipped with a specific extraction system used for pulmonary examinations.

Nine of the 53 facilities inspected had targeted internal radiotherapy (i.e. brachytherapy) rooms.

5.5.1 Radiation protection of nuclear medicine professionals

ASN considers that weaknesses persist with regard to compliance with occupational radiation protection requirements. This is because the working environment analyses are not carried out for all the jobs and do not always include the internal exposure of the workers. While most of the departments have drawn up a programme of radiation protection technical controls, these controls are still frequently incomplete and are carried out at the regulatory frequencies.

Progress must be made in the continuous training of workers in radiation protection, as such training is only provided and recorded in slightly more than half of the inspected facilities. As in the preceding years, the shortcomings in continuous training chiefly concern newly hired persons, nuclear medicine physicians, physicians involved on a non-regular basis (cardiologists) and cleaning personnel.

When outside companies perform work in the nuclear medicine facility, only 34% of the departments formalise the conditions of coordination of the prevention measures. This figure was 37% in 2014.

In cases where automated syringe-filling or radiopharmaceutical injection systems are used, the inspectors examined the taking into account of the good practice recommendations provided in the ASN circular letter published in May 2013. In more than 80% of the facilities concerned, the users were trained in the use of these devices in routine and failure situations. The verifications to carry out were formalised and traced and the utilisation protocols subject to strict quality assurance procedures in nearly 60% of the facilities concerned (20/53).

In 2015, as in 2014, all the departments have defined conditions and means of protection aiming at limiting exposure of workers and the public during the transport of unsealed sources for use outside the nuclear medicine department (utilisation of a radiopharmaceutical in the neurology department or for a synoviorthesis, etc.).

5.5.2 Radiation protection of patients in nuclear medicine

ASN considers that patient radiation protection must be improved by subjecting, in particular, the controls carried out when using automated systems to strict quality assurance procedures.

Although the diagnostic reference levels are sent to IRSN as a matter of course, they are - as in the preceding years - only analysed in 81% of the cases.

The information relative to the provision and recording of occupational training in patient radiation protection is provided in 74% of the facilities inspected. Failures to monitor and record this training mainly concern physicians providing services on a private basis.

External quality control of equipment has been making regular progress since 2012 thanks to the increase in the number of organisations approved by the ANSM to carry out these controls. In 2015, 79% of the departments performed this control.

In 63% of the facilities inspected, work to optimise the activity of administered radiopharmaceuticals was carried out on all the protocols, while in the remaining 37% it was only carried out on certain protocols (more frequent examinations, paediatric examinations, etc.). In 58% of the facilities inspected, the protocols delivered with the computed tomography scanner combined with the gamma-camera had all been optimised.

5.5.3 Protection of the general public and the environment

The management of wastes and effluents contaminated by radionuclides remains one of the priority points of inspection oversight.

The waste and effluent management plan only complies with ASN resolution 2008-DC-0095 of 29th January 2008 relative to contaminated effluents and waste (Article 11) in 74% of the departments inspected in 2015.

The accessible pipes which carry contaminated effluents are identified (Article 20 of said resolution) and signalled in 70% of the facilities. 65% of the facilities were compliant in 2014.

Periodic verifications are carried out at the outlet of the institution at frequencies that vary according to the facilities inspected. Of 48 facilities concerned by these checks, 83% perform the checks at least once a year and 10% have never performed any.

An authorisation to discharge contaminated effluents is delivered by the public sewage network administrator in 32% of the facilities. This level of conformity has remained stable over the last few years.

With regard to the implementation of the recommendations issued in ASN's circular letter of 17th April 2012 drawing up the lessons learned from several ESRs involving leaks in pipes carrying liquid effluents contaminated by nuclear medicine radionuclides, the following observations can be made:
- 51% of the facilities have mapped the networks of pipes of the department and of the Internal Targeted Radiotherapy (ITR) rooms, where applicable (point taken up in ASN resolution 2014-DC-0463 of 23rd October 2014).
- 47 % of the departments monitor the condition of the pipes and tanks.
- About 20% of the departments have both a work intervention protocol and a reflex action sheet in case it is necessary to intervene following a leak on a tank.

5.5.4 Nuclear medicine facilities

ASN resolution 2014-DC-0463 of 23rd October 2014 relative to nuclear medicine facilities set requirements for the ITR rooms with entry into effect on 1st July 2018 (dedicated rooms, independent ventilation system and under negative pressure). A situation assessment was drawn up during the inspections in 2015 in nine facilities concerned:
- Seven out of nine departments had rooms located in another department than nuclear medicine.
- All the rooms were dedicated exclusively to ITR; nearly all the departments had access instructions displayed and personal protective equipment available at the room entrances.
- In five of out nine departments the rooms were not under negative pressure and did not have an independent ventilation system.

Recording of this information was carried over in 2016 and supplemented by a situation assessment of the conformity of the facilities with respect to the independence of the ventilation systems and placing the radiation-proof enclosures under negative pressure.

5.5.5 Notified events in nuclear medicine

One hundred and seventeen ESRs were notified in 2016. The majority of the notified events concerned patients undergoing procedures for diagnostic purposes.

Significant events concerning patients (75 ESRs - 63%)

Roughly fifty events relating to the preparation and administration of radiopharmaceuticals are notified to ASN each year (60 in 2016).

As in the previous years, the errors concern the nature or activity of the administered radiopharmaceutical, and patient identity. Three events concerning patients having received a treatment with yttrium-90 were notified due to an extravasation or an error in the administered activity.

Eight ESRs concerned several patients (from two to eight patients), with four events involving flask reversals when preparing syringes and four involving defective devices. One of these ESRs concerned five patients for which the injected doses of fluorine-18 were higher than the prescribed doses (5.5 MBq to 6 MBq/kg instead of 2.7 to 3 MBq/kg) due to a failure of the dose calibrator.

Among the causes we can note problems with personnel training (newcomers, resident doctors, and trainees), insufficient preparation for technical or organisational changes, and the absence of medical validation. On several occasions ASN observed that examinations were carried out without waiting for the quality control results, and underlines a poor culture of quality and risk management in certain departments.

Some departments are confronted with recurrent radiopharmaceutical administration errors despite the corrective actions put in place following the analyses of the errors. Pondering the lack of effectiveness of the improvement measures implemented and in view of the recurrence of the ESRs, an analysis of the organisational and human factors was carried out and led ASN, in collaboration with IRSN, to once again issue recommendations concerning the handling and administration of radiopharmaceuticals. These recommendations were issued by circular letter of 26th July 2016 addressed to the nuclear medicine professionals and learned societies concerned.

Significant events concerning workers (16 ESRs - 13%)

Sixteen events concerning workers were notified in 2016. The majority of them concerned the contamination of nuclear medicine personnel, mainly with technetium-99m, due to handling errors (syringe plunger/barrel mismatch, incorrect use of catheters, dropped syringe, broken flask), but also with fluorine-18 during the handling of preparation automatons.

Events concerning the public (9 ESRs – 8%)

These ESRs concerned exposure of the foetus in women unaware of their pregnancy.

Significant events concerning radioactive sources, waste and effluents (17 ESRs - 14%)

These ESRs are associated essentially with the loss of radioactive sources or the dispersion of radionuclides (leaks of radioactive effluents from pipes or tanks, uncontrolled discharge of effluents into the collective sewerage network, removal of waste to an inappropriate disposal route).

Despite the feedback from ASN to all the nuclear medicine units in 2009[8] and 2012[9], ESRs of this type are still being notified. It can only be concluded that the management of radioactive effluents is inefficient, as witnessed by the absence of steps to prevent uncontrolled discharges.

5.5.6 Summary

The areas in which the inspections gave unsatisfactory results in 2015 will be reassessed by the inspectors in the coming years. Consequently, priority is given to three areas:
- contaminated effluent management, focusing on the one hand on the knowledge, identification and monitoring of pipes carrying radioactive effluents and, on the other, to the formalising of a response protocol in the event of leakage;
- the use of automatons for the preparation and/or injection of doses and, in particular, protocol quality assurance and protective measures regarding administration of the radiopharmaceutical;
- the radiation protection measures associated with the use of ITR rooms with the provision of work equipment, the existence of access instructions, and the defining of the conditions and means of protection during the transport of sources outside the nuclear medicine unit.

8. *Poster presented at the congress of the SFR - French Society for Radiation Protection (16th-18th June) «Good practices: management of a leak in a contaminated liquid effluents pipe».*
9. *Circular letter of 17th April 2012 on the analysis of experience feedback on leaks in pipes carrying contaminated liquid effluents in nuclear medicine units.*

5.6 Radiation protection situation in conventional radiology and computed tomography

In 2015, ASN renewed the verifications of the radiation protection regulations in the area of computed tomography, given the increase in the contribution of this imaging technique to the average effective dose per capita (chapter 1).

5.6.1 Inspection results

The computed tomography inspections carried out in 2015 concerned 77 facilities dedicated exclusively to medical imaging.

Worker radiation protection seems on the whole to be ensured to a satisfactory level, whereas progress is still required in patient radiation protection, particularly to better embrace the principle of justification.

The strong points are still the involvement of the PCR, performance of the technical controls of facility radiation protection, the equipment quality controls and the technical training in the use of the CT scanner.

The main weak points concern the preliminary analysis of the examination request, optimisation of the examination protocols, training of medical staff in patient radiation protection, the effective involvement of the medical physicist, the analysis of dosimetric data relative to the diagnostic reference levels, and the use of dose-reduction software applications.

What emerges is that there are considerable disparities in application of patient radiation protection regulations (justification and optimisation), with different levels of awareness among professionals. The radiation protection culture must be developed further to achieve better control over radiation doses delivered to patients.

The results observed over 2015 are more satisfactory than for the 2011-2015 period.

In the fields of conventional and dental radiology, seven of the ASN regional divisions carried out a questionnaire-based survey in 2014 and 2015 to assess compliance with the regulatory radiation protection requirements. This survey involved private radiology centres (33 in the provinces and 386 in Ile-de-France) and dental surgeries (89). After analysing the survey results, 49 private radiology centres and 24 dental surgeries equipped with cone-beam computed tomography scanners were inspected.

The results of the inspections in the medical radiology centres revealed nonconformities concerning application of ASN resolution 2013-DC-0349, the frequency of training in worker and patient radiation protection, medical monitoring of physicians, the gathering or analysis of diagnostic reference levels, the involvement of medical physicists, radiation protection technical controls by an approved organisation and external quality controls of the devices.

As far as dental radiology is concerned, the points to improve also concern application of the abovementioned resolution, the frequency of training in worker and patient radiation protection, radiation protection technical controls by an approved organisation and external quality controls of the devices.

5.6.2 Significant events notified in computed tomography and radiology

More than one hundred ESRs in computed tomography (114) were notified in 2016. The majority (103) of the notifications concerned a patient, chiefly the exposure of women unaware of their pregnancy (69) and patient identity errors (26). The analysis of these notifications rarely reveals deficiencies in the information given to women before the examination when making the appointment, through the posters displayed in the waiting rooms and changing cubicles and before performing the procedure. The doses received had no consequences on the foetus or the child after its birth (ICRP, 2007)

The ESR notifications concerning workers (ten or so) are for situations of accidental external exposure associated with treating a patient.

On the whole, although the notification criteria are relatively well known, the management of significant radiation protection events merits being better formalised within the inspected centres.

5.6.3 Summary

The priority issue in computed tomography is still to reinforce the effective application of the principles of justification and optimisation to control the increase in doses delivered to patients due to the growing use of CT, while preserving the medical benefits of this imaging technique.

FOCUS

Radiation protection of patients: ASN initiatives

The justification of radiological examinations, especially computed tomography scans, is a priority issue supported by the recommendation of the Council of Europe of 3rd December 2015. This issue has been taken into consideration by ASN since 2011 in its national action plan.

With regard to the training of professionals

ASN has undertaken major patient radiation protection training actions since 2014. Major progress was made in 2016, particularly for physicians:

- With regard to continuous training, ASN and the National Professional Colleges (CNP) are overhauling the system established in 2004 with progressive in-depth reorganisation of the continuous training physicians are required to follow. Each CNP (for the specialities using X-rays) shall define its own training objectives to match its needs, by adapting in a workable and proportionate manner the general national objectives set out by ASN in a resolution. Each CNP will transcribe its training objectives (content, duration, etc.) in a professional guide which will become the specifications for the training organisations. In 2016, professionals were asked to embrace the process and the first draft guides were written and transmitted to ASN (radiologists, surgeons, nuclear medical physician, radiation oncologists, rheumatologists, etc.). The professional guides will be become mandatory in 2017 by an ASN resolution.
- With regard to the initial training of physicians in patient radiation protection, 2016 witnessed a major step forward which will allow patient radiation protection to be introduced into medical course studies. The most significant progress in 2016 concerned the Ministry of Higher Education's approval of the introduction of a three-level training scheme in the post-graduate syllabus for all future physicians without exception. This three-level scheme comprises:
  - first, the acquisition of generic knowledge by all students, whatever their specialist subject (including general practitioners), chiefly oriented towards the justification of imaging examinations,
  - followed by a complementary course for the specialists performing fluoroscopy-guided procedures (interventional cardiologists, rheumatologists, digestive tract endoscopists and surgeons), oriented towards dose optimisation and the use of X-ray generators,
  - and lastly an expert-level course (which already exists) for specialist areas in which ionising radiation is at the core of the activity (oncology-radiotherapy, nuclear medicine and radiology-medical imaging).

At the European level

The association HERCA (Heads of European Radiological protection Competent Authorities) is also working on the question of justification. HERCA has organised several meetings involving various stakeholders, whether European (European societies of radiology, nuclear medicine, radiographers, representatives of equipment suppliers and manufacturers, the European Commission), international (IAEA, WHO, International Society of Radiographers) or French. The conclusions of a seminar organised by HERCA and held at ASN in October 2016 will be published in 2017.

In November 2016 HERCA also organised a week of inspections targeting implementation of the principle of justification in medical radiology. ASN and the Luxembourg Ministry of Health carried out four cross-inspections in various healthcare institutions in France and Luxembourg; these inspections focused in particular on the computed tomography examination justification process (the follow-up letters to these inspections have been published on *www.asn.fr*).

5.7 Radiation protection situation in interventional practices

For several years now, significant radiation protection events have been regularly notified to ASN in the area of fluoroscopy-guided interventional practices. Although these events represent just a small proportion (~3%) of the medical events notified to ASN, they most often have serious implications with the occurrence of tissue damage (radiodermatitis, necrosis) in patients having undergone particularly long and complex interventional procedures. In addition to these events which emphasise the major implications of radiation protection for patients, events concerning professionals whose exposure sometimes exceeds the regulatory limits, particularly at the extremities (fingers), must also be considered.

The verification of radiation protection in the area of interventional practices has been a priority for ASN since 2009. 169 inspections were carried out in this area in 2015.

5.7.1 Radiation protection of professionals using fluoroscopy-guided interventional procedures

The findings established on completion of the inspections in 2015 confirm the observations made over the last few years. Thus, radiation protection of medical staff is still applied to a greater extent in fixed and dedicated facilities (cardiology, neuroradiology, vascular imaging, etc.) than in operating theatres in which mobile devices are used (scanner, image intensifier, flat panel detector).

The inspections on the whole still reveal inadequacies in the analyses of working practices and conditions, particularly with respect to doses to the extremities and to the lens of the eye, and in dosimetric monitoring (active and at extremities).

The lack of training of medical professionals, especially private practitioners working in operating theatres, is a recurrent inspection finding in this sector in which a poor radiation protection culture is predominant. On the other hand, the training of operators using dedicated rooms is constantly increasing.

Collective radiation protection equipment is available for the dedicated activities but still too rarely present in operating theatres. With regard to Personal Protective Equipment (PPE), it is available and everybody wears it, with the exception of lead glasses. The medical personnel in question show little concern for their own radiation protection and are not aware of the doses they can and/or do receive, due in particular to the failure to wear the appropriate dosimeters (full body, extremities and lens of eye) even though they are available.

The lack of appropriate dosimetric monitoring, particularly of the extremities in certain fluoroscopy-guided procedures, and the absence of medical monitoring of the practitioners, make it difficult to assess the status of worker radiation protection in this sector. ASN does nevertheless observe improvements in the inspected departments and greater awareness among professionals as a result of information feedback from the notified events.

There are still methodological and organisational difficulties for the PCRs who do not always have the means or the necessary authority to perform their duties in full. Moreover, in the private sector, the analyses of private practitioners' working practices and conditions, their dosimetric monitoring, their medical monitoring and, where applicable, that of their employees, represent a recurrent difficulty.

ASN inspection on the theme of interventional radiology, Libourne hospital, June 2016.

5.7.2 Radiation protection of patients undergoing fluoroscopy-guided interventional procedures

The findings established on completion of the inspections in 2015 with regard to patient radiation protection also confirm the observations made over the last few years. This holds true for the shortcomings observed in the application of the dose optimisation principle, be it in the setting of the machines and the protocols used or in the practices. They result from insufficient operator training in patient radiation protection and sub-optimal use of the radiology devices, as the dose optimisation functions of the devices are insufficiently well known.

A significant improvement is however observed in the dedicated facilities, particularly in cardiology and neuroradiology, where dosimetric reviews are becoming more widespread with a view to optimising procedures; reference levels for the most common examinations are increasingly set at the local level. This approach also enables, among other things, alert levels to be put in place to trigger appropriate medical monitoring of the patient according to the dose levels received.

The low level of use of medical physicists in departments practicing fluoroscopy-guided interventional procedures hinders implementation of the principle of optimisation: greater involvement of medical physicists would more specifically allow better use of the equipment and the application of protocols adapted to the procedures performed. When medical centres call upon outside medical physics service providers, it is observed that the centres rarely adopt the procedures and documentation used by these service providers. The analysis of the notified events, detailed in an ASN circular letter dated 24th March 2014[10], has already highlighted substantial reductions in delivered doses, ranging from 40 to 70%, following the optimisation measures implemented by the medical physicist.

5.7.3 Notified events in the area of interventional practices

22 significant events were notified in the area of fluoroscopy-guided interventional practices in 2016.

Seven notifications concerned workers, and more specifically practitioners. They report cases of exceeding the projected doses evaluated during the working environment analysis or exceeding the permissible regulatory dose limits for the whole body and/or the extremities.

Fifteen events concerned overexposure of patients, some of which led to deterministic effects such as transient alopecia (hair loss).

The investigations revealed that overexposure of the patient and/or workers was due in four cases to blocking of the radioscopy pedal, and in one case to the collimator remaining in the open position. These figures are comparable with those for 2015, during which five similar events were notified. These events indiscriminately concerned mobile equipment used in the operating theatre and fixed equipment in rooms dedicated to interventional procedures.

In the other cases, overexposure of the patient and/or practitioner was due to long and complex procedures on account of the patient's illness and/or body size.

ASN observes that although knowledge of the ESR notification system has improved, under-notification is still an issue in this area.

5.7.4 Summary

As in 2015, ASN considers that the urgent measures it has been recommending for several years to improve the radiation protection of patients and professionals in the exercise of interventional practices, particularly in operating theatres, have still not been taken. These measures concern user training, quality assurance, reinforcing the medical physics services, increasing the means allocated to PCRs, training medical professionals in patient radiation protection and the publication of good practice guides by the learned societies.

In the field of medical physics in particular, the efforts made since 2007 to boost the numbers of medical physicists must be continued in order to meet the medical imaging needs.

The review of the actions recommended by ASN in medical imaging, published in 2015, also provided the opportunity to assess the situation concerning specific subjects in the interventional areas, such as the issuance of good practice guides for the various specialities, the training of medical professionals in patient radiation protection, the defining of diagnostic reference levels or the increase in means assigned to the PCRs.

Due to the implications for the radiation protection of professionals, where the exceeding of dose limits limit is still observed, and for that of patients, where ESRs are notified, and because of the shortcomings in the radiation protection culture of medical workers, particularly in operating theatres, ASN maintained the inspection of facilities performing fluoroscopy-guided interventional procedures as a national priority in its 2016 inspection programme. This will be continued in 2017.

10. *http://professionnels.asn.fr/Activites-medicales/Radiologie-interventionnelle/Lettres-circulaires-en-radiologie-interventionnelle*

6. Outlook

In radiotherapy, the measures taken since 2007 concerning human resources and in the areas of training, equipment control, quality and risk management, have enabled the safety of treatments to be improved. Although the ASN inspections provide a means of gauging the progress made by the centres, ASN is concerned by the fact that the increase in activity (number and complexity of treatments), technical changes (implementation of new techniques or practices), human factors (shortage of radiation oncologists) and organisational factors (department groupings, centre mergers/acquisitions, cooperation between centres) are not sufficiently analysed with regard to their impact on the activity of the operators. Yet these changes can weaken the existing safety barriers and be the cause of significant radiation protection events. ASN will examine, with the radiotherapy professionals, the conditions that enable these changes to be better anticipated and managed and will look into the risk management policies of the major health groups.

With regard to the follow-ups given to the GPMED's recommendations concerning the conditions of implementing high-precision irradiation techniques in radiotherapy and the associated practices, ASN - which is actively participating in the radiotherapy monitoring committee coordinated by INCa - will remain particularly attentive to the question of the means necessary for the deployment of these new techniques or practices and the implementation of clinical audit procedures.

Lastly, hypofractionated treatments, for which events have again been notified to ASN in 2016, will continue to receive particular attention in the ASN inspections, given the risks for the patients.

Verification of the control of doses in medical imaging remains a priority for ASN, particularly when associated with interventional practices. The recent and rapid development of new imaging techniques, including the arrival of CT scanners in the operating theatre and their implementation by specialists (surgeons, neurosurgeons, cardiologists, urologists, rheumatologists, orthopaedic surgeons, etc.) who too frequently are insufficiently trained in matters of radiation protection, justifies the reinforcing of the actions conducted by ASN. Thus, the implementation of practical training programmes, as much in the university degree courses as in continuous occupational training, must represent a priority objective to which the professionals and the health centres must commit over the long term.

The emerging efforts to involve medical physicists in the optimisation of doses delivered to patients during both interventional practices and computed tomography examinations must be continued.

10

Industrial, research and veterinary uses and source security

Industrial and research sectors have been using sources of ionising radiation in a wide range of applications and locations for many years now. The purpose of the radiation protection regulations is to check that the safety of workers, the public and the environment is ensured. This protection involves more specifically ensuring proper management of the sources, which are often portable and used on worksites, and monitoring the conditions of their possession, use and disposal, from fabrication through to end-of-life. It also involves monitoring the main stakeholders, that is to say the source manufacturers and suppliers, and enhancing their accountability.

The regulatory framework governing nuclear activities in France falls within the scope of the Public Health Code and the Labour Code, and guides the oversight activities for which ASN is responsible. It results from the transposition of the Euratom Directives and will evolve in the near future with the transposition of Council Directive 2013/59/Euratom that sets the basic standards for protecting health against the dangers arising from exposure to ionising radiation and puts in place a verification of the protection of ionising radiation sources against malicious acts (see chapter 3).

The radiation sources used are either radionuclides - essentially artificial - in sealed or unsealed sources, or electrical devices generating ionising radiation. The practices/applications presented in this chapter concern the manufacture and distribution of all sources, the industrial, research and veterinary uses (medical activities are presented in chapter 9) and activities not covered by the basic nuclear installations system (these are presented in chapters 12, 13 and 14).

1. Industrial, research and veterinary uses of radioactive sources

1.1 Sealed radioactive sources

Sealed radioactive sources are defined as sources whose structure or packaging, in normal use, prevents any dispersion of radioactive substances into the surrounding environment. Their main uses are presented below.

1.1.1 Industrial irradiation

Industrial irradiation is used for sterilising medical equipment, pharmaceutical or cosmetic products and for the conservation of foodstuffs. It can also be used to modify the properties of materials, for hardening polymers, for example.

These consumer product irradiation techniques can be authorised because, after being treated, the products display no residual artificial radioactivity (the products are sterilised by passing through radiation without themselves being "activated" by the treatment).

Industrial irradiators often use cobalt-60 sources, whose activity can be very high and exceeds 250,000 terabecquerels (TBq). Some of these installations are classified as BNIs (see chapter 14). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 2).

1.1.2 Gamma radiography

Gamma radiography is very frequently used in the inspection of materials to detect defects, particularly in the inspection of weld beads. This technique primarily uses sources of iridium-192, cobalt-60, and selenium-75, whose activity can reach about twenty terabecquerels. A gamma radiography device is usually a mobile device which can be moved from one worksite to another. It consists primarily of:
- a source holder containing the radioactive source;
- a source projector, which acts as a storage container and ensures radiological protection when the source is not in use;
- a guide tube and an end-piece to guide the movement of the source between the source projector and the inspected object;
- and a remote control cable allowing remote manipulation by the operator.

FUNDAMENTALS

Selenium-75 gamma radiography

The use of selenium-75 in gamma radiography has been authorised in France since 2006. Implemented in the same devices as those functioning with iridium-192, selenium-75 offers significant radiation protection advantages in gamma radiography. The equivalent dose rates are about 55 millisieverts (mSv) per hour and per TBq one metre from the source, as opposed to 130 for iridium-192. In France, about 15% of gamma radiography devices are equipped with selenium-75. Although the use of selenium-75 is slightly increasing, ASN considers that industry does not use it enough. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical industry, and it enables the safety perimeters to be significantly reduced and facilitates intervention in the event of an incident (see point 5).

Gamma radiography devices mainly use high-activity sources and can present significant risks for the operators in the event of incorrect operation, failure to comply with radiation protection rules, or operating incidents. Gamma radiographyis therefore an activity with serious radiation protection implications that figures among ASN's inspection priorities (see Diagram on page 348).

1.1.3 Verification of physical parameters

The operating principle of these physical parameter verification devices is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the desired information.

The radionuclides most frequently used are carbon-14, krypton-85, caesium-137, americium-241, cobalt-60 and promethium-147. The source activity levels range from a few kilobecquerels (kBq) to a few gigabecquerels (GBq).

These sources are used for the following purposes:
- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most commonly used sources are carbon-14 (activity level: 3.5 MBq) or promethium-147 (activity level: 9 MBq). These measurements are used for air quality monitoring by verifying the dust content of discharges from plants.
- Paper weight (grammage) measurement: a beta radiation beam passes through the paper and is then received by a detector. The signal attenuation on this detector gives the paper density and thus the grammage. The sources used are generally krypton-85, promethium-147 and americium-241 with activity levels not exceeding 3 GBq.
- Liquid level measurement: a gamma radiation beam passes through the container holding the liquid. It is received by a detector positioned opposite. The signal attenuation on this detector indicates the filling level of the container and automatically triggers certain operations (stop/continue filling, alarm, etc.). The radionuclides used depend on the characteristics of the container and the content. As applicable, americium-241 (activity level: 1.7 GBq), caesium-137 - barium-137m (activity level: 37 MBq) are generally used.
- Density measurement and weighing: the principle is the same as for the above two measurements. The sources used are generally americium-241 (activity level: 2 GBq), caesium-137, barium-137m (activity level: 100 MBq) or cobalt-60 (30 GBq).
- Soil density and humidity measurement (gammadensimetry), particularly in agriculture and public works. These devices operate with a pair of americium-beryllium sources and a caesium-137 source.
- Diagraphy (logging), which enables the geological properties of the subsoil to be examined by inserting a measurement probe containing a source of cobalt-60, caesium-137, americium-241 or californium-252.

1.1.4 Neutron activation

Neutron activation consists in irradiating a sample with a flux of neutrons to activate the atoms in the sample. The number and the energy of the gamma photons emitted by the sample in response to the neutrons received are analysed. The information collected allows the concentration of atoms in the analysed material to be determined.

This technology is used in archaeology to characterize ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

Given the activation of the material analysed, this requires particular vigilance with regard to the nature of the objects analysed. Article R. 1333.3-of the Public Health Code prohibits the use of materials and waste originating from a nuclear activity for the manufacture of consumer goods and construction products if they are, or could be, contaminated by radionuclides, including by activation (see point 4.3).

1.1.5 Other common applications

Sealed sources can also be used for:
- eliminating static electricity;
- calibrating radioactivity measurement devices (radiation metrology);
- practical teaching work concerning radioactivity phenomena;
- detection by electron capture. This technique uses sources of nickel-63 in gaseous phase chromatographs and can be used to detect and dose various chemical elements;
- ion mobility spectrometry used in devices that are often portable and used to detect explosives, drugs or toxic products;
- detection using X-ray fluorescence. This technique is particularly useful in detecting lead in paint. The portable devices used today contain sources of cadmium-109 (half-life 464 days) or cobalt-57 (half-life of 270 days). The activity of these sources can range from 400 MBq to 1,500 MBq. This technique, which uses a large number of radioactive sources nationwide (nearly 4,000 sources), is the result of a legislative system designed to prevent lead poisoning in children by requiring a check on the lead concentration in paints used in residential buildings constructed before 1st January 1949 in case of sale, a new rental contract, or work significantly affecting the coatings in the common parts of the building.

Graph 1 specifies the number of facilities authorized to use sealed radioactive sources for the applications identified. It illustrates the diversity of these applications and their development over the last five years.

It should be noted that a given facility may carry out several activities, and if it does, it appears in Graph 1 and the following diagrams for each activity.

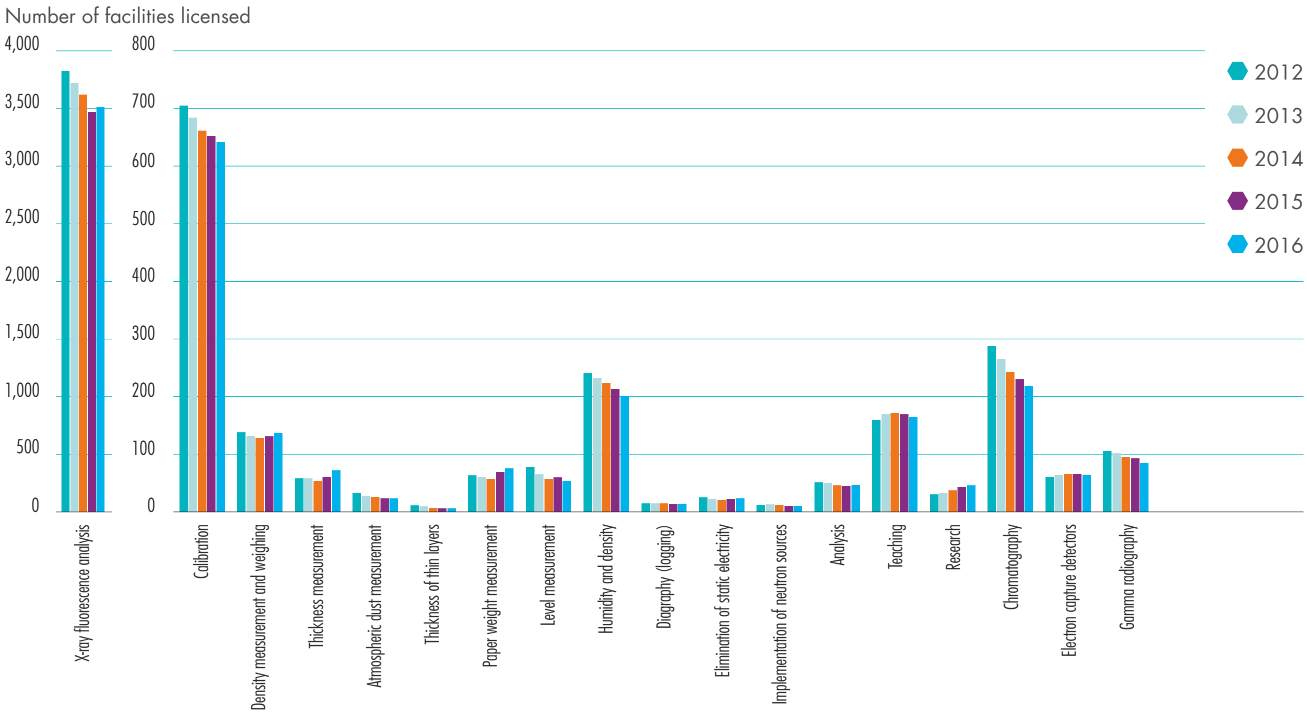
1.2 Unsealed radioactive sources

The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are used in particular in research and in the pharmaceutical sector. They are a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also several industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, looking for leaks or friction spots, building hydrodynamic models and in hydrology.

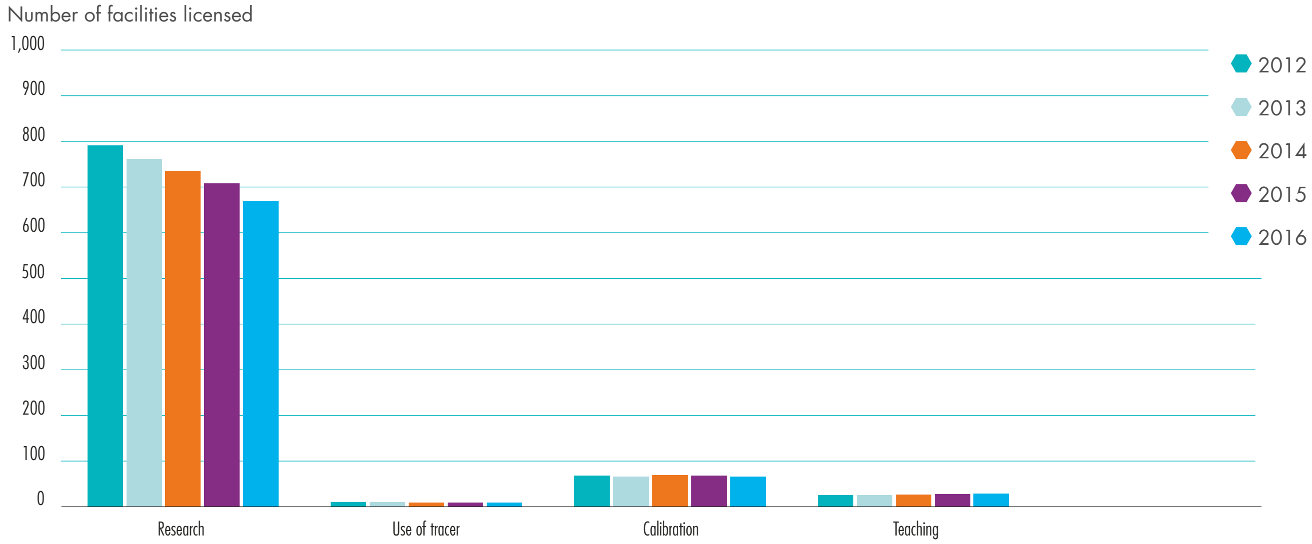
As at 31st December 2016, the number of facilities authorised to use unsealed sources stood at 774.

Graph 2 specifies the number of facilities authorized to use unsealed radioactive sources in the applications inventoried in the last five years.

GRAPH 1: Uutilisation of sealed radioactive sources



GRAPH 2: Use of unsealed radioactive sources



2. The use of electrical devices emitting ionising radiation in the industrial, research and veterinary sectors

In industry, electrical devices emitting ionising radiation are used mainly in Non-Destructive Testing (NDT), where they replace devices containing radioactive sources. They are also used in veterinary diagnostic applications. Graphs 3 and 4 specify the number of facilities authorised to use electrical devices generating ionising radiation in the listed applications. They illustrate the diversity of these applications which have evolved over the last five years. This evolution is closely related to the regulatory changes which have gradually created a new licensing or notification system concerning the use of these devices. At present, the situation of the professionals concerned is being brought into compliance in many activity sectors.

2.1 Industrial applications

The electrical devices emitting ionising radiation are chiefly X-ray generators. They are used in industry for non-destructive structural analyses (analysis techniques such as tomography, diffractometry, also called X-ray crystallography, etc.), for checking the quality of weld beads or inspecting materials for fatigue (in aeronautics in particular).

These devices, which function using the principle of X-ray attenuation, are used as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage and also the detection of foreign bodies in foodstuffs.

The increasing number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does however lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

Radiography for checking the quality of weld beads or for the fatigue inspection of materials

These are fixed devices or worksite devices using directional or panoramic beams which replace gamma radiography devices (see point 1.1.2) if the utilisation conditions so permit.

These devices can also be put to more specific uses, such as radiography for restoration of musical instruments or paintings, archaeological study of mummies or analysis of fossils.

Baggage inspection

Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

The devices with the largest inspection tunnel cross-section are used in airports for screening air freight, large baggage items and hold baggage in airports. This range of devices is supplemented by tomographs, which give a series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometime delimited by doors, but most often simply by one or more lead curtains.

X-ray body scanners

This particular application is given for information only, since the use of X-ray scanners on people during security checks is prohibited in France (in application of Article L. 1333-11 of the Public Health Code). Some experiments have been carried out in France using non-ionising imaging technologies (millimetre waves).

Inspection of consumer goods

The use of devices for detecting foreign bodies in certain consumer products has developed over the last few years, such as for detecting unwanted items in food products or cosmetics.

X-ray diffraction analysis

Research laboratories are making increasing use of small devices of this type, which are self-shielded. Experimental devices used for X-ray diffraction analysis can however be built by experimenters themselves with parts obtained from various suppliers (goniometer, sample holder, tube, detector, high-voltage generator, control console, etc.).

X-ray fluorescence analysis

Portable X-ray fluorescence devices are intended for the analysis of metals and alloys.

Measuring parameters

These appliances, which operate on the principle of X-ray attenuation, are used as industrial gauges for measuring fluid levels in cylinders or drums, for detecting leaks, for measuring thicknesses or density, etc.

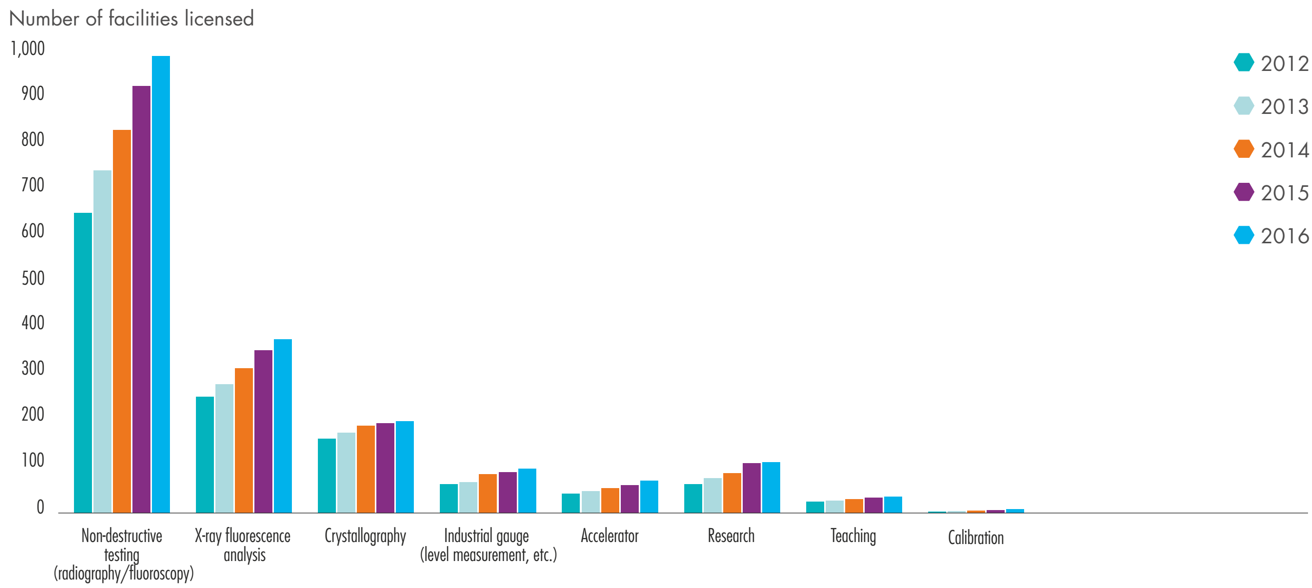
Irradiation treatment

More generally used for performing irradiations, the self-shielded appliances exist in several models that sometimes differ only in the size of the self-shielded chamber, while the characteristics of the X-ray generator remain the same.

2.2 Veterinary diagnostic radiology

The profession counts approximately 16,000 veterinary surgeons and 14,000 non-veterinarian employees. Veterinary surgeons use diagnostic radiology devices in a context similar to that of the devices used in human

GRAPH 3: Use of electrical devices generating ionising radiation (outside the veterinary sector)

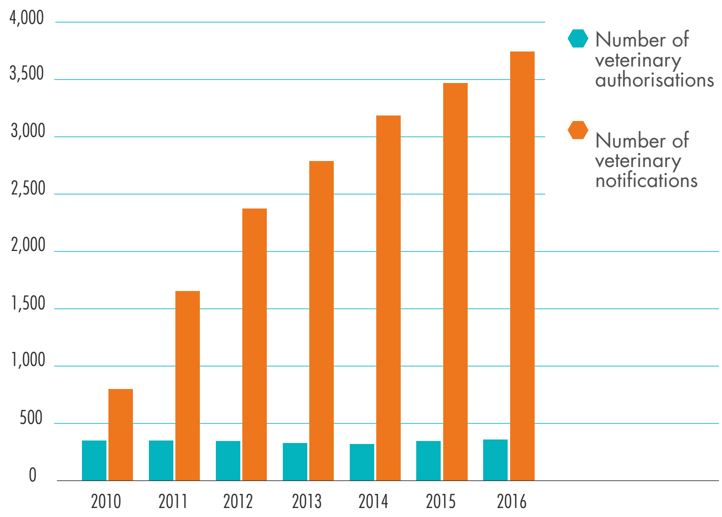


medicine. Veterinary diagnostic radiology activities essentially concern pets:
- 90% of the 5,793 veterinary structures in France have at least one diagnostic radiology device;
- about thirty computed tomography scanners are used in veterinary applications to date;
- other practices drawn from the medical sector are also implemented in specialised centres: scintigraphy, brachytherapy and external-beam radiotherapy.

The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and of portable X-ray generators, used indoors - whether in dedicated premises or not - or outside in the open air. This activity has significant radiation protection implications for veterinary surgeons and grooms.

The devices used in the veterinary sector are sometimes derived from the medical sector. However, the profession is increasingly adopting new devices specially developed to meet its own specific needs.

GRAPH 4: Use of electrical devices generating ionising radiation for veterinary activities



2.3 Particle accelerators

A particle accelerator is defined as a device or installation in which electrically charged particles undergo acceleration, emitting ionising radiation at an energy level in excess of 1 megaelectronvolt (MeV).

When they meet the characteristics specified in Article 3 of Decree 2007-830 of 11th May 2007 concerning the BNI nomenclature, these facilities are listed as BNIs.

Certain applications require the use of particle accelerators which produce photon or electron beams, as applicable. The inventory of particle accelerators in France, whether linear (linacs) or circular (cyclotrons - see point 3 - and synchrotrons), comprises about 60 identified installations (excluding BNIs) which can be used in a wide variety of fields:
- research, which sometimes requires the coupling of several machines (accelerator, implanter, etc.);
- radiography (fixed or mobile accelerator);
- radioscopy of lorries and containers during customs checks (fixed-site or mobile accelerators);
- modification of material properties;
- sterilisation;
- conservation of foodstuffs;
- etc.

In the field of research, two synchrotron radiation production facilities can be mentioned in France: the ESRF (European Synchrotron Radiation Facility) in Grenoble, and the Soleil (Optimised source of energy light) synchrotron in Gif-sur-Yvette.

Recently, particle accelerator imaging systems have been used in France to combat fraud and large-scale international trafficking. This technology, which the operators consider effective, must however be used under certain conditions in order to comply with the radiation protection rules applicable to workers and the public, in particular:
- A ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used excludes any risk of activation of the materials being verified.
- A ban on the use of ionising radiation on the human body for purposes other than medical. Thus, the use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France.
- The setting up of procedures to ensure that the checks conducted on the goods or transport vehicles do not lead to accidental exposure of workers or other individuals. During customs inspections of trucks using tomographic techniques, for example, the drivers must be kept away from the vehicle and other checks must be performed prior to irradiation to detect the presence of any illegal immigrants, in order to avoid unjustified exposure of persons during the inspection.

2.4 Other electrical devices emitting ionising radiation

This category covers all the electrical devices emitting ionising radiation other than those mentioned above and not excluded by the license and notification exemption criteria set out in Article R. 1333-18 of the Public Health Code.

This category notably includes devices generating ionising radiation but not used for this property, such as ion implanters, electron-beam welding equipment, klystrons, certain lasers and certain electrical devices such as high-voltage fuse tests.

FUNDAMENTALS

Synchrotrons

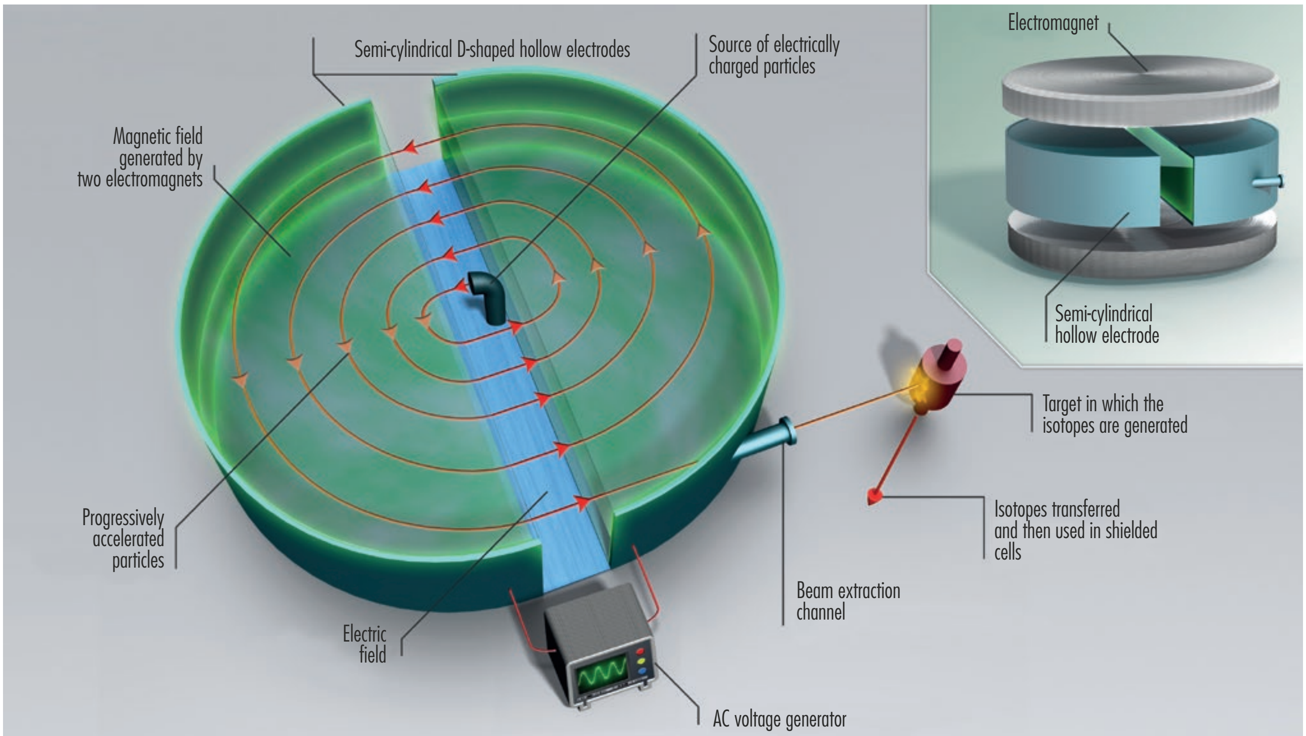
The synchrotron is a member of the same circular particle accelerator family as the cyclotron (see point 3), but is far larger, enabling energies of several gigaelectronvolts to be achieved by means of successive accelerators. Owing to the low mass of the particles (generally electrons), the acceleration created by the curvature of their trajectory in a storage ring produces an electromagnetic wave when the speeds achieved become relativistic: this is synchrotron radiation. This radiation is collected at various locations called beam lines and is used to conduct scientific experiments.

3. Manufacturers and distributors of radioactive sources

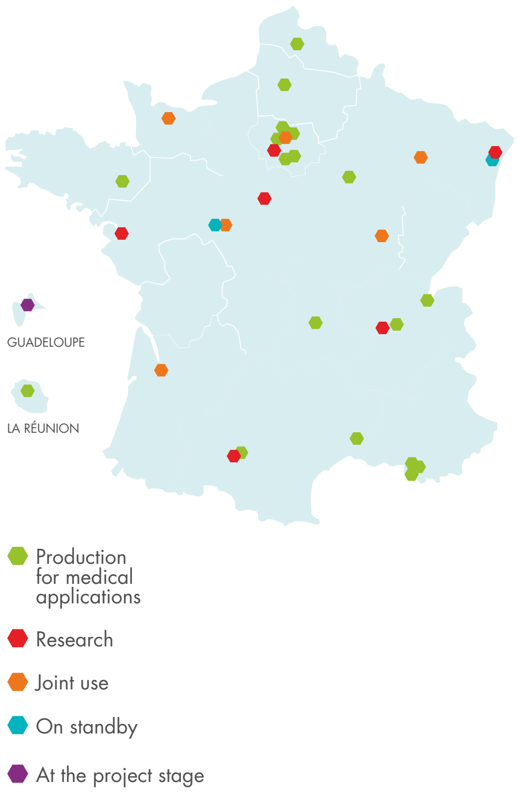
ASN oversight of the suppliers of radionuclide sources or devices containing them is crucial to ensuring the radiation protection of the future users. It is based on the one hand on the technical examination of the devices and sources with respect to operating safety and radiation protection conditions during future utilisation and maintenance. It also allows the tracking of source transfers and the recovery and disposal of disused or end-of-life sources. Source suppliers also play a teaching role with respect to users.

At present, only the suppliers of sealed radioactive sources or devices containing them, and of unsealed radioactive sources, are regulated in France (see point 4.4). There are about 150 suppliers listed, and among them, 32 low and medium-energy cyclotrons are currently licensed under the Public Health Code in France. As at 31st December 2016, 30 cyclotrons are in operation. Among these, 16 are used exclusively for the daily production of radiopharmaceuticals, 6 are used exclusively for research purposes and 8 are used for joint production and research purposes.

SIMPLIFIED DIAGRAM of the operation of a cyclotron



LOCATION of cyclotrons in France



4. Regulation of industrial, research and veterinary activities

The provisions of the Public Health Code relating specifically to the industrial and research applications provided for in the Public Health Code are specified in this section. The general rules are detailed in chapter 3 of this report.

4.1 The Authorities regulating the sources of ionising radiation

ASN is the Authority that grants the licenses and receives the notifications, in accordance with the system applicable to the nuclear activity concerned.

However, to simplify administrative procedures for licensees already licensed under another system, the Public Health Code makes specific provisions and the notification or licensing obligation does not apply. This concerns more specifically:

- The radioactive sources held, manufactured and/or used in installations licensed under the Mining Code (Article 83) or the unsealed radioactive sources held, manufactured and/or used in Installations Classified on Environmental Protection Grounds (ICPE) which come under Articles L. 511-1 to L. 517-2 of the Environment Code, and have a licensing system. In this case the Prefect is responsible for including licence conditions

FUNDAMENTALS

Cyclotrons

A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV. A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electric field, allowing the rotation of the particles and their acceleration at each revolution. The accelerated particles strike a target which is activated and produces radionuclides.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron emitting isotopes, such as fluorine-18 (^{18}F) or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{18}F-FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

Other radiopharmaceuticals manufactured from ^{18}F have also been developed in recent years, such as ^{18}F-Choline, ^{18}F-Na, ^{18}F-DOPA, as well as radiopharmaceuticals for exploring the brain. To a lesser extent, the other positron emitters that can be manufactured with a cyclotron of an equivalent energy range to that necessary for the production of ^{18}F and ^{11}C are oxygen-15 (^{15}O) and nitrogen-13 (^{13}N). Their utilisation is however still limited due to their very short half-life.

The levels of activities involved for the ^{18}F usually found in pharmaceutical facilities vary from 30 to 500 GBq per production bombardment. The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of GBq.

relative to radiation protection for the nuclear activities exercised on the site.
- The installations and activities relating to national defence for which ASND (Defence Nuclear Safety Authority) is responsible for regulating the radiation protection aspects.
- The installations authorised under the BNI System for which ASN regulates the radioactive sources and electrical devices emitting ionising radiation necessary for the operation of these installations as defined by this system. Holding and using other sources within the perimeter of the BNI remain subject to licensing pursuant to Article R. 1333-17 of the Public Health Code.

These provisions do not exempt the beneficiary from compliance with the requirements of the Public Health Code and particularly those relative to source acquisition and transfer; they do not apply to the distribution, importing and exporting of radioactive sources, which remain subject to licensing by ASN under the Public Health Code.

Since the publication of Decree 2014-996 of 2nd September 2014 amending the nomenclature of the ICPEs, some facilities previously licensed by Prefectural order under the Environment Code for the possession and use of radioactive substances are now regulated by ASN under the Public Health Code.

The following are now subject to the Public Health Code System:
- establishments holding or using sealed radioactive sources subject to notification or licensing on account of section 1715 of the ICPE nomenclature;
- establishments holding unsealed radionuclides in quantities of less than 10 m^3 previously subject to notification or licensing under section 1715 of the ICPE nomenclature.


ASN inspection in the Ionisos installation of Sablé-sur-Sarthe, November 2016.

The requirements applicable to these installations are now those of the Public Health Code. However, Article 4 of the abovementioned Decree provides that the license or notification issued under section 1715 shall continue to be valid as a license or notification under the Public Health Code until a new license is obtained under the Public Health Code or, failing this, for a maximum period of five years, that is to say until 4th September 2019 at the latest. Any change relating to the license shall either be notified to ASN or form the subject of a new license application, depending on the case.

Only establishments holding unsealed radioactive substances in quantities exceeding 10 m^3 are subject to the system for classified installations (excluding the medical sector and particle accelerators). Any sealed radioactive sources also possessed or used by these establishments are regulated by ASN under the Public Health Code.

Nuclear materials are subject to specific regulations provided for in Article L. 1333-2 of the Defence Code. Application of these regulations is overseen by the Minister of Defence for nuclear materials intended for defence needs, and by the Minister in charge of Energy for nuclear materials intended for any other use.

4.2 Licensing and notification of ionising radiation sources used for non-medical purposes

4.2.1 Integration of the principles of radiation protection in the regulation of non-medical activities

ASN verifies application of the three major principles governing radiation protection and which are written into the Public Health Code (Article L. 1333-1), namely justification, optimisation of exposure and dose limitation (see chapter 2).

Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit does not seem to outweigh the risk. Either a generic prohibition is declared, or the license required on account of radiation protection is not issued or is not extended. For existing activities, justification is reassessed when license renewal applications are made if the current state of knowledge and technology warrants it.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement on the part of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 3). They are responsible for putting the devices on the market and must therefore design them such that the exposure of the future users is minimised. ASN also checks application of the principle of optimisation when examining the license application files, when conducting its inspections, and when analysing the various significant events notified to it.

4.2.2 Applicable licensing and notification systems

Applications relating to the holding and use of ionising radiation sources are reviewed by the regional divisions of ASN. License applications for the manufacture and distribution of sources or devices containing sources are examined at a central, national level.

The licensing system

As part of a simplification process with a graded approach based on the radiological risks and implications, ASN has produced and deployed licensing application forms for each activity which are available on *www.asn.fr.* Several forms were revised recently to incorporate changes in regulations and experience feedback.

Thus, to better integrate the actual situation of responsibilities in the non-medical sectors, where radioactive sources and devices are often managed by an entity rather than an individual, these new forms allow representatives of artificial persons to apply for a license, pursuant to Article R. 1333-24 of the Public Health Code. They also list the documents that must be enclosed with the application. All the other documents listed in the appendix to ASN resolution 2010-DC-0192 of 22nd July 2010 must of course be held by the applicant and kept at the disposal of the inspectors in the event of inspection. It is moreover possible that ASN will request further information during its examination of the license application.

Small-scale nuclear activities stand out through their extreme heterogeneity and the very large number of licensees concerned. ASN must therefore adapt its efforts to their radiation protection implications to ensure effective oversight of these activities. In this perspective, it is continuing to implement its graded approach which consists in adapting the regulatory constraints and the level of oversight to the risks that the nuclear activity presents.

FOCUS

ASN is co-chairing an international think tank on alternative technologies

Radioactive sources present radiation protection and safety risks for their users, the general public and the environment, which must be taken into consideration in the reflection phase preceding the deployment of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014, and subsequently at the Washington Summit on nuclear safety in April 2016, France was the initiator of an international commitment taken by 29 States and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote their use.

In this context, since April 2015 ASN has, alongside the National Nuclear Security Administration (United States), co-chaired a think tank involving several States working on the theme of replacing high-activity radioactive sources with alternative technologies. The think tank's aim is to share the experience feedback of each State in this area in a way that does not constrain its members, who are volunteers. In application of the principle of justification, ASN has presented in particular the work conducted by the French blood bank to replace its irradiators that use radioactive sources by electric irradiators that emit X-rays. ASN also enabled the French Confederation for Non-Destructive Tests to present the progress of its work in replacing gamma radiography by other non-destructive testing technologies.

These meetings, however, have also revealed difficulties in developing or implementing alternative technologies for which further reflection and work must be must carried out.

In December 2016, during the international conference on nuclear safety organised by the International Atomic Energy Agency (IAEA), ASN presented the work of the working groups at a round table dedicated to this subject.

The notification system

In 2009, to better adapt the regulatory requirements to the radiation protection risks, ASN introduced a notification system in the industrial, research and veterinary sectors. This led to the publication of several approved ASN resolutions (see chapter 3), defining on the one hand the scope of this system and on the other, its implementation procedures.

The following are concerned:
- veterinary diagnostic radiology devices (fixed only) meeting one of the following conditions:
  - the emission beam is directional and vertical, except for all tomography devices;
  - the device is used for intra-oral radiography (ASN resolution 2009-DC-0146 of 16th July 2009, amended by resolution 2009-DC-0162 of 20th October 2009, *Official Journal* of 26th February 2010).
- electrical devices emitting ionising radiation, for which the equivalent dose rate 10 cm from all accessible surfaces in normal conditions of use and as a result of their design, is less than 10 microsieverts per hour.

Through ASN resolution 2015-DC-0531 of 10th November 2015, ASN widened the scope of activities subject to notification to all users and holders of these devices in order to integrate unambiguously into the notification system all the activities using devices in these categories, that is to say putting into service, inspection, maintenance, training, etc., insofar as these uses do not lead to modifications in safety systems or radiation shielding.

The notification system also applies to the activities relating to the installation, maintenance or removal of Ionisation Chamber Smoke Detectors (ICSD) (see point 4.3).

The notification forms drawn up by ASN have been designed to simplify their use and processing. No document is to be enclosed with the notification form. Alongside this, ASN is continuing an on-line notification project which will further simplify procedures. This system is already up and running for transport activity notifications (see chapter 11).

As indicated in chapter 3 which describes the general rules, the transposition of European Directive 2013/59/Euratom of 5th December 2013 into French law will more specifically allow a third administrative system situated between the notification and licensing systems to be put in place: it is a simplified authorisation system called «registration system».

4.2.3 Statistics for 2016

Suppliers

In the light of the fundamental role played in the radiation protection of future users by the suppliers of sources or devices containing them (see points 3 and 4.2.1), ASN exercises particularly strict control in this field. During the course of 2016, 65 license or license renewal applications were examined by ASN, and 36 inspections were carried out.

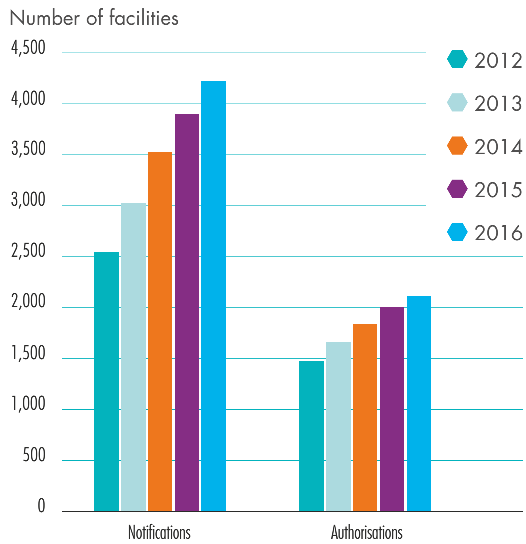
Users

Case of radioactive sources

In 2016, ASN reviewed and notified 277 new licenses, 971 license renewals or updates and 325 license cancellations. Graph 6 presents the licenses issued or cancelled in 2016 and trends in this area for the last five years.

Once the license is obtained, the licensee can procure radioactive sources. To do this, it collects supply request forms from IRSN, enabling the institute to verify - as part of its duty to keep the inventory of ionising radiation sources up to date - that the orders are in conformity with the licenses of both the user and the supplier. If the order is correct, the transfer is then recorded by IRSN, which notifies the interested parties that delivery can take place. If there is any difficulty, the transfer is not validated and IRSN refers the case to ASN (see box).

GRAPH 5: Total number of "user" license and notifications for devices generating ionising radiation



FOCUS

Procedures for recording and tracking radioactive sources

Articles R. 1333-47 to 49 of the Public Health Code provide for prior recording by IRSN of transfers of radioactive sources and Article R. 1333-50 for tracking these sources.

ASN resolution 2015-DC-0521 of 8th September 2015 relative to the tracking and methods of registering radioactive sources and products or devices containing them has defined a clear regulatory framework governing the methods of registering transfers and the rules for tracking transfers of radioactive sources.

This resolution, applicable as of 1st January 2016, takes into account the existing practice and supplements it as follows by:
- grading source monitoring according to how dangerous the sources are;
- confirming the non-registration of sources whose activity is below the exemption thresholds;
- imposing deadlines between the registering of source transfer and the actual transfer;
- making it an obligation for each source to be accompanied by a «source certificate» indicating all its characteristics and which must be transmitted to IRSN within two months after receiving the source.

Case of electrical generators of ionising radiation

ASN has been responsible for regulating these devices since 2002, and is gradually building up its capacity in this area where numerous administrative situations need to be brought into compliance. In 2016, it granted 139 licenses and 265 license renewals for the use of X-ray generators. ASN also issued 324 notification acknowledgements for electrical devices emitting ionising radiation in 2016.

A total of 2,116 licenses and 4,224 notification acknowledgements have been delivered for electrical devices emitting ionising radiation since Decree 2002-460 was issued. Graph 5 illustrates this trend over the past five years.

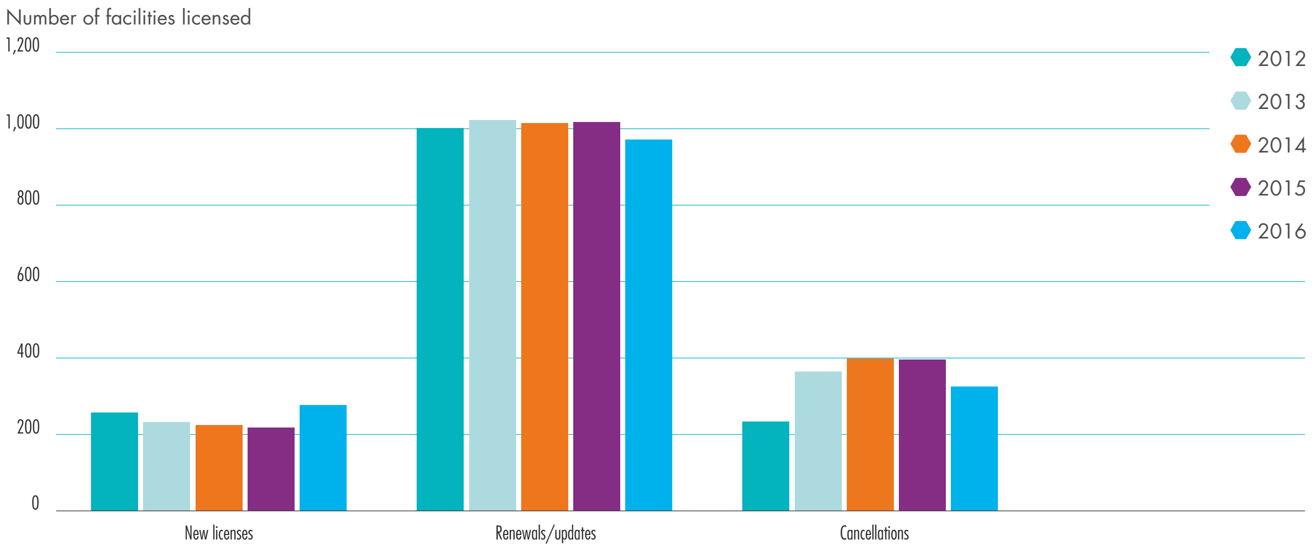
4.3 Unjustified or prohibited activities

4.3.1 Application of the ban on the intentional addition of radionuclides in consumer goods and construction products

The Public Health Code indicates *"that the intentional addition of radionuclides to consumer goods and construction products is prohibited"* (Articles R. 1333-2 and 3).

The trading of radioactive stones or decorative objects, accessories containing sources of tritium such as watches, key-rings, hunting equipment (sighting devices), navigation equipment (bearing compasses) or equipment for river fishing (strike detectors) is specifically prohibited.

GRAPH 6: Radioactive source "user" licenses delivered each year



Article R. 1333-4 of this same Code states that waivers to these prohibitions can, if the advantages they bring outweigh the health risks they might represent, be granted by order of the Minister responsible for Health and, depending on the case, by the Minister responsible for Consumption or the Minister responsible for Construction, after consulting ASN and HCSP (French High Public Health Council). No waiver is possible for foodstuffs, toys, jewellery and cosmetic products.

ASN considers that granting waivers to the regulations must remain the exception. It was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works (Order of 18th November 2011 from the Ministers responsible for Health and Construction, ASN opinion 2011-AV-0105 of 11th January 2011 and ASN opinion 2011-AV-0124 of 7th July 2011). It was then used in 2014 for light bulbs containing very small quantities of radioactive substances (krypton-85, thorium-232 or tritium), serving mainly for applications requiring very high intensity lighting such as public places, professional environments, or for certain vehicles (Order of 12th December 2014 of the Ministers responsible for Health and Construction, opinion 2014-AV-0211 of 18th September 2014).

A waiver request to allow the addition of radionuclides (tritium) in certain watches was also denied (Order of 12th December 2014, opinion 2014-AV-0210 of 18th September 2014).

The list of consumer goods and construction products concerned by an ongoing waiver request or for which a waiver has been granted is published on the website of the French High Committee for Transparency and Information on Nuclear Security (HCTISN).

4.3.2 Application of the justification principle for existing activities

The justification of existing activities must be re-assessed periodically in the light of current knowledge and technological changes in accordance with the principle described in point 4.2.1. If the activities are no longer justified by the benefits they bring, or with respect to other non-ionising technologies that bring comparable benefits, they must be withdrawn from the market. A transitional period for definitive withdrawal from the market may be necessary, depending on the technical and economic context, particularly when a technological substitution is necessary.

Smoke detectors containing radioactive sources

Devices containing radioactive sources have been used for several decades to detect smoke in buildings, as part of firefighting policy. Several types of radionuclides have been used (americium-241, plutonium-238, nickel-63, krypton-85). The activity of the most recent sources used does not exceed 37 kBq, and the structure of the detector, in normal use, prevents any release of radioactive substances into the environment.

New non-ionising technologies have gradually come to compete with these devices. Optical devices now provide comparable detection quality, and can therefore satisfy the regulatory and normative fire detection requirements. ASN therefore considers that smoke detection devices using radioactive sources are no longer justified and that the seven million Ionisation Chamber Smoke Detectors (ICSDs) installed on 300,000 sites must be progressively replaced.

The regulatory framework governing their removal was put in place by the Order of 18th November 2011 and two ASN resolutions of 21st December 2011.

This regulatory framework aims at:
- planning the removal operations over ten years;
- supervising the maintenance or removal operations that necessitate certain precautions with regard to worker radiation protection;
- preventing any uncontrolled removals and organising the collection operations in order to avoid detectors being directed to an inappropriate disposal route, or even simply being abandoned;
- monitoring the pool of detectors.

Five years after the implementation of the new regulatory system for ICSD removal and maintenance activities, as at 31st December 2016 ASN has delivered 294 notification acknowledgements and 7 national licenses (delivered to industrial groups with a total of 104 agencies) for ICSD removal and fire safety system maintenance activities.

With regard to tracking of the pool of ICSDs, in 2015 IRSN put in place, in collaboration with ASN, a computerised system enabling the professionals working on a facility (maintenance technicians, installers or removers) to file annual activity reports electronically. Available information is insufficient to allow an initial assessment.

ASN maintains close relations with Qualdion, an association created in 2011 which certifies the companies that comply with the regulations relative to radiation protection and fire safety. The list of Qualdion-certified companies is available on the association's website page: *www.lne.fr.* ASN participates with the association in communication campaigns targeting the holders of ICSDs and professionals (Expoprotection trade fair, etc.).

Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic,enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate sparkover. The use of surge suppressors has been gradually abandoned since the end of the 1970s, but the number remaining to be removed, collected and disposed of is still very high (several million units). When installed, these devices represent no risk of exposure for individuals. There can be a very low risk of exposure and/or contamination if these objects are handled without the necessary precautions or if they are damaged. ASN issued a reminder of this to Orange (formerly *France Télécom),* which has begun an experimental process of inventorying, removing, sorting and disposing of surge suppressors in the Auvergne-Rhône-Alpes region and has proposed a national removal and disposal plan. This plan was presented to ASN and led in September 2015 to the granting of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their storage on designated sites. The search for a disposal route is in progress in collaboration with Andra, the French national agency for radioactive waste management. This removal plan will be implemented progressively over an eight-year time frame.

Lightning conductors

Radioactive lightning conductors were manufactured and installed in France between 1932 and 1986. The ban on the sale of radioactive lightning conductors was declared in 1987. This Order did not make the removal of installed radioactive lightning conductors compulsory. Consequently, there is no obligation to remove the radioactive lightning conductors installed in France at present, except in certain ICPEs (Order of 15th January 2008 setting the removal deadline at 1st January 2012) and certain installations under Ministry of Defence responsibility (Order of 1st October 2007 setting the removal deadline at 1st January 2014).

ASN nevertheless expects all existing radioactive lightning conductors to be removed and placed in the care of Andra, given the risks they can represent, depending in particular on their physical condition. For several years ASN has been informing professionals to ensure that these objects are removed in compliance with radiation protection requirements for workers and the public. ASN has stepped up its action in this respect by reminding the professionals concerned of their obligations, particularly that of having an ASN license for the activity of removing and storing the lightning conductors pursuant to Articles L. 1333-1, L. 1333-4, and R. 1333-17 of the Public Health Code. ASN conducts field oversight operations targeting the companies involved in recovering these objects, combined with unannounced inspections on the removal sites.

Andra estimated that there were 40,000 radioactive lightning conductors installed in France. Nearly 10,000 have been removed and recovered by Andra. The current rate of removal is about 450 per year.

Additional information on radioactive lightning conductors is available on *www.andra.fr* and the website of the association Inaparad *www.paratonnerres-radioactifs.com*.

4.4 Reinforcement of the regulation of electrical devices generating ionising radiation

ASN resolution 2013-DC-0349 of 4th June 2013 sets the minimum technical rules for the design of facilities in which X-rays are present. This resolution takes into account the revision of standard NF C 15-160 and concerns industrial and scientific (research) facilities such as industrial radiography using X-rays in a bunker, veterinary radiology and medical facilities such as conventional radiology, interventional radiology, dental radiology and scanners (see chapters 3 and 9). It came into effect on 1st January 2014 and replaced the Order of 30th August 1991 setting the required installation conditions for X-ray generators. Its application becomes mandatory for facilities put into service as of 1st January 2016, while facilities put into service prior to this and meeting the requirements of the November 1975 version of standard NF C 15-160 and its associated standards, are deemed to be in conformity with the resolution if they remain in conformity with these standards.

With regard to the design of devices, ASN wishes to supplement the provisions introduced into the Public Health Code in 2007, and thus complete the development of the regulatory framework allowing the distribution of electrical devices for generating ionising radiation to be subject to licensing in the same way as the suppliers of radioactive sources. Experience shows that in this respect the joint technical examination of files by ASN and the device suppliers/manufacturers brings substantial gains in radiation protection optimisation (see points 3 and 4.2.1).

For electrical devices used for non-medical purposes, there is no equivalent of the mandatory CE marking for medical devices, such as to confirm conformity with several European standards covering various fields, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

ASN therefore established contacts with the LCIE (Electrical Certification and Testing Entity for *Bureau Véritas*), CEA and IRSN, and has started looking into the updating of the technical requirements applicable to the devices.

On the basis of this work, draft texts have been produced with the aim of defining minimum radiation protection

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Revision of ASN Resolution 2013-DC-0349 of 4th June 2013

ASN resolution 2013-DC-0349 of 4th June 2013 setting the minimum technical design rules to be satisfied by facilities in which X-rays are produced by devices operating at high voltages of 600 kV or less entered into effect on 1st January 2014.

Experience feedback has shown firstly that the March 2011 version of standard NF C 15-160 mentioned in the resolution does not apply to all the existing situations, and secondly that the identification and justification of equivalent provisions - a possibility provided for in the resolution - pose technical application problems for the manufacturers, suppliers and users.

Given this situation, ASN has been working on a revision of this resolution which is no longer based on the standard NF C 15-160 of March 2011, but sets the radiation protection objectives to achieve by adopting a graded approach according to the risk generated. The requirements relative to the control of radiological risks remain similar but are written so as to meet more clearly formulated objectives. The draft text produced by ASN was posted on the ASN website for public consultation from 2nd August to 30th September 2016. More than forty contributions were submitted on the website or by either electronic or postal mail. These contributions were favourable to the draft resolution and more importantly enabled it to be clarified. The draft resolution is intended to replace the resolution currently in effect without creating additional requirements for installations that are already compliant.

The provisions adopted in the resolution relate to:
- the sizing of the biological protections of the premises for which the radiological zoning objectives are specified in the text;
- signalling of the risk at each access point and within the premises;
- safety:
  - electrical power cut-off devices (emergency stop buttons);
  - access slaving devices;
  - access locking devices;
- the content of the report documenting compliance with the provisions of the resolution.

requirements for the design of X-ray generators, and an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) was conducted in 2015. The various contributions are currently being analysed with the assistance of IRSN and the reference players (CEA and LCIE).

4.5 Detection of abnormal radioactivity in materials and goods in France

ASN considers that the increase in the number of cases of detection of abnormal radioactivity in metals and consumer goods across the world is worrying. Each year it registers on average five events relating to the presence of radioactivity in shipments transported to or from France, whether they involve finished or semi-finished contaminated products, or even sealed sources themselves. They can also involve radionuclides of natural origin. The conclusions of a study carried out at the request of ASN after receiving several reports show that the exposure of a person to the radiation emitted by certain textiles containing thorium-based ceramics remains very low but can in certain cases exceed the annual regulatory limit for the public (1 mSv).

Unlike many countries such as Belgium, Spain and the Netherland, France at present does not have means of detection at strategic points such as transport hubs (ports and airports) and often relies on information received from neighbouring countries. Some companies are equipped with detection systems installed either to comply with the regulations in force pursuant to the Environment Code (landfills, hospitals, waste disposal facilities, etc.), or for commercial reasons dictated by their partners (international trade with the United States).

ASN considers that France must rapidly adopt a national strategy for radioactivity detection on its territory, and make the corresponding investments in equipment and training. It has made its position known to the authorities in charge of these checks and organised several meetings on the subject in 2016.

Given the possible economic side-effects of detecting abnormal radioactivity in products, ASN also recommends that all companies involved in commercial trading of metal-based products with countries outside the European Union, conduct checks on the radioactivity level of the imported products.

4.6 Implementation of monitoring of radioactive source protection against malicious acts

Even if the safety and radiation protection measures as a result of the regulations do guarantee a certain level of protection against the risk of malicious acts, they cannot be considered sufficient for all radioactive sources. Reinforced oversight of protection against malicious acts using hazardous sealed radioactive sources was thus strongly encouraged by IAEA which published a code of conduct for the safety and security of radioactive sources (approved by the IAEA Board of Governors on 8th September 2003) and guidelines for the import and export of radioactive sources (published in 2005). The G8 supported this approach, notably at the Evian Summit in June 2003, and France sent IAEA confirmation that it was working towards application of the guidelines laid out in the code of conduct (undertakings by the Governor for France of 7th January 2004 and 19th December 2012). The general aim of the Code is to obtain a high level of safety and security for those radioactive sources which can constitute a significant risk for individuals, society and the environment.

4.6.1 The organisation adopted for monitoring the safety of sources

Regulatory oversight of sources for radiation protection and safety purposes and to combat malicious acts have many aspects in common and mutually consistent objectives. This is why ASN's counterparts abroad are usually responsible for oversight in both domains. ASN has the necessary hands-on knowledge of the sources concerned and of the entities responsible for nuclear activities, which are regularly inspected by the ASN regional divisions.

For nuclear materials, France can also rely on a system of protection against malicious acts that is run by the services of the Defence and Security High Official (HFDS) of the Ministry responsible for Energy.

The Government has therefore decided to set up an organisation for overseeing the protection of ionising radiation sources against malicious acts (hereinafter called oversight of the security of sources) which takes into account the existing oversight systems by entrusting:
- to the services of the HFDS of the Ministry responsible for Energy, oversight of the security of sources in installations whose security is already under their control;
- to ASN oversight of the security of sources held by the other persons/entities responsible for nuclear activities.

The legislative process necessary for this oversight to be put in place, initiated in 2008 by the Government with the assistance of ASN, was recently concluded though Ordinance 2016-128 of 10th February 2016. The Ordinance allocates oversight competence to the various installations and requires that protection against malicious acts be taken into account by the persons/entities responsible for nuclear activities and the regulatory body examining license applications.

4.6.2 The sources and installations concerned

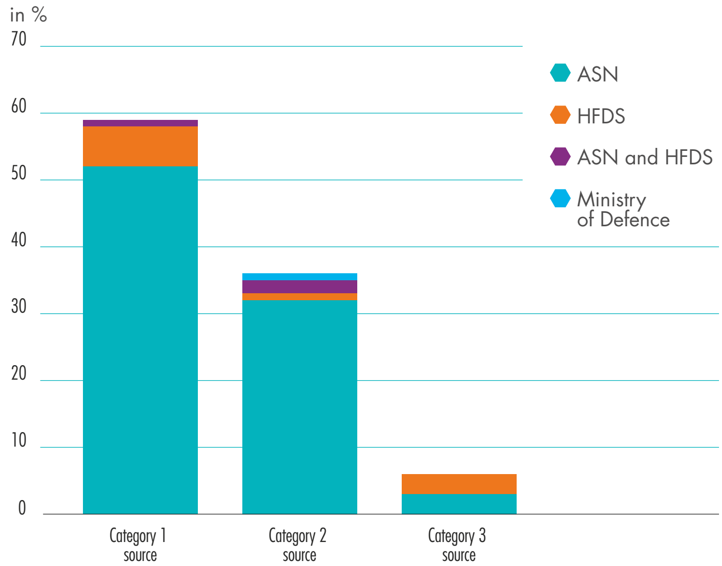
Oversight of source security will concern all sources of ionising radiation. Additional regulatory prescriptions will nevertheless be issued to increase the security of the sources presenting the greatest risks. This concerns more particularly sealed radioactive sources in categories 1, 2 and 3 as defined in the IAEA categorisation scheme.

In the civil sector there are about 4,000 sources presenting such risks held in some 250 installations in France. These sources are used essentially for the purpose of industrial irradiation, telegammatherapy, industrial radiography and brachytherapy. Due to their frequent use on worksites, industrial radiography sources present particular security risks during transport.

As explained in point 4.6.1 above, security oversight of these sources will be ensured essentially by ASN.

Sources that are not in categories, 1, 2 or 3 but which present serious security risks, due to conditions of storage with other sources for example, may also be subject to tightened security provisions.

GRAPH 7: Breakdown of the regulatory oversight of protection of sources against malicious acts



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Categorisation of radioactive sources

Radioactive sources are classified by the IAEA, on the basis of predetermined exposure scenarios, in five categories from 1 to 5, according to their ability to create early harmful effects on human health if they are not managed safely and securely. Category-1 sources are considered extremely dangerous while those in category 5 are considered very unlikely to be dangerous. Sources in categories 1 to 3 are considered dangerous for humans to varying degrees.

It should be noted that the categorisation is based solely on the capacity of the sources to produce deterministic effects in certain exposure scenarios and must not under any circumstances be considered as a claim that there is no danger in exposure to a category 4 or 5 source, as such exposure could cause stochastic effects in the longer term. The principles of justification and optimisation must therefore be respected in all cases.

4.6.3 An initial identification of the situation regarding the security of high-activity sealed sources

ASN has continued its actions to determine the situation regarding the security of high-activity sealed sources or presenting equivalent safety risks, currently held in the existing facilities. This resulted in ASN making some 350 visits. At present, virtually all the licensees holding high-activity sealed sources who will be regulated by ASN for the protection of sources against malicious acts have been visited.

ASN has produced a synthesis of the information gathered during these visits, which has among other things fuelled the work to produce the future regulatory prescriptions coordinated by the HFDS of the Ministry responsible for Energy and enabled the impact of these prescriptions to be assessed.

4.6.4 Regulatory work

In 2016, the working group coordinated by the HFDS of the Ministry responsible for the Environment continued its work to produce draft regulations concerning the security of sources, and more specifically:
- A draft decree applicable, for its section associated with protecting sources against malicious acts, beginning 1st July 2017. More specifically, as from July 2017, some persons/entities responsible for nuclear activities will have to categorise their sources according to the security risks they present and draw up a list of persons who shall be authorised to have access to the most dangerous sources, to transport them, and have access to information concerning their protection against malicious acts.
- A draft ministerial order aiming at setting technical and organisational prescriptions that persons/entities responsible for nuclear activities will have to apply to protect their sources against malicious acts. This order should be published in 2017 and become applicable during 2018. The prescriptions aim, on the basis of a graded approach to the security risks, to limit access to the sources to duly authorised persons, to place one or more physical protective barriers between the sources and persons not authorised access to them, and to make intrusion detection devices mandatory or to ensure the tracking of these sources. Manufacturers and stakeholders have been invited to take part in some of these meetings in order to give their opinions and comments on the proposed principles.

As indicated earlier, ASN, building on its knowledge of the sources and facilities, actively participated in the drafting of this regulation. In 2017 it will be consulted on the draft decree and draft ministerial order concerning the security of sources.

5. The main incidents in 2016

The inspections conducted on radiation sources and a complete round-up of radiation protection events in the non-BNI field notified to ASN are presented in chapter 4 of this report.

Industrial radiography

Each year ASN is notified of several incidents involving industrial radiography activities. Unlike previous years, no incident was rated level 2 on the INES scale in 2016.

Graph 8 illustrates the trends in the number of incidents notified in the last few years. Graph 9 indicates the main causes of these incidents.

The most noteworthy incident in 2016 involved an NDT gamma ray projector used in worksite conditions within a BNI. Following a radiography operation, the operators observed that the projector could not be locked because the source had remained jammed inside the projector, almost in the safe position but with an incompletely closed plug.

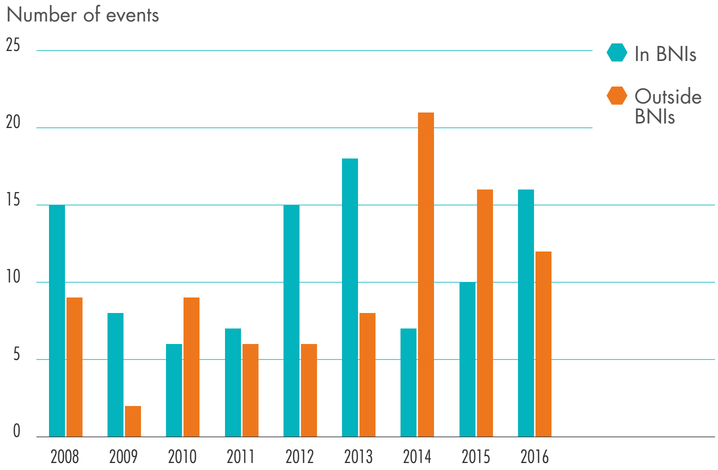
The operators undertook several operations to try to get the source into the safe position. They more specifically disconnected the remote control cable at the back of the device. The operators finally saw that part of the source holder had fractured and stopped their operations.

Exposure of workers was limited because the source was located inside the projector. Nevertheless, the damage to the projector did not facilitate the actions to place the source it contained in safe condition. The area in which the incident occurred had to be kept under permanent surveillance for several days pending the deployment of specific measures to enable the projector to be removed safely.

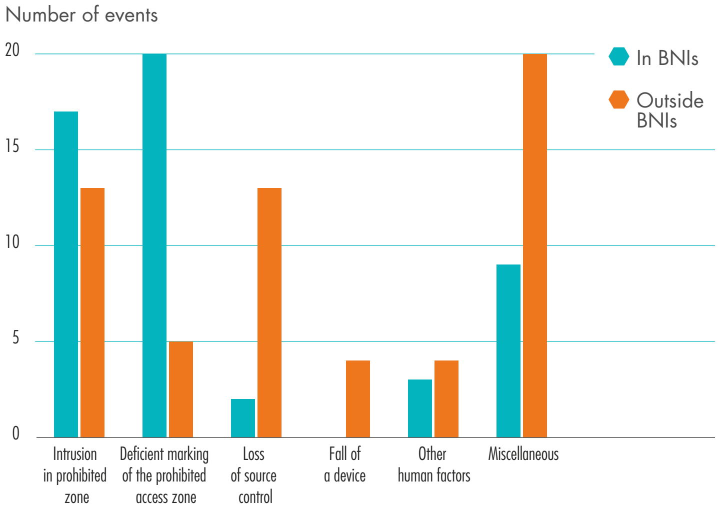
The series of incidents recorded in 2014 caused by rupture of the plug on GAM 80/120 devices had led ASN to require the supplier to implement preventive measures during annual maintenance of the devices. After 2015, a year in which no events of this type were reported to ASN, one event involving the rupture of a plug was notified in 2016. The plug in question was reportedly replaced by a new plug a few weeks before the incident. The incriminated devices will undergo a technical investigation to determine the cause of the rupture.

Other source jamming incidents were reported, caused by failures such as non-connection of the remote control cables or guides or of the guide tubes. These incidents were correctly managed by the operators and managers of the companies concerned, and were rapidly resolved. Even though the French regulations are on the whole adhered to and are more stringent than the international standards, ASN considers that improvements are still required in worksite preparation and incident management.

GRAPH 8: Trend in the number of industrial radiography events notified reported to ASN



GRAPH 9: Main causes of industrial radiography events notified to ASN in 2016



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Loss of control of the source in gamma radiography

Gamma radiography is a non-destructive testing technique consisting in positioning a radioactive source close to the element to be inspected in order to obtain a radiographic image which can subsequently be used to check the quality of the part.

The loss of control of the sources is one of the main causes of incidents in this field. It can lead to significant exposure of the workers nearby, or even of the public if used in an urban area. This loss of control is primarily encountered in two situations:

- The radioactive source remains jammed in its guide tube. The cause of jamming is often the presence of foreign bodies in the tube, or deterioration of the tube itself.
- The source-holder containing the radionuclide is no longer connected to the remote control. The cable joining the source and the remote control is not correctly connected and the source can no longer be moved.

In France, gamma radiography devices have to comply with technical specifications that are stricter than the international standards. However, equipment failures can never be ruled out, especially in the event of poor upkeep of the equipment. Inappropriate operator actions are also often observed following incidents.

Lastly, ASN notes that the procedures and steps to be taken by the device operators when confronted with these situations are not well enough known and applied.

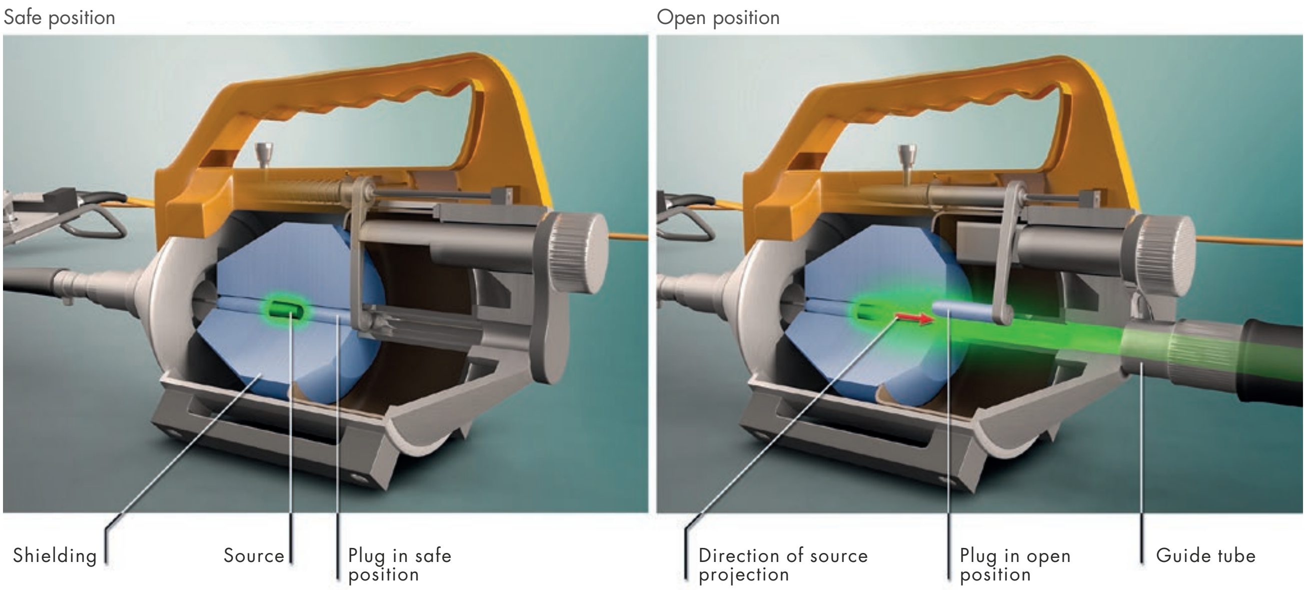
FUNDAMENTALS

Gamma radiography Serious accidents abroad

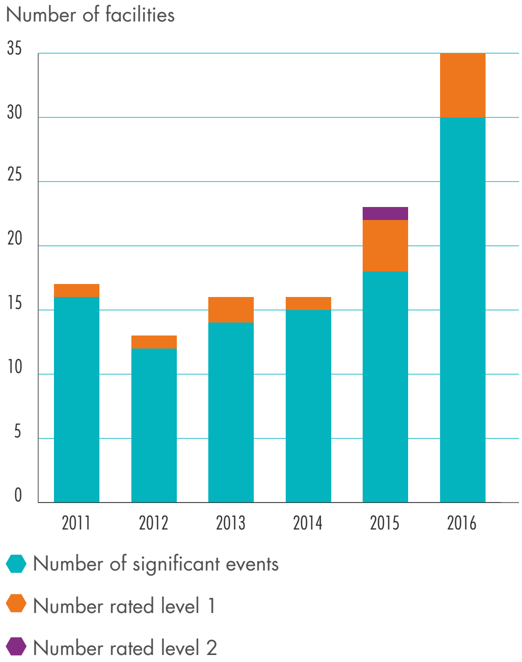
The number and consequences of gamma radiography accidents in France have remained limited since March 1979, when a worker had to have a leg amputated after having picked up a 518 GBq source of iridium-192 and put it in his pocket. This incident led to a tightening of the regulations in effect at the time. ASN continues to keep itself informed of significant accidents around the world which have had severe deterministic effects. Recent examples brought to ASN's attention include:

- In 2016, in Turkey, the operators had apparently not verified that the source had returned to the safe position after using a gamma ray projector. A 16-year old adolescent found the source the day after the inspection and took it home where several persons said they handled it. 20 people in all were reportedly exposed, with most severely exposed person reportedly receiving a dose of 1 gray (Gy). The event was rated level 2 on the INES scale.
- In 2015, in Iran, two operators were exposed to an effective dose of 1.6 and 3.4 gray (Gy) respectively. The gamma ray projector source (iridium-192 of 1.3 TBq) became disconnected and remained blocked in the guide tube without the operators realising it. The operators then spent the night in their vehicle near the guide tube and the source.
- In 2014 in Peru, an employee was exposed to 500 mSv whole body and 25 Gy on the left hip when he moved a guide tube and a collimator without realising that the source was disconnected from the remote control cable and had remained in the collimator (iridium-192, 1.2 TBq, 30 minutes of exposure).
- In 2013, in Germany, an employee of a non-destructive testing company was exposed to more than 75 mSv whole body and 10 to 30 Gy at the extremities (hands) while attempting to release a source from a guide tube.
- In 2012, a Peruvian employee was admitted to Percy hospital in Clamart following exposure of 1 to 2 Gy (whole body) and of 35 Gy to the hand (70 Gy at the fingertips) after handling a guide tube with his bare hands, without first checking the position of the source. The industrial radiographer required partial amputation of the fingers of the left hand.
- In 2011, 5 Bulgarian workers were admitted to Percy hospital in Clamart for major treatment following irradiation of 2 to 3 Gy owing to an error in the handling of a gamma ray projector, from which they believed the source had been removed.
- In 2011, in the United States, an apprentice radiographer disconnected the guide tube, noticed that the source was protruding from the source applicator and tried to push the source into the device with his finger. The estimated dose received at the extremities is 38 Gy.

CROSS-SECTIONAL VIEW of a gamma ray projector



GRAPH 10: Trends in the number of events notified to ASN in the research sector



Research activities

In 2016, ASN registered 35 significant event notifications relating to research activities, that is to say two times more than in the preceding years.

The notified significant events are of two main types:
- theft or loss of radioactive sources (41%);
- detection of contamination (44%).

The predominance of these two themes matches the findings already noted for the period 2011-2013. As for the issues relating to the sources, they can be explained in particular by the lack of measures relating to their disposal when laboratories ceased their activities in the past, thus leading to the existence of this «legacy». They are heightened by the fact that inventories are not drawn up regularly and are not exhaustive.

Detection of contamination causing several significant events is due to the type of sources used in this sector, mainly unsealed sources for which contamination cannot be completely excluded, plus a number of bad practices.

6. Assessment of radiation protection in the industrial, research and veterinary sectors, and outlook

In the regulation of practices involving ionising radiation in the industrial, research and veterinary sectors, ASN is working to ensure that the operators take full account of the risks involved in the use of ionising radiation.

Industrial radiography

Industrial radiography activities have serious radiation protection implications for the workers and are an inspection priority for ASN, with some 100 inspections carried out per year in this field, including unannounced night-time inspections on worksites. The system of on-line notification of worksite schedules for industrial radiography contractors put in place by ASN in 2014 facilitates the organisation of these inspections. A lack of reliability of the information communicated by some contractors has nevertheless been observed.

From its inspection findings, ASN considers that the way risks are taken into account varies between companies. The regulations relating to worker training, to the periodic third party inspection of sources and devices and to worker dosimetry are satisfied on the whole. However, despite the progress made, preparation of work at sites still requires close attention from the various parties involved, more specifically on the worksite to mark out the work zones, for the forecast dose evaluations and for coordination between the ordering customers and the contractors in order to reinforce work preparation and allow effective preventive measures to be taken. ASN is worried by the deficiencies in work zone marking as such delineation constitutes the main safety barrier in the worksite configuration, in particular to prevent inadvertent exposure.

The work conditions on the site (poor accessibility, night work, etc.), equipment maintenance (projectors, guide tubes, etc.) are major factors affecting worker safety. The incidents often result from sources getting jammed outside the safe shielded position. ASN notes that the exposure rates and condition of the equipment are not unrelated to the probability of an incident. It moreover underlines that if any equipment operating anomalies are observed when using a gamma ray projector, such as abnormal source projection or retraction forces, operations should be immediately stopped and the equipment inspected (see point 5). Furthermore, if a source becomes jammed, no attempt should be made to free it, and the on-site emergency plans required by the regulations – though rarely drawn up – should be implemented.

With regard to justification and optimisation, the work undertaken by the non-destructive testing professionals has resulted in the development of guidelines with the aim of promoting the use of alternative methods. The NDT professionals have continued the work, in particular with regard to the updating of the construction and maintenance codes for industrial equipment, in order to favour the use of non-ionising inspection methods.

ASN considers that the ordering customers have a key role to play in ensuring progress in radiation protection in industrial radiography. Enhancing the awareness of all the players is a priority. The regional initiatives to establish charters of good practices in industrial radiography implemented for several years now at the instigation of ASN and the labour inspectorate, particularly in the Provence-Alpes-Côte d'Azur, Normandie, Auvergne-Rhône-Alpes, Hauts-de-France, Bretagne and Pays de la Loire regions, have allowed regular exchanges between the various participants and will thus be continued. The ASN regional divisions and other regional administrations concerned also organise regional awareness-raising and discussion symposia which are attracting growing interest from the stakeholders of this branch.

Since the significant incidents that occurred early in the 2010's involving jamming of industrial gamma radiography sources, the follow-up actions initiated by ASN and conducted with all the stakeholders and IRSN, based on the analysis of the incidents, has identified generic technical solutions that facilitate the recovery of gamma radiography sources following loss of control (see box on page 347). Several specific tools have been designed and implemented by the supplier for this purpose.

According to the survey carried out by ASN in the sector, 70% of the industrial radiography agencies have a specialised fixed facility (bunker) and 70% of the agencies also operate in "worksite" configuration. 50% of the industrial radiography tests performed are in worksite configuration. In this configuration, devices with iridium-192 sources are the most commonly used, representing two-thirds of the worksites. X-ray generators are mainly used on the other worksites. Very few tests are conducted outside the bunker with particle accelerators or gamma ray projectors using cobalt-60 or selenium-75 sources. On the whole, one test in three uses iridium-192 in the worksite configuration. These worksites are primarily located in industrial units and processes and in BNIs.

The significant percentage of tests in worksite configuration within industrial units suggests insufficient application of the justification principle because in many cases parts could probably have been transported to a secure bunker for NDT.

ASN has continued the initiatives undertaken with the DGT (General Directorate for Labour) to overhaul the existing regulatory texts with tightening of requirements regarding justification, given that recognised alternative methods exist. This work will be continued in 2017 as part of the transposition of the BSS Directive.

The design of the devices and facilities, the use of devices, particularly on worksites, and the training of the operators were reviewed during this regulatory overhaul process and within the working group comprising all the stakeholders. This tightening of the regulations will also involve the ordering customers with regard to justification and the human and material resources available in the event of incidents.

Research establishments

ASN's oversight of establishments and laboratories using radioactive sources for research purposes shows a distinct improvement in radiation protection in this sector. Generally

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Mössbauer spectrometry

Mössbauer spectrometry is a technique for exploring matter. From the observation of gamma ray absorption by samples of matter, it enables a magnetic «identity card» of matter to be drawn up at the microscopic level and the properties of matter to be estimated at the macroscopic level. It enables scientific studies to be conducted for diverse practical applications such as the magnets used in electric motors or in cooling systems. This technique only applies to metallic materials in the solid state and is used mainly on iron and tin analysed by the gamma rays of cobalt-57 and tin-199m respectively.

In practice, a sample is placed between a vibrating source and a gamma ray detector. The set-up is coupled to a signal processing system. For cobalt-57 - the most commonly used radionuclide - the activity involved is about 1 to 2 GBq.

In 2015 the ASN regional divisions conducted an inspection campaign in laboratories using Mössbauer spectrometry; seven facilities comprising 16 spectrometers representing about one third of the spectrometer pool were inspected. The results of these inspections, drawn up in 2016, show that the radiation protection of workers using Mössbauer spectrometry is on the whole satisfactory. Under normal conditions, Mössbauer spectrometry presents low radiation risks. ASN does however note a non-negligible risk of exposure of the extremities when putting samples in place. The optimisation of these operations with respect to exposure of the extremities requires particular vigilance and can be improved by using beam shielding systems.

speaking, the steps taken in recent years have produced significant results in the way radiation protection is taken into account in research activities and an overall rise in awareness of radiation protection issues.

The most notable improvements concern the involvement of the Person Competent in Radiation protection (PCR), the training of exposed workers, radiation protection technical controls and waste and effluent storage conditions. Considered on the whole, an improvement in the formalising of procedures is observed, but this trend must be confirmed by actually implementing the predefined actions: in-house radiation protection controls, management and follow-up of significant events and disposal of old sealed sources.

As mentioned in point 5, the notification criteria and the regulatory requirements with regard to reporting to ASN are becoming increasingly well known in research facilities but ASN notes that there is still little in-house supervision of radiation protection event follow-up and notification in the research establishments that have been inspected by ASN, where more than half of them do not have procedures for managing significant events.

The technical, economic and regulatory difficulties concerning the disposal of old sealed sources are often raised by licensees. The work of the ad hoc working group created to address this issue as part of the French National Radioactive Material and Waste Management Plan for 2012-2015 has led to a modification in the regulations (Decree 2015-231 of 27th February 2015 relative to the management of disused sealed radioactive sources) which came into effect on 1st July 2015. This modification, which aims to facilitate the disposal of sealed sources, gives source holders the possibility of seeking different disposal routes with source suppliers or Andra without making it obligatory to return sources to the original supplier.

ASN is continuing its collaboration with the General Inspectorate of the French Education and Research Administration. An agreement signed in 2014 formalises discussions on inspection practices and the setting up of reciprocal information procedures for improving the effectiveness and complementarity of the inspections.

Veterinary surgeons

With regard to veterinary structures, the administrative situation has been continuously improving for a number of years now. At the end of 2016, ASN counted some 4,104 notified or licensed structures out of the 5,000 structures using ionising radiation in France.

Among the veterinary activities, those performed on large animals (primarily horses) and outside specialised veterinary facilities (in so-called "worksite" conditions), are considered to be those with the highest potential radiation risks, more specifically for persons external to the veterinary practice taking part in these procedures. The inspections carried out by ASN on more than 30% of these veterinary facilities as part of a national priority in the inspection programme revealed areas for improvement on which ASN remains vigilant when examining license applications and performing inspections:
- worker monitoring by active dosimetry and in-house radiation protection controls;
- setting up supervised or controlled areas;
- the necessity to reinforce the radiation protection of persons external to the veterinary practice who participate in the diagnostic procedures.

The result of the efforts made by the veterinary bodies in the last few years to ensure conformity with the regulations have been confirmed by the inspectors who have noted good field practices in the inspected structures, and more specifically:
- the presence of in-house PCRs in the majority of structures;
- the virtually systematic use of Personal Protective Equipment;
- efforts to optimise the conditions of diagnosis in nearly all the structures.

The extensive nationwide commitment of this profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting framework documents and guides is viewed in a very positive light by ASN, which each year takes part in meetings with the profession's national bodies (more particularly the

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Research activities

The use of ionising radiation in research activities extends to various fields such as medical research, molecular biology, the agri-food industry, materials characterisation, etc. It primarily involves the use of unsealed sources (iodine-125, phosphorour-32, phosphorous-33, sulphur-35, tritium-3, carbon-14, etc.). Sealed sources (barium-133, nickel-63, caesium-137, cobalt-60, etc.) are also used in gas chromatographs or scintillation counters or, with higher-activity sources, in irradiators. Electric generators emitting X-rays are used for X-ray fluorescence or X-ray diffraction spectrum analyses. One should also note the existence of scanners for small animals (cancer research) in research laboratories and medical schools. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

The number of licenses issued by ASN in the research sector remains stable at around 800. Each year, ASN carries out 50 to 60 inspections on average in this sector.

Veterinary Radiation Protection Commission) jointly with the General Directorate for Labour.

The conventional radiology activities performed on pets (called «canine activities» in France) involve lower radiation risks but represent a very large number of veterinary clinics. As part of its graded approach which consists in adapting the control methods to the radiation risks, ASN conducted an experimental control campaign which called upon new dematerialised control methods based on an on-line self-assessment questionnaire. The campaign was carried out in seven *départements* (Aisne, Allier, Aube, Cantal, Haute-Loire, Pas-de-Calais and Puy-de-Dôme) where the questionnaire was sent to all the veterinary clinics. ASN then carried out a more detailed remote documentary check with a limited number of clinics chosen according to the level of regulatory compliance. Lastly, a field inspection campaign was carried out at 40 clinics. These inspections showed that the main regulatory radiation protection provisions were taken into account fairly satisfactorily. The most positive points observed concern more specifically the availability of personal protective equipment (100% of the clinics inspected), the presence of an PCR (95%), the availability of a dosimeter (90%), compliance of the administrative situation (86% of the inspected clinics had notified ASN of their activity), and performance of the in-house (86%) and third-party (81%) radiation protection controls.

The most common deviation (involving 57% of the inspected clinics) was the lack of a document certifying conformity of the premises in which the radiology devices are used.

It was moreover noted that the clinics contacted took measures to ensure regulatory compliance as soon as the received the self-assessment questionnaires.

This inspection campaign, carried out in close collaboration with the Higher Council of the Order of Veterinarians, started at the end of June 2015 and continued in 2016.

Suppliers of ionising radiation sources

ASN considers that the regulatory oversight of suppliers of electrical ionising radiation generators is still insufficient, even though putting such devices on the market is of prime importance for optimising the future radiation protection of the users of these devices (see point 4.4). The initiative conducted by ASN in this area led to the publication of ASN resolution 2013-DC-0349 of 4th June 2013 and will be continued in order to propose a revision of this resolution in 2017 and a regulatory framework for devices distributed in France.

Cyclotrons

ASN has been exercising its oversight duty in this field since early 2010; each new facility or major modification of an existing facility undergoes a complete examination by ASN. The main radiation protection issues on these facilities must be considered as of the design stage. Application of the standards, in particular standard NF M 62-105 "Industrial accelerators: installations", ISO 10648-2 "Containment enclosures" and ISO 17873 "Nuclear facilities - Criteria for the design and operation of ventilation systems for nuclear installations other than nuclear reactors", ensures safe use of the equipment and a significant reduction in risks.

The entities that operate a cyclotron and use it to produce radionuclides and products containing radionuclides are subject to gaseous effluent discharge limits specified in their license. The discharge levels depend on the frequency and types of production involved.

Systems for filtering and trapping the gaseous effluents are installed in the production enclosures and in the facilities' extraction systems in order to minimise the activity discharged at the stack outlet. Consequently, the very low activities discharged and the short half-life of the radionuclides discharged in gaseous form means there is no impact on the public or the environment.

Some licensees have also installed, beside the shielded enclosures, systems for recovering the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment.

ASN performs about a dozen inspections on these facilities every year. Aspects related to radiation protection, user safety and the correct operation of cyclotrons and production platforms receive particular attention during the inspections. The scope of the inspections performed includes - apart from the aspects relating to radiation protection - monitoring and maintenance of the production equipment, inspection of the surveillance and control systems and the gaseous discharge results. The radiation protection organisation of these facilities is satisfactory and they are fully familiar with the regulations. National action plans have been put in place by the licensees and are monitored by ASN in order to ensure continuous improvement of radiation protection and safety in these facilities.

There are disparities in the technical and organisational means implemented by the licensees according to the age of the facilities and the type of activities performed (research or industrial production). Experience feedback in this area has led ASN to request IRSN to establish recommendations and requirements necessary for the control of the radiological risks applicable to entities using a cyclotron for producing radionuclides and products containing radionuclides. A draft resolution on the minimum technical design, operating and maintenance rules for this type of facility is currently being prepared by ASN and was made available for consultation by the stakeholders in 2016. ASN and IRSN will continue this work in 2017 by analysing the various contributions. The draft text will then again be made available for consultation.

In the same area, ASN wanted to undertake an in-depth study of the discharges emitted into the environment by these facilities. All licensees using a cyclotron to produce radionuclides were sent a questionnaire drawn up by ASN and IRSN. IRSN has been tasked with analysing the responses. The results of these studies are expected in 2017.

The implementation of new administrative systems

As from 2017, ASN will prepare the entry into effect of new administrative systems applicable to nuclear activities by establishing more specifically, as early as possible, a classification nomenclature for the various categories of nuclear activities. It will use this as a basis for issuing the necessary ASN resolutions so that the nuclear activities concerned can be classified in the notification or registration systems and will define the requirements to be satisfied when exercising the activities. It will also modify the resolutions relating to the content of notifications and of the license application files by incorporating the elements necessary for overseeing the security of sources, among other things.

Overseeing the protection of radioactive sources against malicious acts

In 2016, ASN and its institutional partners continued preparing the required for effective implementation of oversight. As from 1st July 2017, the persons/entities responsible for nuclear activities shall take all appropriate measures to protect their ionising radiation sources against malicious acts and, in particular, make access to the most dangerous sources, their transportation and access to sensitive information subject to individual authorisations. ASN has been designated the oversight authority with regard to these provisions for the majority of radioactive sources.

The publication of a decree and a complementary order is planned for 2017. The persons/entities responsible for nuclear activities will have until 1st July 2018 to implement these provisions, which gives them time to look ahead and plan the measures to put in place.

ASN has also continued the actions it had undertaken to keep ahead with its staff training and the development of appropriate tools to ensure prompt and efficient embracing of this new mission. In 2017 it will continue to adapt the tools it already uses for radiation protection control (ASN resolutions setting the contents of license applications, the associated forms, the publication of guides for the licensees and the inspectors, etc.), it will ensure the training of its inspectors accordingly and will also communicate extensively with the licensees. As of July 2017 ASN will check that the requirements enforceable on that date are actually implemented and will review the first requests for waivers, if any, from the abovementioned ministerial order.

11

Transport of radioactive substances


TH1
MATIERES RADIOACTIVES DE
AREVA
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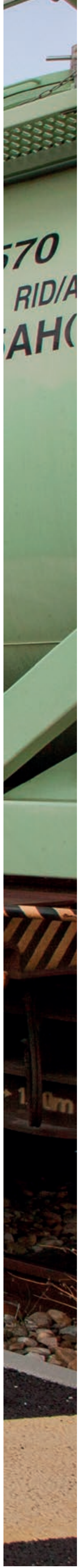


The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity. The scope of regulation of the safety of radioactive substance transport covers various fields of activity in the industrial, medical and research sectors. It is based on stringent and restrictive international regulations.

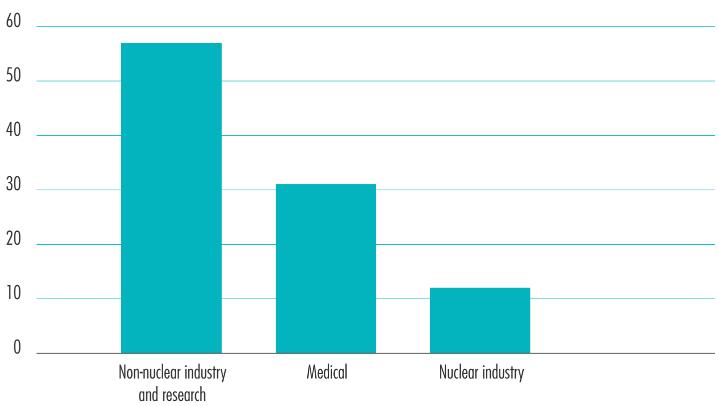
1. Radioactive substances traffic

The regulations divide the dangerous goods liable to be transported into nine "classes" according to the nature of the corresponding risk (for example: explosive, toxic, flammable, etc. materials). Class 7 covers radioactive substances.

The transport of radioactive substances stands out through its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to about a hundred tons and the radiological activity of their content can range from a few thousand becquerels to billions of billions of becquerels for the packages of spent nuclear fuel. The safety issues are also extremely varied. The vast majority of packages have limited individual safety implications, but for a small percentage of them, the potential safety consequences are high.

About 770,000 consignments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, or just a few percent of the total number of dangerous goods packages transported each year in France. The vast majority of shipments are made by road, but some also take place by rail, by sea and by air (see Table 1). These shipments concern three activity sectors: non-nuclear industry, medical sector and nuclear industry (see Graph 1).

GRAPH 1: Proportion of packages transported per field of activity



Most of the packages transported are intended for the non-nuclear industry, or for non-nuclear research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported with considerable frequency. For example, these could be devices for detecting lead in paint, used for real estate sale diagnostics, or gamma radiography devices used to detect defects in materials. Travel to and from the various worksites explains the very large number of transport operations for the non-nuclear industry. The safety issues vary considerably: the radioactive source contained in lead detectors has very low radiological activity, while that contained in gamma radiography devices has a far higher activity.

About one third of the packages transported are used in the medical sector: this is to provide health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and to remove the radioactive waste. The activity of radiopharmaceutical products decays rapidly (for example, the radioactive half-life of fluorine-18 is close to two hours). Consequently, these products have to be regularly shipped to the nuclear medicine units, creating a large number of transport operations, which have to be carried out correctly to ensure the continuity of the health care given. Most of these products have limited activity levels, although a small proportion of them, such as the sources used in radiotherapy or the irradiated sources used to produce technetium (used in medical imaging) have significant safety implications.

Finally, 12% of the packages shipped in France are for the nuclear industry. This represents about 19,000 shipments annually, involving 114,000 packages. These transport operations are necessary for the working of the fuel cycle, owing to the distribution of the various facilities and NPPs around the country (see map below). Depending on the step in the cycle, the physicochemical form and radiological activity of the substances varies widely. Transport operations with very high safety implications are the shipments of uranium hexafluoride (UF_6) whether or not enriched - which are dangerous more specifically owing to the toxic and corrosive properties of the hydrogen fluoride formed by UF_6 in contact with water - the spent fuel shipments to the La Hague reprocessing plant and the transport of certain nuclear wastes.

TRANSPORT operations relating to the fuel cycle in France

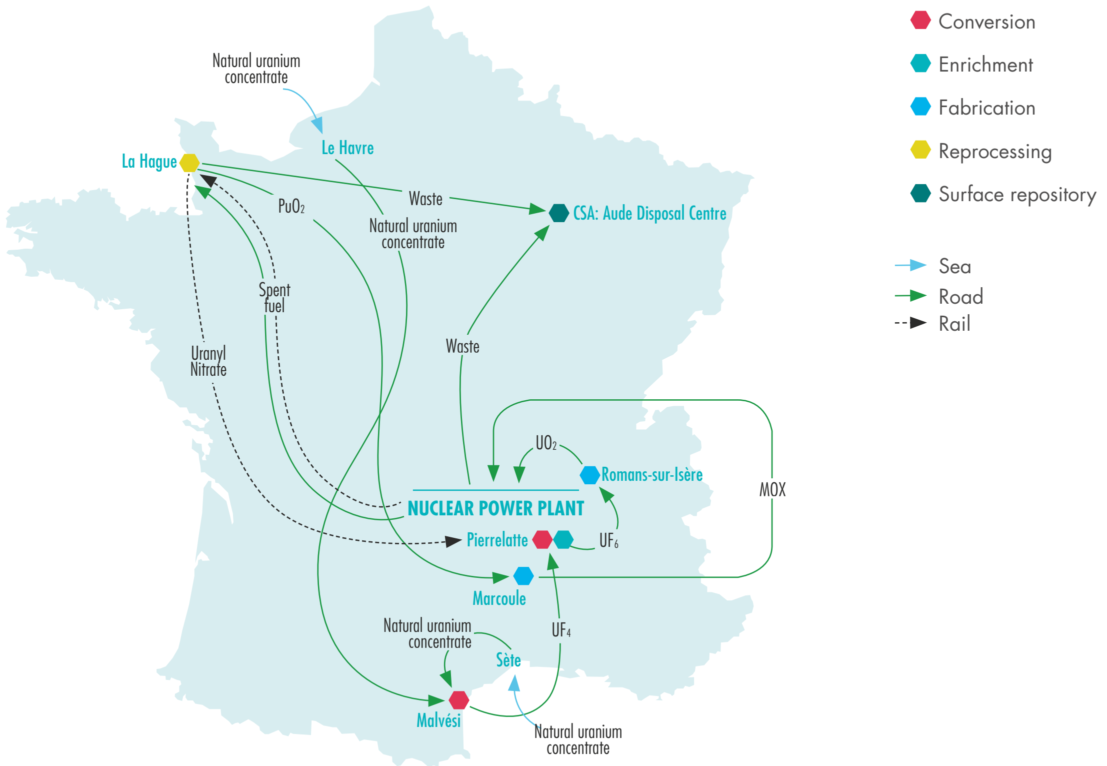


TABLE 1: Breakdown per mode of transport (rounded figures)

APPROXIMATE NUMBER OF PACKAGES AND SHIPMENTS		ROAD	ROAD AND AIR	ROAD AND RAIL	ROAD AND SEA	ROAD, SEA AND RAIL	ROAD, SEA AND AIR
Packages approved by ASN	Number of packages	18,000	1,300	460	1,900	0	0
	Number of shipments	12,500	1,250	380	390	0	0
Packages not requiring approval by ASN	Number of packages	870,000	47,000	2,900	6,800	34,500	5,300
	Number of shipments	740,000	21,000	530	910	80	5,300

The annual transports linked to the nuclear industry can be broken down approximately as follows:

- 200 shipments transporting spent fuel from the nuclear power plants operated by EDF to the La Hague reprocessing plant operated by Areva;
- about 100 shipments of plutonium in oxide form transported from the La Hague reprocessing plant to the MELOX fuel production plant in the Gard *département*;
- 250 shipments of uranium (UF_6) hexafluoride necessary for fuel manufacturing.
- 400 shipments of new uranium-based fuel and some 50 shipments of new uranium and plutonium-based "MOX" fuel;
- 2,000 shipments from or to foreign countries or transiting via France, representing about 58,000 packages shipped.

The statistical data presented in this chapter come from a study conducted by ASN in 2012. It is based on information collected in 2011 from all the consignors of radioactive substances (BNIs, laboratories, hospitals, source suppliers and users, etc.), as well as on reports from the dangerous goods safety advisers. A summary is available on the ASN website[1].

1. *www.asn.fr/Informer/Actualites/Enquete-de-l-ASN-sur-les-flux-de-transport-de-substances-radioactives (ASN survey on radioactive substances traffic).*

2. Regulations governing the transport of radioactive substances

2.1 Risks associated with the transport of radioactive substances

The major risks involved in the transport of radioactive substances are:
- the risk of external irradiation of persons in the event of damage to the “radiological protection” of the packages, a material that reduces the radiation received through contact with the packages of radioactive substances;
- the risk of inhalation or ingestion of radioactive particles in the event of release of radioactive substances out of the packaging;
- contamination of the environment in the event of a release of radioactive substances;
- the onset of an uncontrolled nuclear chain reaction (criticality risk) that can cause serious irradiation of persons. This risk only concerns fissile substances.

Radioactive substances can also present a chemical risk. This, for example, is the case with shipments of natural uranium with low radioactivity, for which the major risk for humans is related to the chemical nature of the compound, more particularly if it is ingested. Similarly, uranium hexafluoride, used in the manufacture of fuels for nuclear power plants can, in the case of release and contact with water, form hydrofluoric acid, a powerful corrosive and toxic agent.

By their very nature, transport operations take place across the entire country and are subject to numerous contingencies that are hard to control or anticipate, such as the behaviour of other vehicles using the same routes. A transport accident at a given point in the country cannot therefore be ruled out, possibly in the immediate vicinity of the population. Unlike events occurring within Basic Nuclear Installations (BNI), the personnel of the companies concerned are generally unable to intervene immediately, or even give the alert (if the driver is killed in the accident).

To deal with these risks, specific regulations have been set up to handle radioactive substance transport operations.

2.2 Principle of defence in depth

In the same way as the safety of facilities, the safety of transport is based on the concept of defence in depth, which consists in implementing several technical or organisational levels of protection, in order to guarantee the safety of the public, workers and the environment, in routine conditions, in the event of an incident and in the event of a severe accident. In the case of transport, defence in depth is built around three complementary levels of protection:
- The robustness of the package is designed to ensure that the safety functions are maintained, including in the event of a severe accident. To guarantee this robustness, the regulations require reference tests which the packages must be able to withstand.
- The reliability of the transport operations minimise the occurrence of anomalies, incidents and accidents. This reliability is guaranteed by compliance with the regulatory requirements, such as training of the various persons involved, the use of a quality assurance system for all operations, compliance with the package utilisation conditions, effective stowage of packages, etc.
- Emergency situation management enables the consequences of incidents and accidents to be mitigated. For example, this third level entails the preparation and distribution of instructions to the various parties, to be applied in an emergency, the implementation of emergency plans, the performance of emergency exercises.

As mentioned in the above paragraph, a transport accident can in theory occur anywhere and could therefore be remote from specialised emergency response services. Consequently, the robustness of the packages is particularly important: the package must, as a last resort, offer sufficient protection to mitigate the consequences of an accident, however severe.

2.3 The requirements guaranteeing the robustness of the various types of packages

There are five main package types: excepted packages, industrial packages, type A packages, type B packages and type C packages. These package types are determined according to the characteristics of the material transported, such as total radiological activity, specific activity, corresponding to the degree of concentration of the material, and its physicochemical form.

The regulations define tests, which simulate incidents or severe accidents, following which the safety functions must still be guaranteed. The severity of the regulation tests is appropriate to the potential danger of the substance transported. Furthermore, additional requirements apply to packages carrying uranium hexafluoride or fissile materials, owing to the specific risks these substances entail.

2.3.1 Excepted packages

Excepted packages are used to transport very small quantities of radioactive substances, such as very low activity radiopharmaceuticals. Due to the very limited safety issues, these packages are not subject to any qualification tests. They must nevertheless comply with a number of general specifications, notably with regard to radiation protection, to guarantee that the radiation around the excepted packages remains very low.

2.3.2 Non-fissile industrial or type A packages

Type A packages can, for example, be used to transport radioisotopes for medical purposes commonly used in nuclear medicine departments, such as technetium generators. The total activity which can be contained in a type A package is limited by the regulations.

Type A packages must be designed to withstand incidents which could be encountered during transportation or during handling or storage operations (small impacts, package stacking, falling of a sharp object onto the packages, exposure to rain). These situations are simulated by the following tests:

- exposure to a severe storm (rainfall reaching 5 cm/hour for at least 1 hour);
- drop test onto an unyielding surface from a height varying according to the mass of the package (maximum 1.20 m);
- compression equivalent to 5 times the weight of the package;
- penetration by dropping a standard bar onto the package from a height of 1 m.

Additional tests are required if the content of the package is in liquid or gaseous form.

Industrial packages allow the transportation of material with a low specific activity, or objects with limited surface contamination. Uranium-bearing materials extracted from foreign uranium mines are, for example, carried in France in industrial drums with a capacity of 200 litres loaded into industrial packages. Three sub-categories of industrial packages exist according to the risk presented by the content. Depending on their sub-category, the industrial packages are subjected to the same tests as type A packages, some of the tests or only the general provisions applicable to excepted packages.

Due to the limited safety issues, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety demonstration files are subject to spot checks during the ASN inspections.

2.3.3 Fissile and type B packages

Type B packages are those used to transport the most radioactive substances, such as spent fuel or vitrified high-level nuclear waste. The packages containing fissile materials are industrial, A or B type packages, which are also designed to carry materials containing uranium-235 or plutonium and which can thus lead to the start of an uncontrolled nuclear chain reaction. These packages are essentially for the nuclear industry. Gamma radiography devices also fall into the type B package category.

Wagon used to transport vitrified waste packages.

Given the high level of risk presented by these packages, the regulations require that they be designed so that, including in the case of a severe transport accident, they maintain their ability to confine the radioactive material and ensure radiological protection (for type B packages) and sub-criticality[2] (for packages containing fissile materials). The accident conditions are simulated by the following tests:

- A 9m drop test onto an unyielding target. The fact that the target is unyielding means that all the energy from the fall is absorbed by the package, which is highly penalising. If a heavy package actually falls onto real ground, the ground will deform and thus absorb a part of the energy. A 9m drop onto an unyielding target can thus correspond to a fall from a far greater height onto real ground. This test can also be used to simulate the case of the vehicle striking an obstacle. During the 9m free-fall test, the package reaches the target at about 50 km/h. However, this corresponds to a real impact at far greater speed, because in reality, the vehicle and obstacle would both absorb a part of the energy.
- A punch test: the package is released from a height of 1 m onto a metal spike. The aim is to simulate the package being damaged by perforating objects (for example debris torn off a vehicle in the event of an accident).
- A fire test at 800°C for 30 minutes. This test simulates the fact that the vehicle can catch fire after an accident.
- An immersion test under 15 m of water for 8 hours. This test is used to verify the pressure-resistance if the package were to fall into water (river by the side of the road or port during offloading from a ship). Certain type B packages must also undergo a more severe immersion test, which involves immersion under 200 m of water for one hour.

The first three tests (drop, punch and fire) must be performed in turn on the same package specimen. They must be performed in the most penalising configuration (package orientation, outside temperature, position of content, etc.).

The type B package models and those containing fissile materials must be approved by ASN or a competent foreign authority, before they can be allowed to travel. To obtain this approval, the designer of the package model must demonstrate the ability to withstand the above-mentioned tests in the safety file. This demonstration is usually provided by means of tests on a mock-up representing the package and by numerical calculations (to simulate the mechanical and thermal behaviour, or to evaluate the criticality risk).

2. *www.asn.fr/Informer/Actualites/Enquete-de-l-ASN-sur-les-flux-de-transport-de-substances-radioactives (ASN survey on radioactive substances traffic).*

2.3.4 Packages containing uranium hexafluoride

Uranium hexafluoride (UF_6) is used in the fuel cycle. This is the form in which the uranium is enriched. UF_6 can thus be natural (i.e. formed from natural uranium), enriched (i.e. with an isotopic composition enriched in uranium-235), and depleted.

Apart from the dangers arising from its radioactivity, or even its fissile nature, UF_6 also presents a significant chemical risk. The regulations thus set out particular prescriptions for packages of UF_6. They must meet the requirements of standard ISO 7195, which governs the design, manufacture and utilisation of packages. These packages are also subject to three tests:

- a free-fall test of between 0.3 and 1.2 metres (depending on their mass) onto an unyielding target;
- a thermal test, with an 800°C fire for 30 minutes;
- a hydrostatic resistance test at 27.6 bar.

Packages containing enriched, and therefore fissile UF_6, are also subject to the prescriptions previously presented (see point 2.3.3).

The UF_6 is transported in type 48Y or 30B metal cylinders. In the case of enriched UF_6, this cylinder is transported with a protective shell, which provides the necessary protection for withstanding the tests applicable to packages containing fissile materials. The package models containing UF_6 must also be approved by ASN or a competent foreign authority, before they can be allowed to travel.

ASN inspection of a shipment of enriched uranium hexafluoride.

2.3.5 Type C packages

Type C package models are designed for the transport of highly radioactive substances by air. In France there is no approval for type C packages for civil uses.

2.4 The requirements guaranteeing the reliability of the transport operations

2.4.1 Radiation protection of workers and the public

The radiation protection of workers and the public around shipments of radioactive substances must be a constant concern.

The public and non-specialised workers must not be exposed to a dose exceeding 1 millisievert (mSv) per year. However, this limit is not intended to be an authorisation to expose the public to up to 1mSv. Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the radiation at the surface of the package must not exceed 2 mSv/h. This limit may be raised to 10 mSv/h in "exclusive utilisation"[3] conditions, because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, the radiation should not exceed 2 mSv/h in contact with the vehicle and should be less than 0.1 mSv/h at a distance of 2 m from the vehicle. Assuming that a transport vehicle reaches the limit of 0.1 mSv/h at 2 metres, a person would have to spend 10 hours without interruption at a distance of 2 metres from the vehicle for the dose received to reach the annual public exposure limit.

These limits are supplemented by requirements relative to the organisation of radiation protection within companies. The companies working in transport operations are required to implement a radiological protection programme, comprising the steps taken to protect the workers and the public from the risks linked to exposure to ionising radiation. This programme is more specifically based on a forecast evaluation of the doses to which the workers and the public are exposed. According to the results of this evaluation, optimisation measures must be taken to ensure that these doses are As Low as Reasonably Achievable (ALARA principle): for example, lead-lined trolleys could be made available to handling staff to reduce their exposure. This evaluation also makes it possible to decide on whether to implement dosimetry to measure the dose received, if it is anticipated that this risk could exceed 1 mSv/year. Finally, all the transport stakeholders must be trained and made aware of the risks linked to radiation, so that they are conscious of the nature of the risks, how to protect themselves and how to protect others.

3. *Exclusive utilisation corresponds to cases in which the vehicle is used by a single consignor. This consignor may then give specific instructions for all the transport operations.*

TABLE 2: Breakdown of transported packages by type

	TYPE OF PACKAGE	APPROXIMATE SHARE OF PACKAGES TRANSPORTED ANNUALLY
Packages approved by ASN	Type B packages, packages containing fissile materials and packages containing UF_6	2%
Packages not requiring approval by ASN	Type A packages not containing fissile radioactive substances	32%
	Industrial packages not containing fissile radioactive substances	8%
	Excepted packages	58%

2.4.2 Package and vehicle signage

So that the workers can be informed of the level of risk involved in each package and so that they can protect themselves effectively, the regulations require that the packages be labelled. There are three types of labels, corresponding to different dose levels in contact and at 1 m from the package. The personnel working in proximity to the packages are thus visually informed of those which lead to the highest dose rates and can thus limit the time they spend close to them or can put them as far away as possible (for example by loading them towards the rear of the vehicle).

The packages containing fissile materials must also carry a special label. This is to ensure that these packages are kept apart to prevent the triggering of a nuclear chain reaction. The special label enables compliance with this prescription to be easily verified.

Finally, the packages must be marked, in particular with their type, the address of the consignor or consignee and an identification number. This enables delivery errors to be avoided and allows packages to be identified if lost.

The vehicles carrying packages of radioactive substances must also have specific markings. Like all vehicles carrying dangerous goods, they carry an orange plate at the front and back. They must also have a placard with the radiation trefoil and the word "RADIOACTIVE". The purpose of these vehicle markings is to provide the emergency services with the necessary information in the event of an accident.

Tank containing uranyl nitrate.

2.4.3 Responsibilities of the different transport players

The regulations define the responsibilities of the various parties involved during the lifetime of a package, from its design up to the actual shipment. These responsibilities entail special requirements. Therefore:

- The corresponding package model must be designed and sized in accordance with the conditions of use and the regulations. For type B or fissile packages, it must be approved by ASN.
- The manufacturer must produce packaging in accordance with the description given by the package designer.
- The consignor is responsible for providing the carrier with a package complying with the requirements of the regulations. It must in particular ensure that the material is authorised for transport, verify that the package is appropriate for its content, use a package that is approved (if necessary) and in good condition, carry out dose rate and contamination measurements and label the package.
- The loader is responsible for loading the package onto the vehicle and for stowing it in accordance with the consignor's specific instructions and the rules of professional good practice.
- The carrier is responsible for carriage of the shipment to its destination. It must notably check the good condition of the vehicle, the presence of the on-board equipment (extinguishers, driver's personal protection equipment, etc.), compliance with the dose rate limits around the vehicle and the positioning of the orange plates and placards.
- The transport may be organised by the carriage commission agent. The carriage commission agent is responsible for obtaining all the necessary authorisations on behalf of the consignor or the consignee, and for sending the various notices. The carriage commission agent also selects the means of transport, the carrier and the itinerary, in compliance with the regulatory requirements.
- The consignee is under the obligation not to postpone acceptance of the goods, without imperative reason and, after unloading, to verify that the prescriptions concerning it have been satisfied. It must more specifically take dose rate measurements on the package after receipt in order to detect any problems that may have occurred during shipment.
- The package owner must set up a maintenance system in conformity with that described in the safety file and the approval certificate in order to guarantee that the elements important for safety are maintained in good condition.

All the transport stakeholders must set up a quality assurance system, which consists of a range of provisions for guaranteeing compliance with the regulatory requirements and providing proof thereof. This for example consists in performing double independent checks on the most important operations, in adopting a system of checklists to ensure that the operators forget nothing, in keeping a trace of all the operations and all the checks performed, etc. The quality assurance system is a key element in ensuring the reliability of transport operations.

The regulations also require that all operators involved in transport receive training appropriate to their functions and responsibilities. This training must in particular cover the steps to be taken in the event of an accident.

FOCUS

Entry into force of the notification obligation for companies carrying out radioactive substance transport operations

On 12th March 2015, the ASN Commission adopted resolution 2015-DC-0503 creating a notification obligation for all companies transporting radioactive substances. This obligation entered into force in 2016 and the notification is made on-line, on the ASN website.

The companies carrying out the following operations are concerned by the notification obligation:
- carriage of packages of radioactive substances;
- loading or unloading of these packages;
- handling of these packages after loading and before unloading;

provided that the corresponding transport operation takes place, at least in part, on French soil.

The information obtained will be made available to the regional divisions. It will in particular provide a means of contacting the company, including in an emergency, of estimating the nature and volume of the activity and identifying the places of loading, unloading and transit storage of the packages. It will also allow improved targeting of the ASN inspections.

In accordance with Article R 4451-1 of the Labour Code, the provisions of the Labour Code concerning the prevention of risks linked to ionising radiation now apply in full to companies which are subject to the notification obligation as at the date of entry into force of this resolution. It should however be noted that the majority of the provisions of the Labour Code were already implemented in a different form under the regulations applicable to transport, which more specifically required that the company draw up a "radiological protection programme" describing all the measures put into place to ensure protection of the workers and the public against ionising radiation. The main innovation resulting from the entry into force of the specific provisions of the Labour Code is that the carriers are required to appoint a radiation protection officer.

Seven days before departure, the transport of some radioactive substances (notably fissile materials) is subject to prior notification of ASN and the Ministry of the Interior by the consignor. This notification stipulates the materials carried, the packagings used, the transport conditions and the details of the consigner, the carrier and the consignee. It is a means of ensuring that the public authorities have rapid access to useful information in the event of an accident. In 2016, 1,267 notifications were sent to ASN.

2.5 Preparedness for emergency management

Emergency management is the final level in the defence in depth system. In the event of an accident involving transport, it should be able to minimise the consequences for the public and the environment.

As a transport accident can happen anywhere in the country, it is probable that the emergency services arriving on the scene would have no specific training in radiological risks and that the population in the vicinity would be unaware of this particular risk. It is therefore particularly important that the national emergency response organisation be robust enough to take account of these points.

In this respect, the regulations set obligations on the various stakeholders in the field of transport. All those involved must therefore immediately alert the emergency services in the event of an accident. This is more particularly true for the carrier, who would in principle be the first party to be informed. It must also transmit the alert to the consignor. Furthermore, the vehicle crew must have written instructions available in the cab, stipulating the first steps to be taken in the event of an accident (for example, trip the circuit-breaker, if the vehicle is so equipped, to prevent any outbreak of fire). Once the alert has been given, the parties involved must place themselves at the disposal of the public authorities to assist with the response operations, more specifically by providing all pertinent information in their possession. This in particular concerns the carrier and the consignor, who have information about the package and its contents that is of great value for determining the appropriate measures to be taken. To meet these regulatory obligations, ASN recommends that the parties involved implement emergency response plans allowing the organisation and tools to be defined in advance, enabling them to react efficiently in the event of a real emergency.

The driver may be unable to give the alert, if injured or killed in the accident. In this case, detection of the radioactive nature of the consignment would be the entire responsibility of the emergency response services. The orange plates on the vehicles indicate the presence of dangerous goods: the emergency response services then automatically evacuate an area with a radius of 100 m around the vehicle. The presence of placards carrying a trefoil indicates that the contents are radioactive, with this information being sent to the office of the Prefect, who then alerts ASN.

Management of the accident would be coordinated by the Prefect, who would oversee the response operations. Until such time as the national experts are in a position to provide him or her with advice, the Prefect would rely on the emergency plan adopted to deal with these situations. This plan more particularly comprises the information sheets drafted by ASN and IRSN, detailing the first steps to be taken according to the type of package involved in the accident, for example the fire fighting means to be used, the need to extend the initial evacuation area or not, the protection necessary for the emergency services, etc. Once its national emergency centre has been activated, ASN would be able to offer the Prefect assistance, by providing technical advice on the more specific measures to be taken. In these situations, IRSN would assist ASN, by assessing the condition of the damaged package and anticipating how the situation could develop. Furthermore, the ASN regional division would dispatch a staff member to the Prefect to facilitate liaison with the national emergency centre.

At the same time, human and material resources would be sent out to the scene of the accident as rapidly as possible (radioactivity measuring instruments, medical means, package recovery means, etc.). The fire service teams specialising in the radioactive risk (the Mobile Radiological Intervention Units – CMIR) would be called on, along with IRSN's mobile units, or the mobile units of certain nuclear licensees (such as CEA or EDF), which could be requisitioned by the Prefect if necessary, even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important issue in the event of a transport accident so that the population can be informed of the situation and given instructions on what to do.

In order to prepare the public authorities for the eventuality of an accident involving a shipment of radioactive substances, exercises are held to test the entire response organisation that would be put into place. In 2016, ASN thus took part in three national emergency exercises simulating an accident and involving the services of the Prefect, the emergency response services, ASN, IRSN and a carrier.

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Local emergency exercises

National emergency exercises are a means of testing the entire emergency response system, but organising them requires considerable resources. Consequently, only a small number of such exercises can be held each year, which means that not all the Prefectures can be trained within a reasonable period of time.

ASN thus aims to set up exercises covering a smaller area but which would be easier to implement. These exercises could be run with the services of the Prefect and the ASN regional division alone, without involving the national emergency response management stakeholders. The aim would then be to test the first moments of an emergency, notably the transmission of the alert, the automatic reflex actions by the emergency response services and the implementation of the first steps of the Prefect's emergency plan. These first moments occur before the national emergency centres are in a position to assist the Prefect.

In conjunction with the Nuclear Risk Management Aid Committee (MARN) at the Ministry of the Interior, ASN tasked IRSN with drawing up a standard scenario for this type of exercise, which could be easily adapted to the various *départements*. These local exercises could be deployed as early as 2017.

2.6 Regulation governing the transport operations within the perimeter of nuclear facilities

Dangerous goods transport operations can take place on the private roads of nuclear sites, in what are referred to as "on-site transport operations". Such operations are not subject to the regulations governing the transport of dangerous goods, which only apply on public highways.

Since 1st July 2013, these transport operations have been subject to the requirements of the "BNI Order" of 7th February 2012 (see chapter 3). This Order requires that on-site transport operations be incorporated into the safety baseline requirements for BNIs. The on-site transport of dangerous goods presents the same risks and inconveniences as the transport of dangerous goods on the public highway. The safety of transport must be overseen with the same rigour as for any other risk or inconvenience present within the perimeter of the BNI.

In 2016, ASN continued to receive notification from most BNIs that they were modifying their general operating rules in order to incorporate on-site transport operations into their baseline safety requirements. These notifications were systematically examined by ASN.

In 2016, ASN more particularly continued the review of the application for modification of the baseline safety requirements applicable to all the EDF nuclear power plants, with a view to incorporating on-site transport operations. ASN also continued its examination of the application submitted by Areva La Hague in order to create a chapter in the general operating rules describing on-site transport operations. During this examination, ASN will take account of the conclusions of the 14th January 2015 joint review by the Advisory Committees for "Transport" (GPT) and "Plants" (GPU) of the safety of certain on-site transport operations. ASN also produced a draft guide designed to provide the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations. However, ASN notes that not all the BNIs licensees have as yet incorporated on-site transport operations into their general operating rules.

3. Roles and responsibilities in regulating the transport of radioactive substances

3.1 Regulation of nuclear safety and radiation protection

The purpose of the safety approach adopted for the transport of radioactive substances is to prevent nuclear accidents and their radiological consequences for people by implementing organisational and technical measures.

In France, ASN has been responsible since 1997 for regulating the safety and the radiation protection of shipments for civil uses, while ASND (the Defence Nuclear Safety Authority) fulfils this role for the shipments relating to national defence. ASN's action in the field of transport comprises:
- from the safety standpoint, checking and overseeing all the stages in the life of a package, from design and manufacture through to maintenance;
- checking compliance with the safety regulations during the shipment and transportation of the packages.

Section 4 of this chapter gives more details on these inspections.

3.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearance, theft and misappropriation of nuclear materials that could be used to manufacture weapons. The Defence and Security High Officials (HFDS), under the Ministers responsible for Energy and Defence, are the Regulatory Authority responsible for preventing malicious acts targeting nuclear materials. In practice, it is the HFDS of the ministry in charge of ecology that is delegated this role by the two abovementioned HFDS.

3.3 Regulation of the transport of dangerous goods

Regulation of the transport of dangerous goods is monitored by the MTMD (Hazardous Materials Transport Mission) of the Ministry of the Environment, Energy and the Sea This entity is tasked with ensuring the measures relative to the safe transport of dangerous goods other than class 7 (radioactive) by road, rail and inland waterways. It has a consultative body (CITMD – Interministerial Hazardous Materials Transport Committee) that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway. Inspections in the field are carried out by land transport inspectors attached to the DREALs (Regional Directorates for the Environment, Planning and Housing).

For regulation of dangerous goods to be as consistent as possible, ASN collaborates regularly with the administrations responsible for applying the regulations in their particular sector of activity. For example, in

TABLE 3: Administrations responsible for regulating the mode of transport and the package

MODE OF TRANSPORT	REGULATION OF MODE OF TRANSPORT	PACKAGE REGULATION
Sea	General Directorate for Infrastructure, Transport and the Sea (DGITM - Ministry of the Environment, Energy and the Sea) In particular, the DGITM is responsible for regulating compliance with the prescriptions applicable to ships and contained in the International Code for the Safe Carriage of Irradiated Nuclear Fuel, Plutonium and High-level Radioactive Wastes on Board Ships ("Irradiated Nuclear Fuel" Code).	The DGITM has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.
Road, rail, inland waterways	General Directorate for Energy and the Climate (DGEC - Ministry for the Environment, Energy and the Sea)	The General Directorate for the Prevention of Risks (DGPR) is responsible for regulating packages of dangerous goods in general and is in close collaboration with ASN for radioactive substances packages.
Air	General Directorate for Civil Aviation (Ministry of the Environment, Energy and the Sea)	The DGAC has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.

2016 ASN took part in the training of DGAC (General Directorate for Civil Aviation) inspectors responsible for monitoring the air transport of hazardous goods in order to teach them about the specific aspects of class 7 and present experience feedback from ASN's inspections on these subjects.

The breakdown of the various regulatory missions is summarised in the following table.

4. ASN action in the transport of radioactive substances

4.1 Delivery of approval certificates and shipment approvals

The type B and C packages, as well as the packages containing fissile materials and those containing more than 0.1 kg of UF_6 must be covered by an ASN transport approval. The designers of the package models who request approval from ASN must support their application with a safety file demonstrating the compliance of their package model with all the regulatory prescriptions. Before deciding whether or not to issue approval, ASN examines this file, drawing on the expertise of the IRSN, in order to ensure that the safety cases are pertinent and sufficient. If necessary, the approval is issued with requests in order to improve the safety cases.

Castor HAW28 packaging being loaded.

In some cases, IRSN's appraisal is supplemented by a meeting of the Advisory Committee for Transport (GPT). The opinions of the Advisory Committees are always published on *www.asn.fr*. The GPT will for example meet in 2017 to examine the TN G3, a new package concept developed by the Areva TN company to transport spent fuel from the EDF NPPs.

The approval certificate specifies the conditions for the manufacture, utilisation and maintenance of the transport package. It is issued for a package model independently of the actual transport operation itself, for which no prior ASN opinion is generally required. But it may be subject to security checks (physical protection of materials against malicious acts under the supervision of the Defence and Security High Official from the Ministry of the Environment, Energy and the Sea).

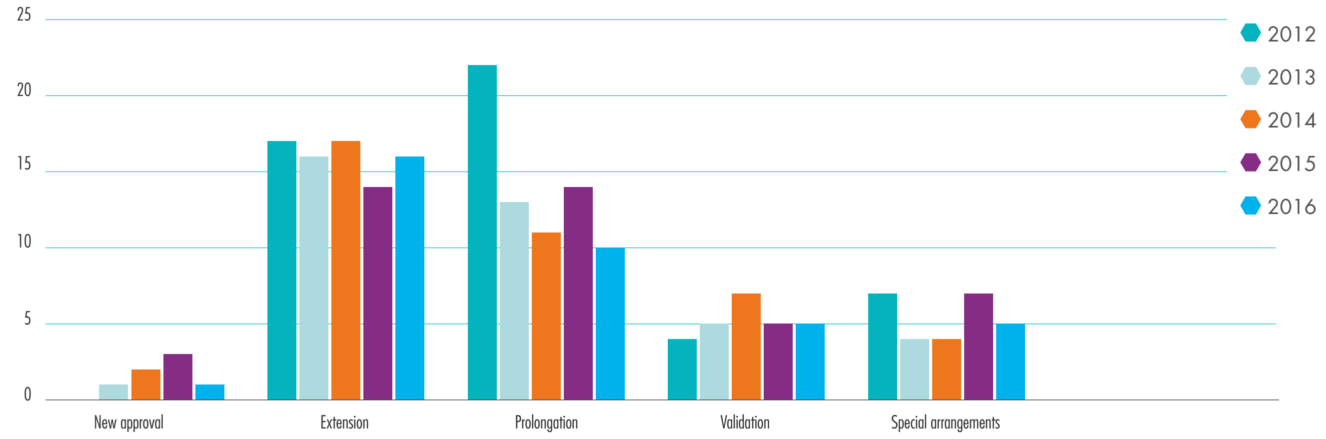
These approval certificates are usually issued for a period of five years. In 2016, 41 approval applications were submitted to ASN by the manufacturers.

If a package is unable to meet all the regulatory prescriptions, the regulations nonetheless allow for its transport by means of a shipment under special arrangement. The consignor must then define compensatory measures to ensure a level of safety equivalent to that which would have been obtained had the regulatory prescriptions been met. For example, if it cannot be completely demonstrated that a package is able to withstand the 9-metre drop, a compensatory measure may be to reduce the speed of the vehicle and have it escorted. The probability of a serious accident (and thus of a violent shock on the package) is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, stipulating the compensatory measures to be applied.

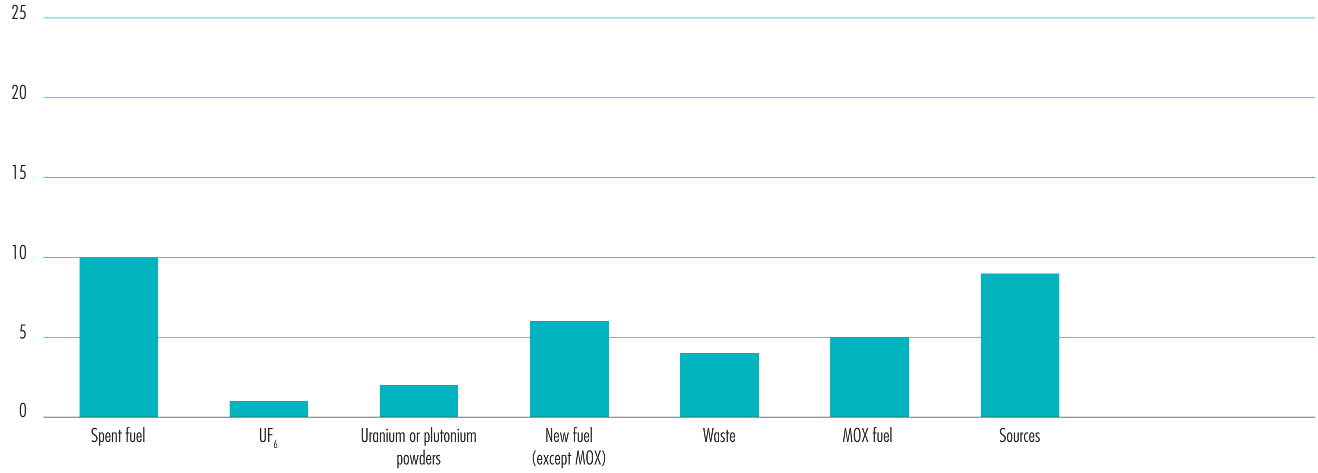
In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if validated by ASN, which then issues a new certificate.

ASN delivered 37 approval certificates or shipment approvals in 2016, for which the breakdown by type is shown in graph 1. The nature of the transport operations concerned by these certificates is shown in Graph 2.

GRAPH 2: Breakdown of the number of approvals according to type



GRAPH 3: Breakdown of the number of approvals according to the transported content



4.2 Monitoring all the stages in the life of a package

ASN performs inspections at all the stages in the life of a package: from manufacture and maintenance of a packaging, to package preparation, shipment and reception.

In 2016, ASN carried out 106 inspections in the field of radioactive substances transport (all sectors considered).

4.2.1 Package manufacturing inspection

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. In accordance with the regulatory requirements, each manufacturer of an approved package model must be able to provide ASN with all information needed to demonstrate the conformity of the manufactured packaging with the package model specifications. These specifications are defined in the safety file on which the ASN approval is based and which contains the safety case for the package model. The safety file also sets packaging design goals. It contains everything relating to the prescriptions concerning the packaging and its content and to the tests required for the package model's safety case.

The role of ASN is to run a second-level check on the conformity of the manufacturing operations and associated checks with the requirements of the safety file. The manufacturer retains prime responsibility for this conformity and must set up a quality assurance system accordingly, covering all the operations from supply up to final inspections.

In 2016, ASN for example checked the organisation set up for welding of the body of the first TN G3 packaging prototype. The approval application for this packaging is currently undergoing technical review by

ASN, with the support of IRSN. ASN also inspected the manufacturing operations on the TN 24 BH type packaging used in Switzerland for the transport and storage of spent fuel. Although it is not actually used in France, this package model was approved by ASN as the competent authority in the country of origin of the designer (Areva TN). This inspection was carried out jointly with the Swiss Authority. In total, ASN carried out six inspections in 2016 on the topic of manufacturing of packagings subject to approval.

The follow-up letters to these inspections are available on *www.asn.fr*.

During these inspections, ASN checks the quality assurance procedures implemented for the production of a package on the basis of the design data, as well as their effective implementation. ASN ensures that the inspections and any manufacturing deviations are traceable. It also visits the manufacturing shops to check the package component storage conditions and the conformity of the various manufacturing operations (welding, assembly, etc.).

When subcontractors are used, ASN checks the monitoring of manufacturing by the lead contractor and may intervene directly on the sites of its subcontractors, which are sometimes located in other countries. For example, the inspection on the welds of the TN G3 package took place in the KSL plant in Japan.

In parallel with these package manufacturing inspections, ASN inspects the manufacture of the specimens used for the regulatory drop tests and fire tests. The objectives are the same as for the series production model, because the specimens must be representative and comply with the maximum requirements indicated in the mock-up manufacturing file, which will determine the minimum characteristics of the actual packaging to be manufactured.

4.2.2 Packaging maintenance inspection

The consignor or user of a packaging filled with radioactive substances must be able to prove to ASN that this packaging is periodically inspected and, if necessary, repaired and maintained in good condition such that it continues to satisfy all the relevant requirements and specifications of its safety file and its approval certificate, even after repeated use. For approved packagings, the ASN inspections concern the following maintenance activities, for example:
- the periodic inspections of the components of the containment system (screws, welds, seals, etc.);
- the periodic inspections of the securing and handling components;
- the frequency of replacement of the package components which must take account of any reduction in performance due to wear, corrosion, aging, etc.

In 2016, ASN carried out five inspections on the conformity of maintenance operations, for example on the TN 12/2 and 13/2 (package model used to transport EDF spent fuel to the La Hague plant), TN BGC1 (package model approved for the transport of various uranium or plutonium contents) or LR 65 (tanks used to transport uranyl nitrate from La Hague to the Tricastin site) packagings.

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Inspection of the Areva Creusot Forge Plant

The Creusot Forge plant has for many years been a subcontractor of the Areva TN Company for the manufacture of certain components of packagings used to transport radioactive substances and covered by ASN approval. These components, primarily shells, are a part of the packaging containment and thus have significant safety implications.

Anomalies of several types have been detected on certain parts forged by Creusot Forge: irregularities in the performance of mechanical tensile strength tests, inconsistencies between the files submitted to the customers and certain Areva Creusot Forge internal files (concealed files) and excessive carbon concentrations in certain parts. The Areva TN Company informed ASN that the transport packagings were concerned by the first two types of anomalies.

On 7th November 2016, ASN thus initiated an inspection of the Areva TN Company in the premises of the Creusot Forge plant in order to examine the organisation put into place by Areva TN, which was the manufacturing ordering customer, to ensure that all the anomalies affecting the transport packaging components are detected and correctly dealt with.

The inspectors found that Areva TN had taken steps but that, in the light of the examination carried out, they considered that these steps were unable to detect all the anomalies affecting the transport packaging components manufactured by the Creusot Forge plant.

With regard to the transport packagings, ASN therefore asked Areva TN to take part in the exhaustive review of the files conducted by the Creusot Forge plant, with definition of a methodology compatible with the transport-specific aspects.

4.2.3 Inspection of packages not requiring approval

For the packages that do not require ASN approval, the consignor must, at the request of ASN, be able to provide the documents proving that the package design complies with the applicable prescriptions of the regulations. More specifically, for each package, a certificate delivered by the manufacturer attesting full compliance with the design specifications must be held at the disposal of ASN.

The various inspections carried out in recent years confirm the improvements to the documents presented to ASN and the integration of the ASN recommendations made in its guide concerning packages which are not subject to approval (Guide No.7, volume 3).

In 2016, ASN published the updated version of this guide. The manufacturers were asked to submit their comments concerning this update, which was opened for public consultation on the ASN website. The guide proposes a structure and a minimum content for the safety files demonstrating that packages which are not subject to approval do comply with all the applicable prescriptions, along with the minimum content of a declaration of conformity of a package design with the regulations.

ASN thus noted improvements in the content of the certificate of conformity and the safety file drawn up by the participants concerned, more specifically for the industrial package models. The representativeness of the tests performed and the associated safety case remain the focal points during the ASN inspections, in particular for type A packages.

Furthermore, ASN still finds that some of the entities (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) display shortcomings in the demonstration of package conformity with the regulations. The areas for improvement focus in particular on the following:
- the description of the authorised contents per type of package;
- the demonstration that there has been no loss or dispersion of the radioactive content under normal transport conditions;
- compliance with the regulatory prescriptions regarding radiation protection, more specifically the demonstration as of the design stage that it would be impossible to exceed the dose limits with the maximum authorised content.

4.2.4 Monitoring the shipment and transportation of packages

ASN devotes more than half of its transport inspections to checking consignors and carriers.


ASN inspection of TN BGC1 maintenance in 2016.

During these inspections, the checks concern all regulatory requirements binding on each of the transport stakeholders, that is compliance with the requirements of the approval certificate or declaration of conformity, training of the personnel involved, implementation of a radiological protection programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, implementation of a quality insurance programme, etc.

Among the observations or findings formulated further to the inspections, the most frequent discrepancies concern quality assurance, compliance with implemented procedures and worker radiation protection.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be substandard in the medical sector in particular, where the procedures adopted by some hospitals or nuclear medicine units for package shipment and reception need to be tightened.

ASN has moreover observed that an increasing number of BNIs are using outside contractors to prepare and ship packages of radioactive substances. ASN is particularly attentive to the organisation set up for the monitoring of these contractors.

4.2.5 Oversight of preparedness for emergency management

In order to reinforce the preparedness of the transport operators (mainly consignors and carriers) for emergency management, ASN published Guide No. 17 in December 2014 on the content of accident and incident management plans concerning the transport of radioactive substances. This guide recommends the drafting of plans to prepare for emergency management and stipulates the minimum content of these plans.

In order to check correct application of this guide, ASN carried out three inspections in 2016 on the topic of preparedness for emergency situations. The inspectors looked in particular at the organisation in place, the material and human resources available, personnel training and the emergency exercises held. ASN also asked some industrial firms involved in transport operations with significant implications to send it their emergency plans for examination.

4.2.6 Analysis of transport events

By listing and analysing the various transport incidents, ASN can identify the problems encountered by the transport operators and the possible safety risks, in order to improve practices and identify any need for changes to the regulations.

ASN must be notified of any deviation from the regulations or the requirements of the safety files and any event which actually or potentially affects safety, in accordance with the events notification guide, as required by Article 7 of the Order of 29th May 2009, amended, concerning the carriage of dangerous goods by road (TMD Order). This events notification guide was communicated by letter to the various stakeholders in the transport of radioactive substances on 24th October 2005 and can be consulted on *www.asn.fr*. It defines the various conditions for notification and rating of transport events on the INES scale. In addition to the notification, a detailed incident report must be sent to ASN within two months. The transport part of this guide is currently being revised.

Events notified in 2016

In 2016, concerning the transport of radioactive substances, ASN was notified of 58 level 0 events and 5 level 1 events. Graph 4 shows the trend in the number of significant events notified since 2000.

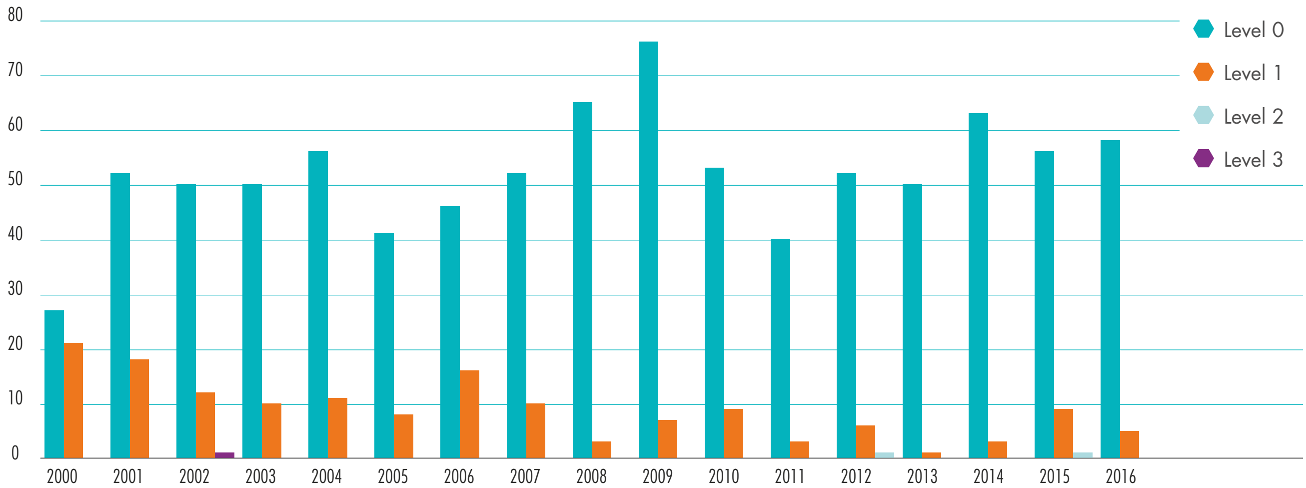
Areas of activity concerned by these events

More than half of the notified events concern the nuclear industry. About one fifth of the significant events concern radioactive pharmaceutical products. The other events concern transport related to non-nuclear industrial activities (gamma radiography for example).

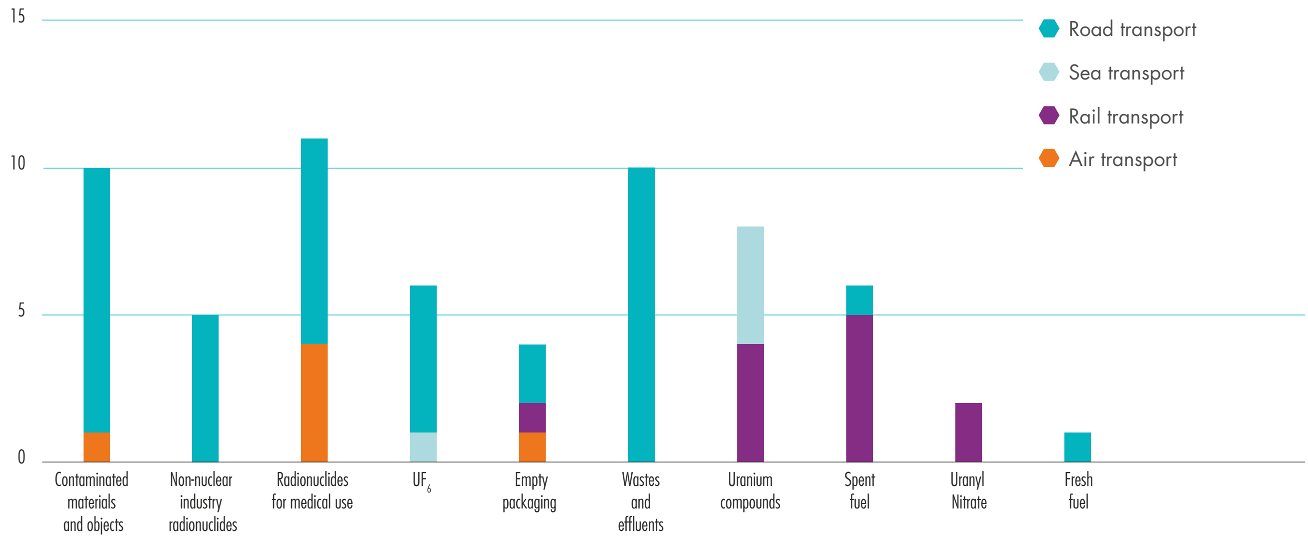
Very few transport-related events are linked to the non-nuclear industry sectors, when compared with the corresponding traffic levels. This small number of events is probably due to medical activity professionals failing to submit notifications, which can be explained by unfamiliarity with the events notification process and its purpose.

The contents concerned by the event notifications are extremely varied: radionuclides for medical uses, contaminated material, fuel, empty packaging, etc. Graph 5 shows the breakdown of notified transport events according to content and mode of transport.

GRAPH 4: Trend in the number of radioactive substance transport incidents or accidents notified between 2000 and 2016



GRAPH 5: Breakdown of notified transport events by content and mode of transport in 2016



Causes of events

The most frequent causes of the significant events notified include the following:

- the presence of contamination spots exceeding the regulation limits. In this respect, it should be noted that the situation has improved over 2015 for packages approved by ASN, more particularly spent fuel packages. However, these situations persist with packages of uranium ore from the mines. The impact of these events on radiation protection is low, because the contamination spots are present on the drums containing the ore, which are themselves carried inside closed metal containers;
- documentary, package labelling and vehicle placarding errors. These errors can in particular lead to packages being temporarily mislaid during transhipment operations;
- faulty or inappropriate stowage measures. In order to improve carrier practices in this field, ASN published a guide of best practices for package stowage in 2016 (Guide No. 27);
- handling accidents, which can lead to package damage. These accidents mainly occur in airports, owing to the large number of packages (radioactive or otherwise) handled in these places.

4.3 Participation in drawing up the regulations applicable to the transport of radioactive substances

4.3.1 Participation in the work of IAEA

ASN represents France on the Transport Safety Standards Committee (TRANSSC) which, under IAEA supervision, brings together experts from all the countries in order to draw up the source document for regulations concerning the transport of radioactive substances. The current edition of this document dates from 2012 and carries number SSR-6.

At the November 2015 meeting of the TRANSSC, the committee voted in favour of a revision of the SSR-6 and a new revision cycle for the SSR-6 was initiated. ASN thus submitted SSR-6 modification proposals to the TRANSSC, after having them validated by the GPT. The work by the TRANSSC committee will continue until 2018, before producing a new version of the document, more particularly so that all the countries concerned can be consulted and any points of disagreement cleared up.

4.3.2 Participation in drafting of national regulations

ASN takes part in the drafting of French regulations relative to the transport of radioactive materials. These regulations mainly consist of the Order of 29th May 2009, amended, concerning the transport of dangerous goods by road (TMD Order), and the Orders of 23rd November 1987 concerning the safety of ships and of 18th July 2000 concerning the transport and handling of dangerous materials in sea ports. In this respect, ASN sits on the CITMD (Interministerial Hazardous Materials Transport Committee) that is consulted for its opinion on any draft regulations concerning the transport of dangerous goods by rail, road or inland waterway. ASN is also consulted by the Ministry of the Environment when a modification of the three Orders mentioned above can have an impact on the transports of radioactive substances. In 2016, ASN thus issued an opinion on a draft order to modify the TMD Order.

4.4 Contributing to public information

Ordinance 2012-6 of 5th January 2012 extends the public information obligations to persons responsible for nuclear activities. It is Article L. 125-10 of the Environment Code that sets the threshold beyond which the person responsible for transport must communicate the information requested by a citizen, by reclassification of the provisions of Decree 2011-1844 of 9th December 2011. The thresholds are defined as being those *"above which, pursuant to the international conventions and regulations governing the transport of dangerous goods, to the Transport Code and to their implementing texts, the transport of radioactive substances is subject to the issue – by Nuclear Safety Authority or by a foreign Authority competent in the field of radioactive substance transport - of an approval of the transport package design or a shipment approval, including under special arrangement"*. Any citizen can therefore now ask the persons in charge of transport for information on the risks presented by the transport operations referred to in the Decree.

A person to whom a nuclear licensee or transport supervisor has refused to communicate information, can refer the matter to the CADA (Administrative Documents Access Commission), for its opinion. The matter must be referred to the CADA prior to any legal action. Disputes relative to communication refusals can then be brought before the administrative jurisdictions, even if they are between two private individuals.

Growing public and media interest in the transport of radioactive substances was observed for several international shipments organised in 2011. Consequently, ASN has developed the information made available to the public concerning the regulation of the safety of transport of radioactive substances. After devoting an issue of Contrôle magazine to this topic in 2012, ASN supplemented the educational file on its website with an analysis of radioactive substances traffic volumes. An information sheet on the transport of radioactive substances, intended for the general public, was drawn up in 2014 and is available on *www.asn.fr* (information sheet No. 8). This sheet answers questions frequently asked by the public, notably concerning the risks inherent in these transport operations, the organisation of the response by the public authorities to an emergency or the routes followed for these transport operations. On the occasion of the transport of Swiss vitrified waste, which crossed France in September 2015, ASN published an information notice on its website presenting this transport operation and the checks it carried out.

In March 2016, ASN took part in the seminar organised by the Anccli and the Bure CLIS on the topic of the transport of radioactive substances. This seminar was an opportunity to present to members of civil society the provisions adopted to regulate these transports and ensure their safety.

4.5 Participation in international relations in the transport sector

International regulations are drafted and implemented as a result of fruitful exchanges between countries. ASN includes these exchanges as part of a process of continuous progress in the level of safety of radioactive substance transports, and encourages exchanges with its counterparts in other States.

4.5.1 Work of the European Association of Competent Authorities on transport

The European Association of Competent Authorities on the Transport of Radioactive Material (EACA) was created in December 2008. Its purpose is to promote the harmonisation of practices in the regulation of the safety of transport of radioactive substances, and to encourage exchanges and experience feedback between the various Authorities. The plenary meeting of May 2016 was for example an opportunity to discuss the lessons learned from certain incidents, the implementation of the new regulatory measures and the contents of a guide designed to harmonise the practices of the various authorities when examining the package model safety files.

4.5.2 Bilateral relations with ASN's foreign counterparts

ASN devotes considerable efforts to maintaining close ties with the competent authorities of the countries concerned by the numerous shipments to and from France. Prominent among these are Germany, Belgium, the United Kingdom and Switzerland.

Germany

In 2016, the French and German Authorities decided to meet regularly to discuss a range of technical subjects. Numerous shipments cross the Franco-German border. ASN participates in the Franco-German technical committees concerning the schedule for returning the waste resulting from the reprocessing of German spent nuclear fuel. A new package is currently being designed in Germany for the transport of compacted waste. The German safety regulator thus informed ASN of the progress being made in the technical review of the approval application. Once issued, the approval certificate will have to be validated by ASN so that the package model can be used in France.

Belgium

For its production of electricity from nuclear power, Belgium uses French-designed containers for fuel cycle shipment. In order to harmonise practices and achieve progress in the safety of these shipments, ASN and the competent Belgian Authority (Belgian Federal Nuclear Regulating Agency - AFCN) regularly exchange know-how and experience.

Since 2005, an annual exchange meeting has been held by ASN and AFCN in order to work more closely on reviewing the safety files for the approved French package models validated in Belgium and to discuss inspection practices in each country. A joint ASN-AFCN inspection was carried out in 2016 (see box).

United Kingdom

Over the last few years ASN and the United Kingdom's Office for Nuclear Regulation (ONR) have developed close ties. Both countries underwent a review coordinated by IAEA, demonstrating the high level of competence of the two authorities with regard to radioactive substances transport, thus enhancing their mutual trust and confidence.

Against this backdrop, ASN and the ONR signed a memorandum of understanding on 24th February 2006, for the mutual recognition of the approval certificates confirming the safety of radioactive substances transport.

Having successfully cooperated on this Memorandum of Understanding, ASN and the ONR extended their cooperation on the following subjects, through an agreement concluded on 27th February 2008:
- licensing procedures;
- inspections;
- emergency procedures;
- guides for domestic and international transport of radioactive substances;
- radioactive substance transport standards;
- quality assurance systems.

Switzerland

ASN began bilateral exchanges with the Swiss Federal Nuclear Safety Inspectorate (IFSN) in 2012. ASN and IFSN have decided to meet regularly in order to discuss the packaging model safety files and the checks on the prescriptions associated with the correct utilization of these transport packages. A joint ASN-IFSN inspection was carried out to check the conformity of the manufacturing operations of a package model approved by ASN and used in Switzerland.

FOCUS

Joint ASN-AFCN inspection

The EDF Company is the owner of packagings used to transport uranium hexafluoride (UF_6). These cylinders are maintained in Belgium. ASN and the AFCN thus decided to conduct a joint inspection of this activity on 27th May 2016.

The maintenance of packagings containing UF_6 is subject to strict compliance with standard ISO 7195, which stipulates tests, in particular a tightness test and a pressure test, in order to verify that the packaging is still able to perform its safety functions.

The inspectors concluded that the organisation put into place by EDF to ensure the conformity of the maintenance operations was on the whole satisfactory. However, a number of minor deviations were identified with regard to the use of alternative provisions in the performance of the tightness test and the distribution of the conclusions of the audits to the subcontractor. EDF was thus asked to take corrective measures.

5. ASN assessment and outlook on the safety of transport of radioactive substances

Oversight of on-site transport operations performed within the perimeter of BNIs

The requirements concerning on-site transport operations performed within the perimeter of BNIs were reinforced on 1st July 2013 with the entry into force of the main provisions of the BNI Order.

ASN observes that certain nuclear sites concerned are not sufficiently engaged and have not yet fully integrated on-site transport operations into their baseline safety requirements. In particular, the safety cases in the files submitted by EDF and Areva in 2015, concerning NPPs and the La Hague site respectively, have proven to be incomplete. The additional information required by ASN was received in 2016 and is currently being examined.

Radiation protection of the carriers of radioactive substances

ASN considers that the radiation protection situation of the carriers could be improved, in particular for the carriers of radiopharmaceuticals, who are significantly more exposed than the average worker. Thanks to the entry into force of the obligation of notification by carrier companies, ASN now has a clearer picture of the characteristics of the companies, enabling it to tailor its oversight resources more closely to the issues. ASN will also publish a guide in 2017 to help carriers achieve a clearer understanding of the regulatory requirements and best practices with regard to radiation protection.

Continuation of inspections of packages that are not subject to ASN approval

When taken individually, the packages not subject to approval represent little danger and accidents involving them have so far had limited radiological health consequences. ASN must however remain vigilant given the very large number of these packages and the sometimes inadequate safety culture of those involved in the transport operations.

Regulatory compliance for packages not subject to approval has on the whole improved with regard to industrial type packages, but ASN considers that this situation is not yet satisfactory for type A packages. Inspections more particularly targeting the verification of the safety files (definition of content, stowage, etc.) and the certificates associated with type A packages will therefore be carried out again in 2017.

Continuation of inspections in the manufacture and maintenance of transport packages subject to ASN approval

The design of transport package models requiring ASN approval is examined in depth prior to the issuance of any approval. Once it has been ascertained that the package model complies with the regulatory requirements, its manufacture and subsequent routine maintenance in accordance with the requirements of its safety file must be verified. ASN intends to maintain a large number of inspections in this area in 2017, particularly with regard to the maintenance of the oldest packagings.

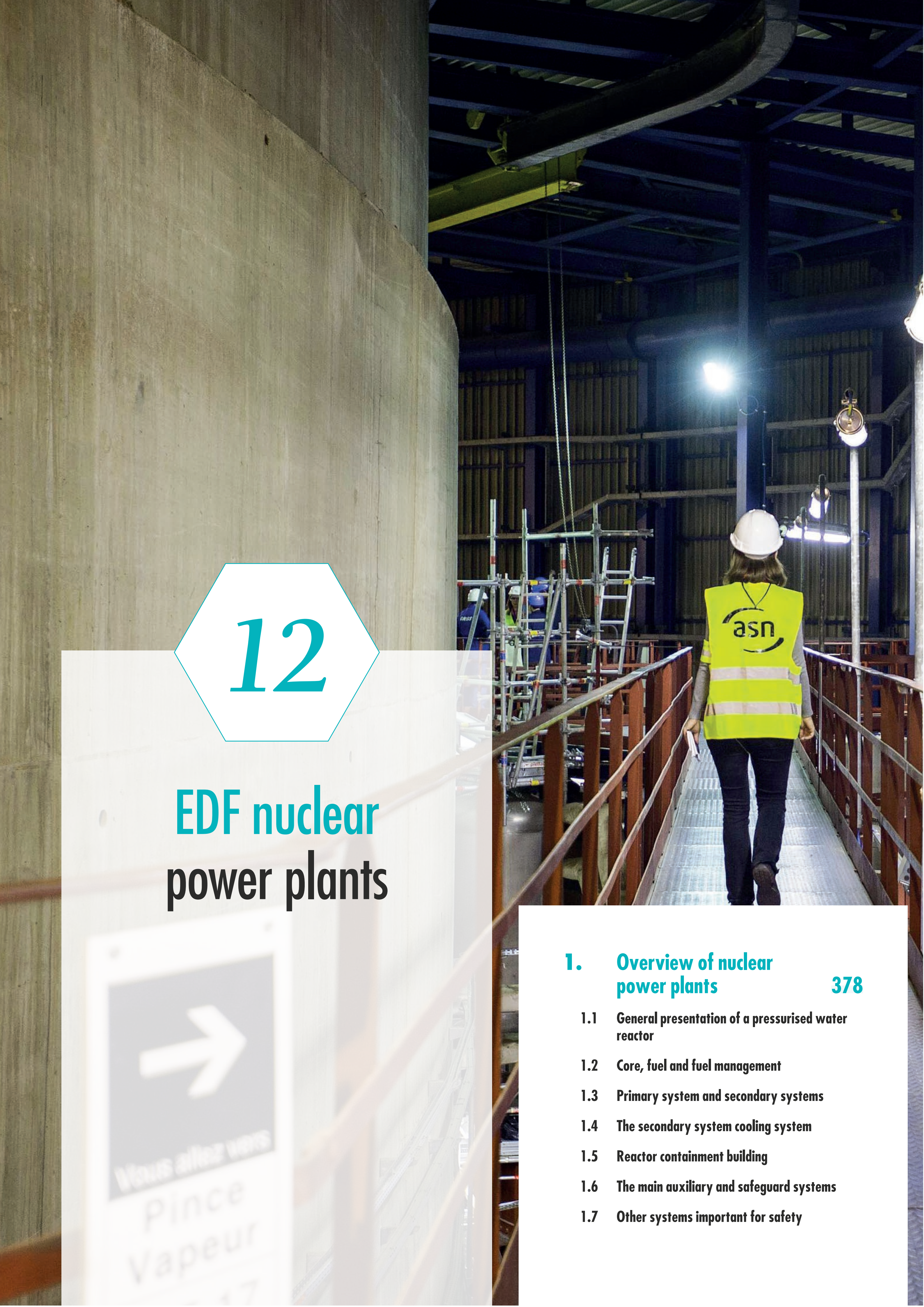
Improved emergency situation preparedness

The management of emergency situations is the final level of defence in depth, in order to mitigate the consequences of an accident. The transport stakeholders are key players in this management, more specifically to give the alert and provide the necessary information to the emergency services. ASN considers that in order to meet these obligations, the stakeholders must be well prepared for emergency situations. In 2017, it will therefore continue its inspections to ensure that the recommendations of its guide on the content of the emergency plans are satisfactorily taken on board.

ASN will also continue to work towards achieving a satisfactory level of preparedness by the public authorities for emergency situations involving a transport operation, in particular by promoting the performance of local emergency exercises.

Examination of the approval application for the TNG3 package model

In 2016, the Areva TN Company submitted an approval application for the TN G3 package model, intended for the transport of spent fuel from the EDF NPPs to the La Hague plant. ASN referred the matter to the GPT to obtain its opinion on the level of safety of this package model with respect to the regulatory requirements. The GPT will issue its opinion in 2017.



12

EDF nuclear power plants

Regulation of the safety of NPPs is a traditional duty of ASN. Nuclear power reactors are at the heart of the nuclear industry in France. Many other installations described in the other chapters of this report produce the fuel intended for NPPs or reprocess it, are used for disposal of the waste produced by NPPs, or are used to study the physical phenomena related to the operation and safety of these reactors. The French reactors are technologically similar to each other and form a standardised fleet operated by *Électricité de France* (EDF). Although this standardisation enables the licensee and ASN to acquire extensive experience of their operation, it does entail an increased risk in the event a design, manufacturing, or maintenance fault is detected on one of these facilities. ASN thus requires a high degree of responsiveness on the part of EDF when analysing the generic nature of these faults and their consequences for the protection of people and the environment. The year 2016 was a particularly good illustration of the potential consequences and risks inherent in this standardisation.

ASN demands a high level of stringency in the monitoring of the NPPs and continuously adapts it, in particular in the light of experience feedback from manufacturing, operation and maintenance of NPP components. Monitoring the safety of the reactors in service, under construction and planned for the future, is the daily task of around 200 members of ASN staff working in the Nuclear Power Plant Department (DCN) and the Nuclear Pressure Equipment Department (DEP), and of the staff of the regional divisions. It also requires the support of some 200 experts from the Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN is developing an integrated approach to facilities monitoring. ASN intervenes at all stages in the life of the NPP reactors, from design up to decommissioning and delicensing. Through its expanded scope of intervention it examines the fields of nuclear safety, organisational and human factors, radiation protection, environmental protection, occupational safety and the application of labour laws, at all stages. This approach requires that it take account of the interaction between these fields and that it adjust its actions accordingly. The resulting integrated view allows ASN to develop a finer appreciation and decide on its position each year with regard to the status of nuclear safety, radiation protection and the environment with respect to NPPs.

1. Overview of nuclear power plants

1.1 General presentation of a pressurised water reactor

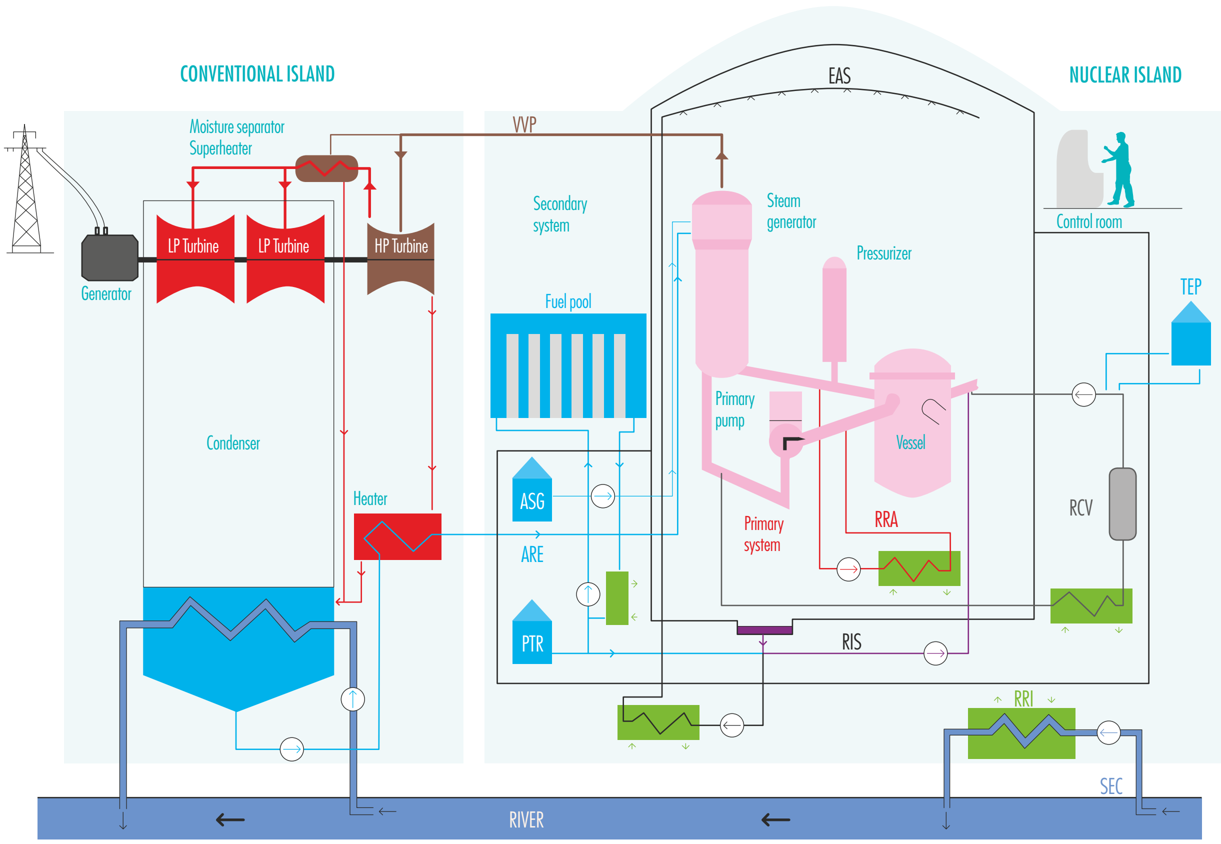
In routing heat from a heat source to a heat sink, all thermal electric power plants produce mechanical energy, which they then transform into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). Nuclear power plants use the heat resulting from the fission of uranium or plutonium atoms. The heat produced is used to vaporise water. The steam is then expanded in a turbine which drives a generator producing a 3-phase electric current with a voltage of 400,000 V. After expansion, the steam passes through a condenser where it is cooled on contact with tubes circulating cold water from the sea, a river or an atmospheric cooling circuit.

Each reactor comprises a nuclear island, a conventional island, water intake and discharge infrastructures and possibly a cooling tower.

The nuclear island mainly consists of the reactor vessel, the reactor coolant system, the steam generators and the circuits and systems ensuring reactor operation and safety: the chemical and volume control, residual heat removal, safety injection, containment spray, steam generator feedwater, electrical, I&C and reactor protection systems. Various support function systems are also associated with these elements: primary effluent treatment, boric acid recovery, feedwater, ventilation and air-conditioning, and backup electrical power (diesel generating sets).

The nuclear island also comprises the systems removing steam to the conventional island (Steam Shutoff Valve on the main steam line) as well as the building housing the Fuel Storage pool (BK). This building, which adjoins the reactor building, is used to store new and spent fuel assemblies (one third or one quarter of the fuel

THE PRINCIPLE of pressurised water reactor operation



is replaced every 12 to 18 months depending on the reactor operating modes). The fuel is kept submerged in cells in the pool. The pool water, mixed with boric acid, on the one hand absorbs the neutrons emitted by the nuclei of the fissile elements to avoid sustaining a nuclear fission reaction and, on the other, acts as a radiological shield.

The conventional island equipment includes the turbine, the AC generator and the condenser. Some components of this equipment contribute to reactor safety. The secondary systems belong partly to the nuclear island and partly to the conventional island.

1.2 Core, fuel and fuel management

The reactor's core consists of fuel assemblies in the form of "rods" comprising "pellets" of uranium oxide or oxides of depleted uranium and plutonium (MOX fuel) contained in closed metal tubes, referred to as the "cladding". As a result of fission, the uranium or plutonium nuclei, referred to as «fissile», emit neutrons which, in turn, produce further fissions: this is known as the chain reaction. These nuclear fissions release a large amount of energy in the form of heat. The primary system water enters the core from below at a temperature of about 285°C, heats up as it flows up along the fuel rods and exits through the top at a temperature close to 320°C.

At the beginning of the operating cycle, the core has a considerable energy reserve. This gradually falls during the cycle, as the fissile nuclei disappear. The chain reaction, and hence reactor power, is controlled by:
- inserting control rod cluster assemblies, which contain elements that absorb neutrons, to varying depths in the core. These enable the reactor to be started and stopped and its power level to be adjusted to the electrical power to be produced. Dropping the control rod assemblies under the effects of gravity enables the reactor to be shut down in an emergency;
- adjusting the level of boron (which absorbs neutrons) in the primary system water during the cycle as the fissile material in the fuel gradually becomes depleted.

At the end of the cycle, the reactor core is unloaded for renewal of part of the fuel.

EDF uses two types of fuels in its pressurised water reactors:

- uranium oxide based fuels (UO_2) with uranium-235 enrichment to a maximum of 4.5%. These fuels are fabricated in several plants in France and abroad, belonging to the fuel manufacturers Areva NP and Westinghouse;
- fuels consisting of a mixture of depleted uranium oxides and plutonium (MOX). The MOX fuel is produced by the Areva NC Melox plant. The initial plutonium content is currently limited to 8.65% (average per fuel assembly) and provides an energy performance equivalent to UO_2 fuel enriched to 3.7% with uranium-235. This fuel can be used in the twenty-eight 900 MWe reactors for which the Creation Authorisation Decrees provide for the use of MOX fuel.

The way in which the fuel is used in the reactors, known as "fuel management", is specific to each reactor plant series. It is, in particular, characterised by:

- the nature of the fuel used and its initial fissile content;
- the maximum degree of fuel depletion at removal from the reactor, characterising the quantity of energy extracted per ton of material (expressed in GWd/t);
- the duration of a reactor operating cycle;
- the number of new fuel assemblies loaded at each reactor refuelling outage (generally 1/3 or 1/4 of the total number of assemblies);
- the reactor operating mode (at constant power or by varying the power to match demand), which determines the loads to which the fuel is subjected.

1.3 Primary system and secondary systems

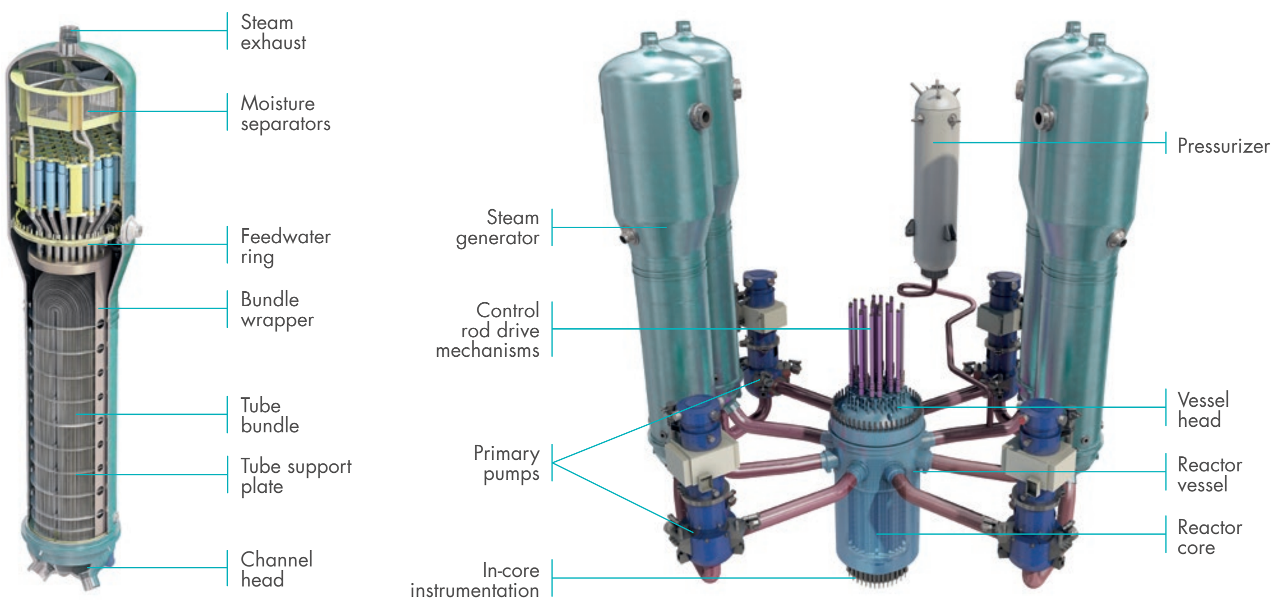
The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbo-generator set which produces electricity.

The primary system consists of cooling loops (three loops for a 900 MWe reactor and four for a 1,300 MWe, 1,450 MWe or 1,650 MWe type EPR reactor). The role of the primary system is to extract the heat given off in the core by circulating pressurised water, referred to as the primary or reactor coolant water. Each loop, connected to the reactor vessel containing the core, comprises a circulating pump (known as the primary or reactor coolant pump) and a steam generator. The primary water, heated to more than 300°C, is kept at a pressure of 155 bar by the pressuriser, to prevent it from boiling. The entire primary system is located inside the containment.

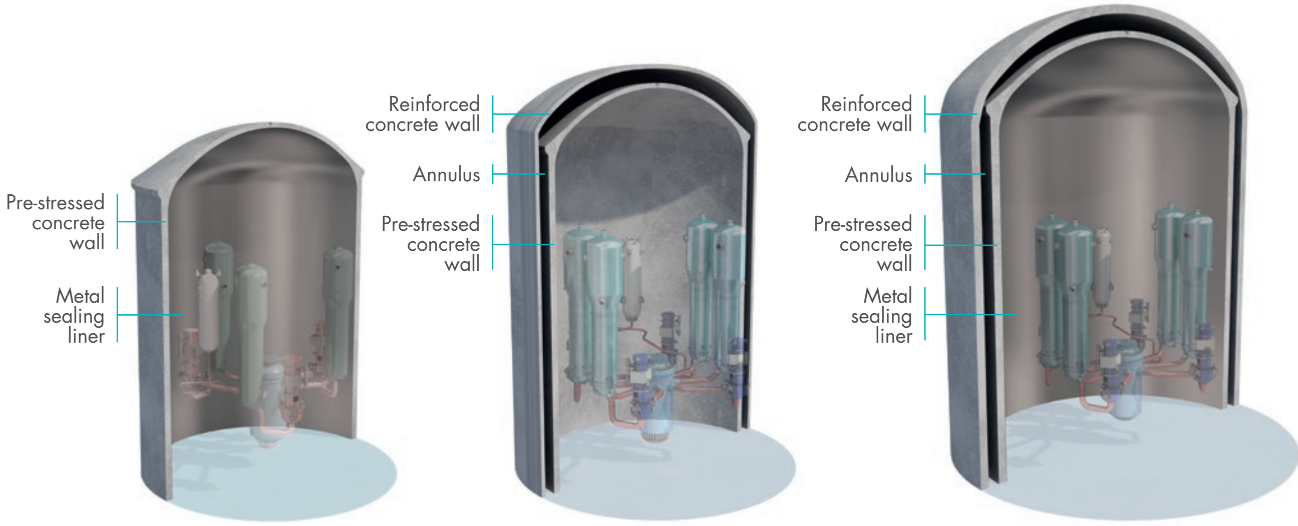
The water in the primary system water transfers its heat to the water in the secondary systems in the steam generators. The steam generators are heat exchangers that contain 3,500 to 5,600 tubes, depending on the model, through which the primary reactor coolant water circulates. These tubes are immersed in the water of the secondary system and boil it, without ever coming into contact with the primary water.

Each secondary system principally consists of a closed loop through which water runs in liquid form in one part and as steam in the other part. The steam produced

A STEAM GENERATOR and a main primary system of a 1,300 MWe reactor



REACTOR containments



900 MWe reactor containments

1,300 MWe/1,450 MWe reactor containments

1,650 MWe reactor containments

in the steam generators is partly expanded in a high-pressure turbine and then passes through moisture separators before final expansion in the low-pressure turbines, from which it is then routed to the condenser. The condensed water is then heated by reheaters and sent back to the steam generators by the condensate extraction pumps and the feedwater pumps.

1.4 The secondary system cooling system

The function of the secondary system cooling system is to condense the steam exiting the turbine. This is achieved by a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. When the steam comes into contact with the tubes it condenses and can be returned in liquid form to the steam generators (see point 1.3). The cooling system water that is heated in the condenser is then discharged to the natural environment (open circuit) or, when the river flow is too low or heating too great in relation to the sensitivity of the environment, it is cooled in a cooling tower (TAR) (closed or semi-closed circuit).

The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. Cooling towers can contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by reinforced maintenance of the structures (descaling, implementation of biocidal treatment, etc.) and monitoring.

1.5 Reactor containment building

The PWR containment building has two functions:
- confine radioactive products likely to be dispersed in the event of an accident. The containments are therefore designed to withstand the pressures and temperatures that could result from the most severe reactor loss of coolant accident and offer sufficient leaktightness in such conditions;
- protect the reactor against external hazards.

Three different containment models have been designed:
- The 900 MWe reactor containments consist of a single wall of pre-stressed concrete (concrete containing steel cables tensioned to ensure compression of the structure). This wall offers mechanical resistance to pressure, as well as structural integrity with regard to an external hazard. Leaktightness is provided by a metal liner covering the entire inner face of the concrete wall.
- The 1,300 MWe and 1,450 MWe reactor containments consist of two walls: an inner wall made of pre-stressed concrete and an outer wall made of reinforced concrete. Leaktightness is provided by the inner wall and the ventilation system (EDE) which collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is primarily provided by the outer wall.
- The Flamanville EPR reactor containment consists of two walls and a metal liner covering the entire internal face of the inner wall.

1.6 The main auxiliary and safeguard systems

In normal operating conditions, at power, or in reactor outage states, the auxiliary systems control nuclear reactions, remove heat from the primary system and residual heat from the fuel and provide containment of radioactive substances. This chiefly involves the Chemical and Volume Control System (RCV) and the Residual Heat Removal System (RRA).

The purpose of the safeguard systems is to control incidents and accidents and mitigate their consequences. This chiefly concerns the following systems:
- the Safety Injection System (RIS), the role of which is to inject water into the primary system in the event of its leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the pressure and temperature in the containment in the event of a primary system leak accident;
- the Steam Generators Auxiliary feedwater system (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system. This system is also used in normal operation during reactor outage or restart phases.

1.7 Other systems important for safety

The other main systems or circuits important for safety and required for reactor operation are:
- the Component Cooling System (RRI) which cools a certain number of nuclear equipment items; this system operates in a closed loop between, on the one hand, the auxiliary and safeguard systems and, on the other, the systems carrying water from the river or sea (heat sink);
- the Essential Service Water System (SEC), which uses the heat sink to cool the Component Cooling System;
- the Reactor Cavity and Spent Fuel Pool Cooling and Treatment System (PTR), used notably to remove residual heat from fuel elements stored in the fuel building pool;
- the ventilation systems, which confine radioactive materials by depressurising the premises and filtering all discharges;
- the fire protection water systems;
- the instrumentation and control system;
- the electrical systems.

2. Monitoring of nuclear safety

2.1 Social, organisational and human factors

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the plant lifecycle (design, construction, commissioning, operation, decommissioning). ASN therefore focuses on the conditions which are favourable or prejudicial to a positive contribution to NPP safety by the operators and worker groups. ASN defines Social, Organisational and Human Factors (SOHF) as being all the aspects of working situations and of the organisation that will have an influence on the work done by the operators.

Article L. 593-6 of the Environment Code requires that the licensee define and implement an Integrated Management System (IMS) designed to ensure that the safety, radiation protection and environmental protection requirements are systematically taken into account in all decisions concerning the facility. The IMS specifies the steps taken with regard to all types of organisation and resources, in particular those adopted to manage important activities. ASN thus asks the licensee to set up an IMS able to maintain and continuously improve safety, notably through the development of a safety culture. The BNI Order of 7th February 2012 more specifically requires that, through an in-depth assessment, the processing of significant events is able to determine the organisational and human causes in addition to the technical causes.

ASN's oversight of organisational and human aspects is in particular based on inspections which concern the measures taken by the licensee to take account of SOHF in all phases of the lifecycle of an NPP. ASN thus regulates engineering activities during the design of a new facility or the modification of an existing one. ASN in particular ensures that the design approach used by the licensee is "focused on the human operator". In addition, the inspections carried out by ASN concern the activities performed for the operation of existing NPPs, the conditions in which these activities are performed (accessibility of premises, noise, heat and light environment, etc.) and the means made available to those concerned (tools, operating documents, etc.). ASN also checks the organisation put into place by EDF to manage the skills and staffing needed to perform these activities. The same applies to the resources, skills and methodology used for implementation of the SOHF approach by EDF. ASN also monitors the EDF safety management system, which must provide a framework and support for the decisions and actions which either directly or indirectly concern safety issues. Finally, ASN monitors EDF's organisation for analysing events, the depth of the analyses carried out to ensure that the root causes are investigated, as well as the preparation and implementation of the follow-up to these analyses.

In addition to the inspections, ASN oversight is based on the evaluations it requests from IRSN and the Advisory Committee for Nuclear Reactors (GPR). For example, the GPR was asked in 2015 to give its opinion on the control of EDF subcontracting of maintenance in NPPs and on the examination of the organisational, human and technical resources used to operate control the EPR reactor.

2.2 Reactor operation

2.2.1 Operation in normal conditions: ensuring compliance with operating rules and examining changes to documents and hardware

The General Operating Rules (RGE) cover the operation of nuclear power reactors. They are drawn up by the licensee and constitute the operational implementation of the hypotheses and conclusions of the safety assessments resulting from the safety analysis report and set the limits and conditions for the operation of the facility.

Changing Technical Operating Specifications

Within the RGE, the Technical Operating Specifications (STE[1]) define the normal operating domains, in order to remain within the design and sizing hypotheses, stipulate the systems necessary for maintaining safety functions, more particularly the integrity of the radioactive materials containment barriers and the operability of the degraded operating procedures (see point 2.2.2) and prescribe the steps to be taken if a normal operating limit is exceeded or a required system becomes unavailable.

The STE evolve to take account of the lessons learned from their application. Furthermore, the licensee can also modify them temporarily if need be, for example to carry out an intervention in conditions that are different from those initially considered. It must then demonstrate the pertinence of this temporary modification and define adequate compensatory measures.

Depending on their nature, STE modifications likely to affect protected interests require either an authorisation application sent to ASN, or notification to ASN before they are implemented. More particularly, the modifications which significantly compromise the safety case are systematically the subject of an authorisation application.

Every year, ASN also carries out an in-depth examination of the temporary modifications made to the STE, on the basis of an assessment prepared by EDF. This examination notably enables recurrent temporary modifications to be identified, which would require a lasting change to the STE. The temporary modifications to the STE considered to be minor may be exempted from the authorisation procedure if eligible for the "internal authorisation system" set up by EDF and regulated by an ASN resolution. The working of the "internal authorisation system" is verified by ASN.

During inspections in NPPs, ASN verifies that the licensee complies with the STE and, as necessary, checks the compensatory measures associated with any temporary modifications. It also checks the consistency between the modifications made and the operating documents, such as instructions, alarm sheets, the STE and the training of the persons responsible for implementing them.

Examination of modifications made to the equipment

To improve the industrial performance of its production tool, process any deviations detected, implement design changes following periodic safety reviews or take account of operating experience feedback, EDF periodically makes changes to the equipment.

As of 29th June 2016, owing to the regulatory changes arising from the Energy Transition for Green Growth Act, applications for notable modifications to NPP reactors require ASN authorisation.

2.2.2 Incident or accident operations

Chapter VI of the RGE comprises all the reactor operating rules for an incident or accident situation. The modifications to Chapter VI of the RGE and likely to affect nuclear safety are subject to authorisation from ASN.

Chapter VI of the RGE changes in order to take account of experience feedback from incidents and accidents and to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews.

ASN also regularly checks the incident or accident operating rules and how they are implemented. To do this, ASN runs simulations with the facility's shift crews. It thus checks that the operating instructions applied are consistent with the rules of Chapter VI of the RGE, the implementation methods for these documents, and the management rules for specific equipment used in accident operating situations.

1. *The STE are a «highway code» for nuclear reactors. They constitute a body of prescriptions and limits which may vary according to the type of reactor, its status (shut down or in production for example), but also any ongoing operations (maintenance, tests, etc.). They ensure that the safety functions are maintained, notably by specifying the required systems and the steps to be taken if these systems are lost.*

2.2.3 Operation in a severe accident situation

If the reactor cannot be brought to a stable condition after an incident or accident and if a series of failures leads to core degradation, the reactor is said to be entering a severe accident situation. To deal with this type of unlikely situation, various steps must be taken to enable the operators to safeguard the containment in order to minimise the consequences of the accident (see point 1.3.1 of chapter 5). The operators then draw on the skills of the emergency response teams set up at both the local and national levels. These teams use the On-site Emergency Plan (PUI) plus the severe accident operation guide and the emergency teams action guides in particular.

ASN periodically examines the strategies presented by EDF in these documents, in particular for the reactor periodic safety reviews.

Fuel pellets.

2.3 Fuel

2.3.1 Changes to fuel management in the reactor

In order to enhance the availability and performance of the reactors in operation, EDF, together with the nuclear fuel manufacturers, researches and develops improvements to fuels and their use in the reactor. The latter is known as “fuel management” and is described in point 1.2.

ASN ensures that each change in fuel management is the subject of a specific safety case for the reactors concerned. When a change in the fuel or its management model leads to EDF revising an accident study method, this requires prior review and cannot be implemented without ASN approval. When significant changes are made to fuel management, their implementation is dependent on an ASN resolution.

2.3.2 Monitoring the condition of fuel in the reactor

Fuel behaviour is an essential element in core safety in normal operation or accident conditions, and its reliability is of prime importance. The leaktightness of the fuel rods, of which there are several tens of thousands in each core and which constitute the first containment barrier, are therefore the subject of particular attention. During normal operation, leaktightness is monitored by EDF by means of continuous measurement of the activity of radioelements in the primary system. Any rise in this activity level beyond predetermined thresholds is the sign of a loss in fuel assembly leaktightness. During shutdown, EDF must look for and identify the assemblies containing leaking rods, which may not then be reloaded. If this activity in the primary system becomes too high, the RGE require reactor shutdown before the end of its normal cycle.

ASN ensures that EDF looks for and analyses the causes of the observed leaktightness losses, in particular by examining the leaking rods in order to determine the origin of the failures and prevent them from reoccurring. Preventive and remedial actions may therefore affect the design of rods or assemblies, their manufacture, or the reactor operating conditions. Furthermore, the conditions of assembly handling, of core loading and unloading, and the measures taken to exclude foreign material from the systems and pools are also the subject of operating requirements, some of which contribute to the safety case and for which EDF’s compliance is verified by ASN. ASN also conducts inspections to ensure that EDF carries out adequate monitoring of its fuel assembly suppliers in order to guarantee that fuel design and manufacture comply with the rules established. Finally, ASN periodically consults the GPR with regard to the lessons learned from fuel operating experience feedback.

2.4 Pressure equipment

2.4.1 Monitoring of the design and manufacture of Nuclear Pressure Equipment (ESPN)

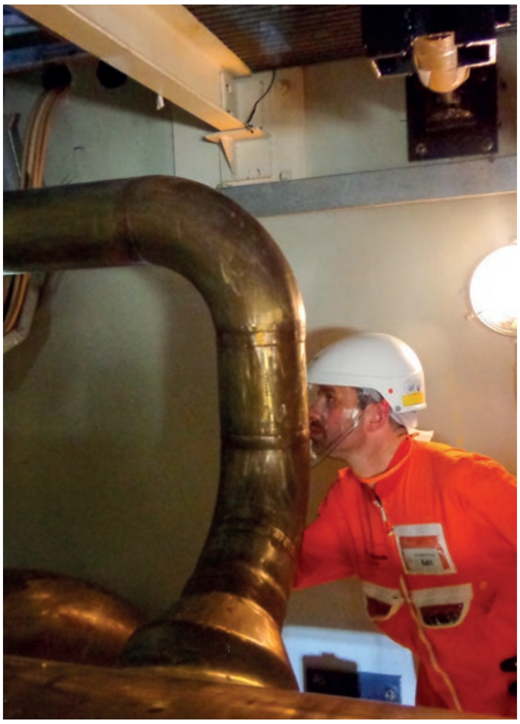
ASN assesses the conformity with the regulatory requirements of the nuclear pressure equipment most important for safety, known as "level N1". This conformity assessment concerns the equipment intended for the new nuclear facilities (EPR Flamanville 3) and the equipment spares intended for nuclear facilities already in operation (replacement steam generators in particular). For the performance of these duties, ASN can rely on the organisations that it approves, which can be tasked by ASN with performing some of the inspections on the level N1 equipment. They are also responsible for assessing conformity with the regulatory requirements applicable to nuclear pressure equipment that is less important for safety, referred to as "level N2 or N3". Oversight by ASN and its approved organisations comes into play at different stages of design and manufacture of nuclear pressure equipment. It takes the form of examination of the technical documentation for each item of equipment and of inspections in the manufacturers' facilities as well as in those of their suppliers and subcontractors. Five inspection organisations or bodies are currently approved by ASN to assess ESPN conformity: Apave SA, Asap, *Bureau Veritas Exploitation*, AIB Vinçotte International and the EDF users inspection entity.

Most of these inspections are performed by the approved organisations, under the supervision of ASN. In 2016, the inspections performed by the approved organisations can be broken down as follows:
- 10,141 inspections, including 1,687 documentary inspections concerning design, to monitor the manufacture of the ESPN intended for the Flamanville 3 EPR, which represented 14,639 man-days;
- 2,326 inspections, including 233 documentary inspections concerning design, to monitor the manufacture of the equipment spares intended for the main primary and secondary systems of the NPP reactors in operation, which represented 6,074 man-days.

2.4.2 Monitoring the main primary and secondary systems

The reactor Main Primary and Secondary Systems (MPS and MSS) operate at high temperature and high pressure and contribute to the containment of radioactive substances, to cooling and to controlling reactivity.

The monitoring of the operation of these systems is regulated by the Order of 10th November 1999 relative to the monitoring of the operation of the main primary and the main secondary systems of nuclear pressurised water reactors mentioned in point 3.6 of chapter 3. These systems are thus monitored and periodically maintained by EDF. This monitoring is itself checked by ASN.



Hydrotesting of the primary system of reactor 4 in the Cruas-Meysse NPP, May 2016.

Control room of the Cruas-Meysse NPP.

These systems are subject to periodic re-qualification every ten years, comprising a complete inspection of the systems involving non-destructive examinations, pressurised hydrotesting and verification of the good condition and proper operation of the over-pressure protection accessories.

2.4.3 Monitoring of nickel-based alloy areas

Several parts of pressurised water reactors are made with nickel-based alloy. The use of this type of alloy is justified by its resistance to generalised or pitting corrosion. However, in reactor operating conditions, one of the alloys adopted, Inconel 600, proved to be susceptible to stress corrosion. This particular phenomenon occurs when there are high levels of mechanical stress. It can lead to the appearance of cracks, as observed on steam generator tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in the Gravelines NPP reactor 1. These cracks require that the licensee repair the zones concerned or isolate them from the rest of the system to prevent any undue risk.

At the request of ASN, EDF adopted an overall monitoring and maintenance approach for the areas concerned. Several parts of the main primary system made of Inconel 600 alloy are thus subject to special monitoring. For each of them, the in-service monitoring programme, defined and updated annually by the licensee, is submitted to ASN, which ensures that the performance and frequency of the checks carried out are satisfactory and able to detect the deteriorations in question.

FUNDAMENTALS

The principles of demonstrating the in-service resistance of reactor vessels

The regulations in force require in particular that the licensee:
- identify the situations that would result in an impact on the equipment;
- take measures to understand the effect of ageing on the properties of the materials;
- take steps to ensure sufficiently early detection of defects prejudicial to the integrity of the structure;
- eliminate all cracks detected or, if this is impossible, provide appropriate specific justification for retaining such a type of defect as-is.

2.4.4 Monitoring the resistance of reactor vessels

The reactor vessel is one of the essential components of a PWR. For a 900 MWe reactor, it is 14 m high, 4 m in diameter and 20 cm thick. It weighs 300 tonnes. It contains the reactor core and its instrumentation. In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bar and a temperature of 300°C. It is made of ferritic steel, with a stainless steel inner liner.

Regular monitoring of the state of the reactor vessel is essential for the following two reasons:
- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- The consequences of the rupture of this item are not considered in the safety assessments. This is one of the reasons for which all steps must be taken in design, manufacture and operation to guarantee its resistance for the operating lifetime of the reactor, including in the event of an accident.

In normal operation, the vessel's metal slowly becomes brittle under the effect of the neutrons from the fission reaction in the core. This embrittlement makes the vessel particularly sensitive to pressurised thermal shocks or to sudden pressure surges when cold. This susceptibility is also aggravated when technological defects are present, which is the case for some of the reactor vessels that have manufacturing defects under their stainless steel liner.

ASN regularly examines the evidence to substantiate the in-service resistance of the vessels transmitted by EDF, to ensure that it is sufficiently conservative.

The Advisory Committee for Nuclear Pressure Equipment (GPESPN) was consulted at the end of 2015 concerning the file transmitted by EDF to substantiate the in-service resistance of the 1,300 MWe reactor vessels after 30 years of operation. Following this consultation, EDF was asked for additional substantiation and the initial data transmitted is currently being reviewed.

In mid-2016, EDF also sent ASN a file substantiating the in-service resistance of the 900 MWe reactor vessels after 40 years of operation and this is currently being reviewed by IRSN and ASN.

2.4.5 Monitoring steam generator maintenance and replacement

Steam Generators (SG) comprise two parts, one of which is a part of the main primary system and the other a part of the main secondary system. The integrity of the main steam generator components, more specifically the tubes making up the tube bundle, is monitored. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a primary system leak to the secondary system. Furthermore, a steam generator tube rupture would lead to bypassing of the reactor containment, which is the third containment barrier. Steam generators are the subject of a special in-service monitoring programme, established by EDF, reviewed periodically and examined by ASN. After inspection, tubes that are too badly damaged are plugged to remove them from service.

Clogging of the tubes and internals of the secondary part of the steam generators

Over time, the SGs tend to become clogged with corrosion products from the secondary system exchangers. This leads to a build-up of soft or hard sludge at the bottom of the SGs, fouling of the tube walls and clogging of the tube bundle tube support plates. The corrosion products form a layer of magnetite on the surface of the internals. On the tubes, the layer of deposits (fouling) reduces the heat exchange capacity. In the tube support plates, the deposits prevent the free circulation of the water-steam mixture (clogging), which creates a risk of damage to the tubes and the internal structures and which can degrade the overall operation of the steam generator.

In 2016, very high levels of fouling were detected on the SGs of several reactors. This anomaly, which had been inadequately anticipated by EDF, led ASN to ask EDF to implement reinforced monitoring of this equipment and make provision for rapid chemical cleaning of the reactor 4 SGs at the Cattenom NPP.

To prevent or mitigate the fouling effects described above, various solutions are used to minimise metal deposits: preventive chemical cleaning or mechanical cleaning (using hydraulic jets), material replacement (brass by stainless steel or titanium alloy, which are more corrosion-resistant) in certain secondary system exchanger tube bundles, along with an increase in the pH conditioning of the secondary system. Some of these operations require licensing for the discharge of the conditioning products.

Discussions are in progress between EDF and ASN to guarantee that the products employed during certain chemical cleaning operations are harmless. A corrosion risk detected on reactors which had undergone such cleaning in 2016 required the implementation of special maintenance measures.

Replacement of steam generators

Since the 1990s, EDF has been running a Steam Generator Replacement programme (SGR) for those SGs with the most heavily degraded tube bundles, with priority being given to those made from Inconel 600 without heat treatment (600 MA) and then those made from Inconel 600 with heat treatment (600 TT).

The replacement campaign for SGs with a tube bundle made of 600 MA (26 reactors) was completed in 2015 with Le Blayais NPP reactor 3. It is being continued with the replacement of SGs with heat treated Inconel (600 TT) tube bundles. The steam generator replacements scheduled for 2016 have been postponed for various reasons: deviations in the manufacture of a steam generator intended for Gravelines reactor 5 and fall by a steam generator in Paluel reactor 2 (see point 3.2).

2.4.6 Monitoring the other reactor pressure equipment

ASN is also responsible for monitoring EDF's implementation of the regulations applicable to non-nuclear pressure equipment utilised in the NPPs. In this respect, ASN notably carries out audits and surveillance visits of the site inspection departments. These departments, under the responsibility of the licensee, are responsible for carrying out inspections to ensure the safety of pressure equipment.

2.5 The containments

The containments undergo inspections and tests to check their compliance with the safety requirements. Their mechanical performance in particular must guarantee a good degree of reactor building tightness in the event of its internal pressure exceeding atmospheric pressure, which can happen in certain types of accidents. This is why, at the end of construction and then during the ten-yearly inspections, these tests include an inner containment pressure build-up with leak rate measurement, as specified in Article 8.1.1 of the BNI Order of 7th February 2012.

2.6 Protection against natural events, fire and explosions

2.6.1 Prevention of seismic risks

Even though seismic activity is low to moderate in France, ASN pays particularly close attention to EDF's inclusion of this risk in the safety case of its reactors, given the possible large-scale consequences of an earthquake on the facilities. Seismic protection measures are taken into account in the design of the facilities. They are periodically reviewed in line with changing knowledge and changes to the regulations, on the occasion of the periodic safety reviews.

Design rules

Basic Safety Rule (RFS) 2001-01 of 31st May 2001 defines the methodology for determining the seismic risk for surface BNIs (except for radioactive waste long-term repositories).

This RFS is supplemented by a 2006 ASN guide which defines acceptable calculation methods for study of the seismic behaviour of nuclear buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

Buildings and equipment important for the safety of NPPs are designed to withstand earthquakes of an intensity greater than the most severe earthquakes that have ever occurred in the region of the site. EDF's NPPs are thus designed for seismic levels with incorporation of the local geological features specific to each one.

Seismic reassessment

As part of the periodic safety reviews, the seismic reassessment consists in verifying the adequacy of the seismic design of the facility, taking account of advances in knowledge about seismic activity in the region of the site or in the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from experience feedback concerning earthquakes in other countries are also analysed and integrated into this framework.

The studies carried out for the periodic safety review associated with the Third Ten-yearly Outages of the 900 MWe reactors (VD3-900) led to the definition of equipment or structural reinforcements, which are implemented on the occasion of the ten-yearly outage inspections.

Changes in the available knowledge have led EDF to reassess the seismic hazard for the periodic safety review associated with:
- the Third Ten-yearly Outages for the 1,300 MWe reactors (VD3-1,300);
- the Fourth Ten-yearly Outages for the 900 MWe reactors (VD4-900);
- the Second Ten-yearly Outages for the 1,450 MWe reactors (VD2-N4);

ASN considers that the seismic hazard levels determined by EDF are acceptable, with the exception of those concerning the Saint-Alban, Fessenheim, Chinon and Chooz NPPs, which are too low given the current state of knowledge. ASN therefore asked EDF:
- to reassess the seismic spectra for the SaintAlban, Fessenheim, Chinon and Chooz sites in order to take account of the uncertainties;
- to define a working programme to verify the strength of the equipment and civil engineering structures and make any necessary seismic reinforcements for the periodic safety reviews.

Extreme earthquakes

Following the Fukushima Daiichi accident, ASN asked EDF to define and install a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations which, in the French context, are comparable to those which occurred in Japan on 11th March 2011. This hardened safety core shall notably be designed to withstand an earthquake of an exceptional level, exceeding those adopted in the design or periodic safety review of the installations. In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, which would be more closely in line with international best practices (see point 3.1). In July 2016, ASN adopted a stance on the "extreme" earthquake levels proposed by EDF for its sites and made a number of additional requests. ASN more specifically asked EDF to include additional margins on the extreme seismic levels adopted for the Bugey, Cruas, Blayais, Belleville and Chinon sites. ASN also asked EDF to conduct additional investigations into the possible "site effects" linked to the particular geological configuration of the Gravelines, Tricastin, Belleville, Golfech, Blayais and Fessenheim NPPs.

2.6.2 Drafting of flooding protection rules

The partial flooding of the Le Blayais NPP in December 1999 led the licensees, under the supervision of ASN, to reassess the safety of the existing BNIs with respect to this risk in more severe conditions than previously and to make a number of safety improvements, with a schedule proportionate to the potential consequences. In accordance with the ASN prescriptions, EDF completed the required work on the entire NPP fleet by the end of 2014.

At the same time, to ensure more exhaustive and more robust integration of the flooding risk, as of the facilities design stage, ASN published Guide No. 13 in 2013 concerning BNI protection against external flooding. For the existing facilities, ASN asked EDF in 2014 to take account of the recommendations of the guide on all its reactors.

Following the stress tests performed in the wake of the Fukushima Daiichi accident, ASN considered that, with regard to protection against flooding, the requirements arising from the complete reassessment performed after the flooding of the Le Blayais NPP in 1999 provided the nuclear power plants with a high level of protection against the risk of external flooding. However, in June 2012, ASN issued several resolutions to ask the licensees:
- to reinforce NPP protection against certain hazards, such as intense rainfall and earthquake-induced flooding;

• to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations and in particular in the case of flooding beyond the design-basis safety requirements (see point 3.1).

In July 2016, ASN adopted a stance on the hazard levels to be considered in the design of the hardened safety core and issued a number of additional requests relating to the definition of extreme flood levels.

2.6.3 Prevention of heat wave and drought risks

During the heat waves in recent decades, some of the rivers used to cool NPPs experienced a reduction in their flow rate and significant warming.

Significant temperature rises were also observed in certain NPP facilities housing heat-sensitive equipment.

EDF took account of this experience feedback and initiated reassessments of the operation of its facilities in air and water temperature conditions more extreme than those initially included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF initiated the deployment of priority modifications (such as an increase in the capacity of certain heat exchangers) and adopted operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

In 2012, ASN approved the application of these baseline requirements to the 900 MWe reactors as well as implementation of the resulting modifications. ASN also asked EDF to take account of the comments it made during this examination process with a view to drafting and implementing baseline requirements applicable to other types of similar reactors.

For the periodic safety review of the 1,300 MWe reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against the effects of heat wave situations. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a monitoring programme in order to anticipate climate changes, which could compromise the hypotheses adopted in the "extreme heat" baseline safety standards.

The lessons learned from the heat wave events of 2015 and 2016 and their effects on the facilities will be incorporated into the studies planned for the periodic safety reviews associated with the Fourth Ten-yearly Outage inspections of the 900 MWe reactors (VD4-900). The conclusions of these studies could, as applicable, be taken into account in the revision of the studies concerning other types of reactors.

The impact on thermal discharges from the NPPs

NPPs discharge hot effluents into rivers or the sea, either directly, from those NPPs operating with direct or "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. Thermal discharges from NPPs lead to a temperature rise between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. This warming is regulated by ASN resolutions.

Since 2006, changes have been made to these resolutions in order to define in advance the operating modes of NPPs during exceptional climatic conditions that would lead to significant warming of the river. These special provisions are however only applicable if the security of the French electricity grid is at stake.

2.6.4 Consideration of fire risk

In the same way as the other BNIs, NPPs are subject to ASN resolution 2014-DC-0417 of 28th January 2014 on the control of fire risks.

Controlling the fire risk in nuclear power plants is built around the principle of defence in depth, based on three levels: facility design, prevention and fire-fighting.

The design rules should prevent the spread of any fire and limit its consequences. This is primarily built around "fire zoning", that is the principle of dividing the facility into sectors designed to contain the fire within a given perimeter, each sector being bounded by sectoring elements (fire doors, fire-walls, fire dampers, etc.), offering a specified fire resistance duration. The main purpose is to prevent a fire from spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists of the following:
• ensuring that the nature and quantity of combustible material present in the premises remain below that of the scenarios used for zoning;
• identifying and analysing the fire risks in order to take steps to avoid them. In particular, for all work liable to cause a fire, a "fire permit" must be issued and protective measures must be taken.

Finally, fire detection and fire-fighting procedures should enable a fire to be tackled, brought under control, and extinguished within a time compatible with the fire resistance duration of the sectoring elements.

ASN checks that the fire risk is taken into account in the NPPs, notably through an analysis of the licensee's baseline safety requirements, monitoring of significant events notified by the licensee and inspections performed on the sites.

2.6.5 Consideration of explosion risks

An explosion can damage elements that are essential for maintaining safety or may lead to failure of the containment with the release of radioactive materials into the facility, or even into the environment. Steps must therefore be taken by the licensee to protect the sensitive parts of the facility against explosions.

ASN checks these prevention and monitoring measures, paying particular attention to ensuring that the explosion risk is included in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "Explosive Atmospheres" (ATEX) regulations with respect to worker protection.

2.7 Maintenance and testing

2.7.1 Regulation of maintenance practices

ASN considers that preventive maintenance is an essential line of defence in maintaining the conformity of a facility with its baseline safety requirements.

In order to improve the reliability of the equipment contributing to safety but also to industrial performance, EDF seeks to optimise its maintenance activities in the light of best practices used in the industry and by NPP licensees in other countries.

In 2010, EDF thus informed ASN of its intention to deploy a new maintenance methodology developed by the American licensees, called AP-913. The main interest of this method is to make the equipment more reliable through in-service monitoring, in order to improve preventive maintenance and through sharing of best maintenance practices among the NPPs.

Deployment of the AP-913 maintenance methodology is based on implementation of the following six processes:
- identification of critical equipment and definition of the associated maintenance and monitoring programmes;
- definition of equipment monitoring and maintenance requirements;
- equipment and systems performance analysis;
- definition and oversight of corrective measures;
- continuous improvement of baseline requirements and oversight of reliability;
- equipment lifecycle management.

Although it has no objection to the use of this method, ASN however considers that proactive steps must be taken with the NPPs to allow its correct implementation and ensure that it is effective. EDF must in particular more closely oversee the implementation of the AP-913 maintenance methodology in its various NPPs and allocate the necessary manpower to this task. EDF must also ensure that all participants follow the recommended methods for filling out the equipment monitoring indicators, for the preparation, performance and write-up of field visits and for the traceability of maintenance decisions.

2.7.2 Monitoring the test programmes

The elements important for the protection of persons and the environment, identified by the licensee, undergo qualification in order to guarantee their ability to perform the functions assigned to them, in terms of loadings and the ambient conditions associated with the situations in which they are required. The periodic tests help verify that this qualification is maintained and regularly ensure that these elements are available in the conditions in which they are required. The associated rules constitute Chapter IX of the General Operating Rules. These rules set the nature of the technical inspections, their frequency and the corresponding criteria, allowing periodic verification of compliance with the qualification requirements.

ASN ensures that the periodic technical checks on the elements important for protection mentioned above are relevant and are continuously improved. It also checks that they are performed in accordance with the general operating rules.

2.7.3 The use of efficient monitoring methods applied to main primary and secondary system pressure equipment

Article 8 of the Order of 10th November 1999 concerning monitoring of the operation of the main primary system and the main secondary systems of pressurised water reactors specifies that the non-destructive testing processes used for in-service monitoring of the pressure equipment of the main primary and secondary systems of nuclear reactors must, before they are used for the first time, be qualified by an entity comprising experts from inside and outside EDF, whose competence and independence are verified by the French Accreditation Committee.

Qualification is a means of guaranteeing that the examination method actually achieves the level of performance stipulated and is described in a precise set of specifications.

Owing to the radiological risks linked to radiography, ultrasound applications are preferred, provided that they can offer equivalent inspection performance.

To date, more than 90 inspection methods have been qualified by the in-service inspection programmes. New inspection methods are currently being developed and qualified in order to meet new needs.

With regard to the Flamanville EPR reactor, virtually all of the processes have been qualified ahead of the pre-service inspection of the main primary system and the main secondary systems.

2.7.4 ASN oversight of reactor outages

Licensees need to periodically shut down their reactors in order to renew the fuel, which gradually becomes depleted during the operating cycle. At each outage, one third or one quarter of the fuel is renewed.

These outages mean that it is possible to access parts of the installation that would not normally be accessible during operation. Outages are therefore an opportunity to verify the condition of the facility by running checks and tests and performing maintenance work, as well as to implement the scheduled modifications on the facility.

These refuelling outages can be of several types:
- Simple Refuelling Outage (ASR) and Partial Inspection (VP) outage: these outages last a few weeks and are devoted to renewing part of the fuel and conducting a programme of verification and maintenance that is more extensive during a Partial Inspection (VP) than during a Simple Refuelling Outage (ASR);
- Ten-yearly Outage (VD): this outage entails a wide-ranging verification and maintenance programme. This type of outage, which lasts several months and takes place every 10 years, is also an opportunity for the licensee to carry out major operations such as a complete inspection and hydrotest on the primary system, a containment test or incorporation of design changes decided as part of the periodic safety reviews.

These outages are scheduled and prepared for by the licensee several months in advance. ASN checks the steps taken by the licensee to guarantee safety and radiation protection during the outage, and the safety of operation during the coming cycle(s).

The checks carried out by ASN mainly concern the following aspects:
- during the outage preparation phase, the conformity of the reactor outage programme with the applicable baseline requirements. As necessary, ASN asks for additions to this programme;
- during the outage – through regular briefings and inspections – the implementation of the programme and the handling of any unforeseen circumstances;
- at the end of outage, when the licensee presents its reactor outage report, the condition of the reactor and its readiness for restart. After this inspection, ASN will either approve reactor restart or not;
- after the reactor restarts, the results of all tests carried out during the outage and during the restart phase.

All of these measures are provided for by ASN resolution 2014-DC-0444 of 15th July 2014 concerning pressurised water reactor shutdowns and restarts.

2.8 Maintaining and continuously improving nuclear safety

2.8.1 Management of subcontracted activities

The maintenance of French reactors is to a large extent subcontracted by EDF to outside contractors, with the total workforce representing about 20,000 employees. EDF justifies the use of subcontracting by the need to call on specific or rare expertise, the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

The nuclear licensee's decision to resort to subcontracting must not compromise the technical skills it must retain in-house, in order to carry out its responsibility for safety and be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality of work and have a negative impact on the safety of the facility and the radiation protection of those involved (as subcontractors receive a large share of the ionising radiation dose linked to the work done on all the reactors: (see point 4.1.4)). These consequences can in particular result from the use of insufficiently qualified personnel, insufficient monitoring of the contractors by the licensee or degraded working conditions.

Therefore, if the decision to outsource certain activities is determined by EDF's industrial policy strategy, the conditions for the use of subcontracting must be such that the licensee retains full responsibility for the safety of its facilities at all times. The regulations covering the use of subcontractors changed in 2016 (see chapter 3, point 3.1.3).

In addition, owing to the large number of nuclear reactors operated by EDF, its outsourcing decisions have a direct impact on the industrial fabric specialising in nuclear supplies and maintenance. The licensee must also ensure the availability of a sufficient number of contractors with the expertise needed to perform the maintenance operations required to ensure the safety of the reactors.

A system of prior contractor qualification was put into place by EDF. It is based on an assessment of the technical know-how and the organisation of the subcontracting companies. The principles are described in the "Progress and sustainable development Charter" signed by EDF and its main contractors. In 2013, the French nuclear sector defined "social specifications" applicable to the provision of services and work performed in a nuclear facility. Since July 2013, EDF has transposed these social specifications into its subcontracting contracts for reactors in operation.

ASN carries out inspections on the conditions in which subcontracting takes place at EDF. ASN in particular checks EDF's implementation of and compliance with a process to ensure the quality of the activities subcontracted: the choice of contractors, monitoring of the work done, integration of experience feedback and adequacy of the resources for the volume of work to be done. For its labour inspectorate duties, ASN also pays close attention to worker protection, notably compliance with health and safety rules and working and rest times, and checks the legality of the service contracts, in particular assessing the independence of the subcontractors carrying out the service from the ordering customer.

FUNDAMENTALS

The defined requirements

The BNI Order of 7th February 2012 states that a defined requirement is a *"requirement assigned to an Element Important for Protection (EIP), so that, with the expected characteristics, it performs the function stipulated in the safety case mentioned in the second paragraph of Article L. 593-7 of the Environment Code, or to an Activity Important for Protection (AIP) so that it meets is objectives with respect to this safety case"*.

For the EIP, these requirements can in particular concern:

- the characteristics of the materials used;
- the manufacturing, assembly, erection and repair processes;
- the physical parameters and criteria characteristic of the performance of the EIP.

For the AIP, these requirements can in particular concern:

- the skills needed to perform the activity;
- any qualifications necessary;
- checks and hold points;
- the equipment and hardware needed to enable the activity to be carried out in accordance with the regulatory or even contractual requirements, such as to guarantee compliance with the safety case.

2.8.2 Correction of deviations

The checks carried out at the initiative of EDF and the additional verifications requested by ASN can lead to the detection of deviations from the defined requirements[2], which must then be processed. These deviations can have a variety of origins: design problems, construction defects, insufficient control of maintenance work, degradation as a result of ageing, etc.

The measures for detecting and correcting deviations, the performance of which is prescribed by the BNI Order of 7th February 2012, play an important role in maintaining the level of safety of the facilities.

"Real time" verification

The performance of periodic tests and preventive maintenance programmes on the equipment and systems helps identify deviations. Routine field inspections are also an effective means of discovering faults.

Verifications during reactor outages

EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections that cannot be performed when the reactor is in service. These operations are mainly used to remedy anomalies already identified, but also lead to the detection of new ones. Before each reactor restart, ASN asks EDF to identify any anomalies not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these anomalies with respect to the protection of persons and the environment for the coming operating cycle.

Ten-yearly verifications: conformity checks

EDF carries out periodic safety reviews of the nuclear reactors every ten years, in accordance with the regulations (see point 2.9.4). EDF thus compares the actual condition of the NPPs with their applicable safety requirements and identifies any deviations. These verifications can be supplemented by a programme of additional investigations designed to check the parts of the facility which are not covered by a preventive maintenance programme.

Informing ASN and the public

When a deviation is detected, and in the same way as any BNI licensee, EDF is required to assess the impacts on nuclear safety, radiation protection or protection of the environment. If necessary, EDF sends ASN a significant event notification. As of level 1 on the

2. The BNI Order of 7th February 2012 defines the notion of deviation as " non-compliance with a defined requirement, or non-compliance with a requirement set by the licensee's integrated management system liable to affect the provisions mentioned in the second paragraph of Article L. 593-7 of the Environment Code ".

INES scale, the public is informed on *www.asn.fr* of the events thus notified by the licensees.

ASN's remediation requirements

On 6th January 2015, ASN published Guide No. 21 concerning the handling of non-compliance with a defined requirement for Equipment Important for Protection (EIP). This guide applies to all anomalies affecting an EIP that performs a function necessary for the nuclear safety case with regard to radiological accidents affecting a pressurised water reactor.

It presents ASN's requirements concerning the correction of non-conformities and presents the approach expected of the licensee in accordance with the principle of proportionality. This is based more specifically on an assessment of the potential or actual consequences of any deviation identified and on the licensee's ability to guarantee control of the reactor in the event of an accident, by taking appropriate compensatory measures.

2.8.3 Examination of events and operating experience feedback

Operating experience feedback is a source of continuous improvement for the protection of the interests mentioned in Article L. 593-1 of the Environment Code. ASN requires that EDF notify it of the significant events occurring in its NPPs, in accordance with predetermined notification criteria (see point 3.3.1 of chapter 4). Each significant event is therefore rated by ASN on the International Nuclear Events Scale (INES), which comprises eight levels from 0 to 7.

ASN checks how EDF organises and analyses operating experience feedback from significant events and events that have occurred in other countries. At the local and national levels, it examines all significant events notified (a summary of their analysis for 2016 is given in 4.1.6). The significant events considered to be noteworthy owing to their recurrent or generic nature undergo detailed analysis with the support of IRSN. During inspections in the NPPs and EDF head office departments, ASN checks the organisation of the licensee and the steps taken to deal with significant events and take account of operating experience. Finally, at the request of ASN, the GPR periodically reviews experience feedback from PWR reactor operations.

2.9 NPP operating life extension

Although the regulations governing the operation of the NPPs in France set no time limit for their operating authorisation, Article L.593-18 of the Environment Code states that the licensee must carry out a periodic safety review of each reactor every ten years.

FUNDAMENTALS

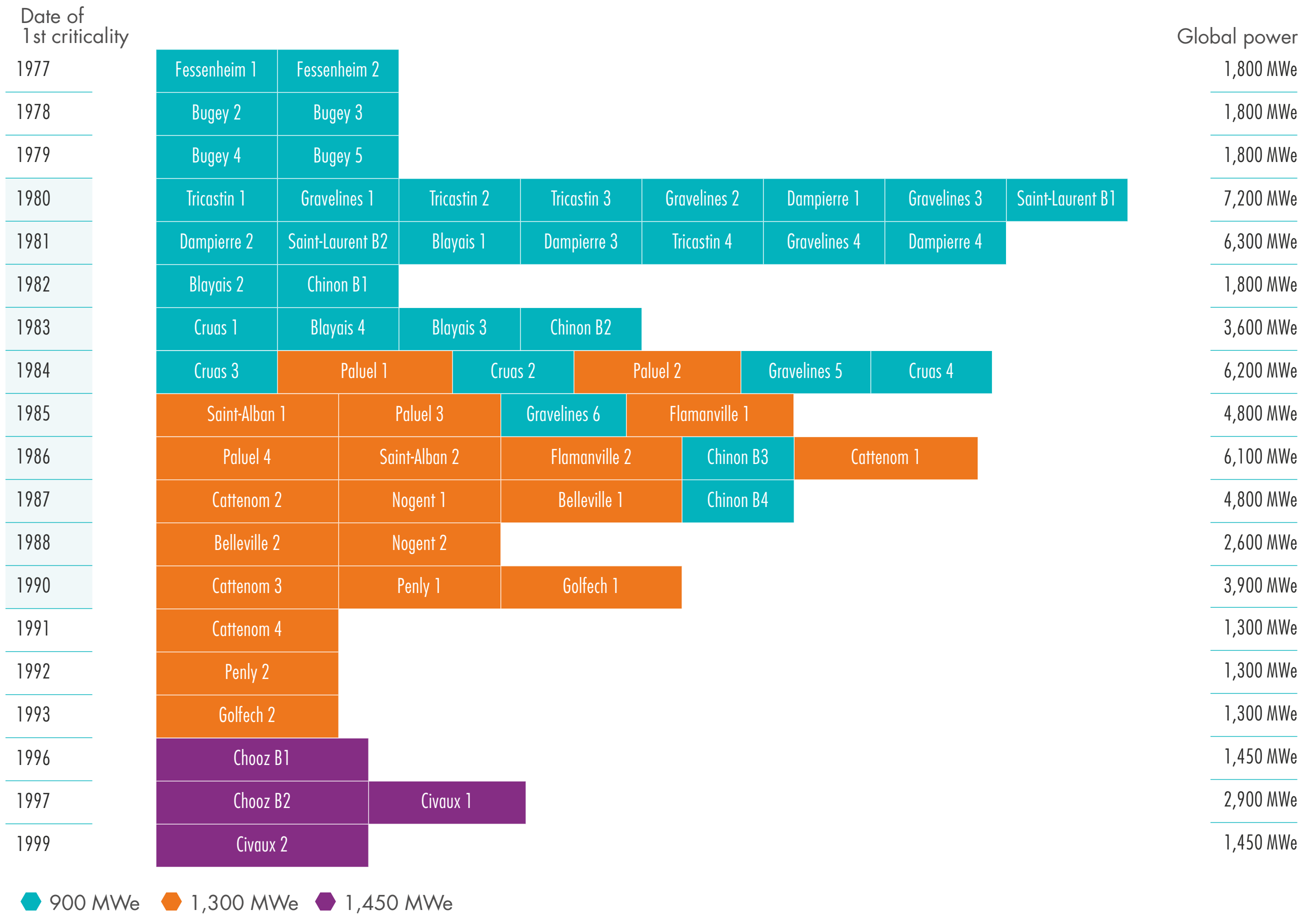
Deviation handling

A deviation is non-compliance with a defined requirement or a requirement set by the licensee's integrated management system. A deviation may thus affect a structure, a system or a component of the facility. It may also concern compliance with an operating document or an organisation. The regulations require that the licensee identify all deviations affecting its facilities and handle them. The activities involved in deviation handling are important for the protection of interests (public health and safety and protection of nature and the environment, as mentioned in Article L. 593-1 of the Environment Code). They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

2.9.1 The age of NPPs

The NPPs currently in operation in France were built over a relatively short period of time: 45 reactors, representing nearly 50,000 MWe, or three quarters of the power output by all the reactors in the French fleet, were started up between 1980 and 1990 and seven reactors, representing a further 10,000 MWe, between 1991 and 2000. In December 2016, the average ages of the reactors, calculated from the date of initial reactor criticality, were as follows:
- 35 years for the thirty-four 900 MWe reactors;
- 29 years for the twenty 1,300 MWe reactors;
- 19 years for the four 1,450 MWe reactors.

AGE PYRAMID of the French NPP reactors (French NPP fleet as at end 2016; by date of first criticality; power per reactor)



Source: ASN

2.9.2 The main challenges in managing ageing

Like all industrial facilities, nuclear power plants are subject to ageing. ASN ensures that, in line with its general operating and maintenance strategy, EDF takes account of ageing-related phenomena in order to maintain a satisfactory level of safety in the installations for their operating lifetime.

To understand and manage the ageing of an NPP, apart from simply the time elapsed since its start up, a certain number of factors must be taken into account, in particular the existence of physical phenomena that can degrade the characteristics of the equipment, depending on its function or conditions of use.

Deterioration of replaceable items

Equipment ageing is the result of phenomena such as the hardening of certain steels under the effect of irradiation or temperature, swelling of certain concretes, hardening of polymers, corrosion of metals and so on. These degradations are generally considered at the facilities design and manufacturing stages and then in a monitoring and preventive maintenance programme, or even a repair or replacement programme as necessary.

The lifetime of non-replaceable items

Non-replaceable items such as the reactor vessel (see point 2.4.4) and the containment (see point 2.5) are closely monitored in order to ensure that they are ageing as anticipated and that their mechanical properties remain within limits that guarantee their correct performance.

Equipment or component obsolescence

Before it is installed in the NPPs, some equipment undergoes a "qualification" process designed to ensure that it is able to perform its functions in the stress and atmosphere conditions corresponding to the accident situations in which it would be required. The availability of spares for this equipment is heavily dependent on changes in the industrial network of suppliers, with the cessation of manufacture of certain components or the closure of the manufacturing company, potentially leading to supply difficulties. Prior to installing these parts, EDF must check that the new spares that are different from the original parts do not compromise the "qualification" of the equipment on which they are to be installed. Given the length of this procedure, EDF must anticipate these needs well in advance.

2.9.3 How EDF manages equipment ageing

The approach adopted by EDF to control the ageing of its facilities is based on three key points:
- Anticipate ageing in the design: in the design and during manufacture of components, the choice of materials and the installation arrangements must be tailored to the intended operating conditions and take into account the kinetics of known or presumed deterioration processes.
- Monitor the actual condition of the facility: during operation, degradation phenomena other than those considered in the design can be discovered. The periodic monitoring and preventive maintenance programmes, the additional investigation programmes as well as examination of operating experience feedback (see points 2.7.1, 2.8.2 and 2.8.3) are all designed to detect these phenomena sufficiently early.
- Repair, renovate or replace equipment: given the operating constraints liable to be generated by such routine or exceptional maintenance operations, especially when they can only be performed during reactor outages, EDF must seek to anticipate them, to take account of the time needed to procure new components, the time required to prepare for and carry out the work, the risk of obsolescence of certain components and the loss of technical skills on the part of the workforce.

At the request of ASN, EDF established a methodology for controlling the ageing of its reactors after 30 years of operation, the aim of which is to demonstrate their ability to continue to function until their fourth ten-yearly outage inspection in satisfactory conditions of safety, on the one hand in the light of the understanding of and ability to control the mechanisms and kinetics of the damage modes linked to ageing and, on the other, according to the condition of the facilities during their Third Ten-yearly Outage inspections (VD3).

This methodology comprises a first generic phase, which aims to determine the extent to which account has been taken of ageing for an identical reactor series. Subsequently, on the occasion of the Third Ten-yearly Outage inspection (VD3) on each reactor of this type of similar reactors, a summary file specific to the reactor is produced in order to demonstrate control of the ageing of the equipment and the reactor's ability to continue to operate for the ten-year period following its VD3.

Given the fact that EDF envisages continuing to operate its reactors beyond 40 years, control of ageing, in particular of equipment the integrity of which is essential for safety (such as the reactor vessel – see point 2.4.4 – and its containment – see point 2.5), and the management of obsolescence are crucial to maintaining a satisfactory level of safety (see point 3.2). ASN considers that the approach adopted by EDF, both generic and for each reactor, complies with most of its requirements but needs to be supplemented in order to be more specifically able to:
- identify the possible vulnerabilities in the industrial processes for replacement of components, including in the case of an unforeseen operational event on the reactors, and propose steps to improve the robustness of these processes;
- provide a robust demonstration of the mechanical resistance of the vessels beyond their fourth ten-yearly outage inspection.

This approach, which is currently being reviewed with IRSN, will be examined in early 2018 by the GPR and GPESPN.

In addition, control of ageing will be the subject of the first topical peer review stipulated by Directive 2014/87/Euratom amending the 2009 Directive, to take account of the lessons learned from the accident that struck the Fukushima Daiichi NPP. This Directive requires a peer review, every six years, of a technical aspect relating to the nuclear safety of their nuclear facilities. The procedures of this review are defined by ENSREG (European Nuclear Safety Regulators Group) (see chapter 7, point 1.1) reporting to the European Commission.

2.9.4 The periodic safety review

In accordance with the provisions of Article L. 593-18 of the Environment Code, EDF must carry out a periodic safety review of its reactors every ten years, comprising the following two parts:
- A check on the condition and conformity of the facility: this step aims to verify the situation of the facility with respect to the rules applicable to it. It is based on a range of inspections and tests in addition to those performed in real-time. These verifications can concern checks on the initial design studies as well as field inspections of equipment not addressed by maintenance programmes, or tests conducted every ten years such as the containment pressure tests. Any deviations detected during these investigations are then restored to conformity within a time-frame commensurate with their potential consequences.
- The safety reassessment: this step aims to improve the level of safety in the light of the experience acquired during operation, changing knowledge, the requirements applicable to the more recent facilities and international best practices. Following these reassessments, EDF identifies the modifications it intends to make to its facilities in order to reinforce their safety.

The review process for the EDF reactors

In order to benefit from the standardisation of the reactors operated by EDF, these two parts of the review are first the subject of a generic design programme for a given plant series (900 MWe, 1,300 MWe and 1,450 MWe reactors). The results of this programme are then implemented on each of the reactors on the occasion of its ten-yearly outage inspection.

In accordance with the provisions of Article L. 593-19 of the Environment Code, following the ten-yearly outage inspection, the licensee sends ASN a periodic safety review conclusions report. In this report, the licensee states its position on the regulatory conformity of its facility as well as on the modifications made to remedy deviations observed or to improve the safety of the facility. The review report contains elements stipulated in Article 24 of Decree of 2nd November 2007, amended.

The ASN analysis

The guidelines of the generic programmes proposed by the licensee to verify the status of the facility and reassess safety are the subject of an ASN position statement issued following consultation of the GPR and possibly of the Advisory Committee for Nuclear Pressure Equipment (GPESPN). On this basis, EDF carries out safety reassessment studies and defines modifications.

Following consultation of the GPR at the end of the periodic safety review generic phase, ASN issues a position statement on the results of the reassessment studies and on the modifications envisaged by EDF that aim to improve safety.

ASN informs the Minister responsible for Nuclear Safety of its analysis of the review conclusions report for each reactor, mentioned in Article L. 593-19 of the Environment Code and can issue new prescriptions regarding its continued operation.

The Energy Transition for Green Growth Act 2015-992 of 17th August 2015 supplemented the framework applicable to the periodic safety reviews on NPP reactors. It more specifically requires ASN authorisation, following a public inquiry, of the provisions proposed by the licensee during the periodic safety reviews beyond the thirty-fifth year of operation of an NPP reactor. Five years after submitting the periodic safety review report, the licensee also submits an interim report on the condition of these equipment items, in the light of which ASN may supplement its prescriptions.

2.10 The Flamanville 3 EPR reactor

The EPR reactor is a pressurised water reactor based on a design which is an evolution of the design of the reactors currently in service in France, enabling it to comply with reinforced safety objectives.

After a period of about ten years during which no nuclear reactors were built in France, EDF submitted an application in May 2006 to the Ministers responsible for Nuclear Safety and Radiation Protection for the creation of a 1,650 MWe EPR type reactor, called Flamanville 3, on the Flamanville site, which already houses two 1,300 MWe reactors.

EPR control room.

The Government authorised its creation by Decree 2007-534 of 10th April 2007, following ASN's favourable opinion, subsequent to the inquiry conducted with the assistance of its technical support organisations.

After issue of this Creation Authorisation Decree and the building permit, construction of the Flamanville 3 reactor began in September 2007. The first pouring of concrete for the buildings in the nuclear island began in December 2007. Since then, the civil engineering (structural) work has continued and is now almost completed.

In 2016, the civil engineering finishing work continued. Installation of components (tanks, pipes, valves, pumps, cables, etc.) is also continuing, with the completion of the primary system welds and erection of the connected systems. After a major I&C modification, the start-up tests resumed with a view to beginning the tests on all the systems.

According to EDF, fuel loading and start-up of the Flamanville 3 reactor are scheduled for the end of 2018.

2.10.1 The stages up to commissioning of the Flamanville 3 reactor

Pursuant to the Decree of 2nd November 2007 (see chapter 3, point 3.1.3), ASN authorisation is required to bring nuclear fuel inside the perimeter of the facility and to commission it. Partial commissioning corresponds to the reception of nuclear fuel within the perimeter of the BNI and, for a nuclear reactor, commissioning of the facility corresponds to the insertion of nuclear fuel into the reactor vessel.

In accordance with Article 20 of this same Decree and Article 3 of the Flamanville 3 Creation Authorisation Decree, EDF sent ASN its commissioning authorisation application and its partial commissioning application in March 2015. This included the safety analysis report, the general operating rules, a study of waste management in the facility, the on-site emergency plan, the decommissioning plan and an update of the facility's impact assessment (see point 3.3). ASN expressed its comments and requests for additional information regarding these applications in letters dated 12th June and 13th July 2015 (available on *www.asn.fr*).

ASN also assists the Ministry of the Environment in reviewing the file applying for a change to the commissioning time-frame for Flamanville 3 in the Decree of 10th April 2007 authorising the creation of the BNI.

In parallel with the examination of these commissioning authorisation requests, ASN also checks the construction, the first facility start-up tests and the preparedness of the teams in charge of operating the facility following its commissioning.

ASN inspection during the start-up tests of the SRU system, Flamanville 3, October 2016.

Finally, ASN assesses the conformity of the nuclear pressure equipment that is most important for safety with the requirements set by the regulations. This assessment revealed an anomaly in the chemical composition of the steel in certain parts of the vessel (see point 3.4), regarding which ASN will issue a position statement in 2017.

In addition, in accordance with Article 9 of the Order of 10th November 1999 concerning monitoring of the operation of the PWR primary and secondary systems, EDF began the "pre-service inspection" in order to ensure the feasibility of the scheduled operational maintenance, in particular before loading of the fuel. ASN checks the performance of non-destructive tests carried out for this purpose on the Flamanville site. During an inspection on 12th April 2016, ASN identified several areas for improvement in the quality of how these tests were implemented, which led EDF to stop the pre-service inspection for several weeks.

2.10.2 Monitoring of construction, start-up tests and preparation for operation

ASN is faced by numerous challenges when checking construction, start-up tests and preparation for the operation of Flamanville 3. They concern:
- checking the quality of equipment manufacturing and installation construction and testing in a manner commensurate with the safety, radiation protection and environmental protection issues, in order to be able to rule on the ability of the installation to meet the defined requirements;
- building on the experience acquired by each party concerned during the construction of this new reactor;

- ensuring that the start-up tests programme is satisfactory, correctly performed and that the expected results are obtained;
- ensuring that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN issued prescriptions for the design, construction and commissioning tests of Flamanville 3 and for the operation of the two Flamanville 1 and 2 reactors located close to the construction site. As the subject is a nuclear power reactor, ASN is also responsible for labour inspectorate duties on the construction site. In addition, ASN oversees the manufacture of pressure equipment that will form part of the primary and secondary systems and of the nuclear steam supply system. ASN's main actions in this field in 2016 are described in point 3.3.

2.10.3 Cooperation with foreign nuclear regulators

To be able to share experience feedback, ASN multiplies technical exchanges with its foreign counterparts on the topic of regulating the design, construction and operation of new reactors.

Bilateral relations

ASN enjoys close relations with foreign nuclear regulators in order to share previous and current experience of authorisation procedures and regulation of the construction of new reactors. Since 2004, reinforced cooperation has existed with the Finnish nuclear safety regular (STUK, *Säteilyturvakeskus*) around the construction of the Olkiluoto (Finland) and Flamanville (France) reactors. In 2016, a technical progress meeting concerning the two projects was held in Finland and a visit to the Olkiluoto reactor 3 construction site was organised.

In 2016, ASN and the British Office for Nuclear Regulation (ONR) met in London. The agenda included ASN monitoring of the construction of Flamanville reactor 3, the inspections conducted on the construction site, in the EDF head office departments and in the Areva laboratory in Erlangen, as well as ASN's position with regard to the work initiated by Areva to characterise the anomalies found in the Flamanville reactor vessel closure head and bottom head.

Multinational cooperation

Some international structures such as the Nuclear Energy Agency (NEA) and the Western European Nuclear Regulators Association (WENRA) also provide opportunities for exchanges on practices and lessons learned from overseeing reactor construction.

ASN is a member of the Multinational Design Evaluation Programme (MDEP) which evaluates the design of new reactors (see point 3.3 of chapter 7). With the support of IRSN, ASN took part in the work concerning severe accidents, I&C, probabilistic safety assessments and the modelling of accidents and transients, the inspection of suppliers and in the work by the new technical group, set up in 2016 and responsible for the commissioning of new reactors. The plenary group devoted to EPR type reactors also met twice.

ASN also takes part in the Working Group on the Regulation of New Reactors, which is a technical group of the Committee on Nuclear Regulatory Activities (CNRA) of the Nuclear Energy Agency (NEA) (see chapter 7, point 3.2.). ASN took part in a seminar organised jointly with the MDEP on the regulatory checks to be carried out during the commissioning of new reactors. ASN inputs the deviations observed on Flamanville 3 to the database recording the anomalies and deviations observed on recent constructions.

For ASN, these international exchanges are one of the driving forces behind the harmonisation of safety requirements and inspection practices.

2.11 Studies on reactors of the future

Since 2000, in partnership with EDF and Areva, CEA has been looking at the development of fourth generation nuclear reactors, notably within the framework of the Generation IV International Forum (GIF). The six technologies covered by the work of this forum are the following:
- SFR: Sodium-cooled Fast Reactor;
- GFR: Gas-cooled Fast Reactor;
- HTR/VHTR: Gas-cooled High Temperature (850°C) and Very High Temperature (1,000°C) fast reactors;
- LFR: Lead-cooled Fast Reactor;
- MSR: Molten Salt Reactor;
- SCWR: Super Critical Water Reactor.

For their promoters, the main challenge for fourth generation reactors is to ensure sustainable development of nuclear energy while improving the use of natural resources, reducing the production of radioactive waste, improving safety (reducing the risk of core melt and improved protection of the population) while offering a greater ability to withstand security, proliferation or terrorism risks. For those promoting them, the industrial deployment of fourth generation reactors is envisaged in France no earlier than the middle of the 21st century. It will require prior creation of a prototype, for which the planned commissioning date is set at 2020 by the Act of 28th June 2006 on the sustainable management of radioactive materials and waste (see point 1.1 of chapter 16).

With this simultaneously medium and long-term view, much earlier than required by the regulatory procedure, ASN wishes to monitor the development of fourth generation reactors by French industry, as well as the associated safety concerns – as was the case with development of the EPR so as to be in a position, at the appropriate time, to establish the safety objectives for these future reactors. For ASN, fourth generation reactors will have to meet stricter nuclear safety, radiation protection and environmental protection objectives. ASN in particular considers that fourth generation reactors will require a level of safety significantly higher than that of the third generation reactors, represented in France by the EPR.

ASN underlines the importance it attaches to the safety justification of the plant technology chosen over those adopted by the GIF. In this context, and on the basis of the documents transmitted at its request by CEA, Areva and EDF in 2009 and 2010, ASN asked the Advisory Committees for Nuclear Reactors (GPR), for Plants and for Waste for their opinion on the range of various reactor technologies envisaged for the fourth generation, with regard to the prospects for more stringent nuclear safety, radiation protection and environmental protection objectives, as well as with respect to the possibility of separation and transmutation of long-lived radioactive elements mentioned by the Programme Act of 28th June 2006 on the sustainable management of radioactive materials and waste. The Advisory Committees returned an opinion on these subjects in April 2014. ASN will issue a position statement in 2017 on the objectives and orientations of the fourth generation reactors.

At the same time, CEA undertook studies for a prototype Sodium-cooled Fast Reactor (SFR): the Astrid project (Advanced Sodium Technological Reactor for Industrial Demonstration). In mid-2012, CEA sent ASN the safety orientations document for the Astrid prototype. This document was the subject of an ASN position statement in April 2014 (see chapter 14).

2.12 Labour Law in nuclear power plants

ASN carries out labour inspectorate duties in the 19 nuclear power plants in operation, the eight reactors undergoing decommissioning and the EPR reactor under construction at Flamanville. The number of people working in an NPP varies between 800 and 2,000 employees. The total number of staff assigned to all the nuclear sites is about 24,000 for the employees of EDF SA, and 23,000 for the employees of the subcontractors, which more specifically take part in maintenance during reactor outages.

The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors. This oversight applies to the health, safety and working conditions of the employees: exposure to ionising radiation, to conventional risks involved in any industrial activity (electrical risks, chemical risks, explosion risks, risks linked to work at height, to work in confined spaces, to machinery in service, or to the handling of heavy loads), but also with regard to working hours, the operation of the personnel representative bodies, the conditions concerning the use of subcontracting, transnational secondment of staff, etc.

The health, safety, working conditions and quality of employment of the employees of EDF or the subcontractors are thus the subject of ASN regulation, in the same way as the safety of the facilities.

The labour inspectorate duties carried out and the other NPP regulation duties are complementary, with the aim of improving working conditions and the quality of operations and maintenance work. ASN thus has an integrated regulatory vision and scope of action, in particular in the fields of radiation protection, monitoring of certain equipment, subcontracting or Organisational and Human Factors (OHF).

As of 31st December 2016, the ASN resources for its labour inspectorate duties are:
- fifteen labour inspectors, assigned to the regional divisions and working directly with the sites;
- a central labour director, responsible for managing and coordinating the network of labour inspectors and acting as the interface with the Ministry responsible for Labour. The agreement with the General Directorate for Labour of the Ministry responsible for Labour, renewed in 2015, is implemented in the regions by agreements between the ASN regional divisions and the Regional Directorates for Enterprises, Competition, Consumption, Labour and Employment.

2.13 Personnel radiation protection

Exposure to ionising radiation in a nuclear power reactor comes from activation of corrosion products (primarily) and from fuel fission products. All types of radiation are present (neutrons, α, β and γ) and the risk of exposure is both external and internal. In practice, more than 90% of the doses come from external exposure to β and γ radiation. Exposure is primarily linked to maintenance operations during reactor outages.

ASN checks compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN concerns itself with all workers active on the sites, whether EDF or contractor personnel.

This oversight is carried out during inspections (specifically on the topic of radiation protection, one to two times per year and per site, during reactor outages, following incidents, or occasionally in the EDF head office departments and engineering centres), and during the review of files concerning occupational radiation protection (significant events, design, maintenance or modification files, EDF documents implementing the regulations, etc.) with the support of IRSN when necessary.

Finally, meetings are held periodically with EDF in order to monitor the progress of the technical or organisational projects or to compare ASN's analysis with that of the licensee, more specifically through annual reviews, and to identify possible areas for improvement.

2.14 The environmental and health impacts of NPPs

2.14.1 Revision of the prescriptions concerning water intake and discharges

The Environment Code empowers ASN to define prescriptions concerning BNI water intake and discharges (see point 4.4.1 of chapter 4). On the occasion of the renewals or modifications of these prescriptions, ASN sets the limit values for emissions, water intake and discharge of effluents on the basis of the best available technologies in technically and economically acceptable conditions, taking into consideration the characteristics of the installation, its location and the local environmental conditions.

ASN also sets the rules concerning the management of nuisances and the impact on health and the environment of the pressurised water reactor NPPs. These prescriptions are notably applicable to the management and monitoring of water intake and effluent discharge, to environmental monitoring and to information of the public and the authorities.

In order to set these rules, ASN bases its work on operating experience feedback from all the reactors, while taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatments, etc.) and changes to the general regulations.

FOCUS

Radiological impact of discharges

The calculated radiological impact of the maximum discharges given in the EDF files on the most heavily exposed population group, still remains well below the allowable public dosimetric limit (1 mSv/year).

The annual effective dose delivered to the population reference group (group subject to maximum radiological impact) is thus estimated at between a few microsieverts and several tens of microsieverts per year, depending on the particular site. This exposure represents less than 0.1% of the average total dose to which the French population is exposed (see chapter 1).

2.14.2 Oversight of waste management

The management of the conventional and radioactive waste produced by the NPPs falls within the general framework of management of BNI waste.

In compliance with the Environment Code, EDF carries out waste sorting at source, differentiating in particular between waste from nuclear zones and other waste. For all the waste, ASN examines the licensee's "waste management assessment" a document that is specific to each facility and required by the regulations, as described in point 3.2.2 of chapter 3. This document more specifically presents a description of the operations which are the cause of production of the waste, the characteristics of the waste produced or to be produced, an estimation of the waste traffic volumes and a waste zoning plan.

Every year, each site also sends ASN a summary report on its production of waste and the corresponding

Storage of drums in the packaging auxiliaries building in the Cruas-Meysse NPP, 2016.

disposal routes, a comparison with the results of previous years, a summary of deviations observed and of the organisation of the site, the list of significant events which have occurred and the outlook for the future.

The licensee and ASN hold regular meetings to discuss waste-related matters and waste management, notably through annual reports. Inspections are also held regularly, during which the inspectors verify the site's waste management organisation.

2.14.3 Increased protection against other risks and nuisances

Some cooling systems in NPPs are environments that are favourable to the development of legionella and other amoebas (see point 1.4). ASN therefore sets maximum legionella concentration levels for cooling systems equipped with cooling towers and for *Naegleria fowleri* amoeba concentration levels downstream of the environmental discharge, along with facility monitoring requirements.

Through file reviews and its field checks, ASN closely monitors the progress of the preventive or remedial measures taken by EDF to reduce the risk of the proliferation of these micro-organisms and the results of these actions, including the chemical discharges resulting from biocidal treatment.

On 6th December 2016, ASN adopted a resolution on the prevention of microbiological risks linked to cooling installations on the secondary system of NPP reactors. This text enables these regulations to be updated consistently with those for Installations Classified on Environmental Protection Grounds (ICPE).

FOCUS

ASN Resolution 2016-DC-0578 of 6th December 2016 on the prevention of risks resulting from the dispersal of pathogenic micro-organisms (legionella and amoeba) by PWR secondary system cooling installations

The ASN resolution reinforces the prevention of risks resulting from the dispersal of pathogenic micro-organisms. It stipulates requirements concerning:
- the design, upkeep and monitoring of the facility;
- the maximum legionella concentrations in the water in the facility and downstream of it with regard to amoeba;
- the steps to be taken in the event of proliferation of microorganisms in the systems or infection identified in proximity to the facility;
- information of the public and the administrations in the event of proliferation of micro-organisms.

To the extent possible, the resolution aims to align the requirements applicable to the NPP large cooling towers with those applicable to cooling towers of other industries with respect to legionella.

However, owing to the considerable flow rates and volumes of water in the NPP cooling towers, certain requirements applicable to other industries would lead to an excessive environmental impact from biocidal treatments. Certain provisions were therefore adapted.

Finally, given the link between the amoeba risk and the legionella risk and in order to harmonise and clarify the requirements currently given in the individual regulations of the NPPs, ASN also adopted provisions concerning these risks.

While forming an integral part of the general and operating regulations of BNIs, the ASN resolution includes most of the prevention principles in the regulations applicable to the cooling towers of other facilities*. Certain provisions were adapted:
- the Legionella pneumophila concentration in the water of the installation must be less than 10,000 CFU**/L;
- Permanent preventive treatment of the water is not mandatory for the duration of operation of the facility (current practice is to treat the systems during the summer, which is currently sufficient to limit colony formation in the winter).
- The shutdown threshold of 100,000 CFU/L for ICPEs is adopted. However, if this threshold is exceeded, while no biocidal treatment is in progress, the licensee may inject a remedial biocidal product to reduce the legionella concentration. If it remains higher than 100,000 CFU/L, immediate shutdown of dispersion is then required.
- The performance of the demisters*** in the NPP large cooling towers must be higher than that set by the regulations applicable to other industries****, thus limiting the dispersion of legionella into the environment.
- The prescribed frequency of monitoring of the legionella concentration is greater than that applicable to the cooling towers of other industries*****, thus limiting the potential duration of legionella proliferation beyond the thresholds.

** Performance of a methodical risk assessment to define prevention measures, periodic cleaning of the installations, personnel training, etc.*

*** Colony Forming Unit (the CFU per litre is the unit used to measure the legionella concentration)*

**** Cooling towers are equipped with a device through which the plume has to pass and which limits the number of potentially contaminated water droplets dispersed.*

***** Mist entrainment rate in the large cooling towers less than 0.003 % as opposed to 0.01 % for the ICPE cooling towers.*

****** In the large cooling towers of NPPs, regulatory monitoring takes place every two weeks, or once per week as of the first time the threshold of 10,000 CFU/L is exceeded. In the ICPE cooling towers, regulatory monitoring is monthly, or every two weeks if the 1,000 CFU/L threshold is exceeded several times consecutively.*

3. Nuclear safety and radiation protection news

3.1 Experience feedback from the Fukushima Daiichi accident

After the Fukushima Daiichi accident, ASN issued a set of resolutions dated 5th May 2011 asking the licensees of major nuclear facilities to perform stress tests in the light of this accident.

ASN issued a position statement on the results of these stress tests on 3rd January 2012, which was itself reviewed by the European stress tests, in April 2012.

On the basis of the opinions of the Advisory Committee and the conclusions of the European stress tests, ASN issued a series of resolutions dated 26th June 2012 requiring that EDF implement:

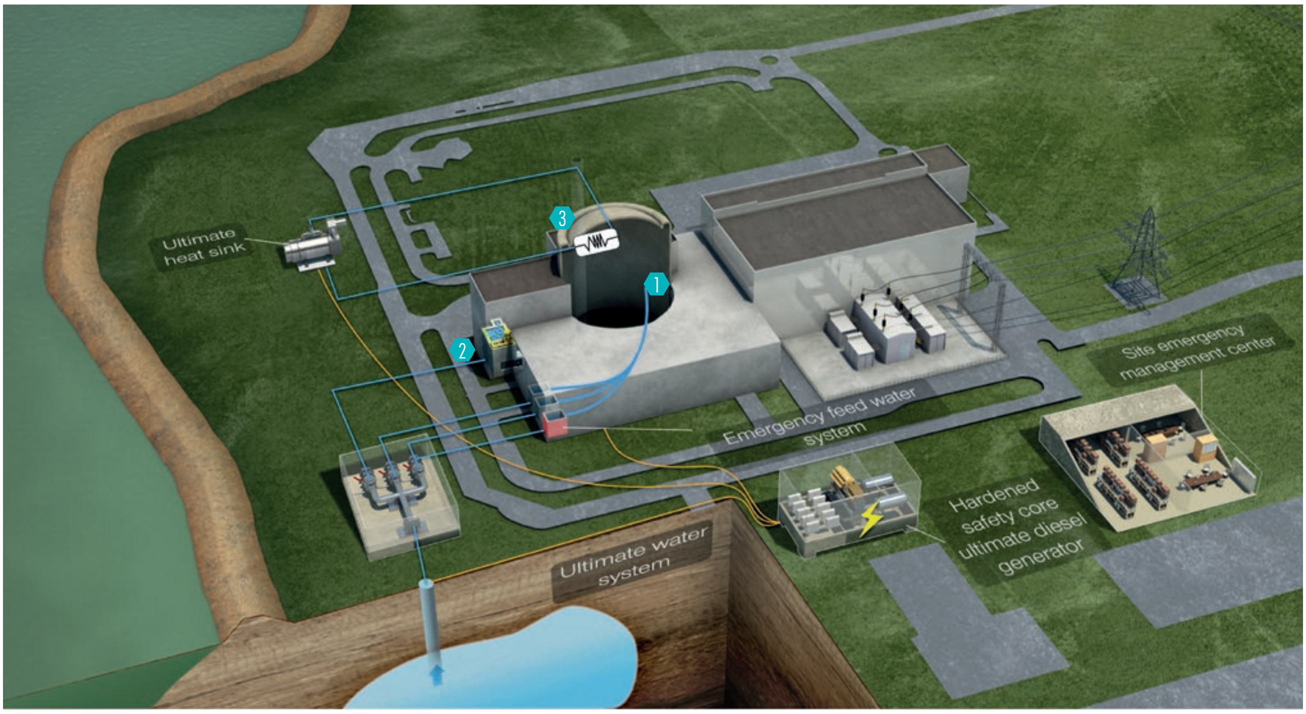
- a "hardened safety core" of material and organisational measures which, in the event of an extreme external hazard, are designed to:
  - prevent an accident with fuel melt, or limit its progression,
  - limit large-scale radioactive releases,
  - enable the licensee to carry out its emergency management duties;
- a local emergency centre allowing emergency management of the nuclear site as a whole in the event of an extreme external hazard;
- a Nuclear Rapid Intervention Force (FARN) which, using mobile means external to the site, can intervene on a nuclear site in a pre-accident or accident situation;
- a range of corrective measures or improvements, notably the acquisition of additional communication and radiological protection means, the implementation of additional instrumentation, extensive consideration of internal and external hazard risks, improvement of the way in which emergency situations are taken into account.

In addition to its requests, ASN issued a range of resolutions dated 21st January 2014 aiming to clarify certain design provisions for the «hardened safety core", in particular the definition and justification of the extreme external natural hazard levels to be considered for the hardened safety core.

This last point was examined in 2015-2016 and the conclusions were presented to the GPR in January and February 2016. ASN adopted a position statement on the contingencies to be considered for the "hardened safety core» in July 2016 and asked EDF for a number of additional studies.

ASN's demands are part of a continuous process to improve safety and aim to be able to cope with situations

THE PRINCIPLE of the hardened safety core



1 reactor cooling
2 pool cooling
3 reactor building cooling

far beyond those normally considered for this type of installation. They concern measures to prevent and mitigate the consequences of an accident for all the installations on a site, beyond their initial design conditions. They require both additional fixed resources and off-site mobile resources. In the international context, these demands stand out through the scope and scale of the fixed systems required.

Given the nature of the required work, the licensee must carry out studies for the design, construction and installation of new equipment, which first require lead times and then require a schedule to optimise their implementation on each NPP. Insofar as these major works are carried out on nuclear sites which are in service, it is also necessary to ensure that their implementation does not degrade the safety of the power plants.

To take account of both the engineering constraints involved in these major works and the need to introduce the post-Fukushima improvements as soon as possible, their implementation is organised in three phases:

Phase 1 (2012-2015)

Deployment of temporary or mobile measures to enhance protection against the main situations of total loss of the heat sink or electrical power supplies

At the end of 2015, EDF had deployed the planned measures.

In particular the FARN, which is one of the main emergency management measures, was deployed. Since 31st December 2015, the FARN teams have the capacity for simultaneous intervention on all the reactors of a site in less than 24 hours (up to six reactors in the case of the Gravelines site).

Phase 2 (2015-2020)

Deployment of certain final design and organisational means that are robust to extreme hazards, in order to deal with the main situations of total loss of the heat sink or of electrical power supplies beyond the baseline safety requirements in force. The most important measures are:
- installation of a large-capacity ultimate backup diesel-generator set, requiring the construction of a dedicated building to house it;
- setting up of an ultimate water source;
- creation of an ultimate water make-up system for each reactor and each spent fuel pool;
- reinforcement of the earthquake resistance of the containment venting filter;
- construction on each site of a local emergency centre capable of withstanding extreme external hazards (functionally independent in an emergency situation).

On the various sites, EDF has begun to implement a large part of the final measures recalled above, more

Installation of an ultimate back-up diesel generator on the Saint-Laurent-des-Eaux NPP, November 2016.

particularly the construction of buildings intended to house the high-capacity ultimate back-up diesel generator sets. With regard to this last point, ASN authorised these changes, making sure that they could not lead to risks for the installations. It also inspects the performance of the works.

Phase 3 (as of 2019)

This phase will supplement phase 2, in particular to take account of other potential accident scenarios. The most important measures are:
- removal of the residual power by the steam generators, by means of an independent ultimate backup feedwater system supplied by the ultimate heat sink;
- addition of a new makeup pump to the primary system;
- completion of the fixed connection systems for the SG backup feedwater supply, the PTR cooling water tank and the spent fuel pit;
- installation of an ultimate instrumentation & control system and the definitive instrumentation of the "hardened safety core";
- installation of a reactor containment ultimate cooling system that does not require opening of the containment venting-filtration system in the event of a severe accident;
- implementation of a solution for flooding the reactor pit to prevent corium melt-through of the basemat.

These last two points were examined in 2015-2016 and the conclusions were presented to the GPR in July 2016.

All of the provisions of phase 3 on each of the EDF reactors will be reviewed by ASN prior to implementation.

3.2 Examination of NPP operating life extensions

The licensee of a nuclear facility must conduct a periodic safety review of its facility every ten years (see point 2.9.4).

900 MWe reactors

The periodic safety review associated with the third ten-yearly outage inspections

In July 2009, ASN adopted a position statement on the generic aspects of the continued operation of the 900 MWe reactors beyond 30 years. ASN did not identify any generic elements compromising EDF's ability to ensure the safety of the 900 MWe reactors up until the next periodic safety review. ASN considers that the new baseline safety requirements presented in the generic safety report for the 900 MWe reactors and the modifications to the installation envisaged by EDF are such as to maintain and improve the overall level of safety of these reactors.

As this generic assessment does not take account of any specific individual features, ASN gives an opinion on the ability of each reactor to continue to function, more specifically based on the results of inspections performed during the reactor conformity check during the third ten-yearly outage and on the assessment of the reactor review report submitted by EDF.

In 2016, two reactors (Chinon B2 and Cruas 4) incorporated the improvements resulting from the periodic safety review on the occasion of their third ten-yearly outages, thus raising to 29 (out of 34) the number of 900 MWe plant series reactors which had carried out their third ten-yearly outage inspection.

In 2016, ASN also sent the Minister responsible for Nuclear Safety its analysis of the review conclusions reports for the Dampierre 2 and Gravelines 1 reactors. On the basis of this analysis, ASN has not identified any element that would compromise EDF's ability to satisfactorily control the safety of these two 900 MWe reactors until the next periodic safety review. Pursuant to Article L.593-19 of the Environment Code, ASN took this opportunity to issue additional prescriptions designed to reinforce the safety of these reactors.

As part of the additional tests ASN requested following the third ten-yearly outage inspection of Bugey reactor 5, the containment tightness test revealed a defect and led to the prolonged shutdown of this reactor in 2015, which continued in 2016.

The periodic safety review associated with the fourth ten-yearly outage inspections

The continued operation of the nuclear reactors beyond their fourth ten-yearly outage inspection is of particular importance in a number of respects:
- The period of forty years of operation corresponds to the initial design hypotheses for a certain number of equipment items, in particular with regard to their ability to function in accident operating conditions (qualification). The studies concerning the conformity of the installations and the management of equipment ageing therefore need to be reviewed to take account of the degradation mechanisms actually observed and the maintenance and replacement strategies adopted by the licensee.
- This periodic safety review is also an opportunity to complete the integration on the 900 MWe reactors of the modifications prescribed following the stress tests carried out in the wake of the Fukushima Daiichi NPP accident. This concerns the phase 3 work (see point 3.1).
- Finally, the wish expressed by EDF in 2010 to significantly extend the operating life of the reactors beyond 40 years was examined by ASN. By this time frame, the 900 MWe reactors will be operating alongside EPR or equivalent type reactors, which are designed to meet significantly reinforced safety standards. Their safety must therefore be reassessed in the light of these new safety requirements, the state of the art nuclear technologies and the operating life targeted by EDF.

After familiarising itself with ASN's requests of June 2013 concerning the orientations of the generic studies programme carried out by EDF in order to extend the operating life of the reactors beyond 40 years, EDF drafted and, in October 2013, transmitted its orientation file for the Periodic Safety Review (DOR) associated with the Fourth Ten-yearly Outage inspections for the 900 MWe reactors (DOR VD4-900). Further to ASN's requests for additional data in March 2014, EDF updated its file.

ASN examined this file with the assistance of IRSN. In April 2015, it asked the GPR for its opinion on the orientations of the generic studies being envisaged by EDF on the various topics contained in the DOR VD4 900 file.

Following the GPR meeting, EDF completed its generic studies programme in June 2015 with a certain number of measures and clarified a certain number of its proposals.

In April 2016, ASN issued a position statement on the orientation of the generic studies to be carried out in preparation for the fourth periodic safety reviews on the nuclear reactors, after consulting the public on the draft requests for additional information to be sent to EDF concerning the studies and verifications to be carried out.

With the support of IRSN, ASN is currently examining the generic studies linked to this review. It is also taking part in the work of the monitoring group set up by the High Committee for Transparency and Information on

Nuclear Security (HCTISN) to propose means of involving the public in the service life extension project.

In 2019, Tricastin reactor 1 will be the first 900 MWe reactor to undergo its fourth ten yearly outage inspection. The fourth ten-yearly outage inspections for the 900 MWe reactors will continue until 2030.

1,300 MWe reactors

The periodic safety review associated with the second ten-yearly outage inspections

In 2006, ASN gave a favourable opinion to the generic aspects of continued operation of the 1,300 MWe reactors up to their third ten-yearly outage inspections, provided that the modifications decided on during this review were effectively implemented.

The twenty 1,300 MWe reactors have now all undergone their second ten-yearly outage inspections and have incorporated the improvements identified by the periodic safety review.

Pursuant to Article L.593-19 of the Environment Code, ASN in 2014 sent its position statement on the continued operation of the two Saint-Alban reactors, Cattenom reactors 2 and 3, the two Nogent reactors and Penly reactor 1 and took this opportunity to issue additional prescriptions designed to reinforce the safety of these reactors. It is currently preparing its position regarding the continued operation of the other 1,300 MWe reactors.

The periodic safety review associated with the third ten-yearly outage inspections

In early 2015, ASN ruled on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years. ASN considers that the steps taken or being envisaged by EDF to assess the condition of its 1,300 MWe reactors and manage their ageing up until the periodic safety review associated with their fourth ten-yearly outage inspections are acceptable. ASN also considers that the modifications identified by EDF during this study phase will help to significantly improve the safety of these installations. These improvements in particular concern reinforcing protection of the facilities against hazards, reducing releases of radioactive substances in the event of an accident, with or without core melt, and preventing the risk of uncovering of the fuel assemblies stored in the spent fuel pit or during handling.

FOCUS

ASN's position regarding the guidelines for the fourth periodic safety review of the 900 MWe reactors

In a letter dated 20th April 2016, ASN issued a position statement on the EDF guidelines file for the fourth periodic safety review of the 900 MWe nuclear reactors, taking account of the comments collected during the public consultation from 26th January to 16th February 2016.

After examination of the programme proposed by EDF, ASN considers that the topics selected by EDF are pertinent with respect to the safety issues. However, ASN asks EDF to supplement several aspects of its programme, more specifically concerning the scope of the inspection programmes and the design improvement objectives. The requests primarily concern:

- The conformity of the facilities: ASN more particularly asks that the planned reactor examination be reinforced, that design reviews be carried out on certain systems and that EDF's organisation be strengthened, so that during the course of the ten-yearly outage inspections, it is in a position to correct the conformity deviations affecting certain equipment.
- Controlling ageing and obsolescence: For nuclear pressure equipment, the additional aspects notably concern the verification of the mechanical strength of the vessels, taking account of environmental effects on the mechanical fatigue phenomenon and the evolution of the properties of the materials.
- The safety of the spent fuel pools: ASN thus asked EDF to substantiate the steps taken to limit the radioactive inventory in each fuel building of the reactors in operation to a value as that as low as reasonably achievable.
- Mitigating the consequences of accidents (except severe accidents): For a reassessment of the consequences of accidents, including the events and the operator reaction times adopted for the EPR design, ASN notably asked EDF to apply the rules of the conservative design-basis operating conditions study rules.
- Improved management of accidents with core melt, more specifically with analysis of the steps aiming to reduce the frequency and consequences of core melt situations with opening of the containment venting-filtration system: ASN also asked EDF to demonstrate the qualification of the equipment necessary in the event of an accident with core melt.
- Internal and external hazards, with reinforcement of the requirements to be applied to the hazard levels to be considered and assuming failure of some of the planned protection systems: Demonstration of fire risks management shall also be reinforced.

FOCUS

Paluel reactor 2: fall by a steam generator during replacement of the steam generators

The Paluel NPP reactor 2 had been shut down since May 2015 for its third ten-yearly outage inspection and a steam generator fell while being handled on 31st March 2016. Steam generator replacement was being carried out for the first time on this type of reactor (this operation had already been carried out on numerous 900 MWe reactors). The SG which fell was the third of the four SGs to be handled. The first two had been removed from the reactor building normally.

Removal of a replaced SG from the reactor building comprises the following phases: it is first of all raised by the polar crane equipped with special devices and is then placed on a trolley for removal from the reactor building. During this second operation, the SG is tilted from its original vertical position to a horizontal position. It was during this operation that the fall occurred.

On the day of the incident, ASN carried out a reactive nuclear safety and labour inspectorate inspection. A second inspection was carried out by ASN on 7th April 2016 in order to determine the initial findings in the Paluel reactor 2 building. It is continuing with an in-depth inquiry into the causes of this accident.

In accordance with the Labour Code, ASN prescribed verifications by approved organisations of the regulatory conformity of the SG lifting chain (polar crane and special devices designed and implemented for SG handling). Regular briefings are also held with EDF on the protection of the persons who are to intervene to clear the damaged area and subsequently remove the steam generator.

Pursuant to the Environment Code, EDF declared a significant event on 1st April 2016. ASN thus oversees the corrective measures adopted and ensures that EDF has learned lessons from the operating experience feedback.

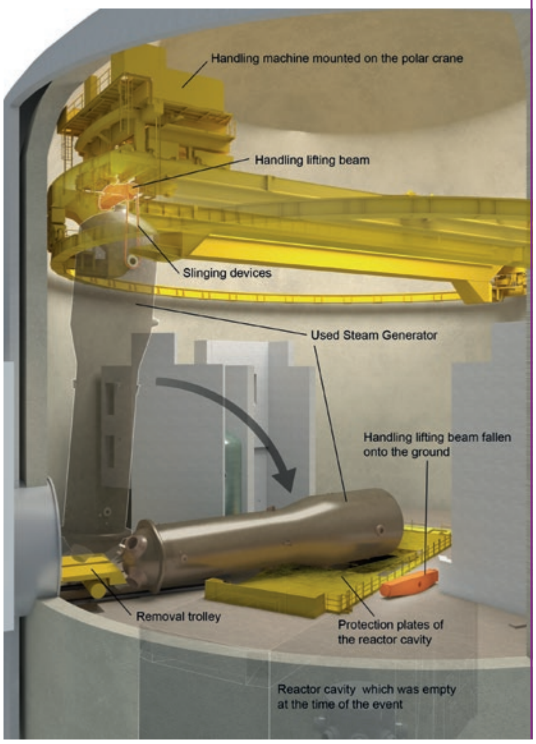
In June 2016, pending its removal, EDF secured the fallen SG in order to prevent any movement. It was then removed at the beginning of 2017.

ASN is continuing its actions, more specifically to understand the origin of the SG fall. One of the main causes identified by EDF is the use of special devices added to the polar crane for the 1,300 MWe reactors that are different from those used for the 900 MWe reactors (design flaw in the new lifting beam making it inherently unstable). At this stage, ASN considers that failure of the lifting chain which led to the fall by the Paluel reactor 2 SG also reveals flaws in the monitoring and decision-making process on the part of EDF, with regard to the contractor in charge of replacing the SGs.

ASN is also examining EDF's proposals for the resumption of operations to to remove the fallen SG and carry out replacement of the SGs. The reactor building clearance operations will make it possible to access the various equipment items present in it, so that the assessments needed to identify the direct and indirect damage to the installation can be carried out (potential impacts resulting from the fall of an SG weighing more than 450 tonnes). The examinations carried out so far have revealed several areas of damage to the metal liner of the reactor building cavity, which will probably entail major repairs.

Pending the performance of all these checks and the end of the works, Paluel reactor 2 remains shut down. Further to recent changes to the regulations, EDF submitted a file to the Minister responsible for Nuclear Safety for extension of this outage pursuant to Article L. 593-24 of the Environment Code and Article 41 of the modified Decree of 2nd November 2007, so that shutdown is not considered to be definitive after a period of two years.

ASN will monitor performance of the necessary repairs and checks to be conducted with a view to restarting the installation.



Paluel reactor 1 was the first 1,300 MWe reactor to carry out its third ten-yearly outage inspection, in 2016. These third ten-yearly outage inspections for the 1,300 MWe reactors will continue until 2023.

1,450 MWe reactors

The periodic safety review associated with the first ten-yearly outage inspections

The generic studies and modifications associated with the first periodic safety reviews of the 1,450 MWe reactors were the subject of an ASN position statement in 2012, which in particular requested additional work by EDF to demonstrate the adequacy either of the studies carried out, or of the modifications made to the installations during their first ten-yearly outage inspection, in order to comply in full with the objectives set in the periodic safety review.

The first ten-yearly outage inspections took place between 2009 and 2012.

EDF's answers and the periodic safety review conclusions reports for the four 1,450 MWe reactors are currently being assessed and ASN intends to issue its position statement on their continued operation to the Minister in charge of Nuclear Safety in 2017.

The periodic safety review associated with the second ten-yearly outage inspections

In 2011, EDF transmitted its orientation proposals for the generic studies programme for the periodic safety review associated with the second ten-yearly outage inspections of the 1,450 MWe reactors. After consulting the GPR in 2012, EDF supplemented its generic studies programme with a number of measures and clarified some of its proposals. In February 2015, ASN ruled on the orientations of the periodic safety review associated with the second ten-yearly outage inspections of the 1,450 MWe reactors. ASN more specifically considers that the safety objectives to be considered for the VD2 N4 safety review must be defined in the light of the objectives applicable to the new reactors and asked EDF to study the measures liable to comply with this requirement as rapidly as possible, so that they can be implemented as of the second ten-yearly outage inspections on the 1,450 MWe reactors.

The second ten-yearly outage inspections for the 1,450 MWe reactors are scheduled to start in 2019 with the Chooz B2 reactor and will run until 2022.

3.3 Monitoring of the EPR Flamanville 3 reactor

Oversight of the Flamanville 3 engineering activities

In 2016, ASN carried out three inspections in the EDF engineering services responsible for the Flamanville 3 detailed design studies, concerning the production and utilisation of the 3D mock-up for the Flamanville 3 detailed design studies, the analysis of the results obtained during the BNI 167 start-up tests and the qualification of equipment for accident conditions.

Examination of the commissioning authorisation application and the partial commissioning authorisation application for Flamanville 3

In March 2015, ASN received the commissioning authorisation application for Flamanville 3. Following this preliminary examination, ASN confirmed that all the documents required by the regulations were indeed present, but it considered that additional information was needed to enable ASN to rule on a possible commissioning authorisation for Flamanville 3.

ASN did however begin a technical examination of the file on those subjects for which only very little data was still missing. Certain subjects led to requests from ASN in 2016. These concern justification of the study method used for the medium term phase of a control rod ejection accident, justification of the 3D method used to study a zero power uncontrolled rod assembly extraction accident, reactivity control, justification of the fully-coupled 3D method for studying a steam tube rupture, qualification of the CIGAL scientific computing tool for calculating the control rod fall time, the general design and development approach for the F1A classified part of the protection system, analysis of the exhaustiveness of the start-up test programme, the detailed design of the Steam Generators Auxiliary feedwater system (ASG), the detailed design of the Safety Injection and Residual Heat Removal System (RIS-RA), examination of the organisational, human and technical means for reactor control, which were the subject of a GPR meeting in 2015 and the provisions for managing and mitigating the consequences of a severe accident, which had been examined by the GPR in 2015.

The general operating rules will be the subject of ASN requests in 2017.

Three GPR meetings were devoted to Flamanville 3 in 2016 on the following subjects: the safety case studies, the safety of fuel storage and handling, the design of the safety systems and protection against the effects of internal and external hazards. ASN will shortly be issuing its requests resulting from these analyses.

In March 2015, ASN also received the partial commissioning authorisation application for Flamanville 3, needed to admit fuel within the perimeter of the facility and carry out certain tests. ASN carried out a preliminary examination of this file and concluded that a certain amount of additional information was required, more specifically to assess the risks and detrimental effects which could result from tests using radioactive tracer gases to verify the correct operation of certain effluent treatment systems. ASN will thus shortly be updating its 2010 resolutions defining the limits and procedures for environmental discharge of liquid and gaseous effluents for the nuclear reactors on the Flamanville site.

Oversight of construction activities on the Flamanville 3 site

In 2016, ASN carried out twenty inspections on the Flamanville 3 construction site to monitor construction, the performance of the start-up tests and the preparedness of the teams who will be in charge of operating the reactor. These in particular concerned the following technical topics:
- the mechanical assembly activities, more particularly concerning the systems connected to the primary system and to the secondary systems of the nuclear power plant, the vessel head equipment, the nuclear auxiliary systems, the containment mechanical penetrations, including the transfer tube, the spent fuel storage racks in the pool and the equipment needed to operate the back-up electricity generating sets;
- the electrical systems installation activities, including cable drawing and connection in the buildings;
- implementation of a major reactor I&C modification;
- occupational radiation protection, in particular through a reinforced three-day inspection of this topic;
- continued start-up tests and the associated organisation, in particular for the equipment situated in the reactor pumping station;
- non-destructive inspection of welds, in particular during the pre-service inspection of the primary system, and worker radiation protection;
- the organisation of the shift crew for the future Flamanville 3 reactor, for production of the operating documentation, utilising the start-up tests to validate a part of this documentation, preparations for emergency situations and integration of organisational and human factors;
- the environmental impact of the construction site;
- the civil engineering finishing activities.

In its construction site oversight activities, ASN devoted particular attention to the following subjects in 2016:
- continued mechanical assembly of the installation with worksite cleanness and organisation standards similar to those that would be used in operation. ASN more specifically ensures that EDF implements a robust organisation to manage the risk of foreign material being introduced into the systems. ASN also maintains its oversight of EDF monitoring of the outside contractors and in particular ensures that there is adequate management of deviations detected by this monitoring, with the implementation of any interim measures should they prove to be necessary;
- maintaining a strategy to conserve the equipment and structures present on the construction site until the commissioning of Flamanville 3. Owing to the postponements to reactor commissioning announced by EDF and following the deviations encountered during the conservation of new heat exchangers, ASN ensures that EDF continues to focus particular attention on defining and complying with the requirements associated with the conservation of equipment already installed and the structures built, notably taking account of the impact of filling the systems with water for hydro-testing and start-up tests. ASN regularly examines this point during its inspections, in particular ensuring that EDF manages the risks associated with work being carried out in the buildings simultaneously by several trades[3];
- long-term continuation of the actions defined following major shortcomings detected by ASN with regard to checks on the main primary system welds during the pre-service inspection;
- the preparation for and performance of the start-up tests on the pumping station equipment. The start-up tests must help demonstrate that the reactor's structures, systems and components meet the requirements assigned to them;
- the preparation for operation of the Flamanville 3 reactor by the EDF entity which will be responsible for it after start-up. This entity currently comprises more than 400 staff. With a view to reactor commissioning, EDF is continuing with a process of gradual transfer of responsibility for the operation of the structures, systems and components from the entity in charge of construction and reactor start-up operations to the entity in charge of its future operation. The steps in this process enable future operating personnel to upgrade their skills, familiarise themselves with the reactor equipment, draw up operating documentation and develop the appropriate tools. Through its oversight, ASN verifies whether the future operating staff take advantage of operating experience and best practices employed in EDF's NPPs and whether they correctly assimilate the working of the equipment during reactor construction and systems start-up tests;
- appropriate EDF management of environmental protection and more particularly correct identification and rigorous operation of the site equipment contributing to this;
- radiation protection of workers and notably compliance with the baseline safety requirements and the design measures, as well as management of sources.

Labour inspectorate duties on the Flamanville 3 reactor construction site

The actions carried out by the ASN labour inspectors in 2016 consisted in:
- performing checks on the contractors working on the site;
- answering direct queries from the employees;
- carrying out inquiries following occupational accidents.

3. *Distinct activities by several staff taking placing simultaneously within a restricted time-frame and in the same space.*

Application of the safety rules was regularly checked.

In 2016, the ASN labour inspectors also initiated and carried out a number of checks on the regulatory provisions governing transnational secondment of workers and continued with the judicial procedures to tackle illegal work, for which investigations were under way.

Radiation protection inspections

In 2016, ASN carried out a reinforced radiation protection inspection on the Flamanville 3 reactor (see point 3.5.2). The inspectors more specifically examined the organisation and management of radiation protection, construction site management, radioactive sources management, conformity with the design provisions and compliance with the baseline safety requirements (safety analysis report, general operating rules).

Monitoring the design of nuclear pressure equipment for the Flamanville 3 reactor

During the course of 2016, ASN continued to assess the conformity of the design of the nuclear pressure equipment for the main primary and secondary systems.

Having observed inadequate justification and incomplete design files for this equipment, more specifically with regard to the risk assessments, choice of materials and in-service inspectability of the equipment, ASN held numerous technical meetings with Areva NP in 2013 and 2014 and numerous technical meetings to define the additional data to be provided. Areva NP began a revision of all technical design documentation for this equipment in 2015, which it continued in 2016. This revision will be completed in 2017.

The organisations approved for assessment of nuclear pressure equipment conformity are authorised by ASN to assist it with the examination of this design documentation. The first equipment for which these examinations will be completed are the pipes and valves of the reactor Safety Injection System (RIS).

Monitoring the manufacture of nuclear pressure equipment for the Flamanville 3 reactor

During the course of 2016, ASN continued to assess the conformity of manufacture of the Nuclear Pressure Equipment (ESPN) for the main primary and secondary systems. Manufacturing has been completed for the large items excluding the vessel nozzles, for which hydrotesting should take place in 2017 and it is still in progress for certain valves control valves and check valves.

ASN and the approved organisations review the technical documentation and the monitoring of the assembly of nuclear pressure equipment carried out on the site. They require that Areva NP analyse the feedback from one assembly sequence before initiating the next one. This was in particular the case following the discovery in late 2014 and in 2015 of defects in several primary system welds. These defects occurred during connection of the steam generators to the primary system and during welding of a section of the pressuriser expansion line. In 2016, ASN carried out two inspections of Areva NP concerning the assembly of the NSSS and one inspection of approved inspection organisations or entities mandated by ASN to monitor these activities. These inspection organisations and entities themselves carried out several hundred inspections in 2016.

Since the end of 2014, a certain number of notable deviations affecting forged parts manufactured at Le Creusot and intended for Flamanville 3 have been discovered (see below).

3.4 Pressure equipment

The discovery of a positive carbon macrosegregation problem on the Flamanville 3 EPR vessel closure head and bottom head domes

In late 2014, Areva NP informed ASN that tests performed on a vessel head representative of that intended for Flamanville 3 showed the presence of an area with a high carbon concentration (carbon segregation) leading to lower than expected mechanical properties. Measurements confirmed the presence of this anomaly in the composition of the steel at the centre of the closure head and bottom head of the Flamanville 3 EPR vessel.

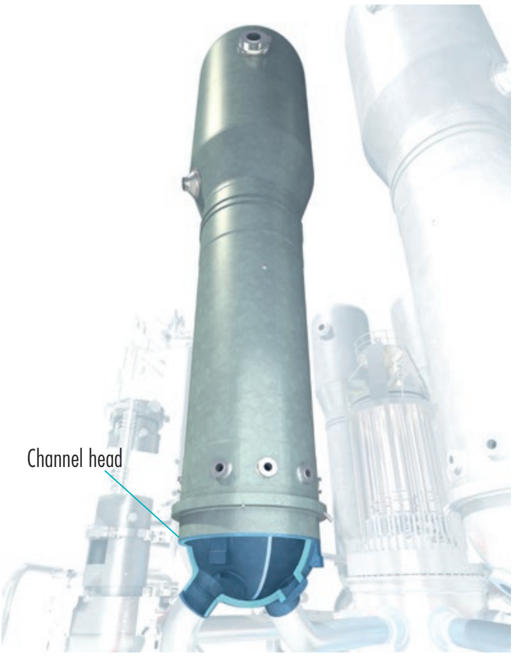
ASN made this information public on 7th April 2015.

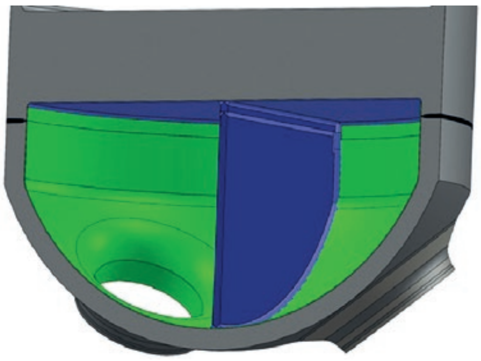
Areva NP sent ASN a file in mid-2015 presenting the approach it plans to implement to demonstrate the sufficiency of the mechanical properties of the material used in the manufacture of the vessel closure head and bottom head for the future Flamanville EPR reactor. This approach is in particular based on the future results of a programme of mechanical and chemical tests.

After joint examination of this file with IRSN, ASN convened the Advisory Committee for Nuclear Pressure Equipment (GPESPN) on 30th September 2015. Representatives from the HCTISN, the national association of local information committees and commissions (Anccli) and foreign safety regulators concerned by the construction of an EPR reactor attended this session as observers. The GPESPN submitted an opinion and recommendations to ASN.

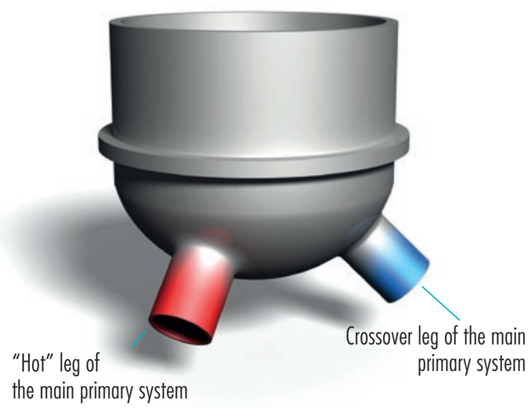
On this basis, ASN issued a position statement on 12th December 2015 concerning the approach proposed by Areva to substantiate the mechanical properties of the Flamanville 3 EPR vessel closure head and bottom head.

STEAM GENERATOR channel head





Cross-section of an SG channel head, with the partition plate in blue



Subject to its observations and demands being taken into account, ASN considers that the approach proposed by Areva is acceptable in principle and it made no objection to the start of the new planned test programme.

The test programme was run during the course of 2016.

At the beginning of April 2016, the first test results led Areva NP to modify its substantiation approach. This change was presented to the GPESPN at the 24th June 2016 session, at which representatives of the HCTISN and Anccli were present as observers.

Areva NP transmitted a technical file resulting from the test programme in December 2016. Additional data is still expected. ASN will issue a position statement on the serviceability of the vessel no later than the end of the first half of 2017.

Lessons learned from detection of the Flamanville EPR vessel anomaly

The detection of the Flamanville EPR vessel anomaly led ASN to ask Areva NP and EDF to learn all possible lessons from this event.

Three processes were implemented:
- A search for technical anomalies similar to that detected on the Flamanville EPR vessel was initiated on other components of the EDF reactors. This search led ASN to prescribe inspections on the channel heads of certain EDF reactor steam generators.
- Quality reviews were carried out on parts manufactured in the past in the Areva NP manufacturing plants, enabling Areva NP to detect irregularities in the Creusot Forge manufacturing files.
- A review of BNI licensee monitoring of their contractors and subcontractors, of ASN oversight and of the alert mechanisms, in the event of poor manufacturing quality was undertaken.

Carbon segregation of the steam generator channel heads

Following ASN's requests, EDF informed ASN at the end of 2015 that the channel heads of the steam generators fitted to eighteen 900 or 1,450 MWe reactors, manufactured by Creusot Forge and Japan Casting and Forging Corporation (JCFC), were also concerned by the carbon segregation problem.

The presence of an anomaly such as this is liable to alter the mechanical properties of the steel making up the steam generator and could in particular lead to a risk of fracture of these items.

A detailed characterisation of these channel heads by EDF was carried out at ASN's request in order to consolidate the hypotheses utilised by EDF in the fracture strength calculations and to confirm that there was no risk. Examinations were thus carried out on the channel heads in service and a destructive test programme was initiated on channel heads specifically set aside for this programme in order to improve understanding of the segregated material.

The channel heads manufactured by JCFC and fitted to 12 reactors comprise a higher carbon content which requires specific measurements, in particular with regard to operation. The need for additional checks on some of the channel heads manufactured by JCFC more particularly led ASN on 18th October 2016 to direct EDF to perform them within three months, entailing the shutdown of five reactors concerned before January 2017. The inspections had already been performed or were in progress on the seven other reactors.

The detection of irregularities in the manufacture of components in the Areva NP Creusot Forge plant

Further to the detection of several anomalies concerning the production of the Areva NP plant in Le Creusot, in particular including the carbon positive macrosegregations, ASN asked Areva NP to conduct a general review of the quality of its previous and ongoing nuclear activities in this plant. The purpose of this review was to obtain an overall picture of the pertinence of the organisation and practices at Creusot Forge, the quality of the parts produced since manufacturing started for the Flamanville 3 EPR and the safety culture within the facility.

The audits carried out by Areva NP and transmitted to ASN in October 2015, which only went back as far as 2010, were considered by ASN to be insufficient because they did not give it a complete picture of the organisation and practices at Creusot Forge, the quality of the parts produced and the safety culture prevailing within the plant. At the end of 2015, ASN asked Areva NP to take the process further and go back to at least 2004, which was when the first parts intended for the EPR were manufactured.

These reviews revealed irregularities in the oversight of manufacturing, including inconsistencies, modifications or omissions in the production files, concerning manufacturing parameters or test results. These irregularities concern EDF reactor pressure equipment (vessels, steam generators and main primary system piping) and transport packagings for radioactive substances.

As at the end of 2016, Areva NP had identified 91 irregularities concerning EDF reactors in operation, 20 affecting equipment intended for the Flamanville EPR reactor, one concerning a steam generator intended for but not yet installed in Gravelines NPP reactor 5 and four affecting transport packagings for radioactive substances.

ASN conducted its own analysis of each of the irregularities, jointly with IRSN.

Areva NP took the decision in September 2016 to review all the files for all the nuclear components produced in the past by the Areva NP Creusot Forge plant. Areva NP considers that this review will take a year.

Regardless of their actual safety consequences, these irregularities reveal unacceptable practices. Some of these irregularities could constitute falsifications. ASN is in contact with the services of the Ministry of Justice on this subject.

The reviews initiated by Areva NP must continue and could well bring further irregularities to light. ASN is ensuring that the review process is seen through to completion, more specifically by means of inspections at Creusot Forge.

The particular case of the lower shell of a Fessenheim 2 steam generator

The irregularities detected in the Creusot Forge files include a deviation that was brought to light concerning the manufacture of the lower shell of a steam generator installed on Fessenheim NPP reactor 2. The forging process for the lower shell of this steam generator, made in 2008, was not compliant with the technical file submitted to ASN and with the state of the art. ASN had not been informed of this nonconformity. Had ASN been aware of this nonconformity, for which there was no particular justification, it would not have issued the test certificate in 2012. In July 2106, ASN thus suspended the test certificate which it had issued to Areva NP in 2012 for this steam generator. Fessenheim reactor 2 is currently shut down and restart is subject to ASN consent.

3.5 The other notable findings of 2016

3.5.1 Notable findings relating to labour inspectorate duties

Oversight of occupational health and safety

With regard to occupational health and safety, the ASN inspections more specifically covered the following topics in 2016:
- monitoring of construction site activities, with particular attention being paid to lifting work, welding operations and risks linked to work being performed by several contractors simultaneously and to work at height;
- the use of carcinogenic, mutagenic or reprotoxic chemical products, as well as asbestos;
- operating experience feedback from the viewpoint of occupational safety during steam generator replacement operations;
- risk assessment and prevention during preparations for the operations requiring personnel entry inside the steam generators or reactor buildings at power;

- mandatory checks on polar cranes in reactor buildings and the heavy-lift cranes in the fuel buildings.

Occupational accident inquiries are systematically held in the event of serious accidents or near-accidents.

International subcontracting and provision of services

ASN closely monitors the criminal proceedings instigated in previous years, more specifically through regular contacts with the public prosecutor's offices. Steps were taken with regard to inspections carried out on notifications and the conditions for secondment of staff from foreign contractors.

3.5.2 Notable findings relating to radiation protection of personnel

Reinforced radiation protection inspections

In 2016, ASN carried out reinforced radiation protection inspections in the Paluel, Penly and Flamanville NPPs (including the Flamanville 3 EPR reactor). Each of these inspections required eight to nine ASN inspectors and two to four IRSN experts. They examined radiation protection organisation and management, construction site management, application of the optimisation approach, management of radiological cleanness, management of radioactive sources and compliance with design provisions and conformity with the baseline safety requirements (safety analysis report, general operating rules) on the Flamanville 3 EPR reactor.

Significant contamination events

Five significant contamination events (rated level 1 on the INES scale) were notified in the NPPs operated by EDF in 2016. These events, which led to exposure greater than one quarter the regulation limit per square centimetre of skin, were rated level 1 on the INES scale. They concern:

- contamination of the face of a contractor staff member assigned to installation of the depressurisation machine on the primary system of the Paluel NPP;
- contamination of the leg of a contractor staff member assigned to inspection of the welded supports of the reactor residual heat removal system in the Gravelines NPP;
- contamination of the foot of a contractor staff member assigned to security duties on the clothing contamination monitoring gates at the exit from the controlled area and management of the laundry used by the intervention personnel in the controlled area in the Gravelines NPP;
- contamination of the face of a contractor staff member assigned to maintenance work on the fuel loading machine in the Chinon B NPP;
- contamination of the face of a contractor staff member assigned to security duties at the Chinon B NPP, reactor 2 building entrance hatch.

A generic significant radiation protection event

EDF declared a generic significant radiation protection event regarding radiological zoning deviations during resin transfer activities. Certain areas which could contain a dose equivalent rate higher than 2 mSv/h during this activity and which would thus be limited stay or prohibited areas, were not identified. The NPPs concerned by this deviation are Chinon, Dampierre-en-Burly, Nogent-sur-Seine and Belleville-sur-Loire. This event was rated level 0 on the INES scale.

3.5.3 Notable findings relating to the environmental impacts of NPPs and discharges

Revision of the prescriptions concerning water intake and effluent discharges

In 2016, ASN completed its review of the files concerning water intake and effluent discharges by the Fessenheim and Cruas-Meysse NPPs and continued to examine the revision of that of Paluel.

The ASN resolutions issued accordingly (see point 2.14.1) enable the modifications made by EDF to the installations to be regulated, such as changes to the chemical conditioning of the secondary system, or the adoption of anti-scaling or biocidal treatment of the cooling systems. They also take account of changes to the regulations.

At the same time, ASN initiated a revision of the orders regulating water intake, discharges and environmental monitoring of the Le Blayais and Gravelines NPPs.

ASN also continued its review of the EDF files concerning implementation of water intake systems designed to guarantee "ultimate makeup" water in the event of an accident, as prescribed by the "post-Fukushima" stress tests (see point 3.1). ASN is currently reviewing the files for the Gravelines, Tricastin, Bugey and Nogent-sur-Seine NPPs for this ultimate makeup water.

Automatic stoppage of discharge of radioactive effluents

In 2016, the Saint-Laurent-des-Eaux, Cruas-Meysse, Chinon and Gravelines NPPs each notified a Significant Environmental Event (ESE) during which the upper alarm threshold for the activity monitoring systems on the discharges from the liquid Radioactive Effluents Storage tanks (KER) was reached. This threshold is set at 40,000 becquerels per litre (Bq/L). The checks prior to discharge were unable to detect the activity level, which led to the discharge automatic shutdown process being activated. As this functioned correctly, the volumes of effluents discharged into the environment were small and had no impact on the environment.

4. Assessments

4.1 Assessments of the overall performance of the NPPs in service

4.1.1 Nuclear safety assessment

Reactor operations

ASN considers that there are differences in operational rigour between the various NPPs in 2016. The number of reactor scrams by activation of the protection systems is smaller than in previous years, reflecting progress in the management of certain operating activities. However, non-compliance with the technical operating specifications is once again the cause of a non-negligible number of significant events, despite improved control of system configurations (line-up and lock-out). These events are the result of a lack of rigour in the preparation and performance of operating activities. They also reflect insufficient assimilation of the risks arising from these activities.

More generally, ASN considers that EDF places insufficient emphasis on preventing operating deviations. More specifically, as in 2015, the checks reveal operational documentation that is inadequately designed and practices that are sometimes lacking in rigour, despite EDF's clearly stated aim of "improving intervention design and reducing operational errors".

In addition, in the light of recent adaptations made to its internal processes for identifying these deviations, ASN is concerned about the licensee's ability to foresee the possible consequences and take the appropriate remedial measures. This should lead the EDF management to increase the emphasis on technical assessment of the deviations. A questioning attitude, leading to an in-depth and rigorous assessment of the situations, contributes to the development of the safety culture.

EDF's in-house Independent Safety Organisation (FIS) plays its role of verifying the actions and decisions taken by the departments in charge of operating the installations, with greater involvement than in the previous year. The positioning of the FIS in relation to the department in charge of operation is however sometimes not robust enough on certain sites. The complexity of the various roles performed by the safety engineers (verifications, audit, consulting and support for other departments) is clearly a decisive factor in this fragility, more particularly during periods of heavy workload.

FUNDAMENTALS

The Independent Safety Organisation

The FIS verifies and analyses compliance with the safety requirements by the operational teams. It comprises three levels: the inspector general reporting to the Chairman of the EDF Group, assisted by a team of inspectors, the safety director delegate of the DPN, assisted by the nuclear inspectorate and the head of the safety-quality delegation in each unit, assisted by the safety-quality department. The safety engineers from the safety-quality department perform daily checks on the safety status of the facility.

Conduct in an incident, accident or emergency situation

In 2016, ASN carried out more than twenty inspections on EDF's organisational and technical provisions in the event of an incident, accident, severe accident and emergency situation.

The inspections on the organisation and emergency resources revealed that the organisation, preparedness and management principles for emergency situations covered by a PUI have been correctly assimilated. These principles are described in the harmonised national baseline requirements of November 2014 validated by ASN. The teams in charge of implementing this plan would appear to be satisfactorily sized with respect to the requirements specified in the licensee's baseline requirements. All the emergency team members take part in an annual exercise. The sites and the EDF head office departments must however take greater account of experience feedback from these exercises.

The relations between each NPP and the third-parties involved in emergency situation management (hospitals, emergency services) are on the whole satisfactory, even though some sites encounter difficulties in holding exercises with these outside entities.

In 2016, ASN also checked the procedures for updating, assimilating and improving the documents necessary for controlling a degraded situation. This oversight is extended to the procedures for managing and implementing the mobile resources required in an accident or severe accident situation.

The inspections carried out in 2016 led ASN to ask EDF to reinforce:
- its processes for verification and validation of the documents used in an incident or accident situation;
- the maintenance and management of the mobile equipment used in a degraded situation or an emergency situation;

- the integration of experience feedback from emergency exercises.

Fire and explosion risks

In 2016, ASN carried out 15 inspections on fire and explosion risk management in 15 NPPs.

Fire

Following its inspections and with regard to the fire risk, ASN notes that the relations between the sites and the departmental fire-fighting and emergency response services are on the whole satisfactory. The number of outbreaks of fire recorded for 2016 is below that for 2015.

However, the findings made in previous years are still valid with regard to some of the sites inspected:
- management of zoning anomalies in the premises could be improved in order to prevent the spread of fire;
- deviations linked to the management of fire detection inhibitions;
- deviations in the management of stores of equipment representing significant heat potential, in particular during reactor outage phases;
- deviations in the use of fire permits;
- problems with the accessibility of fire-fighting equipment.

ASN notes the efforts made by certain sites to reduce these deviations through the deployment of tools and action plans, but considers that if they are to be effective, the personnel must receive more comprehensive assistance with their implementation. In addition the time taken to remedy certain deviations or to take corrective actions as a result of experience feedback could be reduced.

Explosion

During its inspections, ASN also assessed the organisation of the sites for dealing with the explosion risk, including nuclear safety and worker protection aspects in the management of this risk.

Certain maintenance work and inspections required by EDF's internal doctrine (nitrogen tightness tests of the double wall of certain pipes carrying hydrogenated fluids, etc.) are not always carried out. Furthermore, the updating of certain documents (periodic test procedures and document concerning protection against explosions), the integration of lessons learned, the handling of certain deviations and the deployment of certain modifications can be postponed, something that cannot always be justified with regard to the potential safety consequences.

ASN considers that EDF must pay particular attention to this point and ensure that the explosion risk prevention approach is implemented with all necessary rigour on all the sites.

Maintenance activities

ASN notes that the quality of maintenance work could be improved and that the number of quality defects found is not falling. The workers still have to deal with constraints linked to work organisation, insufficient preparation for certain activities, scheduling changes and problems with worksite coordination, leading to activity delays or postponements. These difficulties are more particularly reported with regard to unscheduled activities such as the handling of unexpected events.

ASN observes the persistence of problems in the management of activities owing to problems with the procurement of spares and with equipment repairs.

Furthermore, delays in the inspections or in incorporating new maintenance programmes into the documents mean that deviations or equipment deterioration are detected belatedly.

ASN also regularly observes a lack of rigour in technical oversight of interventions and in monitoring of contractors.

However, ASN notes an improvement in the management of maintained qualification of equipment for accident conditions as well as in requalification of this equipment following maintenance work.

Finally, ASN considers that the AP-913 maintenance method (see point 2.7.1) is such as to provide the licensee with a clearer picture of the condition of its facilities and ensure more regular maintenance, but that its practical implementation in the NPPs could be improved.

With a view to extending the service life of the NPPs in operation, the "major overhaul" programme and the lessons learned from the Fukushima Daiichi accident, ASN considers that it is important for EDF to continue the efforts started to resolve the problems mentioned and improve the effectiveness of its maintenance work (see point 4.1.2).

Equipment condition

The periodic tests, equipment maintenance and replacement programmes, the periodic safety review approach and the correction of conformity deviations should make it possible to check and ensure the lasting ability of the equipment in an NPP to perform the functions assigned to it for protection of the interests mentioned in Article L.593-1 of the Environment Code.

The detection, characterisation and handling of deviations are regulatory provisions of the BNI Order of 7th February 2012. These provisions are important because they contribute to controlling the conformity of the facilities with the requirements for protection of the interests stipulated by the law, a pre-condition for their operation. Moreover, control of conformity should enable the improvements that result from the periodic reviews to be based on a known and robust actual status of the facilities.

In 2016 and in 2017, ASN identified the management of deviations affecting NPPs as one of its priority inspection topics. The results of the inspections carried out in 2016 highlight the difficulties encountered by the NPPs with identification, characterisation and handling of deviations.

The inspections carried out by ASN in 2016 during the reactor maintenance and refuelling outages and during reactor operating periods, revealed a number of deviations which called into question the actual availability of certain systems important for the safety of the installations, such as the electrical systems or the back-up systems. Some of the defects identified are linked to equipment design: under-sizing of the combustion turbines, risk of interaction between the Safety Injection System (RIS) and Containment Spray System (EAS) in the event of an earthquake, owing to their layout. ASN also observes inadequacies in the maintenance and periodic test programmes: uncertainty calculations that are either erroneous or not performed, periodic test procedures comprising inconsistent criteria, preventive maintenance programmes that are insufficient to deal with proven degradation phenomena.

Therefore, in 2017, ASN will continue with inspections of the maintenance performed on the equipment and of deviations processing.

Control of the conformity of the facilities in operation will also be examined with a view to preparing for the fourth periodic safety review of the 900 MWe reactors, for which the first exercise is scheduled as of 2019.

The first containment barrier

In 2016, ASN considered that the condition of the first containment barrier, which is the fuel cladding, was on the whole satisfactory, except for the particular situation of the Golfech site, where fuel cladding leaks and the presence of significant foreign material in the primary system were observed.

The organisation put into place to prevent fuel damage from the introduction of foreign material into the primary system helped improve the condition of the first barrier, notably when it was first implemented. In 2016, the number of significant events linked to fuel handling was small and considered to be stable with respect to 2015.

FOCUS

Reducing outstanding deviations

In 2015, ASN published Guide No. 21 on the management of conformity deviations in PWRs, which introduced the principle of correction of a deviation "as soon as possible" and clarified ASN requirements concerning the "correction time appropriate to the potential consequences" mentioned in the BNI Order of 7th February 2012. 2016 was an opportunity to confirm a trend observed in recent years with regard to EDF's handling of deviations: in several cases, the licensee prefers to justify the acceptability of the deviation rather than eliminate it.

In addition, the persistence of deviations for several years was confirmed by a certain number of findings made this year on the reactors in service, such as the presence of objects in the dry risers of the containment spray system, which is a reactor safeguard system.

However, for 2016, ASN notes the following events:
- incorrect positioning of a fuel assembly in the spent fuel pool of the two Belleville-sur-Loire reactors;
- the recurring presence of leaking assemblies in the two reactors on the Civaux site, more specifically with the presence of four leaking assemblies in Civaux 2;
- the rupture of a fuel rod found to be leaking when an attempt was made to extract it from the Golfech 2 spent fuel pool.

In 2016, ASN noted no particular difficulty concerning the effectiveness of the neutron absorber rod drop mechanism.

Second containment barrier

ASN considers that in 2016, the situation of the second barrier was worrying, the year having been marked by the discovery of the segregation anomaly in the steam generator channel heads. This carbon segregation in the channel heads is liable to alter the mechanical properties of the steel making up this equipment and could in particular lead to a risk of rupture. The prevention of this risk, which concerns 18 reactors, led to the implementation of additional operational precautionary measures to limit the impact of thermal loadings on the steam generator channel heads.

In 2016, very high levels of fouling were found in certain steam generators in several reactors, which could be liable to impair their operating safety. This finding revealed the inadequacy of maintenance for maintaining a satisfactory level of cleanness. ASN also notes that the use of cleaning processes to restore the required cleanness of the equipment led to corrosion requiring in-service monitoring.

In addition to the assessment of this situation, which is less satisfactory than in 2015, ASN notes that the recent steam generator replacement operations on the 900 MWe reactors were delayed owing to numerous deviations affecting the manufacture of this equipment and will entail the implementation of operations to safeguard a number of cracked tubes until the steam generator replacement operations can be carried out.

The in-service monitoring of the other equipment on the main primary system, pursuant to the Order of 10th November 1999, is carried out appropriately. The detection of a new crack on the vessel bottom head penetration No. 58 on Cattenom reactor 3 illustrates the risk of further deterioration owing to the ageing of the facilities and confirms the need to adapt the level of in-service monitoring accordingly and to bring forward the development of repair processes. ASN notes the performance of the final repair work on vessel bottom head penetration No. 4 on Gravelines reactor 1, which demonstrated the licensee's ability to deploy adequate resources on this subject.

Third containment barrier

Overall management of the containment function

By comparison with 2015, ASN notes that the organisation set up by the plants to monitor activities and systems liable to have an impact on static and dynamic containment in the installations remains on the whole satisfactory. The rules for maintenance of systems contributing to maintaining the containment of the facilities are on the whole known, understood and applied by the NPP licensees. However, improvements are still needed with regard to the condition of the containment, of the third barrier and its components, in particular concerning maintenance of the static tightness systems.

Single wall containments with an internal metal liner

The ageing of the 900 MWe reactor containments was examined in 2005 during the safety review associated with their third ten-yearly outage inspection, in order to assess their leaktightness and mechanical strength. The reactor containment tests performed during the ten-yearly outage inspections on these reactors since 2009 have brought to light no particular problems liable to compromise their operation for a further ten years, with the exception of Bugey reactor 5.

Although it was actually conforming (acceptable leak rate), a test on the containment of this reactor in 2011 showed that its tightness was diminishing. In prescription [BNI 89-36] of its resolution 2014-DC-0474 of 23rd December 2014, ASN asked the Bugey NPP to schedule a further test. During the maintenance outage of reactor 5 which began on 27th August 2015, the tightness tests were performed and revealed a further increase in the containment leak rate. In resolution 2015-DC-0533 of 1st December 2015, ASN asked that the handling of defects in the metal tightness liner of this containment be submitted to ASN for prior approval. Adequate handling of these defects is a pre-condition for restart of the reactor. ASN is currently examining the repair file submitted by EDF in 2016.

For the rest of the 900 MWe reactor containments, the results of the third ten-yearly reactor containment tests have hitherto shown leak rates conforming to the regulatory criteria (29 of the 34 reactors have undergone this test).

Double-wall containments

The test results for the double-wall containments performed during the first ten-yearly outages of the 1,300 MWe reactors detected a rise in the leak rate from the inner wall of some of them by comparison with the commissioning of the facilities, under the combined effect of concrete deformation and loss of pre-stressing of certain cables that was higher than expected in the design.

EDF then initiated significant work consisting in using a resin sealant locally to cover the interior surface of the inner wall of the most severely affected 1,300 MWe reactors, but also 1,450 MWe reactors. The tests performed since this work, during the second ten-yearly outages of the 1,300 MWe reactors and the first ten-yearly outages of the 1,450 MWe reactors, showed that they all complied with their regulation leak rate criteria. In order to guarantee that these criteria are met during the next ten-yearly outage inspections, EDF is considering supplementing the tightness coatings on the outside walls with a coating of the same type as that applied to the inside surface of the reactor building inner containments.

ASN is remaining vigilant with regard to the development of the leaktightness of these containments, not originally designed to have an integral metal liner. An analysis of the issues linked to the double-wall reactor containments was thus examined by the GPR on 26th June 2013, in the run-up to the third ten-yearly outage inspections for the 1,300 MWe reactors. ASN issued a ruling on this subject in June 2014 and will be attentive to compliance with the undertakings that EDF made on this occasion.

4.1.2 Evaluating human and organisational measures

Organisation of work and working conditions

In 2016, ASN still observed a very large number of shortcomings with regard to personnel working conditions. EDF is making significant investments to improve the logistics of maintenance operations. ASN however noted equipment inappropriate for the tasks in question, owing to its unavailability or poor design, cramped or inaccessible work spaces, errors in signage, or instructions that are hard to read. On several sites, strained relations between EDF and its overall site assistance contractor have a negative impact on the management of worksite assistance, for example entailing problems with procurement of consumables for radiation protection.

On all the sites, the documents placed at the disposal of the workers by EDF are regularly excessively complex, inappropriate, incomplete or unsuitable. They are even sometimes missing. ASN has repeatedly made this observation for many years now, thus calling into question the efficiency of the documentary drafting and revision process in use at EDF, in particular given that these inadequacies can make for difficult working conditions for the personnel and thus degrade performance. Inappropriate documents are frequently cited among the causes of significant events.

In addition, accessibility and the physical working environment (light, heat, noise) continues to create degraded working conditions. On several sites, ASN thus observed inefficient lighting in the reactor building.

Major efforts are being made by EDF to develop the use of error reduction practices. ASN considers that site-specific measures to improve organisation and working conditions must also be developed. Staff members are also faced with constraints relating to the organisation of work, in particular during reactor outages, such as inadequate preparation for certain activities, scheduling changes and problems of joint contractor work and coordination between those involved. These constraints can also lead to degraded working conditions.

ASN noted with satisfaction that in 2016 several sites had worked on easing stress and tension in the control room. In the light of the extensive work to be performed by EDF following the stress tests or as part of the periodic safety reviews, ASN considers that EDF must continue its efforts with regard to the tranquillity of the EDF and contractor personnel in the turbine hall and in the reactor building, by offering them an appropriate working environment allowing optimum working conditions (more specifically in terms of documentation, lighting, management of joint contractor work and scheduling of activities).

Provisions concerning staff and organisations in operational reactor modification activities

At the national level, EDF has developed the "Social, Organisational and Human – SOH" approach, the aim of which is to transform engineering practices at EDF, to take greater account of people and organisations in the changes made to the systems and in modifications to hardware and organisations, as of the design stage. ASN considers the philosophy of the SOH approach to be pertinent and important in guaranteeing the security of the facilities and the safety of the workers. However, the efforts made by EDF to deploy the SOH approach - in particular in all the engineering centres - must be continued in order to achieve the intended effects.

Hardware and documentation modifications are mainly managed at the national level, so the sites do not always have the ability to implement changes necessary to improve the working environment when a difficulty is identified locally. The improvements made by the sites therefore generally consist in implementing mitigation measures rather than actually solving the problem itself.

Skills management, training and qualifications

The organisation in place on the sites for managing skills, qualifications and training is on the whole satisfactory. EDF has allocated major investments to hiring and training, in order to anticipate the renewal of the skills as a result of staff retirements. Most of the sites have thus set up local training committees involving the executive level, the management and the workers. One of these committees rapidly detects staff training requirements and, with the help of the production engineering training unit, creates short and specifically targeted training programmes according to the identified needs.

Generally speaking, the training programmes are implemented satisfactorily and the establishment of «academies» for the different professional disciplines is highlighted as a strong point for the training of newcomers to the sites. Nonetheless, the range of training proposed by certain sites is not always adapted rapidly enough. Furthermore, the persons concerned do not always receive the scheduled training. Finally, in 2016 ASN still founds that shortcomings in the knowledge of the personnel – for example with regard to the operation of equipment or certain particular reactor control rules – combined with incomplete or erroneous documentation, may have contributed to a working situation which led to the occurrence of significant events.

Given the considerable work to be accomplished by EDF subsequent to the stress tests or for the periodic safety reviews, ASN considers that EDF's recruiting and training efforts must be continued.

4.1.3 Health and safety assessment, professional relations and quality of employment in the NPPs

The conclusion of an agreement concerning the number of days to be worked by management provides some of the answers to the question of management working times. In addition, there is on the whole better compliance with the daily and weekly rest periods. Certain occupational risk situations are still worrying and must be improved: risks linked to working equipment and more specifically to lifting gear, chemical risks and electrical risks. The question of addressing the asbestos risk is still one that concerns the labour inspectorate, as this risk is not always identified before the works.

Progress is still required in the management of multiple contractors working simultaneously (quality of prevention plans in particular) and the use of subcontracting and the secondment of foreign employees. Labour disputes occurred within certain subcontractor companies, occasionally revealing tense relations with EDF.

ASN also asked EDF to improve the dissemination of operating experience and best practices among the sites.

4.1.4 Evaluation of radiation protection

In 2016, ASN carried out 24 radiation protection inspections. The Paluel, Penly and Flamanville NPPs and the EPR under construction underwent a reinforced inspection in 2016.

The collective dosimetry on all the reactors was up in 2016 by comparison with 2015 (Graph 2) with an increased volume of maintenance. The average dose received by the workers for one hour of work in a controlled area also increased in 2016 but remains lower than the value recorded in 2014. The doses received by the workers are broken down as shown below in Graphs 1 and 3.

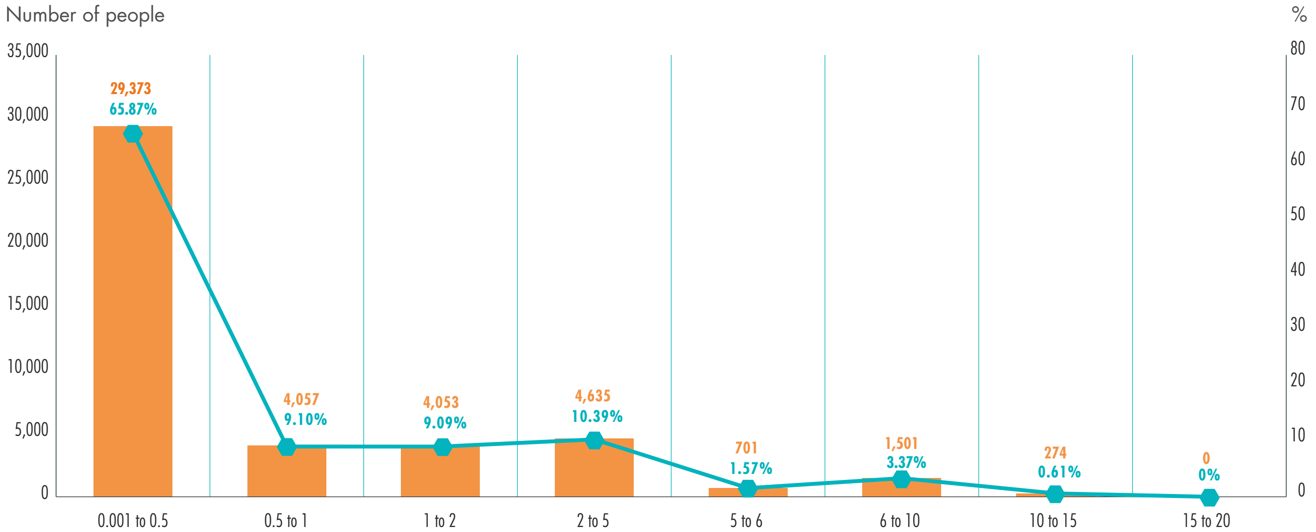
Graph 1 shows the breakdown of the population in terms of whole body external dosimetry. It can be seen that the dosimetry for 75% of the exposed workers is less than 1 mSv for the year 2016, which corresponds to the annual regulation limit for the public. The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2016.

Graph 2 shows the trend in the collective dose received by NPP workers over the past ten years. This graph shows a stabilisation in the average collective dose per reactor, reflecting contrasting results between the sites, and the continued optimisation efforts at a time of rising volumes of maintenance work in controlled areas in recent years.

Graph 3 shows the trend in whole body average individual dosimetry according to the worker categories in NPPs. The most exposed worker categories in 2016 are those in charge of installing and removing thermal insulation and welders.

ASN considers that the radiation protection situation of the NPPs in 2016 could be improved on a certain number of points:
- Control of radiological zoning and the associated provisions could be improved. More specifically the risk assessments for the work do not always identify the risk of entering a specially regulated "limited stay" or "prohibited" area.

GRAPH 1: Breakdown of the population per dose range over the year 2016



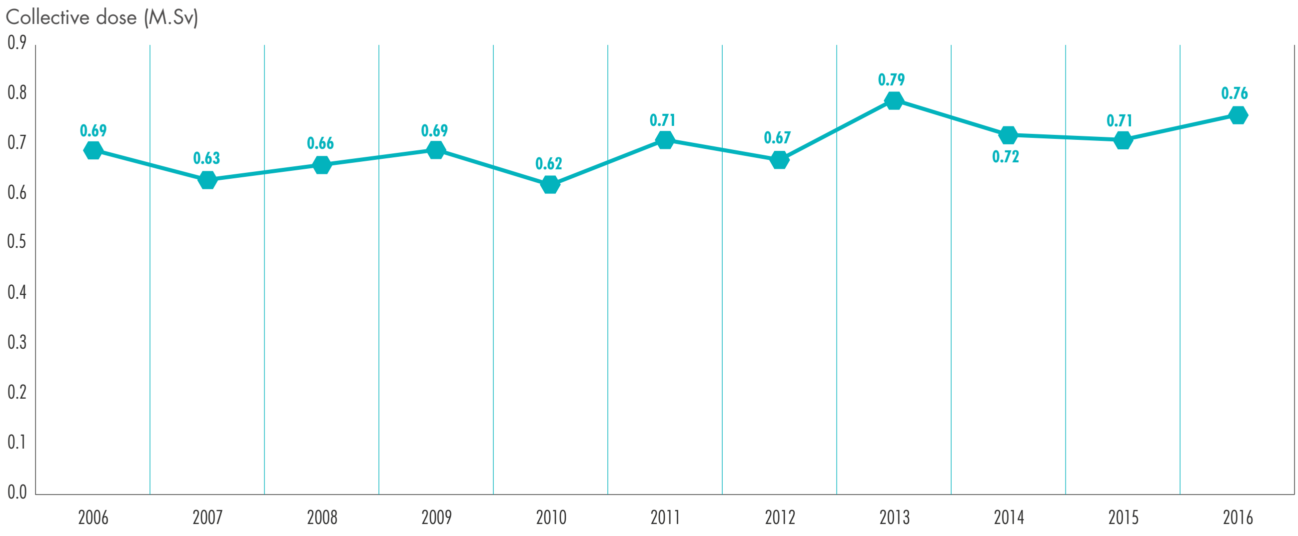
Source: EDF

- Weaknesses remain in the control of industrial radiography sites: ASN more specifically identifies several events involving overstepping of operation areas demarcation lines or the presence of workers inside the exclusion zone demarcation lines. Progress is required in the preparation of the worksites, more specifically multiple contractor activities and the quality of the installation visits carried out when preparing these worksites.
- Management of contamination dispersal inside the reactor building is still insufficient, owing to inadequate worksite containment or contamination level signage errors. ASN repeatedly observes non-compliance with instructions for contamination checks on personnel exiting worksites.
- On several sites, the ASN inspectors found a lack of radiation protection culture on the part of certain workers.

ASN notes that five bodily contamination situations leading to the workers integrating dosimetry greater than one quarter the regulation limit per square centimetre of skin were recorded in 2016. The above-mentioned inadequacies in radiological cleanness can contribute to the delayed detection of worker bodily contamination (see point 3.5.2).

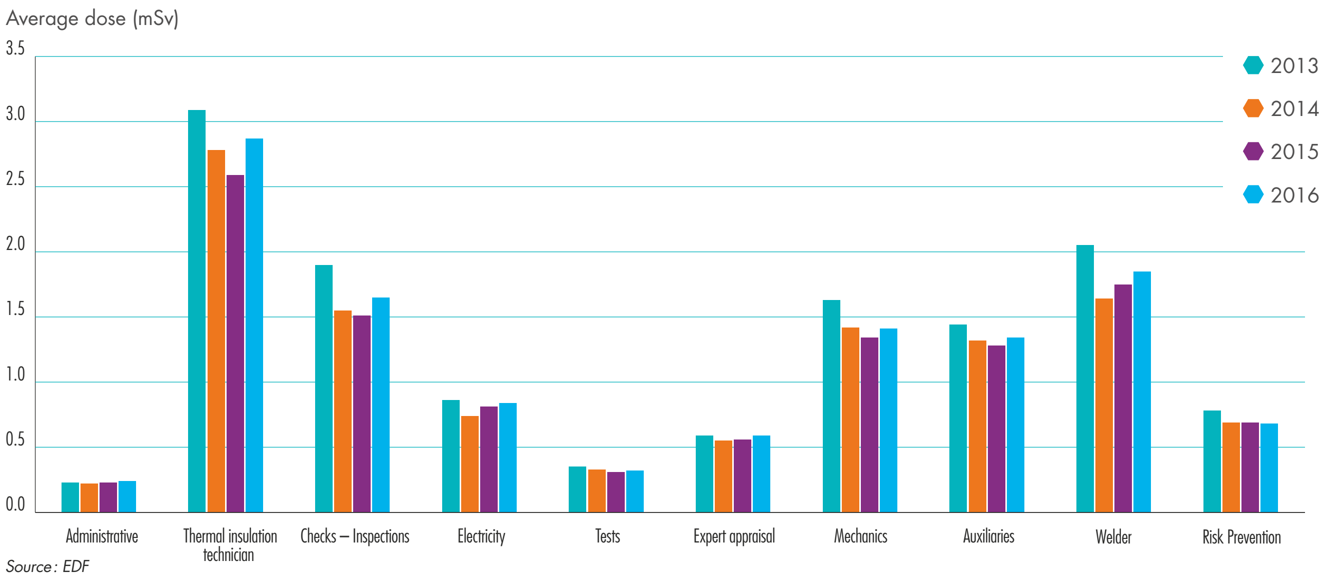
Despite the actions presented to ASN, improvements are still required in optimisation of the forecast dosimetry for reactor outages and in preparation of the worksites.

GRAPH 2: Mean collective dose per reactor



Source: EDF

GRAPH 3: Evolution of mean individual dose according to categories of workers in NPPs



Source: EDF

4.1.5 Control of detrimental effects and impact on the environment

In 2016, ASN carried out 43 inspections on the control of the detrimental effects and environmental impact of NPPs, mainly concerning the prevention of detrimental effects, management of environmental discharges and waste management. The Cattenom, Chooz and Cruas-Meysse NPPs underwent a reinforced inspection.

Even if the organisation in terms of management of detrimental effects and the impact of NPPs on the environment is considered to be on the whole satisfactory on most sites, ASN found that several deviations observed during the previous inspections persist. Incorporating operating experience feedback remains an area for improvement and ASN observes that deviations persist in the operation and monitoring of the installations. In particular:

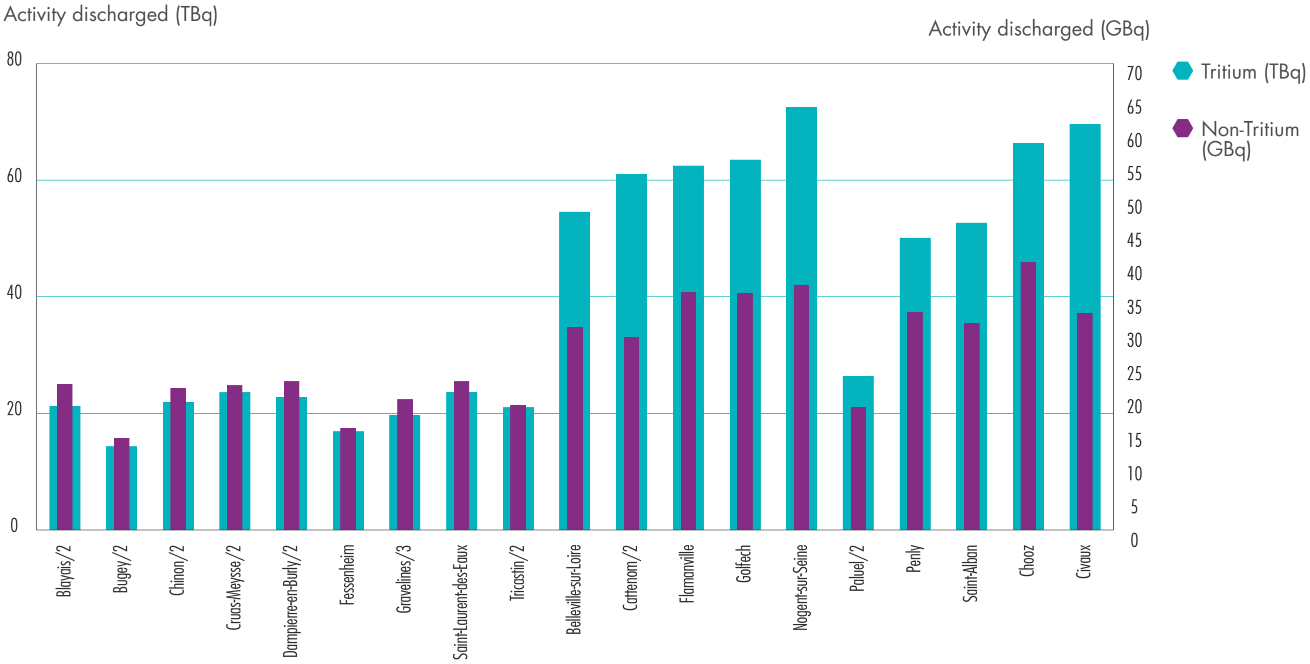
- The detection and handling of deviations concerning the conformity of the facilities could be improved, or are sometimes even completely inadequate.
- The monitoring of contractor activities is often insufficient.
- Liquid containment problems also show that certain operating and maintenance provisions are inadequate.
- The quality of the documentation on conventional risks and on the operation of the installations could be improved, in particular with regard to the display of certain instructions inside the installations and the labelling of hazardous substances.
- EDF's approach to integrating the items and activities concerning the control of detrimental effects and environmental impacts, from among the equipment and activities important for protection defined by the BNI Order of 7th February 2012, is still insufficient and must be significantly reinforced.
- Deviations from the operating baseline requirements concerning waste management persist, more particularly with regard to the operation of radioactive waste storage buildings.

4.1.6 Analysis of operating experience

The operating experience feedback process

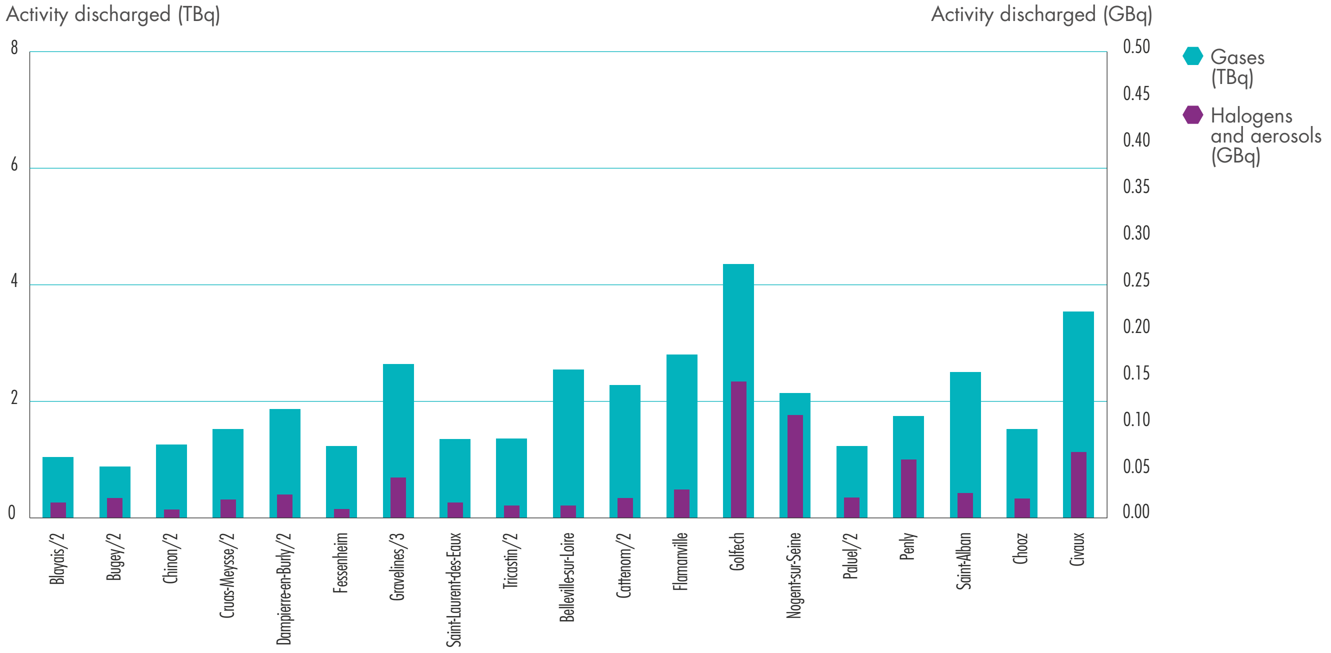
Operating experience feedback, as an organised and systematic process of collecting and analysing the signals emanating from a system, is one of the key tools in managing safety and radiation protection. It is a major issue for EDF which, in this respect, has notably developed and implemented a new method for analysing significant events on all of its sites.

GRAPH 4: Liquid radioactive discharges for the NPPs in 2016 (per pair of reactors)



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails:
- *keeping the results as-are for the Golfech site, which has two reactors;*
- *dividing by two those of Chinon, which has four reactors (Chinon/2);*
- *dividing by three those of Gravelines, which has six reactors (Gravelines/3).*

GRAPH 5: Gaseous radioactive discharges for the NPPs in 2016 (per pair of reactors)



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails:
- *keeping the results as-are for the Golfech site, which has two reactors;*
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- *dividing by three those of Gravelines, which has six reactors (Gravelines/3).*

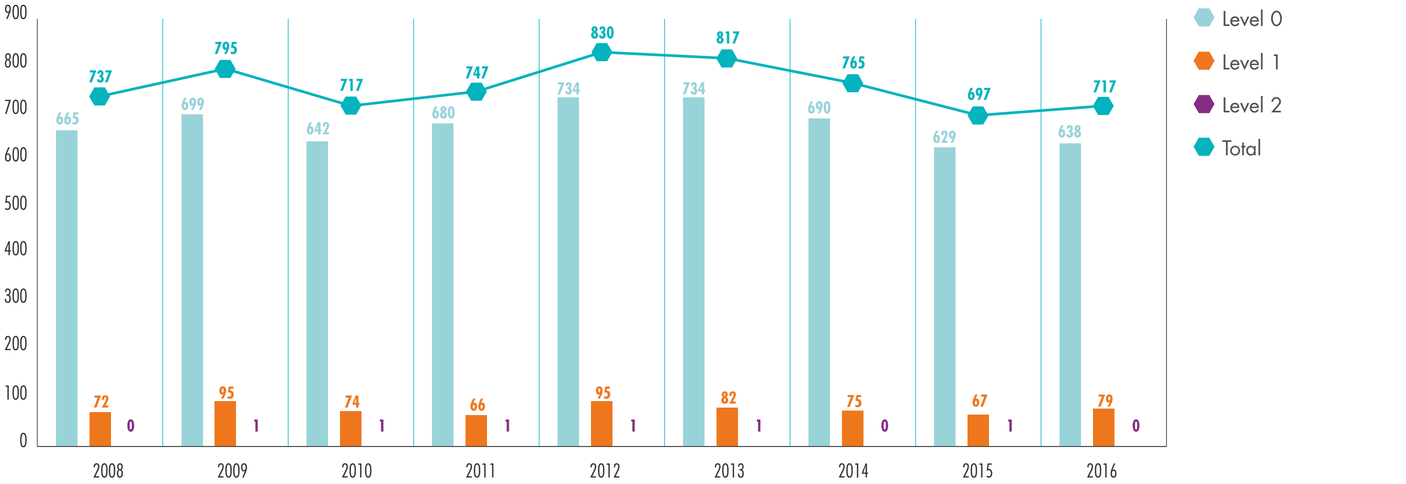
However, in 2016 ASN still noted a lack of depth with respect to the analyses. The process of verification by the EDF head office departments of the quality of the significant event reports issued by the NPPs has not yet fully borne fruit, in that ASN continues to find that there are still considerable discrepancies between the analyses needed to define corrective and preventive measures. While the analyses conducted by some sites do make it possible to go beyond the apparent causes and highlight organisational malfunctions, the analyses performed on other sites still look on the whole at the apparent causes, even if the site has personnel competent in the field of analysing organisational and human factors.

A frequent ASN observation is that the corrective measures adopted by the sites are not able to address the organisational malfunctions highlighted in the analyses. The inclusion of subcontractors in these analyses, when they are the ones carrying out most of the maintenance work during reactor outages, is still insufficient, although it should be pointed out that some sites are beginning to experiment with opening up the database to permanent contractors so that deviations can be logged.

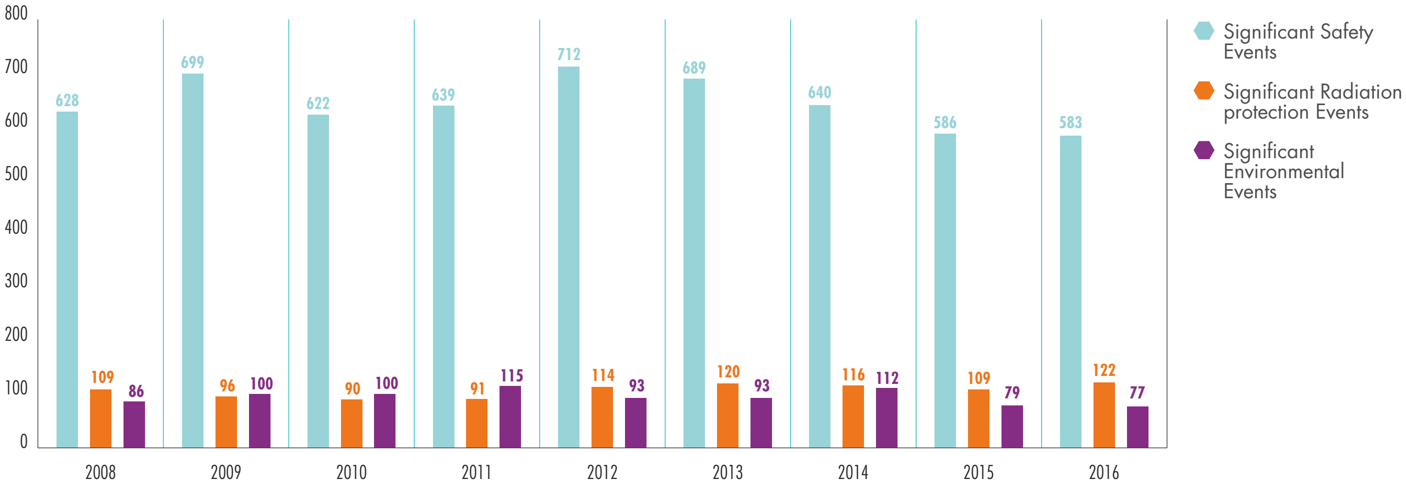
The deviations leading to significant events are analysed by the EDF head office departments in order to assess to what extent they are generic. This phase is more specifically able to identify the deviations for which processing requires national level oversight by the licensee and the definition of harmonised remedial, corrective and preventive measures from one site to another. ASN inspections in the head office departments revealed that the system for identifying generic events is not yet as efficient as it needs to be, in particular for the prevention of deviations.

Generally speaking, there is still insufficient sharing and insufficient actual use of the lessons learned from experience feedback, be it between the sites, between the departments on a given site, or at the level of the activities, during periodic tests or maintenance during reactor outages. In this respect, the risk assessments of the "worker OEF sheets" available in the work file and presented at the worksite preparatory meeting are still inadequate. EDF must therefore progress in providing personnel with experience feedback and enabling them to devote sufficient time to this activity.

GRAPH 6: Trend in the number of significant events rated on the INES scale in EDF nuclear power plants from 2008 to 2016



GRAPH 7: Trend in the number of significant events per domain in EDF nuclear power plants from 2008 to 2016



Events off the INES scale are also taken into account.

Analysis of significant events statistics

In accordance with the rules concerning the notification of significant events (see point 3.3 of chapter 4), EDF in 2016 notified ASN of 583 significant safety events, 122 radiation protection events and 77 environmental protection events.

Graph 6 shows how the number of significant events notified by EDF and classified on the INES scale has evolved since 2008.

Graph 7 shows the trends in the number of significant events per area concerned by notification since 2008: Significant Safety Events (ESS), Significant Radiation protection Events (ESR) and Significant Environmental Events (ESE).

Whatever the notification area, several of these events, which are similar in the NPPs or are the result of common causes, are together referred to as Generic Significant Events (ESG). Eleven were notified in 2016 in the field of safety and one in the field of radiation protection.

The number of ESS notified is stable year in 2016 by comparison with 2015 (- 0.5%).

The number of ESR increased by about 12% by comparison with 2015.

The number of ESE is stable by comparison with 2015.

The details of the significant events for each site are presented in chapter 8.

4.2 Evaluation of the manufacture of nuclear pressure equipment

Irregularities in the manufacturing plants

The year 2016 was marked by the detection of irregularities in several nuclear pressure equipment manufacturing plants, which could constitute falsification and concealment of deviations, with varying degrees of scale and severity. This was in particular the case in the Areva NP Creusot Forge plant (see point 3.4), where these practices had continued for several decades.

ASN considers that these irregularities reveal unacceptable practices. These practices compromise the absolute level of quality expected in the manufacture of equipment, which is a factor in guaranteeing its in-service strength. These irregularities more particularly concern the primary system components, which are among the most important components in an NPP and for which the consequences in the event of failure are not examined in the nuclear safety case.

This experience feedback and the ASN inspections highlight significant shortcomings in the quality and nuclear safety culture on the part of some of the staff present in these plants. Even though they are geographically and culturally extremely remote from the activities performed in the NPPs, they participate in the safety of these facilities and must be aware of the full implications of the work they carry out.

ASN therefore requires that the various industrial firms, in particular the licensees, who are responsible for nuclear safety, implement fundamental measures to guarantee a high level of quality in the supply chains.

Reinforcing justification of the design of nuclear pressure equipment

ASN has regularly observed that the justifications and demonstrations provided by the manufacturers with regard to nuclear pressure equipment regulations, more particularly concerning the correct design of this equipment, are still unsatisfactory. The industrial firms, EDF and Areva NP in particular, therefore took fundamental measures as of the first half of 2015 to change their practices and bring them into line with the regulatory requirements. ASN monitored these measures, most of which were carried out within the framework of the French Association for NSSS design, construction and monitoring rules (AFCEN) and involved the majority of the profession. ASN considers this approach to be a positive one and in 2016 recognised the appropriate nature of certain publications from AFCEN. It will be attentive to ensuring that this approach is seen through to completion.

5. Outlook

In 2017, ASN actions in the field of the oversight of NPPs will more specifically concern the following topics.

The periodic safety reviews

2017 will allow the continued examination of the generic studies for the fourth periodic safety review of the 900 MWe reactors, as well as the second periodic safety review of the 1,450 MWe reactors.

ASN will take part in the work of the HCTISN to define the procedures for the public consultation on the provisions proposed by EDF for the continued operation of its reactors on the occasion of the first periodic safety review after the thirty-fifth year of operation, so that this public participation is effective and can assist ASN in its decision-making process.

Monitoring the implementation of the material and documentary modifications resulting from the third ten-yearly outage inspections on the 1,300 MWe reactors remains a particular challenge, given their scope and their nature, at a time of significant turnover between generations of staff.

ASN will also contribute to drafting the French report on the ageing of nuclear reactors, for a European level peer review under the auspices of ENSREG.

Experience feedback from the Fukushima Daiichi accident

Monitoring the implementation of the prescribed material and organisational measures enabling EDF to justify satisfactory control of the basic safety functions in extreme situations remains a priority for ASN.

In 2017, ASN will continue to review the design, construction and operating provisions adopted by EDF to address the prescriptions concerning the "hardened safety core". Within this context, the provisions for prevention of a severe accident will be examined. ASN will also continue to oversee the work to deploy the fixed items of the «hardened safety core» on the sites (ultimate back-up diesels, ultimate water source, local emergency centre). It will also examine the authorisation application files for the deployment of other "hardened safety core" modifications or equipment.

Oversight of the EPR reactor

In addition to the review of the detailed design of the Flamanville 3 EPR reactor, ASN is actively involved in overseeing the deployment of the equipment and preparation of the start-up tests of this reactor on-site, in the engineering centres and at EDF's suppliers. The nuclear safety inspectors will continue with inspections at a sustained rate.

2017 will also see the continued review of the commissioning authorisation application for this reactor, as well as the partial commissioning application, corresponding to the arrival of nuclear fuel on the site. The review of this application will enable ASN to check that the requirements of the Flamanville 3 Creation Authorisation Decree and the additional prescriptions it has issued are taken into account. ASN will also continue with the conformity assessments of the nuclear pressure equipment most important for safety. It will more particularly issue a position statement on the serviceability of the vessel.

Deviation handling

Operating experience feedback from the NPP reactors reveals that there are still inadequacies in the processes employed by the licensee to obtain conformity of the facilities with their design and operating baseline requirements and then maintain this compliance over the long term. It also highlights weaknesses in the design of modifications and of their operating documents. Some of the conformity deviations are discovered during equipment verifications as part of the periodic checks or spot checks. On the occasion of the fourth periodic safety review of the 900 MWe reactors, ASN will ensure that design reviews are developed to complete the latent conformity deviations detection process. It will also learn lessons from operation of the reactors during the period 2012-2014 to improve the maintained conformity of the equipment and efficient processing of deviations.

Oversight of nuclear pressure equipment

2016 was marked by two major events in the field of nuclear pressure equipment: the detection of a generic anomaly on the steam generator channel heads led to the shutdown of several reactors so that inspections could be carried out, along with the discovery of irregularities which could be construed as falsifications within the Areva NP Creusot Forge plant.

In 2017, ASN will continue the measures it undertook further to these two events. It will in particular check implementation of the review of all the components manufactured in the past at Creusot Forge. It will ensure that this review process is seen through to completion, in order to assess all the irregularities which could have affected past production and establish all the possible consequences for the safety of the facilities.

ASN will also finalise its ongoing review of the necessary adaptation of oversight methods in order to combat fraudulent practices. ASN expects action on the part of each of the firms concerned and especially the nuclear licensees, who are responsible for nuclear safety. These adaptations shall cover fraud prevention, detection, notification and processing if a case is detected.

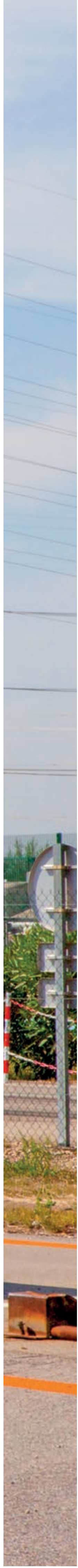
Finally, in 2017, ASN will continue the important in-depth work started in 2015 with the manufacturers, licensees and approved organisations with regard to the application of the regulations concerning nuclear pressure equipment.

The organisation of the nuclear sector stakeholders

2017 will be marked by continued changes to the Areva group, which is involved in the NPPs mainly through engineering, provision of maintenance services and design and manufacture of equipment. ASN will ensure that the new organisations adopted take account of the safety issues and that the safety improvement measures already under way are pursued. It will continue with high-level exchanges with the stakeholders in the nuclear sector to ensure that this is the case.

13

Nuclear fuel cycle installations



The fuel cycle begins with the extraction of uranium ore and ends with packaging of the various radioactive wastes from the spent fuels so that they can be sent for disposal. In France, all the uranium mines have been closed since 2000, so the fuel cycle concerns the steps involved in the fabrication of the fuel and then its reprocessing once it has been used in nuclear reactors.

Fuel cycle plants comprise all the facilities performing uranium conversion and enrichment, design and fabrication of fuels for nuclear reactors, that is the "front-end" part of the cycle - in other words before irradiation - as well as facilities for reprocessing spent fuel, that is the "back-end" part of the cycle. These facilities utilise nuclear material, transformed into fuel, based on uranium oxide or a mixture of uranium and plutonium oxides (called MOX), the plutonium having been generated by burn-up of the enriched natural uranium fuel in power reactors and then extracted from the irradiated fuels during the reprocessing operations.

The main plants operating in the fuel cycle – Areva NC Tricastin (Comurhex and TU5/W), Georges Besse II (GB II), Areva NP Romans-sur-Isère (ex-FBFC and ex-Cerca), Areva NC Mélox, Areva NC La Hague and Areva NC Malvési (which is an Installation Classified on Environmental Protection grounds – ICPE) – are part of the Areva Group (of which Areva NC and Areva NP are subsidiaries). ASN regulates these industrial facilities and considers that steps must be taken for all of the Group's facilities in order to promote safety and radiation protection coherently and allow the use of international best practices. ASN also monitors the overall consistency of the fuel cycle in terms of safety and radiation protection. Areva and EDF must in particular demonstrate that their industrial fuel management choices do not compromise the safety of the facilities.

1. The fuel cycle

The uranium ore is extracted, then purified and concentrated into "yellow cake" on the mining sites. The solid yellow cake is then converted into uranium hexafluoride gas (UF_6). This raw material, which will be subsequently enriched, is made at the Areva NC and Comurhex plants in Malvési (which converts to UF_4) and Tricastin (which converts to UF_6). The facilities in question – most of which are regulated under the legislation for Installations Classified on Environmental Protection grounds (ICPEs) - use natural uranium in which the uranium-235 content is around 0.7%.

Most of the world's NPPs use uranium which is slightly enriched in uranium-235. For example, the fleet of Pressurised Water Reactors (PWR) requires uranium enriched to between 3% and 6% with the U-235 isotope. In France, this enrichment is carried out using an ultra-centrifuge process in the GB II plant.

The process used in the FBFC plant at Romans-sur-Isère transforms the enriched uranium hexafluoride (UF_6) into uranium oxide powder. The fuel pellets manufactured with this oxide are clad to make fuel rods, which are then combined to form fuel assemblies. These assemblies are then placed in the reactor core where they release power by the fission of uranium-235 nuclei.

After a period of use of about three to five years, the spent fuel is removed from the reactor and cooled in a pool, firstly on the site of the plant in which it was used and then in the Areva NC reprocessing plant at La Hague.

In this plant, the uranium and plutonium from the spent fuels are separated from the fission products and other transuranic elements[1]. The uranium and plutonium are packaged and then stored for subsequent re-use. However, at present, the uranium obtained from this reprocessing is no longer used to produce new fuels. The radioactive waste produced by these operations is disposed of in a surface repository if it is low-level waste, otherwise it is placed in storage pending a final disposal solution[2].

The plutonium resulting from the reprocessing of uranium oxide fuels is used in the Areva NC plant in Marcoule, called Mélox, to fabricate MOX fuel (mixture of uranium and plutonium oxides) which is mainly used in certain 900 MWe nuclear power reactors in France.

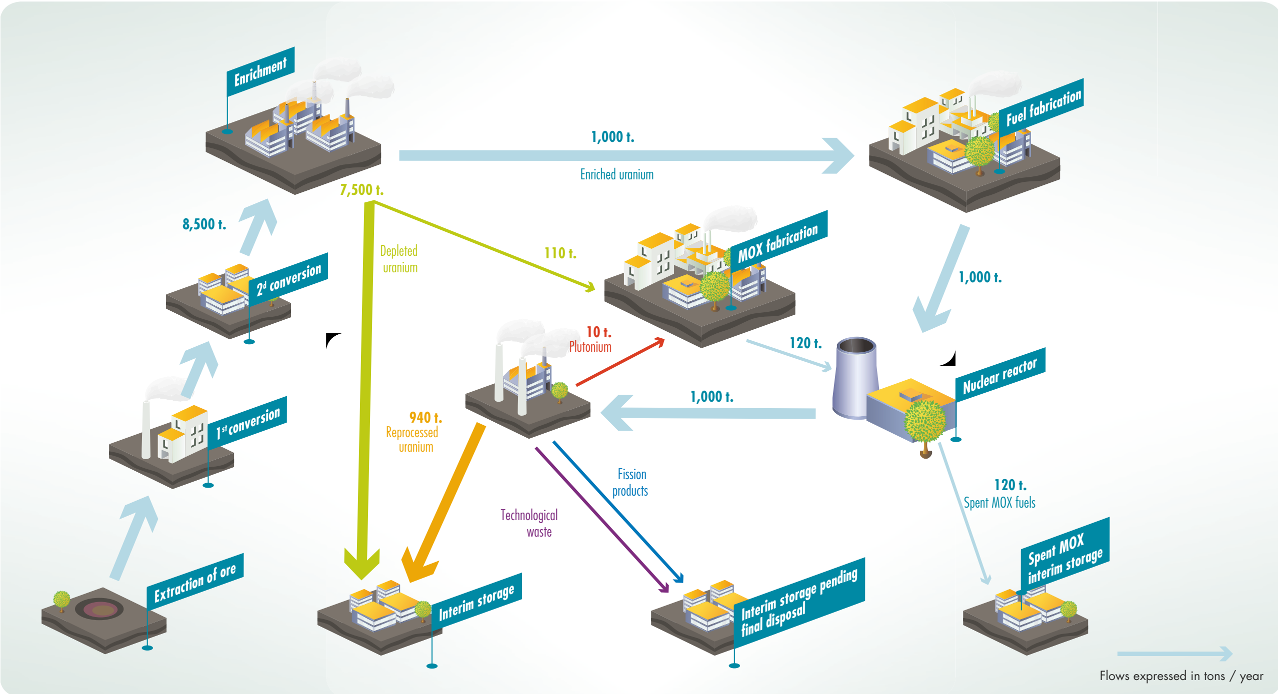
1. *Transuranic elements are chemical elements heavier than uranium.*
2. *Storage is temporary, while disposal is final.*

TABLE 1: Fuel cycle industry movements in 2016

INSTALLATION	ORIGIN	PRODUCT	TONNAGE (unless otherwise specified)	PRODUCT	TONNAGE (unless otherwise specified)	DESTINATION	TONNAGE (unless otherwise specified)
Comurhex Pierrelatte	SBNI Marcoule	Uranyl Nitrate	-	U_3O_8	-	BNIS Pierrelatte	-
	ICPE Malvési	UF_4	11,871 t	UF_6	13,335 t	Areva NC Tricastin	13,335 t
Areva NC Pierrelatte TU5 facility	Areva NC La Hague	Uranyl Nitrate	1,099 t	U_3O_8	1,282 t	Areva NC Tricastin	1,282 t
Areva NC Pierrelatte W plant	Urenco	UF_6 depleted	4,992 t	U_3O_8	3,984 t	Areva NC Tricastin	3,984 t
	SET		8,770 t		6,984 t		6,984 t
	BUE		1,606 t		1,302 t		1,302 t
FBFC Romans-sur-Isère	CER Ensam, IES, Labo Garching, United States	Depleted uranium or natural	0.950 kgU	Fuel elements and targets for research reactors, scrap	0.343 kgU	CER Ensam, RCN, United States, ENSC Lille, Andra	1.842 kgU
						Andra TFA	265.822 kgU
	Areva, CER Ensam, ENSC Lille, Labo Garching, CEN MOL, United States	Uranium LEU	462.807 kgU		348.187 kgU	France, Netherlands, Poland, Germany, Belgium, South Africa, Australia, Jordan, South Korea, United States	523.128 kgU
	Russia, United States	Uranium HEU	388.537 kgU		44.382 kgU	Andra, ILL, CEN BR2, FRM2, Institut REZ, Petten, United States	119.072 kgU
				UA based Uf_6		SET	8.926 tU (3)
				UO_2 powder and UA based fuel mock-ups	0.954 tU	CEA	0.851 tU
	ANF Lingen	Natural UO_2 rods	3.694 tU	UN fuel assemblies		EDF	3.701 tU
	SET	UF_6 (based on enriched uranium)	328.856 tU	UO_2 based on enriched uranium		CEA	2.988 tU
	Urenco, Gronau, Caphurst		303.200 tU	Fuel elements based on enriched uranium	629.990 tU	EDF	644.456 tU
	Russie		8.288 tU			Tihange	16.564 tU
	ANF Lingen	UA based UO_2 rods	5.382 tU			Koeberg	26.029 tU
				Uf_6 (based on enriched uranium)		SET	7.597 tU
Mélox Marcoule	Areva NC Lingen	UO_2 depleted	135.69 tU	Fuel elements MOX	113.55 tHM (4)	EDF	103.73 tHM
	Areva NC La Hague	PuO_2	12.95 tPu			EPZ	3.86 tHM
Areva NC La Hague	**Fuels reprocessed in the La Hague plant**						
	EDF, Trino	UOX, MOX	1,117.914 tHM	Uranyl nitrate	1,122.857tU	Areva NC Tricastin	1,212.069 tU
	Orphée, BR2 MOL	RTR	0.138 tHM	PuO_2	13.872 t	Mélox Marcoule	12.721 $tPuPO_2$
	Fuels stored in the La Hague plant pools						
	EDF, Borssele, Sogin, Phénix, RNR, BR2 MOL, Orphée, Osiris	Spent fuel elements	1,160.554 tHM	-	-	-	-
GB II Pierrelatte	Converters	UF_6	10,872 t	UF_6 depleted	9,221 t	Defluoration	9,221 t
				UF_6 enriched	1,448 t	Fuel manufacturers	1,448 t

(1) The products obtained may be shipped or stored in the facility concerned
(2) The shipped products may have been obtained during previous years
(3) tU: metric ton of uranium
(4) tHM: tonne equivalent heavy metal (mainly uranium, plutonium)

THE FUEL cycle



Given the design of the French NPP fleet, the MOX nuclear fuels are not reprocessed after being used in the reactors. They would only be reprocessed if future fast neutron reactors were to be commissioned. Since the shutdown of the Superphénix reactor in 1996, no company has as yet initiated the official process to build such a reactor (see chapter 12). CEA is studying a prototype called Astrid (see chapter 14). Pending reprocessing or disposal, the spent MOX fuels are stored at the La Hague plant.

The main material flows are presented in Table 1.

The existence of nuclear facilities which are necessary for the operation of the BNIs mentioned above must also be noted, in particular Socatri, which handles the maintenance and decommissioning of nuclear equipment and the processing of nuclear and industrial effluents from the Areva Group's companies in Tricastin, or from Somanu in Maubeuge, which provides off-site servicing and repairs for certain nuclear components.

1.1 The front-end fuel cycle

To produce fuels that can be used in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the "yellow cake" through to conversion into uranium hexafluoride (UF_6), the form required for enrichment. These operations take place primarily on the Tricastin site, in the Drôme and Vaucluse *départements*, also known as the Pierrelatte site.

1.1.1 The facilities on the Tricastin site

With a view to simplifying the legal organisation of the Areva Group, a process to merge the subsidiaries of Areva present on the Tricastin site had been initiated by this Group in 2012, so that Areva NC could become the licensee of all the BNIs there. This process was completed for the Comurhex BNI in 2013. The process to change the licensee at Socatri, initiated in 2013, was suspended at the request of Areva NC in 2014. It resumed in 2016 but can only be completed in accordance with the regulations when Areva NC has sufficiently increased its financial provisions to cover all the long-term costs involved in decommissioning its facilities and processing its waste. In Romans-sur-Isère, Areva NP took over responsibility for operating the two BNIs on the site in 2014.

In addition, the Tricastin site management submitted an authorisation application with ASN on 18th April 2016 for a change to the organisation of BNIs 93, 105, 138, 168 and 155. This change is part of the Areva Group's competitiveness plan and follows on from the "Tricastin 2012" project to pool the site resources. The application aims to achieve an integrated organisation by creating management structures common to all the BNIs on the site for the production, maintenance and decommissioning activities of the facilities on the platform. This modification would also lead to a reorganisation of the management in charge of safety and the environment. Areva still needs to demonstrate that the technical capabilities of each licensee on the platform will be maintained so that they remain individually capable of assuming their safety responsibilities.

Areva NC TU5 facility and W plant - BNI 155

On the Tricastin site, Areva NC operates:
- the TU5 facility (BNI 155) for conversion of uranyl nitrate $UO_2 (NO_3)_2$ produced by reprocessing spent fuel into uranium sesquioxide (U_3O_8);
- the W plant (ICPE within the perimeter of the BNI) for converting depleted UF_6 into U_3O_8;
- the Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) and UF_6;
- a defence BNI (INBS) which more particularly operates the nuclear materials storage areas, virtually all of which are for civil uses.

U_3O_8 is a stable solid compound making storage of uranium safer than in liquid or gaseous form. BNI 155, called TU5, can handle up to 2,000 tonnes of uranium per year, which allows all the $UO_2(NO_3)_2$ from the Areva plant at La Hague to be processed. Once converted, the uranium from reprocessing is placed in storage on the Areva NC Tricastin site.

The periodic safety review report for BNI 155 was submitted to ASN on 28th November 2014. The conclusions of the review of this file will be issued at the beginning of 2017.

ASN considers that the facilities located within the perimeter of this Areva NC BNI are operated with a satisfactory level of safety.

The new hydrofluoric acid transfer and storage area commissioned at the beginning of 2015 ensures improved management of the chemical risks involved in the transfer of this substance.

Moreover, the licensee is creating a new "emissions area" in which the depleted UF6 will be heated so that it can be injected into the process used in the W Plant (EM3). Its commissioning is planned for 2018 and it should ensure a higher level of protection thanks to the creation of a concrete building (in place of the existing building made of cladding), in order to improve seismic resistance, fire, explosion and dispersion risk prevention and also improve the containment and purification of gaseous effluents. Examination of the file began in 2015, as did preparations for the construction site.

The Areva NC uranium conversion plants – BNI 105

The part of BNI 105, which notably transformed reprocessed uranyl nitrate into UF_4 or U_3O_8, is being decommissioned (see chapter 15).

ICPEs not necessary for operation of the BNI are included within its perimeter with respect to the risks that they create for the safety of the BNI itself. These ICPEs carry out fluorination of UF_4 into UF_6 so that it can be subsequently

ASN inspection on the Tricastin site, radiological inspection of a tank of uranium tetrafluoride, September 2016.

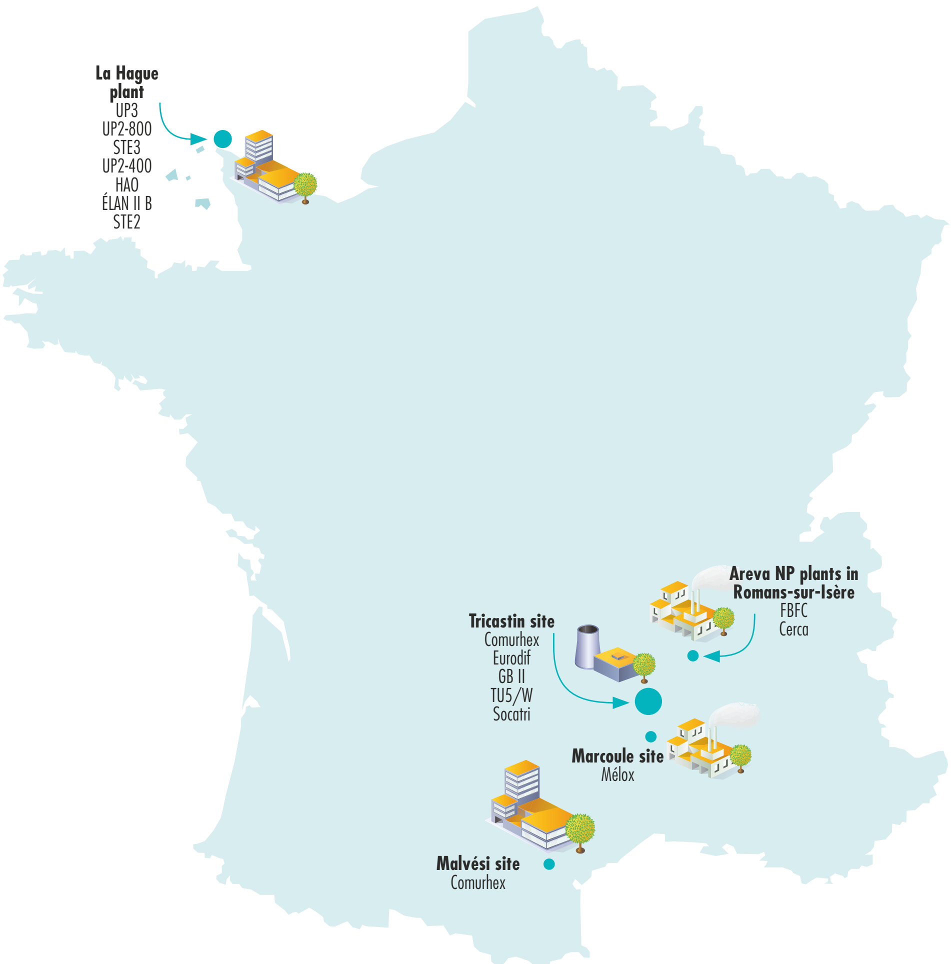
enriched. Each year, they produce about 14,000 tonnes of UF_6 from the UF_4 coming from the Areva NC Comurhex facility in Malvési. Their status is that of an ICPE subject to licensing with institutional controls ("Seveso" installations) and they are subject to the system of financial guarantees for ensuring the safety of the installations and, finally, to the Directive on Industrial Emissions.

This installation is scheduled to be extensively renovated by the "Comurhex II" fluorination unit, the construction of which is nearing completion. The licensee has started testing its systems and aims to commission this unit in early 2019.

In addition, on 30th June 2015, ASN postponed the mandatory removal of the hydrofluoric acid from the fluorination unit in the "Comurhex 1" plant to the end of 2017. It prescribed work to reinforce this plant, in particular mitigation means to limit the consequences of a major hazardous gas leak in the process buildings, the anticipated shutdown of the installations (storage of propane and ammonia, recycling of the hydrofluoric acid), extension of the gas pressure reduction control system and improvement of the safety system to make it independent of the control system. In 2016, Areva NC continued with measures to improve the containment of the installation, which began in 2015 and also carried out work on the new hydrofluoric acid storage buildings further to the stress tests performed in the wake of the Fukushima Daiichi nuclear accident.

Although the events notified in 2016 had no significant consequences for site personnel or the environment, they did however lead to containment failures for radioactive or hazardous substances. Analysis of these events and the inspections carried out by ASN revealed shortcomings more specifically concerning the monitoring of interventions on the equipment, management of alarms and abnormal situations and the management of the workforce during the summer outage. Areva NC is required to conduct an analysis to identify the underlying causes and rapidly implement lasting corrective measures. ASN will be particularly attentive to these measures, including with regard to the perimeter of the installations for which outage is scheduled at the end of 2017. Experience feedback from these events will in particular need to be taken into account for the commissioning of the new facilities.

THE INSTALLATIONS OF THE FUEL CYCLE in operation or undergoing decommissioning



The Eurodif gaseous diffusion enrichment plant – BNI 93

This finally shut down facility is the subject of a decommissioning application and is dealt with in chapter 15.

The Georges Besse II gas centrifuge enrichment plant - BNI 168

BNI 168, called Georges Besse II (GB II), licensed in 2007 and operated by the *Société d'enrichissement du Tricastin* (SET), is a plant enriching uranium by means of gas centrifugation. The principle of this process involves injecting UF_6 into a cylindrical vessel rotating at very high speed. The centrifugal force concentrates the heavier molecules (containing uranium-238) on the periphery, while the lighter ones (containing uranium-235) are recovered in the centre. By combining several centrifuges, creating what is known as a cascade, it is then possible to recover a stream enriched with fissile U-235 isotope and a depleted stream. This process has two key advantages over the Eurodif gaseous diffusion process previously used: it consumes far less electrical energy (75 MWe as against 3,000 MWe) and is safer because the quantities of material present in the centrifuge cascades are far smaller (6 tonnes in GB II instead of 3,000 tonnes in Eurodif) and utilised in gas form at below atmospheric pressure.

The plant comprises two enrichment units (South and North units) and a support unit, the REC II. At the beginning of 2009, ASN authorised commissioning of the South unit, comprising eight modules, followed in 2013 by the North unit, comprising six modules, the first two of which are designed to enrich the uranium from spent fuel reprocessing. ASN authorised commissioning of the REC II unit in 2014.

Enrichment of the uranium resulting from reprocessing has never been implemented in the facility and requires prior authorisation from ASN. The gradual start-up of the enrichment cascades[3] was virtually completed in 2015 under the supervision of the cascades start-up internal authorisation committee, which functions satisfactorily.

In 2016, the level of safety of the Georges Besse II plant was satisfactory. The technologies utilised in the facility enable high standards of safety and radiation protection to be maintained. However, an analysis of the events which have occurred show a slight deterioration in operating rigour, which will need to be corrected.

The gradual start-up of the enrichment cascades has been virtually completed but the plant's production rate was slowed down in order to allow further training of the centrifuge installation contractor's personnel. It should be completed in 2017.

Operation of the REC II unit was improved in 2016 following the malfunctions observed in 2015.

The Atlas facility - BNI 176

Decree 2015-1210 of 30th September 2015 authorised Areva NC to create the Atlas BNI (Areva Tricastin Analysis Laboratories). The purpose of this facility is to pool the activities currently performed by the industrial analysis laboratories specific to the various Areva facilities on the Tricastin and Romans-sur-Isère sites.

The purpose of the Atlas facility is:
- to carry out industrial physico-chemical and radio-chemical analyses;
- to monitor liquid and atmospheric discharges and monitor the environment of the Tricastin facilities.

The creation of this new laboratory will ensure compliance with the most recent safety requirements. The building chosen for the siting of Atlas is more robust to external hazards than the buildings containing the laboratories it is replacing.

ASN authorised the commissioning of this facility on 7th March 2017.

ASN carried out an inspection on this facility in the first half of 2016 to check the organisation in place for monitoring the construction and outfitting of the Atlas facility and to ensure that its layout and outfitting were in conformity with the scheduled provisions. The monitoring of this construction site appeared to be rigorous and the scheduled technical provisions for compliance with the safety requirements are satisfactorily documented. The level of surveillance put in place by Areva NC would appear to be appropriate for the risks.

In 2017, ASN will ensure that the active tests and the initial assessments are carried out in satisfactory conditions of safety and in accordance with the commitments made at the time of the review of the commissioning file.

The Tricastin uranium storage facility – BNI 178

Following the delicensing of part of the Pierrelatte defence BNI by decision of the Prime Minister on 20th July 2016, the Tricastin storage facility BNI was created. This installation groups the uranium storage facilities and the new emergency management premises. ASN registered this facility in December 2016.

Together with the Defence Nuclear Safety Authority (ASND), ASN ensured the continuity of nuclear safety oversight for this facility (see point 3.2). Joint actions are carried out: an inspection and visits to the facility also took place, enabling ASN to verify the facility's

3. *Here refers to a group of interconnected centrifuges enabling a certain level of enrichment to be achieved.*

baseline requirements, which must be brought into line with the BNI regulations.

New uranium storage facility project on the Tricastin site

In 2012, Areva submitted a safety options file for the Écureuil project for the creation on the Tricastin site of an extension to the storage capacity for U_3O_8 from reprocessing, using existing and previously delicensed buildings. ASN issued an opinion on this options file in October 2013. This project was then abandoned by the licensee.

In February 2015, Areva informed ASN that it wanted to create a new BNI intended for management of the stock of uranium-bearing materials on the Tricastin site. After carrying out work to optimise the existing storage facilities on the site so that the storage saturation date can be pushed back from 2019 to 2021, Areva sent ASN a safety options file in April 2015 concerning the creation of new storage buildings to replace the Écureuil project. ASN issued a negative opinion on this file, which failed to take account of the changes made to the regulations since 2012 and which was based on obsolete natural hazards. Areva submitted a new safety options file to take account of ASN objections and envisages submitting a creation authorisation application for a new BNI in 2017.

1.1.2 Nuclear fuel fabrication plants in Romans-sur-Isère

Following the uranium enrichment process, the nuclear fuel is fabricated in various installations, depending on the type of reactors for which it is intended. The fabrication of fuels for electricity generating reactors involves the transformation of UF6 into uranium oxide powder. The pellets fabricated from this powder in the Areva NP plant in Romans-sur-Isère (BNI 98) are placed in metal tubes to constitute the fuel rods, which will in turn be grouped together to form fuel assemblies. The fuels used in experimental reactors are more varied and some of them for example use highly-enriched uranium in metal form. These fuels are fabricated in the Areva NP plant at Romans-sur-Isère (BNI 63).

The two BNIs located on the Romans-sur-Isère site, previously operated by the FBFC company, have been operated by the Areva NP company since 1st January 2015.

In 2016, Areva NP continued its work to improve the safety of the two facilities in the context of increased ASN scrutiny of the site since 2014.

In 2016, the verification inspection of the measures taken further to the 2014 in-depth inspection confirmed the improvement in safety management and operating rigour. On the whole, the licensee correctly met its commitments: coordination of safety measures has been improved and the planned documentary updates have been carried out. Furthermore, ASN observed improved management of technical oversight of activities, more specifically through the deployment of operations safety engineers since mid-2015.

The improvements to the rigour of operations, in particular for management of the criticality risk, equipment qualification or the performance of periodic checks and tests, are confirmed for 2016.

In terms of environmental protection, ASN considers that Areva NP Romans must make progress in the management of the waste disposal routes, especially with regard to the distinction between nuclear waste and conventional waste. However, the repair work on the leak pans, the rainwater networks and the creation of storm surge tanks all represent improvements in safety.

The situation is not as yet fully satisfactory in the field of radiation protection, be it in the development of the ALARA approach (As Low As Reasonably Achievable

FUNDAMENTALS

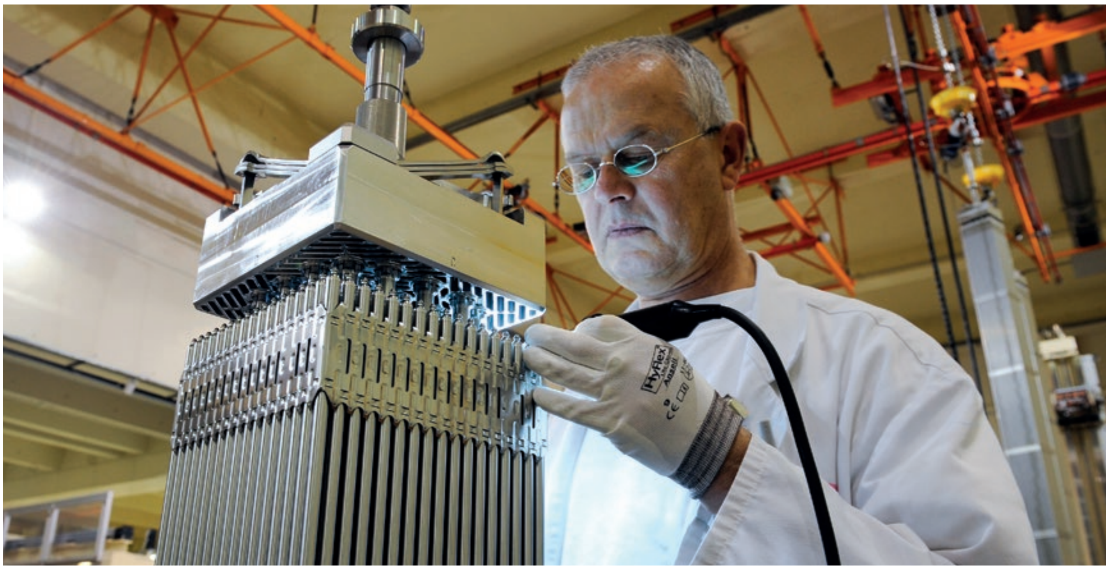
The risks associated with the Tricastin storage facilities

The Tricastin site houses a large number of storage areas. These areas are mainly used to store uranium, in various physico-chemical forms. Areva stores uranium for itself and on behalf of its customers, pending its utilisation according to the technico-economic context.

One of the main risks associated with the Tricastin storage facilities is the dissemination of radioactive and chemical substances. Most of the uranium is stored in the form of oxide (U_3O_8) which is more stable than in liquid form (UF_6). In the form of UF_6, the uranium can react with water, particularly steam and thus produce hydrofluoric acid gas.

The second risk inherent in the storage facilities is the risk of external and internal exposure to ionising radiation.

To limit these risks, strict storage rules are applied to the various storage areas on the site. These rules are determined primarily by the physico-chemical form of the uranium stored and the organisation and layout of the drums stored (stacking level, arrangement of empty and full drums, etc.).



Assembly unit, visual inspection of an assembly, FBCF plant, Romans-sur-Isère.

– forecast dosimetric assessment, optimisation) or in the performance and monitoring of internal and external technical inspections. Dosimetric issues regarding the facility however remain limited.

The FBFC nuclear fuel fabrication plant – BNI 98

Most of the work to ensure conformity and to reinforce the BNI 98 installations has been completed. However, examination of the review file for this facility shows that some of the questions raised in 2003 have still not been closed, in particular regarding control of the seismic and fire risks. The need to improve the way in which the risks associated with dangerous substances are addressed was also brought to light. In 2017, ASN will prescribe the conditions for continued operation of BNI 98.

The Cerca nuclear fuel fabrication plant – BNI 63

This plant is one of the oldest French nuclear facilities still in service.

Work to ensure the conformity of the facility has started. However, work to improve the containment and control of seismic and fire risks in the main building has yet to be carried out. This is the subject of particularly close attention on the part of ASN. In this respect, the licensee submitted an authorisation application to ASN for the construction of a new uranium zone in conformity with the current requirements.

Compliance with ASN resolution 2015-DC-0485 of 8th January 2015, which requires that by the end of 2017, Areva NP implements its undertakings to reinforce the facility, will be examined during the ongoing examination of the review file. Following this examination, ASN will at the end of 2017 issue a ruling on the continued operation of BNI 63.

1.2 The back-end fuel cycle - reprocessing

1.2.1 Areva NC reprocessing plants in operation at La Hague

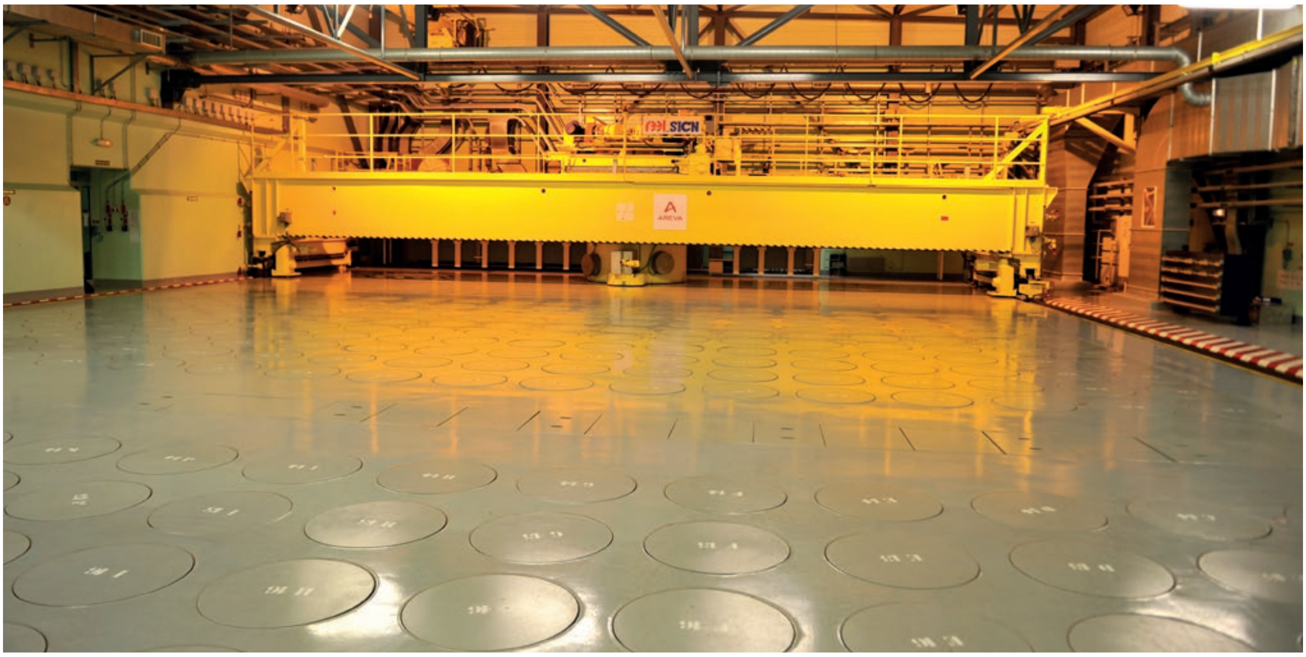
The La Hague plants, intended for reprocessing of spent fuel assemblies from nuclear power reactors, are operated by Areva NC.

The various facilities of the UP3-A (BNI 116) and UP2-800 (BNI 117) plants and of the STE3 (BNI 118) effluent treatment station were commissioned from 1986 (reception and storage of spent fuel assemblies) to 1994 (vitrification facility), with most of the process facilities entering service in 1989-1990.

The Decrees of 10th January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year, in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 tonnes per year.

Areva asked for an increase in the capacity and maximum storage duration of Standard Vitrified (CSD-V) and Compacted (CSD-C) Waste Packages within the UP3-A plant, which was authorised by Decree 2016-1501 of 7th November 2016.

The limits and conditions for discharges and for water intake by the site are defined by two ASN resolutions of 22nd December 2015.



T7 vitrification unit, spent fuel reprocessing plant at La Hague.

Operations carried out in the plant

The reprocessing plants comprise several industrial units, each of which performs a specific operation. There are thus the reception and storage installations for spent fuel, facilities for shearing and dissolving it, for chemical separation of fission products, uranium and plutonium, for purification of the uranium and plutonium and for treatment of effluents and conditioning of waste.

When they arrive in the plants, the spent fuel assemblies in their transport casks are unloaded either under water in the spent fuel pool, or in a dry, leaktight, shielded cell. The assemblies are then stored in pools for cooling.

Afterwards, the assemblies are sheared and dissolved in nitric acid to separate the pieces of metal cladding from the spent fuel itself. The pieces of cladding, which are insoluble in nitric acid, are removed from the dissolver, rinsed in acid and then water, and transferred to a compacting and drumming unit.

The nitric acid solution comprising the dissolved radioactive substances is then processed in order to extract the uranium and plutonium and leave the fission products and other transuranic elements.

After purification, the uranium is concentrated and stored in the form of uranyl nitrate $UO_2(NO_3)_2$. It is intended for conversion in the TU5 facility on the Tricastin site into a solid compound (U_3O_8), called “reprocessed uranium”.

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and placed in storage. The plutonium is then intended for the fabrication of MOX fuels in the Areva NC plant in Marcoule (Mélox).

The effluents and waste generated by the operation of the plants

The fission products and other transuranic elements resulting from reprocessing are concentrated, vitrified and packaged in Standard Vitrified Waste Packages (CSD-V). The pieces of assembly cladding are compacted and packaged in CSD-C.

The reprocessing operations described in the previous paragraph also use chemical and mechanical processes, the operation of which generates gases and liquid effluents as well as solid waste.

The solid waste is also packaged on-site, either by compacting, or by encapsulation in cement. The solid radioactive waste from the reprocessing of spent fuel assemblies from French reactors is, depending on its composition, either sent to the low- and intermediate-level, short-lived waste repository at Soulaines (see chapter 16) or stored on the Areva NC site at La Hague, pending a final disposal solution (in particular the CSD-V and CSD-C).

In accordance with Article L. 542-2 of the Environment Code, radioactive waste from the reprocessing of spent fuels of foreign origin is shipped back to its owners. It is however impossible to physically separate the waste according to the fuel from which it comes. In order to guarantee fair distribution of the waste resulting from the reprocessing of the fuels from its various customers, the licensee proposed an accounting system to track items entering and leaving the La Hague plant. This system, called Exper, was approved by Order of the Minister responsible for Energy on 2nd October 2008.

The gaseous effluents are given off mainly during fuel assembly shearing and during the dissolving operation. These gaseous effluents are processed by scrubbing in a gas treatment unit. Residual radioactive gases, in particular krypton and tritium, are checked before being released into the atmosphere.

The liquid effluents are processed and generally recycled. After verification and in accordance with the discharge limits, certain radionuclides, such as iodine and tritium, are sent to the marine outfall pipe. The others are sent to on-site conditioning units (solid glass or bitumen matrix).

FUNDAMENTALS

The installations at La Hague

Shut down installations undergoing decommissioning:

- **BNI 80:** Oxide High Activity facility (HAO)
  - HAO/North: Facility for underwater unloading and spent fuel storage
  - HAO/South: Facility for shearing and dissolving of spent fuel elements
- **BNI 33:** UP2-400 facility, first reprocessing unit
  - HA/DE: Facility for separation of uranium and plutonium from fission products
  - HAPF/SPF (1 to 3): Facility for fission product concentration and storage
  - MAU: Facility for uranium and plutonium separation, uranium purification and storage in the form of uranyl nitrate
  - MAPu: Facility for purification, conversion to oxide and initial packaging of plutonium oxide
  - LCC: Central product quality control laboratory
  - ACR: Resins packaging facility
- **BNI 38:** STE2 facility: Collection, treatment of effluents and storage of precipitation sludge, and AT1 facility, prototype installation currently being decommissioned
- **BNI 47:** ELAN II B facility, CEA research installation currently being decommissioned

Installations in operation:

- **BNI 116:** UP3-A facility
  - T0: Facility for dry unloading of spent fuel elements
  - D and E pools: Pools for storage of spent fuel elements
  - T1: Facility for shearing of fuel elements, dissolving and clarification of solutions obtained
  - T2: Facility for separation of uranium, plutonium and fission products, and concentration/storage of fission product solutions
  - T3/T5: Facilities for purification and storage of uranyl nitrate
  - T4: Facility for purification, conversion to oxide and packaging of plutonium
  - T7: Facility for vitrification of fission products
  - BSI: Facility for plutonium oxide storage
  - BC: Plant control room, reagent distribution facility and process control laboratories
  - ACC: Hull and end-piece compaction facilities
  - AD2: Technological waste packaging facility
  - ADT: Waste transit area
  - EDS: Solid waste storage area
  - D/E EDS: Storage/removal from storage of solid waste
  - ECC: Facilities for storage and recovery of technological waste and packaged structures
  - E/EV South-East: Vitrified waste storage facility
  - E/EV/LH and E/EV/LH 2: Extension of vitrified residues storage capacity
- **BNI 117:** UP2-800 facility
  - NPH: Facility for underwater unloading and storage of spent fuel elements in pool
  - C pool: Pool for storage of spent fuel elements
  - R1: Fuel elements shearing, dissolving and resulting solutions clarification facility (including the URP: plutonium re-dissolution facility)
  - R2: Uranium, plutonium and fission product separation, and fission product solution concentration facility (including the UCD: alpha waste centralised processing unit)
  - R4: Facility for purification, conversion to oxide and initial packaging of plutonium oxide
  - SPF (4, 5, 6): Facilities for storage of fission products
  - BST1: Facility for secondary packaging and storage of plutonium oxide
  - R7: Facility for vitrification of fission products
  - AML - AMEC: Packaging reception and maintenance facilities
- **BNI 118:** STE3 facility: Effluent recovery and treatment and storage of bituminised waste packages
  - D/E EB: Storage of alpha waste
  - MDS/b: Mineralisation of solvent waste

1.2.2 Operation of the La Hague plants

Examination and follow-up of the periodic safety review files

In 2008, ASN examined the conclusions of the periodic safety review of BNI 118 which includes the Effluent Treatment Station (STE3), the Solvents Mineralisation Facility (MDS/B) and the sea discharge pipe. ASN is particularly attentive to compliance with the undertakings made by the licensee during this periodic safety review. It observes that, on the whole, Areva NC is late in meeting its initial undertakings, in particular concerning the performance of conformity examinations on the facility and the processing of legacy waste.

In 2010, the licensee transmitted the periodic safety review report for the UP3-A plant (BNI 116). At the request of ASN, the Institute for Radiation Protection and Nuclear Safety (IRSN) assessed this report and presented the results of its assessment to the Advisory Committee for Laboratories and Plants (GPU) during six meetings from mid-2012 to March 2015.

Following this examination, ASN directed Areva NC to make safety improvements in a resolution of 3rd May 2016. This review showed the need for a significant improvement in the protection of the installation against the risk of fire and against the lightning risk. ASN also stipulated greater checks on equipment used to concentrate the fission products in the facility (the "evaporators") as this equipment, which concentrates particularly radioactive substances, is corroding more rapidly than had been anticipated at the design stage.

Areva spent fuel reprocessing plant at La Hague, Manche *département*.

ASN asked Areva NC to take account of experience feedback from the examination of the review file for the UP3-A (BNI 116) plant as part of the examination of the review orientation file for the UP2-800 (BNI 117) plant, in particular with regard to the completeness of the analyses provided in support of these files and in terms of methodology for identification of the Elements Important for Protection (EIP). The periodic review file for the UP2-800 plant was submitted by Areva NC at the beginning of January 2016 and is currently being examined. A first meeting of the GPU is scheduled for November 2017 and will mainly concern the R1 unit.

Areva NC monitoring of the status of evaporator capacity

For the periodic safety review of BNI 116, ASN asked Areva in 2011 to examine the conformity and ageing of the fission products concentration evaporators in units T2 (BNI 116) and R2 (BNI 117). In 2014, Areva NC informed ASN that the corrosion of these items was on a scale greater than that considered in the design. During the course of 2015, Areva NC sent ASN the results of the in situ measurement campaigns. As the maintained integrity of these items has major safety implications, the ASN Commission heard the Areva CEO on 11th February 2016. In its resolution 2016-DC-0559 of 23rd June 2016, ASN stipulated the conditions to be met by Areva NC for continued operation of the fission products concentration evaporators in the La Hague plants. It is particularly attentive to the development of corrosion in this equipment and may demand shutdown of the facility in the event of excessive deterioration.

In 2016, Areva NC submitted a request to ASN for its opinion regarding the safety options for the new evaporators, with a view to commissioning them in 2021.

In 2011, Areva NC also brought to light several perforations of the shell of an evaporator used to concentrate fission product solutions prior to vitrification in the R7 unit (BNI 117). It was impossible to restart this evaporator which will now need to be replaced. In 2016, the licensee sent ASN an authorisation application for replacement and commissioning of a new evaporator, today envisaged for the 2018 time-frame.

Radiation protection

In 2016, as in previous years, ASN considers that worker radiation protection in the La Hague plant is on the whole satisfactory. The staff of outside contractors, in particular those working on the decommissioning of the UP2-400 plant, are the most exposed workers in the facility.

1.2.3 Ongoing and future plant modifications

Authorisation applications for processing of new types of fuels

The operating domain of the La Hague plants is defined in their Creation Authorisation Decrees of 12th May 1981, updated in 2003 and in 2016. The Decrees specify the operating domain of the plants for each type of fuel assembly. The applications for authorisation to process new types of fuels, covered by the operating domain defined in the modified Decrees of 12th May 1981, are the subject of ASN resolutions:
- spent fuel pins from the Phenix reactor: resolution of 11th March 2014;
- fuels based on enriched reprocessed uranium: resolution of 24th April 2014;
- irradiated MOX fuels from the Italian Trino reactor: resolution of 31st March 2015;
- fuels based on enriched natural uranium from EDF's Galice fuel management process: resolution of 15th July 2015;
- fuels based on uranium oxide and mixed uranium and plutonium oxide from the Italian Garigliano reactor: resolution of 21st June 2016.

In 2015, Areva NC also applied for authorisation to receive and process low enrichment uranium silicide fuels from test and research reactors, in plant UP3-A. This file is currently being reviewed by ASN.

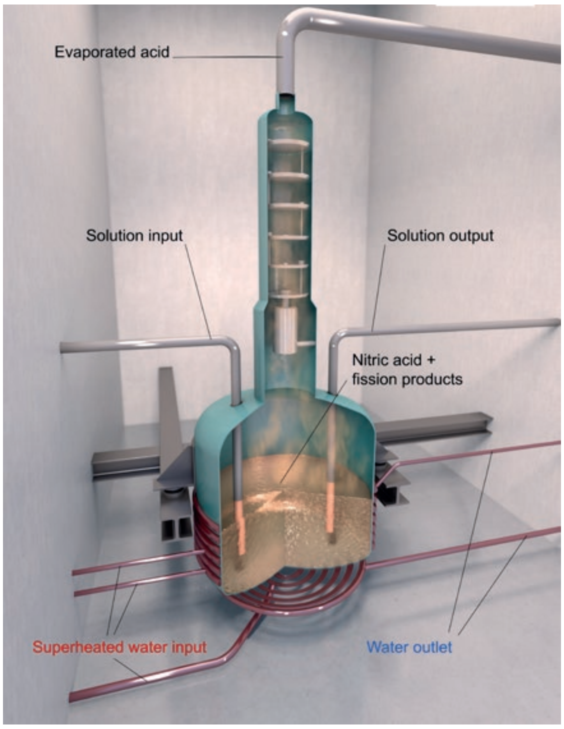
Implementation of new storage capacity for vitrified waste packages

The construction of the first vitrified waste storage extension on the La Hague site (E/EV/LH) in order to anticipate saturation of storage capacity for CSD-V (R7, T7 and E/EV/SE) which began in 2007, was completed in 2013. This extension comprises two pits, referred to as "pits 30 and 40". The forecasts of the storage capacity for CSD-V on the La Hague site show the need for a doubling of current capacity by 2017.

Initially, only pit 30 was equipped with its storage shafts. This pit was commissioned in two stages, through resolutions CODEP-CLG-2013-051991 and CODEP-CLG-2015-022857 of 12th September and 11th June 2015. ASN had considered the safety case to be insufficient, more specifically in terms of removal of heat from the waste packages if the pit were to be completely filled.

On 4th June 2013, Areva NC sent the Minister in charge of Nuclear Safety a file requesting authorisation to modify the UP3-A plant in order to increase this storage capacity:
- creation of 4,199 additional spaces with the outfitting of pit 40 of the E/EV/LH extension;
- creation of 8,398 additional spaces with the construction of the E/EV/LH 2 extension, a facility with an identical design to that of the E/EV/LH and comprising two new pits (pits 50 and 60).

DIAGRAM OF AN EVAPORATOR and details of the half-tubes of the heating circuit



Following the examination of this file, the Decree of 7th November 2016 sets the capacity and maximum storage duration for CSD-C and CSD-V within the UP3-A plant. Pit 40 of the E/EV/LH extension is currently being fitted out with its storage shafts. Commissioning of this pit, which requires ASN authorisation, is scheduled for the autumn of 2017.

Implementation of new process in STE3

On 4th May 2012, Areva NC submitted a modification authorisation application file for BNI 118 to the Minister responsible for Nuclear Safety. The purpose of this modification application is to allow processing and packaging of the sludges stored in the STE2 facility, by means of a new process to be utilised within an existing building of the STE3 facility, in place of one of the two bituminisation lines (line A).

This process comprises:
- drying of the STE2 treatment sludges;
- compacting of the powder resulting from drying in the form of pellets;
- packaging of the pellets in a package filled with an inert material (C5 package);
- storage of the C5 packages, pending opening of a long-term management solution.

This authorisation application was examined by ASN and was the subject of a draft decree by the Minister responsible for Nuclear Safety, for which ASN issued a favourable opinion on 3rd December 2015. Decree 2016-71 authorising the modification was signed on 29th January 2016.

The special fuels reprocessing unit project

With a view to obtaining authorisation to receive and reprocess spent fuels from the Phénix reactor, Areva transmitted a safety options file for this new reprocessing unit at the beginning of 2016. This file is currently being examined. The Areva NC application is in response to ASN resolution 2014-DC-0422 of 11th March 2014 which more particularly prescribes the submission of an application for authorisation to modify the facility before 31st December 2018. This will also be the subject of a public inquiry.

Areva therefore presented ASN with a project to install a new special fuels reprocessing unit. This unit would comprise new shearing and dissolving equipment, in particular for the spent fuels from test and research reactors and in particular from the Phénix reactor.

1.2.4 Recovery and packaging of legacy waste

The former UP2-400 plant has been finally shut down since 1st January 2004. The final shutdown and decommissioning operations for the UP2-400 (BNI 33), HAO (BNI 80) and STE2 (BNI 38) facilities and the ELAN II B (BNI 47) unit are described in detail in chapter 15.

Unlike the waste produced by the new UP2-800 and UP3-A plants at La Hague that is packaged directly on-line, most of the waste produced by the first UP2-400 plant was stored in bulk without any final packaging. The operations involved in recovering this waste are technically difficult and require the use of considerable resources. The difficulties associated with the age of the waste, in particular the need for characterisation prior to any recovery and processing, confirm ASN's approach which, for any project, requires the licensees to assess the corresponding production of waste and make provision for processing and packaging as and when the waste is produced. The recovery of the waste contained in the old storage facilities on the La Hague site is also a precondition for the decommissioning and clean-out of these storage facilities.

The recovery of legacy wastes from the La Hague site is thus monitored particularly closely by ASN, mainly because of the major safety and radiation protection implications associated with it. Furthermore, recovery of the site's legacy waste is one of the Areva Group's major commitments, made within the framework of the ministerial authorisations to start up new spent fuel reprocessing plants (UP3-A and UP2-800) at the beginning of the 1990s.

The initial schedule for the recovery of these wastes had slipped considerably and has continued to slip in recent years. ASN considers that the deadlines can no longer be pushed back, because the buildings in which this legacy waste is stored are ageing and no longer comply with acceptable safety standards. ASN in particular considers that Areva NC must as rapidly as possible recover the legacy waste produced by operation of the UP2-400 facility, more specifically the sludges stored in the STE2 silos, the waste from the HAO facility and silo 130 and the fission products solutions stored in the SPF2 unit.

The solutions for elimination routes or new interim storage facilities must be definitively decided upon, because their implementation involves large-scale projects: further postponement would jeopardise compliance with the deadlines set by the "Waste" Act of 28th June 2006, which states that the owners of medium-level long-lived waste produced before 2015 must package it by 2030 at the latest (see the video on the *Rules for recovery and packaging of legacy waste at La Hague* on *www.asn.fr)*.

ASN issued prescriptions regarding all the legacy waste recovery and packaging programmes in resolution 2014-DC-0472 of 9th December 2014. This resolution defines priorities in terms of the safety of the legacy waste Recovery and Packaging Operations (RCD) and sets milestones for each of the programmes concerned. ASN also carried out an in-depth inspection of the RCD projects in October 2016 (see chapter 15).

STE2 sludges

The scenario presented in 2010 concerning the recovery and packaging of STE2 sludges is split into three steps:
- recovery of sludges stored in silos in STE2 (BNI 38);
- transfer and treatment by drying and compacting in STE3 (BNI 118);
- packaging of the pellets obtained into C5 packages for deep geological disposal.

ASN authorised the first phase of the recovery of the STE2 sludges in 2015.

The Creation Authorisation Decree for the STE3 effluents treatment station was modified by the Decree of 29th January 2016 to allow the installation of the STE2 sludges treatment process.

Moreover, in a resolution of 4th January 2011, ASN states that it must first approve the production of the C5 package, for which the risk of radiolysis leading to the production of hydrogen must be considered as of the design stage (see chapter 16).

However, at the end of 2016, Areva NC informally notified ASN that the process adopted for the treatment of sludges in STE3 could lead to more complex equipment operating and maintenance conditions. If it were to confirm this, the licensee would need to present the alternative scenario it intends to implement. The first elements presented by the licensee indicate that it would be very difficult to meet the objectives defined by the law with regard to the packaging of legacy waste. If these doubts were to be confirmed, ASN would need to take appropriate measures to ensure that the law is applied.

ASN will be particularly vigilant in ensuring that Areva NC does everything in its power to meet the deadlines prescribed for the recovery of the STE2 sludges.

Silo 130

Silo 130 is a reinforced concrete underground storage facility, with carbon steel liner, designed for dry storage of solid waste from the reprocessing of Gas-Cooled Reactor fuels (GCR). As of 1973, the silo received waste of this type, until the 1981 fire which forced the licensee to flood the waste. The tightness of the silo thus filled with water is today ensured by means of a single containment barrier consisting of a steel "skin". Silo 130 is monitored by a network of piezometers situated nearby.

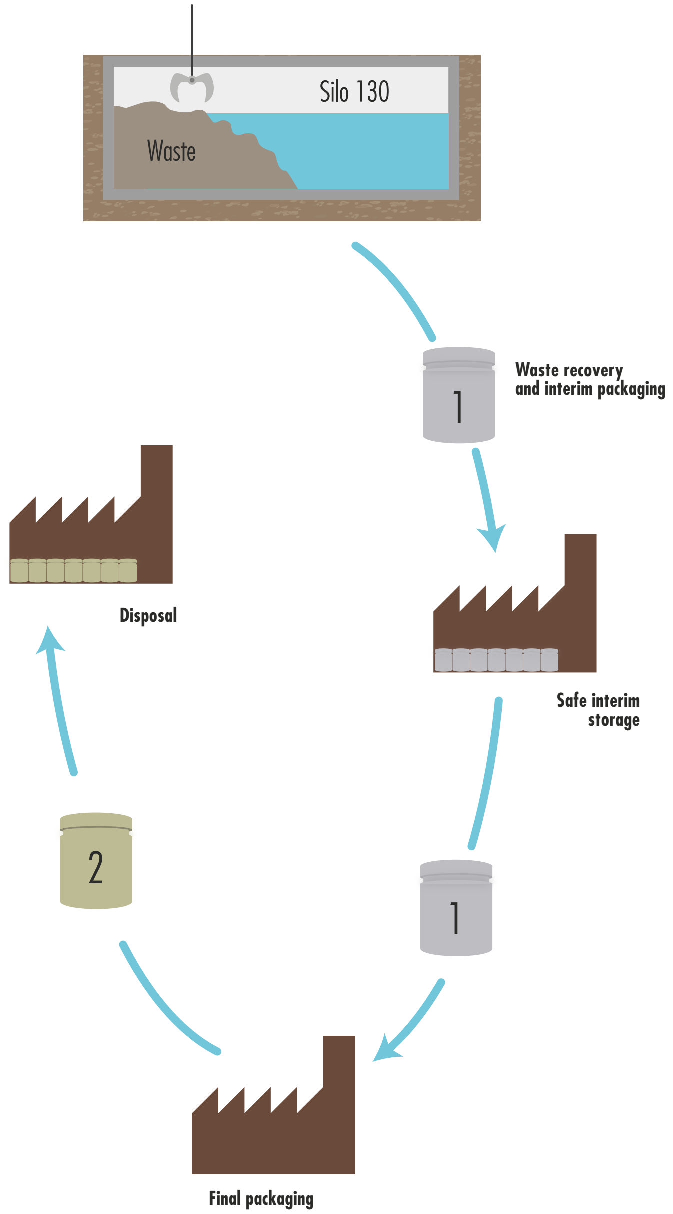
Areva NC is today focusing on the construction of the recovery unit. ASN set 1st July 2016 and 31st December 2022 as the latest dates for the beginning and end of the recovery operations for all the waste. During an inspection in July 2016, ASN found that Areva NC had not actually begun to recover the waste stored in silo 130. ASN therefore initiated administrative procedures so that Areva NC begins this recovery without delay.

Old fission product solutions stored in the SPF2 unit in the UP2-400 plant

To package fission products from reprocessing of Gas-Cooled Reactor fuel, in particular that containing molybdenum (UMo FP), the licensee has opted for cold crucible vitrification. The package thus produced is a standard Umo Vitrified Waste Package (CSD-U).

The use of the cold crucible with legacy solutions was authorised by a resolution of 20th June 2011. The first CSD-U packages were produced in 2013, but the cold crucible experienced a number of technical problems in 2014 and 2015. CSD-U packages were produced during short production campaigns. Areva NC is currently continuing its efforts to produce CSD-U packages at a nominal rate and meet the end of recovery deadline set for 31st December 2017 by the resolution of 14th June 2011.

DIAGRAM of recovery and packaging operations



1. Interim package - 2. Final package

Other legacy waste recovery and packaging projects

With regard to other lower-priority legacy waste recovery and packaging projects, the following events in 2016 are worthy of note:
- continued R&D studies on the packaging processes for GCR and low granulometry type wastes;
- the change in transfer scenario and the investigations on the elution columns and strontium titanate capsules currently stored in ÉLAN IIB (BNI 47).

1.3 The back-end fuel cycle: fabrication of MOX fuel

The Mélox uranium and plutonium-based fuel fabrication plant

BNI 151 Mélox, situated on the Marcoule nuclear site, operated by Areva NC, is today the world's only nuclear installation producing MOX fuel, which consists of a mixture of uranium and plutonium oxides.

The facility's periodic safety review file was sent by the licensee on 21st September 2011. One of main issues which came out of the review was controlling worker exposure to ionising radiation and adaptation of the facility and its organisation to changes in the composition of the materials used. In its resolution 2014-DC-0440 of 15th July 2014, ASN stipulates that continued operation of the plant is dependent on compliance with the prescriptions for controlling the risk of worker exposure to ionising radiation, the criticality risk and the risk of fire. It more particularly prescribes the procedures to be followed by the licensee to confirm implementation of the measures identified during the review and the commitments it had made.

Visual inspection of rods, Mélox MOX fuel fabrication plant, Bagnols-sur-Cèze.

In 2016, ASN observed that the safety situation in the facility is on the whole satisfactory. The containment barriers remain effective, the radiation protection and criticality risk control issues are dealt with rigorously.

On the other hand, ASN notes delays in the prescribed work to improve control of fire risks and in implementation of the licensee's commitments regarding the monitoring of subcontracted operations. ASN therefore initiated sanction procedures.

The licensee has expressed its intention to produce a limited quantity of experimental fuels in order to qualify new types of fuels for possible use in fast neutron reactors. This operation is not authorised in the Mélox BNI and would need to be the subject of a modification of the Creation Authorisation Decree for this facility.

2. Integration of experience feedback from the Fukushima Daiichi accident

All of the fuel cycle facilities were dealt with as a priority in the light of the experience feedback from the Fukushima Daiichi accident. The licensees supplied stress test reports in September 2011 for all facilities and sites, with the exception of BNI 63 (Cerca), for which the report was submitted in September 2012.

In its resolution 2012-DC-0302 of 26th June 2012, ASN set additional prescriptions for the Areva Group facilities assessed in 2011, in the light of the conclusions of the stress tests. These prescriptions more specifically require the deployment of a "hardened safety core" of material and organisational provisions designed to prevent a severe accident or limit its spread, mitigate large-scale releases and enable the licensee to fulfil its emergency management duties. The licensee is more specifically required to propose the level characterising the extreme natural hazards to be considered in the design and sizing of the "hardened safety core" equipment.

ASN reviewed the proposals from the Areva Group to define the "hardened safety core" and its functions, including for the Areva NP BNI 63 in Romans-sur-Isère.

The ASN resolutions of 9th January 2015 prescribe the hazard levels and associated requirements for the "hardened safety core" and the deadlines for deployment of this "hardened safety core" for all cycle installations. The reference earthquake was in particular defined in it, based on an earthquake liable to occur every twenty thousand years. The current state of knowledge in seismology makes it particularly difficult to characterise such events, whereas the design of industrial facilities presupposes a precise definition of the loadings the facility must be able to withstand. Even if a reference earthquake has today been characterised for the "hardened safety core" at La Hague, technical discussions are continuing for the other Areva sites at Romans-sur-Isère, Marcoule and Tricastin.

In 2016, the technical debate had progressed sufficiently to enable ASN to issue a position statement in early 2017 on the hazard levels on most of the sites.

3. Regulating the nuclear fuel cycle facilities

ASN regulates the fuel cycle facilities at different levels:
- the safety cases produced by the licensee during the various steps in the operation of the nuclear facilities;
- the organisation of the licensees through inspections conducted in the field;
- fuel cycle consistency;
- operating experience feedback within the fuel cycle BNIs.

This part specifies how the steps taken by ASN apply to the fuel cycle facilities.

3.1 The main steps in the life of nuclear facilities

When the facilities undergo a significant modification or make the transition to decommissioning, ASN is responsible for reviewing these modifications and proposes the draft decrees for these changes to the Government. ASN also establishes prescriptions for these main steps. Finally, ASN also reviews the safety files specific to each BNI, paying attention to their integration into the broader framework of laboratory and plant safety.

The Areva Group has not yet carried out the first periodic safety reviews on all its facilities. The series of initial periodic safety reviews to be completed before the end of 2017 is a major challenge for the Areva facilities. The review of the methodology and the conclusions of the review of the UP3-A facility on the La Hague site presented by the licensee must be an opportunity for Areva to improve its process for the future periodic safety reviews. When examining each new file, ASN will be attentive to ensuring that experience feedback from the previous reviews has been correctly taken into account. ASN will in particular ensure that lessons are learned from the safety review of UP3-A, completed in 2016, with regard to identification of the EIP and the corresponding defined requirements, in accordance with the BNI Order of 7th February 2012.

3.2 Particular regulatory actions conducted in consultation with the Defence Nuclear Safety Authority

The upcoming declassification of the Tricastin INBS to a BNI will mean that ASN will take over responsibility for oversight of these facilities. Together with the ASND, ASN ensures that consistency is maintained in the application of the safety and radiation protection requirements on the facilities under its responsibility on the Tricastin site. Most of the facilities regulated by the ASND have in fact been shut down or are being decommissioned and no longer play a role in national defence. In this respect, they no longer need to be subject to secrecy measures and will thus be gradually declassified to BNI status in the coming years.

The facilities which are currently reprocessing the effluents and wastes from the entire site are scheduled for decommissioning and their activities will be taken over by the Trident unit (integrated processing of Tricastin nuclear waste) in the Socatri facility (see chapter 14). Some of the uranium storage facilities will be dismantled and the others will be incorporated into the project to group the storage areas on the Tricastin site within the same BNI (see point 1.1.1).

ASN and ASND have set up a working group to clarify the steps involved in ASN's takeover of the regulation of the safety of activities on this site. The decision was made that this takeover would be gradual, comprise as few steps as possible and be an opportunity to reorganise the oversight of the Tricastin site, so that the whole site, including soils contaminated by legacy pollution, are under the control of one or other of the safety regulators.

FOCUS

Declassification of Tricastin

The process to declassify the Tricastin INBS envisaged by the ASND and ASN should enable oversight of the Tricastin nuclear facilities to be reinforced and simplified. In terms of risks, this unified oversight will mean that ASN will be responsible on the one hand for overseeing the upgrading of the old facilities required for operation of the BNIs and, on the other, for handling legacy dossiers.

The first step in the declassification to BNI status led to the creation of the Tricastin uranium storage areas BNI (BNI 178) which was registered by ASN on 1st December 2016.

As the regulatory process is now clearly defined, the next steps in the BNI declassification, leading to the creation of at least two new BNIs, will continue in 2017.

Jointly with the ASND, ASN will propose a breakdown to the Minister responsible for Nuclear Safety, as a result of the ongoing process to declassify the site from INBS to BNI.

The Tricastin INBS, which houses a wide diversity of facilities, should be broken down into BNIs grouping facilities according to their purpose. Their safety baseline requirements will then need to be brought into line with the BNI System.

3.3 The licensee's organization and management structure for fuel cycle nuclear installations

For each facility, ASN regulates the organisation and means chosen by the licensee to enable it to assume its responsibilities in terms of nuclear safety, radiation protection, emergency management in the event of an accident and protection of nature, the environment and public health and safety. ASN issues an opinion or recommendations regarding the chosen organisations and may issue prescriptions on specific identified points, if it considers that there are shortcomings in these organisations concerning internal oversight of safety and radiation protection or that they are not pertinent.

ASN assesses the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management.

During the various periodic safety reviews of the Areva plants, ASN examines the management processes which it was not possible to deal with during the overall safety management review, the conclusions of which were sent to Areva on 21st September 2012. A final opinion will be issued on all the national and local management processes following all of these reviews, which will be completed in 2018.

In 2017, ASN will continue to be particularly vigilant in ensuring that the ongoing reorganisation of the Areva Group does not compromise the progress made in safety management across the Group. Within the current Areva Group, the conversion, enrichment and nuclear fuel reprocessing activities are combined in a new entity which could also call on other foreign partners, on the one hand, and the nuclear fuel fabrication and nuclear equipment manufacturing activities are combined in an entity jointly owned by several industrial groups, on the other. In accordance with the law, the entities which, as a result of this split-up, have become licensees of existing BNIs within the Areva Group, will need to prove to ASN that they do in fact have the technical and financial capacity enabling them to assume their nuclear safety and radiation protection responsibilities. In this respect, the separation of the group's engineering departments has major implications for the safety of the facilities. Although the historical ties between the two parts of Areva mean that each temporarily draws on the expertise of the other, it is essential that each party acquire the technical skills necessary to take on its responsibility as licensee.

Examining the measures taken by the Areva Group head office departments in terms of safety

ASN's regulatory action also covers the current Areva head office departments, which are responsible for the Group's safety, radiation protection and environmental protection policy. So far, ASN has looked at how these departments draft and implement this policy in the various establishments within the Group. In 2016, ASN monitored Areva's preparations for splitting up the Group into several legal entities, including New Co (which will take over the Romans-sur-Isère and Maubeuge sites) and New Areva (which will take over the other French BNIs of the Areva Group). In 2017, ASN will focus on the answers it receives regarding safety management.

Areva is however significantly behind schedule in integrating EIP regulations (these regulations aim to ensure that each element of a BNI on which the licensee has built its safety case does actually meet the requirements stipulated in this safety case).

3.3.1 Taking account of social, organisational and human factors

Formalisation of the way Social, Organisational and Human Factors (SOHF) are taken into account really began in 2005-2006 for the fuel cycle installations, with the drafting of internal policies specific to each licensee. This approach began to be centralised within the Areva Group as of 2008, which is when the Group's head office departments started employing SOHF specialists. Since then, a national policy has been developed and is being gradually deployed among the Group's licensees. The GPU meeting held in 2011 on safety management at Areva also made it possible to initiate development and follow-up of the SOHF measures adopted. ASN considers that this approach must be continued for it to fully bear fruit. Most of the various licensees within the Areva Group are now staffed with persons competent in SOHF.

Concerning the safety management tools produced by Areva in response to the undertakings made by the Group to the GPU in 2011, the examination shows that their deployment in the BNIs is on the whole well managed by Areva, but that improvements are required, more specifically on assistance for outside contractors and the time taken to implement Group directives.

With regard to the emergency organisation in an extreme situation, the Areva head office departments satisfactorily assisted the sites with the initial deployment of the

SOHF methodology defined within the context of the ECS. Its robustness must be further improved, but the emergency response organisations on the various Areva nuclear sites have been modified to take account of extreme situations.

3.4 Fuel cycle consistency

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have an impact on safety. To do this, on the basis of the "Cycle impact" file transmitted by EDF and drafted every ten years jointly with the fuel cycle stakeholders, Areva and the National Agency for Radioactive Waste Management (Andra), ASN reviews the consequences for the various steps of the fuel cycle of EDF's use of new fuel products in its reactors and new fuel management processes.

The issue of long-term management of spent fuel, mining residues and depleted uranium is examined taking account of the unforeseen variables and uncertainties attached to these industrial choices. In the short to medium-term, ASN more particularly wishes to see the licensees anticipate and prevent saturation of spent fuel storage capacity in the NPPs or the pools of the Areva plant at La Hague, as has been observed in other countries. The aim is to avoid the use of old facilities with a lower level of safety as an interim measure by licensees. ASN is assisted in this approach by the Ministry in charge of Energy, which it consults in particular to obtain information relative to materials traffic, industrial constraints that could affect safety, or energy policy guidelines. In order to maintain an overall and constantly appropriate view of the fuel cycle, these data must be periodically updated. ASN thus periodically asks that, together with the firms in the fuel cycle, EDF provide data to demonstrate the compatibility between changes to the fuel characteristics and fuel management and changes to the fuel cycle facilities. In addition, for any new utilisation of the fuel, EDF must demonstrate that it has no harmful effect on the management of risks in the fuel cycle installations.

In 2015, ASN therefore asked EDF to conduct an overall review of the "Cycle impact" file by 2016. The aim is to *"obtain a robust long-term overview of the developments which could affect all fuel cycle activities and the consequences of these developments on facilities and transports."* The period covered by the study is from January 2016 to December 2030 and identifies the limit thresholds (capacity saturation, fuel isotope limit reached, etc.) foreseeable up until 2040.

This file will be required to show that the changes in fuel characteristics or in irradiated fuel management and the developments to the fuel cycle facilities envisaged by the industrial players concerned will in no respect be unacceptable, over the coming fifteen years, whether with regard to the operation of the NPPs, the operation of the front-end and back-end plants in the cycle or the medium and long-term management of the waste. It shall also demonstrate long-term management of traffic and stocks of materials, fuels and waste and anticipate difficulties or contingencies in the operation of the fuel cycle.

Given the anticipated time-frame for saturation of spent fuel storage capacity and given the time needed to design and build such a facility, ASN *"drew the attention [of EDF] to the prospect of saturation of French spent fuel storage capacity"* and asked EDF *"in the next update of the file to present [its] strategy concerning this subject and the various contingencies associated with the creation of new storage capacity"*. In the light of the information at its disposal, ASN stated that transmission of a safety options file by EDF in 2017 is necessary with a view to creating such capacity.

The update of the "Cycle impact" file comprises a number of innovations with respect to the previous approaches initiated in 1999 and 2006:
- The study period, which habitually covered ten years, is increased to fifteen years, in order to take account of the time actually observed in the nuclear industry to design and build any new facilities identified as being necessary further to the assessment carried out.
- Radioactive substances transport contingencies are explicitly incorporated into the assessment.
- Nuclear reactor closures are studied for the period of time considered, in particular assuming stable electricity demand until 2025, to take account of the planning provisions included in the Energy Transition for Green Growth Act 2015-992 of 17th August 2015.
- The strategy for managing and storing spent fuels pending reprocessing or disposal is part of the scope of the assessment. Saturation of existing capacity is in fact highly probable during the period in question.

EDF submitted the updated "Cycle impact" file to ASN on 30th June 2016. This file is currently being examined by ASN, which will issue its position statement in 2018.

4. ASN international actions

ASN enjoys regular discussions with its foreign counterparts to share best practices for regulating the nuclear safety of fuel cycle facilities.

Bilateral relations with the British safety regulator, the ONR (Office for Nuclear Regulation), were intense in 2016 concerning the recovery and packaging of legacy waste on the La Hague and Sellafield sites. These discussions will continue and go further in 2017 with reciprocal site visits, which will also include the services of the ASND.

ASN also took part in a seminar held by the American Nuclear Society (ANS) concerning the authorisation processes for fuel cycle facilities.

ASN also had contacts with its Spanish counterpart, the CSN (*Consejo de Seguridad Nuclear)*, on the long-duration storage of high-level waste.

5. Outlook

Cross-disciplinary aspects

ASN will be continuing its review of several of the Areva Group's BNIs and will extend this process to new facilities at La Hague and Romans-sur-Isère in particular, but also to EDF's inter-regional fuel stores (in Chinon and Bugey). At the end of 2017, ASN shall more specifically issue a position statement on the continued operation or otherwise of the Cerca facility at Romans-sur-Isère, which is required to carry out major reinforcement works.

ASN will continue to monitor the implementation of the additional safety measures required following the stress tests, more specifically the Areva proposals concerning the definition of systems, structures and components robust to extreme hazards and the management of emergency situations, in particular compliance with the new prescriptions issued at the end of 2014 and in early 2015. In 2017, ASN will more particularly issue a position statement on the reference contingencies to be considered for the "hardened safety core" (in particular seismic aspects) and define how to reach a decision on sites for which seismological data is limited and require special approaches.

With regard to the current Areva Group, ASN will be particularly vigilant in ensuring that the BNI licensees to be created as a result of the ongoing split-up of the group, are in full possession of the capabilities needed to meet their responsibilities. In particular, the capabilities of the two groups resulting from the split-up of Areva as it currently stands shall be robust enough to make any modifications to the installations concerned and manage any internal crises.

Fuel cycle consistency

In 2016, ASN began to examine the updated "Cycle impact" file, covering the period 2016-2030 and aimed at anticipating the various emerging needs in order to manage the nuclear fuel cycle in France. ASN in particular focuses on monitoring the level of occupancy of the spent fuel underwater storage facilities (Areva and EDF). It asked EDF, as overall ordering customer, to examine the impact of the shutdown of a reactor or of a possible modification in the spent fuel reprocessing traffic on the anticipated saturation dates for these storage facilities, as well as the solutions envisaged for pushing back these dates. ASN considers that Areva and EDF must rapidly define a management strategy beyond 2030. The examination of the "Cycle impact" file submitted in 2016 is in progress and will be the subject of a joint review by the advisory committees for laboratories and plants, for wastes, for reactors and for transports, at the beginning of 2018.

ASN will also continue to monitor the files associated with fuel cycle consistency, notably the creation of a BNI dedicated to the storage of uranium from reprocessing on the Tricastin site and UP3-A in La Hague for the storage of compacted waste packages from spent fuel reprocessing.

Tricastin site

In 2017, ASN should be examining the creation authorisation application for a BNI comprising the new uranium storage buildings on the site and will continue to examine the modification to the Socatri facility as part of the Trident project (see chapter 14). ASN will be particularly attentive to the reorganisation of the site with regard to nuclear waste management, pending the construction of the Trident unit, which should start in 2017.

ASN will be attentive to the satisfactory commissioning of the Atlas facility, which is designed to replace a number of ageing laboratories.

ASN will continue to monitor the reorganisation of the Tricastin platform to ensure that these major organisational changes within the group have no impact on the safety of the various BNIs on the site. It will also ask the platform licensees to complete the unification process scheduled for 2012 or, failing this, ask that either they forego the pooling of the equipment and entities that each of them will be required to have, or that they ensure their independence by abandoning the pooling of the equipment and entities which they today require.

ASN will initiate an examination of the periodic safety reviews of BNIs 93 and 105 for which the files must be submitted no later than November 2017.

Jointly with the ASND, ASN will propose the final BNI breakdown to the Minister responsible for Nuclear Safety, resulting from the ongoing process to declassify the site from INBS to BNI.

Romans-sur-Isère site

Areva NP still needs to carry out major conformity work on several buildings.

Given the malfunctions observed in recent years, ASN will pursue its heightened surveillance of the facility in 2017 in order to ensure that this licensee's nuclear safety performance is improved. It will be attentive to compliance with the deadlines for performance of the work defined in the facility's safety improvement plan and the revision of its safety baseline requirements. It will also be attentive to ensuring the implementation of the improvements planned as part of the stress tests.

The report presenting the conclusions of the ten-yearly periodic safety reviews carried out on BNI 63 (Cerca) and submitted at the end of 2015, will be examined to enable ASN to reach a conclusion with regard to the conditions for authorisation of possible continued operation of these facilities for the next ten years.

Mélox plant

ASN will continue to monitor compliance with the licensee's undertakings and the prescriptions it issued following the periodic safety review of the facility in 2011, more particularly with regard to the fire risk and the monitoring of outside contractors.

In addition, the changes to fuel management for power reactors requiring adaptation of the characteristics of the MOX fuel, will be a subject of interest for ASN. Areva NC will be required to demonstrate that these changes have no consequences for the safety of the facility and, as necessary, will submit the necessary modification files.

In addition, the licensee announced its intention to carry out experimental fabrication of fuels compatible with the Astrid project and could submit an application for modification of its operating baseline requirements accordingly.

La Hague site

In 2017, ASN will be particularly vigilant with regard to the development of corrosion in the fission products concentration evaporators. Areva NC shall be required to consolidate its methods for inspecting this equipment and its corrosion forecasts. Areva NC has started to replace this equipment for gradual commissioning between 2020 and 2021. ASN will examine the applications concerned.

With regard to the periodic safety reviews, ASN will in 2017 be monitoring the performance of the conformity work on the UP3-A plant and compliance with the prescriptions of the resolution of 3rd May 2016. The implementation of the EIP identification methodology and the reassessment of the control of fire risks will be the subject of particularly close scrutiny. In addition, the examination of the periodic safety review file for the UP2-800 plant will undergo an initial review by the GPU at the end of 2017.

The work done following the stress tests performed in the wake of the Fukushima Daiichi accident should be completed in the first quarter of 2017. ASN will check correct performance and the proper functioning of the equipment installed, along with the corresponding provisions.

With regard to future changes to reprocessing in the La Hague facility, ASN attaches particular importance to two modifications: on the one hand, the project to reprocess special fuels, which will allow the reprocessing of several fuel assemblies which hitherto could not be reprocessed, thus pushing back the saturation of the storage pools and, on the other, the replacement of the R7 evaporator, for which the particularly corrosive solutions are currently concentrated in other equipment in the plant and are liable to damage it. ASN will also be required to prescribe special operating procedures for commissioning of pit 40 in the E/EV/LH unit for storage of CSD-V by the autumn of 2017.

ASN will also be vigilant in ensuring that all the fuels received in the Areva NC plant are intended for reprocessing in accordance with the plant's authorization decrees.

With regard to the recovery and packaging of legacy waste, ASN considers that efforts must be continued. It will ensure that the changes to Areva's industrial strategy do not entail non-compliance with the prescriptions for the recovery and removal of waste from silo 130, sludges from STE2 and HAO. ASN already issued prescriptions to this effect in 2010 for silo 130 and in 2014 for the RCD programme as a whole.

14

Nuclear research and miscellaneous industrial facilities


asn

The various nuclear research or industrial installations differ from the BNIs involved directly in the generation of electricity (reactors and fuel cycle facilities). These BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), by other research organisations (for example the Laue-Langevin Institute (ILL), the ITER international organisation and the Ganil) or by industrial firms (for instance CIS bio international, Synergy Health and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

These activities, which range from fundamental research to applied developments, started in the late 1940s in France. They support medical and industrial activities, more specifically the fuel cycle, nuclear power generation, reprocessing and waste disposal. The variety of the activities covered and their past history explains the wide diversity of facilities concerned.

The safety principles applicable to these facilities are identical to those applied to power reactors and nuclear fuel cycle facilities, while taking account of their specificities with regard to risks and detrimental effects. In order to reinforce how these risks and drawbacks are dealt with, ASN defined three categories for the facilities it regulates in its resolution of 29th September 2015 (see chapter 3).

1. CEA installations

The CEA centres comprise facilities devoted to research (experimental reactors, laboratories, etc.) and "support" facilities specifically for waste storage, effluent treatment, etc. Research at CEA focuses on areas such as the lifetime of power plants, future reactors, nuclear fuel performance, or the reprocessing and packaging of nuclear waste.

Point 1.1 below lists the generic subjects which marked the year 2016. Point 1.2 describes topical events in the various CEA installations currently operating. The CEA facilities undergoing clean-out or decommissioning are covered in chapter 15 and those devoted to the management of waste and spent fuel are covered in chapter 16.

1.1 Generic subjects

Through inspection campaigns, analysis of the lessons learned from operation of the facilities, or the technical review of safety files, ASN identifies generic topics on which it questions and monitors CEA. Generic subjects on which ASN focused in 2016 were:
- the periodic safety reviews, in particular concerning the integration of aspects common to the BNIs on a given site and the integration of the ASN requests during the examination of CEA installation files;
- radioactive waste management and decommissioning of CEA installations: the in-depth inspection of the Saclay and Fontenay-aux-Roses sites, performed in May 2016, which confirms that the *"current organisation of CEA […] would not appear to be robust enough for the successful completion of these operations within the allotted time and in the best conditions of safety and radiation protection"*;
- safety management at CEA, checked by two specific inspections on the Cadarache and Saclay centres in 2016.

During the course of 2016, the ASN commission called the CEA Chairman to a hearing concerning:
- the reorganisation of CEA with regard to decommissioning, post-operational clean-out and management of radioactive waste at CEA (see chapter 15);
- the progress of the Jules Horowitz Reactor (RJH) construction site;
- the safety review of the LECA and the prospects for this facility.

1.1.1 Lessons learned from the Fukushima Daiichi accident

In the wake of the Fukushima Daiichi accident, ASN undertook stress tests of the nuclear facilities. The approach consists in assessing the safety margins in the facilities with regard to the loss of electrical power, or cooling, and with regard to extreme natural hazards.

In May 2011, ASN instructed CEA to carry out stress tests on the BNIs with the highest risks in the light of the Fukushima Daiichi accident (batch 1). For the experimental reactors of batch 1, and in the light of the conclusions of the stress tests, ASN in June 2012 prescribed the implementation of "hardened safety cores" (see chapter 12) of organisational and material provisions. The stress tests were continued for a second group (batch 2) of 22 facilities with lesser safety implications. These include CEA research facilities. The emergency management resources on the Cadarache and Marcoule sites underwent stress tests as part of this second batch.

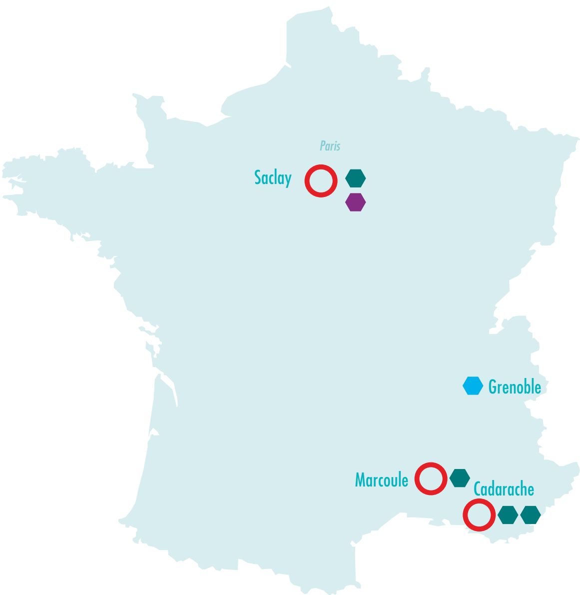
In January 2015, ASN prescribed requirements for CEA associated with the equipment and provisions of the "hardened safety core" for the facilities, along with the deadlines for their implementation, which should continue until 2018 (see Figure 1).

During the course of 2016, ASN issued a position statement on CEA's measures to prepare for and manage extreme situations, with regard to Social, Organisational and Human Factors (SOHF) regulated by the ASN resolutions of 26th June 2012 and 8th January 2015.

The file concerning the new emergency management room in the Cadarache centre, which should be operational in October 2018, was the subject of an ASN position statement and requests for additional work, which will have to be taken into account in its construction.

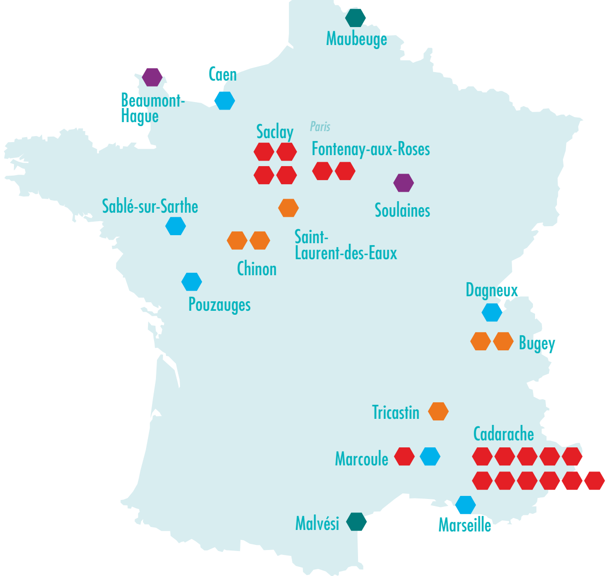
For the Saclay centre, the stress tests review led ASN on 12th January 2016 to prescribe the implementation of a "hardened safety core" for emergency management. CEA complied with the initial deadlines of this resolution and forwarded additional studies and justifications

FIGURE 1: CEA centres and facilities, ILL and CIS bio international concerned by the "hardened safety core" additional prescriptions in 2015



- CEA Centre
  - CEA Cadarache Centre
  - CEA Marcoule Centre
  - CEA Saclay Centre
- Research facilities operated by CEA
  - Cadarache site: CABRI, Jules Horowitz Reactor
  - Marcoule site: Phénix
  - Saclay site: Orphée
- Facility operated by the Institut Laue-Langevin
  - Grenoble: High-Flux Reactor
- Facility operated by CIS bio international (project)
  - Saclay: Radiopharmaceuticals production plant

FIGURE 2: Research facilities concerned by the stress tests prescribed in November 2013 (batch 3)



- 18 CEA facilities
  - 11 BNIs at Cadarache
  - 4 BNIs at Saclay
  - 2 BNIs at Fontenay-aux-Roses
  - Diadem (Marcoule)
- 6 EDF facilities
  - MIR (Chinon and Bugey)
  - BCOT (Tricastin)
  - AMI (Chinon)
  - The Saint-Laurent-des-Eaux silos
- 6 accelerators and irradiators
  - Ganil (Caen)
  - Ionisos (Dagneux, Sablé-sur-Sarthe, Pouzauges)
  - Synergy Health (Chusclan, Marseille)
- 2 LLW/ILW waste storage facilities (Andra)
  - Aube Disposal Centre (CSA) (Soulaines)
  - Manche Disposal Centre - CSM (Beaumont-Hague)
- 2 AREVA Group facilities
  - Écrin (Comurhex Malvési)
  - Somanu (Maubeuge)

concerning its ability to activate its emergency organisation in extreme situations. These elements are currently being examined by ASN.

The review of the extreme natural hazard levels adopted for the "hardened safety core" for the CEA facilities will soon be completed.

Finally, for the thirty or so other facilities with lesser safety implications (batch 3), ASN set out a calendar on 21st November 2013 for CEA to submit the stress test reports, a process which will run until 2020 (see Figure 2).

1.1.2 Management of nuclear safety and radiation protection at CEA

ASN monitors management of safety at CEA at several levels:
- regarding the Chairman, ASN ensures compliance with the scheduled deadlines and the integration of safety and radiation protection issues concerning CEA's "major commitments" with respect to the upgrading of old facilities, the final shutdown and decommissioning of facilities which cannot be upgraded and waste management;
- with respect to the General and Nuclear Inspectorate, ASN asks CEA to increase exchanges and transparency with regard to the authority, so that it can better evaluate the internal monitoring measures;
- with respect to the Protection and Nuclear Safety Division, ASN examines how CEA's nuclear safety and radiation protection policy is drafted and to what extent it is developing an overall approach to generic subjects;
- and as regards the centres, ASN examines the files specific to each BNI, being attentive to their integration into CEA policy; with this in mind, it more particularly examines the conditions in which safety management measures are carried out.

Moreover, the topics concerning the organisation of decision-making and internal monitoring, the integration of safety issues into project management, the integration of SOHF, skills management, subcontracting, operating experience feedback and safety in routine operations were examined and two specific ASN inspections of the Cadarache and Saclay centres were held in 2016. These actions were able to assess and monitor the effective implementation of the CEA measures resulting from its commitments and the ASN requests. These measures were considered to be on the whole satisfactory, subject to reinforcement of the SOHF and safety skills of certain personnel in charge of events analysis and project management. The targeted topics for the next examination on the management of safety and radiation protection will be discussed with CEA in 2017 so that they are integrated into its three-yearly reports.

1.1.3 Monitoring of CEA's "major commitments" to nuclear safety and radiation protection

In 2006, ASN stated that it wanted to see rigorous monitoring of the CEA safety issues with the highest potential consequences, by means of a high-level oversight tool, in particular for the decision-making process. In 2007, CEA therefore presented ASN with a list of "major commitments". In 2015, at ASN's request, CEA defined nine new "major commitments" staggered between 2016 and 2022 (see Table 1).

TABLE 1: New CEA "major commitments"

SITE	BNI	ACTION	DEADLINE
Cadarache	42-95	Remove radioactive materials from ÉOLE-Minerve to reduce the radiological impact in the event of an accident	1st half 2016
	55	Deploy the resources linked to the STAR STEP project	1st half 2016
	37	Transmit the file defining structural reinforcements of the renovated STD	2nd half 2017
	53	Removal of all radioactive materials from the MCMF, subject to consolidation of the inventory	2nd half 2017
	56	Complete recovery of waste from trench T2, excluding earth	2nd half 2017
Marcoule	71	Transmit the NOAH commissioning file for decommissioning of Phénix	2nd half 2021
	177	Transmit the Diadem commissioning file	1st half 2019
Saclay	35	Recovery of effluents from tank MA500	2nd half 2018
Fontenay-aux-Roses	165-166	Decommissioning of the facilities	To be defined in connection with the BNI decommissioning decrees modification application files

Despite the delays in meeting certain commitments, the results of this arrangement are on the whole positive. It allows targeted tracking of priority actions, which have a clearly set deadline. Any extension must therefore be duly justified and discussed with ASN.

In 2016, the commitments concerning the removal of a significant share of the radioactive materials from ÉOLE-Minerve and the removal of certain fuels from the Pégase pool were met. However, CEA was unable to meet its commitment to recover waste from pits 5 and 6 of BNI 56. The BNI 56 recovery deadlines will be prescribed by its decommissioning decree. Finally, non-compliance with the commitment concerning reinforcement of the Treatment, Clean-out and Reconditioning Station (STAR), covered by a prescription, led ASN in July 2016 to serve CEA with formal notice to perform the works before the end of April 2017.

FUNDAMENTALS

The periodic safety reviews

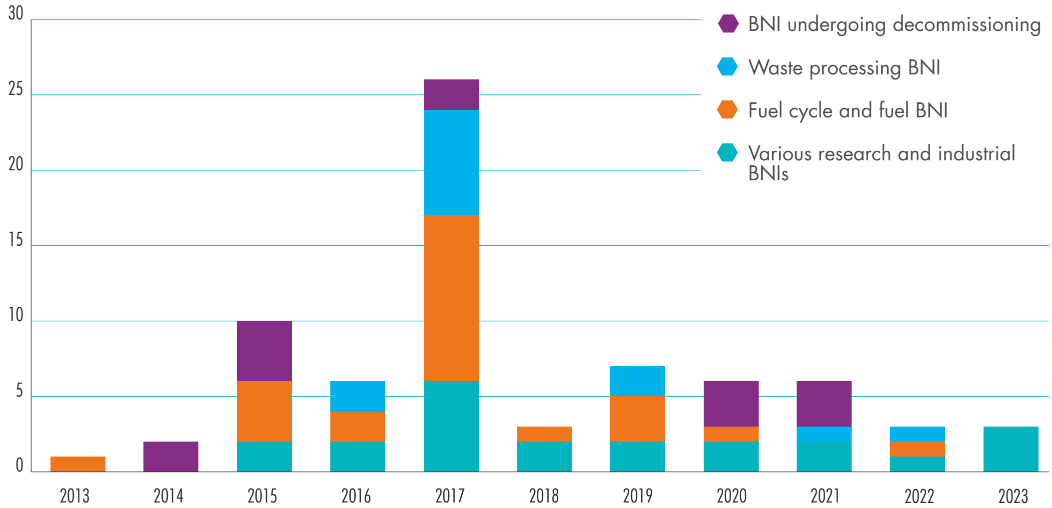
The Environment Code requires that the licensees carry out a periodic safety review of their facilities every ten years. All the French BNIs, including the facilities being decommissioned, must comply with this regulatory obligation. This review is designed to allow an appraisal of the situation of the facility with respect to the rules applicable to it and to update the assessment of the risks or detrimental effects presented by the facility, notably taking into account the condition of the facility, acquired operating experience, the development of knowledge and of the rules applicable to similar facilities.

Unlike the NPP reactors in operation, the other facilities (called LUDD – Laboratories, plants, waste and decommissioning – which are covered by chapters 13, 14, 15 and 16 of this report) entail specific issued with regard to the protection of the interests (more particularly safety, protection of nature and the environment and radiation protection) specific to each BNI. In addition, numerous companies operate LUDD facilities: the periodic safety reviews of these BNIs are therefore not generic. Each periodic safety review file requires specific examination on the part of ASN.

These periodic safety reviews are thus an opportunity for upgrades or improvements in fields in which the regulations and safety requirements have changed, in particular seismic resistance, protection against fire and confinement. For some facilities, the licensee may decide to shut down the facility at the end of its operations as the result either of the excessive technical difficulty involved in performing the safety improvements needed to bring it into line with the safety requirements applicable to the more recent facilities, or of the cost of these improvements felt to be disproportionate.

Owing to the fact that many of these facilities were commissioned in the early 1960s, their licensees musts submit the first periodic safety review conclusions report no later than November 2017. 26 facilities will therefore be required to submit a periodic safety review file in 2017, which represents an unprecedented major challenge for ASN pursuant to the analysis of the conditions which could allow continued operation of these facilities.

GRAPH 1: Number of periodic safety reviews according to type of BNI



1.1.4 The periodic safety reviews

Commissioning of the CEA installations began in the early 1960s. The equipment in these installations is ageing. Furthermore, it has been subject to modification, sometimes with no overall review of its safety. Since 2006, the Environment Code has required such a safety review every ten years. The periodic safety reviews (see box page 453) of the CEA facilities have been scheduled. As CEA opted not to act in advance of the deadlines, a safety review file will need to be submitted for 14 operational CEA facilities before November 2017, which represents a considerable workload. In 2016, ASN carried out its first in-depth inspection of the LECA, which more particularly shows that CEA must revise the national process implemented for performance of the reviews.

1.1.5 Revision of the prescriptions concerning water consumption and effluent discharges

In 2016, ASN completed the update of the prescriptions setting limit values and procedures for the discharge of effluents and consumption of water on the Marcoule site.

In 2016, ASN continued its review of the applications for updating the prescriptions regulating water intake and effluent discharges for the Cadarache BNIs and in 2017 will set limit values and define procedures for the discharge of effluents and consumption of water.

The review of the application for updating the prescriptions concerning effluent discharges and transfers and the environmental monitoring of the BNIs on the Fontenay-aux-Roses site should be completed in 2017.

1.2 Operation of the facilities

1.2.1 CEA Centres

Cadarache Centre

The Cadarache Centre is located at Saint-Paul-lez-Durance, in the Bouches-du-Rhone *département*. It employs about 5,000 people and occupies a surface area of 1,600 hectares. As part of CEA's strategy of specialising its centres, the Cadarache site deals mainly with nuclear energy. Twenty one BNIs are sited on it. The purpose of these Cadarache centre installations is R&D to support and optimise existing reactors and to design new generation systems. Facilities are also under construction on the Cadarache centre, notably the RJH.

In 2016, ASN carried out 41 inspections on BNIs in the CEA Cadarache centre. Although ASN considers that the level of safety remains on the whole satisfactory, it still observes persistent disparities between the installations in the centre and points out that it had to use its power of enforcement to obtain compliance with certain safety requirements. More particularly, as a result of a lack of operational rigour and non-compliance with commitments encountered in the solid Waste Treatment Station (STD) and the Effluents Treatment Station (STE) since 2012, ASN had to serve CEA with formal notice to improve the management of safety deviations on these two BNIs.

Saclay Centre

The Saclay Centre is located about 20 km from Paris in the Essonne *département*. This centre occupies an area of 223 hectares and employs about 6,000 staff. Since 2006, it has been home to CEA headquarters.

This Centre has focused mainly on material sciences since 2005, from fundamental to applied research in a wide variety of fields and disciplines, such as physics, metallurgy, electronics, biology, climatology, simulation, chemistry and the environment. The purpose of applied nuclear research is to optimise the operation and safety of the French nuclear power plants and to develop future nuclear systems.

The centre houses eight BNIs as well as an office of the French National Institute for Nuclear Science and Technology (INSTN), a training Institute, and two industrial firms: Technicatome, which designs nuclear reactors for naval propulsion, along with CIS bio international (see point 3.2).

ASN considers that the BNIs of the Saclay Centre are operated in satisfactory conditions of safety. However, the in-depth inspection performed by ASN in 2016 shows that the organisation in place for managing decommissioning projects does not enable decommissioning, including soil remediation, to be carried out on-schedule. Management of decommissioning projects is a key issue in that these operations will eventually become the main activity of the centre's BNIs. ASN considers that the CEA announcement at the end of 2016 that it was postponing the submission of the decommissioning file for Osiris by more than two years, can only reinforce this assessment.

This in-depth inspection showed that operating rigour in the waste storage facilities, notably with regard to compliance with operating instructions or keeping an up-to-date waste inventory, was not always satisfactory, despite the progress made since 2015.

ASN is attentive to changes in liquid effluent management in the BNIs in the current context of lock-out of the BNI 35 head tanks area and the robustness of the provisions in place for management of the solid waste produced by the centre's BNIs, with the prospect of final shutdown of BNI 72.

ASN also observes the correct implementation of the action plan to ensure compliance with the regulatory procedures, notably with regard to change management. The internal authorisation process for minor modifications is managed correctly but a few deviations observed show that CEA must remain vigilant in this area.

ASN is in favour of the definition of an action plan to prevent the obsolescence of the "radiation monitoring charts" in several BNIs and will be attentive to its correct implementation. The inspections reveal that the analysis of deviations and their subsequent classification as a significant event or interesting event could be more systematic and dealt with at greater depth. However, the commitments are being monitored with the expected degree of rigour. Increased vigilance is required with regard to monitoring of the maintained integrity over time of the fire protection measures.

CEA must also pursue its upgrading of the outside contractor monitoring process and reinforce the presence of its personnel in the field as a part of this process.

Finally, given the important changes planned for 2017 (reorganisation of decommissioning, merging of the Saclay and Fontenay-aux-Roses Centres), ASN considers that CEA must be attentive to guaranteeing the conditions necessary for managing safety and radiation protection in the Saclay BNIs during the period in which this new organisation is put into place and consolidated.

Marcoule Centre

The Marcoule Centre is the CEA centre of excellence for the back-end fuel cycle and in particular for radioactive waste; it plays an important role in the research carried out pursuant to the provisions of the 28th June 2016 planning Act 2006-739 on the sustainable management of radioactive materials and wastes. Defence nuclear facilities are installed on it, along with three CEA BNIs - Atalante, Phenix (see chapter 15) and Diadem (see chapter 16).

The site also comprises three other BNIs, not operated by CEA: the Gammatec irradiator, Melox (see chapter 13) and Centraco (see chapter 16).

In 2016, ASN carried out ten inspections on the CEA Marcoule centre, two of which were conducted jointly with the Defence Nuclear Safety Authority (ASND). ASN considers that the level of nuclear safety and radiation protection in the centre is satisfactory.

The centre's transverse waste management organisation appeared to be satisfactory. The quality of the numerous products produced and shipped by the centre is correctly monitored, the waste correspondents in the facilities hold regular meetings and the waste management baseline requirements are periodically revised to take

ASN inspection of the RJH, December 2016.

account of ASN and ASND resolutions. However, in terms of protection against the fire risk, ASN considers that the instructions and procedures in force on the site should be harmonised and that the descriptive and prescriptive documentation of the centre needs to be expanded.

Fontenay-aux-Roses Centre

The two BNIs in this centre are currently being decommissioned (see chapter 15).

Grenoble Centre

The CEA BNIs in this centre are currently being decommissioned (see chapter 15).

1.2.2 Research reactors

The purpose of experimental nuclear reactors is to contribute to scientific and technological research and to support the operation of the nuclear power plants. Each one is a facility for which ASN adapts its regulation and oversight to the particular risks and detrimental effects, taking account of safety practices and rules. In recent years, the licensees have developed a more generic approach to the safety case for these facilities, derived from that used for the power reactors. This approach in particular concerns the safety assessment based on "operating conditions" (postulated initiating events) and the safety classification of the equipment. It led to the identification and implementation of additional provisions and thus to progress in terms of safety. This approach is also used for the periodic safety reviews of the facilities as well as for the design of new reactors.

Critical mock-ups

Masurca reactor (Cadarache)

The Masurca reactor (BNI 39), whose creation was authorised by a Decree dated 14th December 1966, is intended for neutron studies – chiefly on the cores of fast neutron reactors – and the development of neutron measurement techniques. This installation has been shut down since 2007. The reactor core has been unloaded and the fuel has been stored in the fissile materials Storage and Handling Building (BSM). The analysis carried out for the stress tests confirmed that the facility's seismic resistance was insufficient and that the fissile materials needed to be transferred to the Magenta facility (BNI 169), for which the seismic design is satisfactory.

CEA submitted an application for a substantial modification to the facility in February and then submitted a supplementary application in June 2016, for modernisation of the existing buildings and construction of a New Storage Building (N-BSM). After examination of this file, ASN asked CEA in October 2016 to add to the file, notably with regard to the characteristics of the fissile materials and the justification of their utilisation, the hypotheses adopted for assessing the impact of discharges, the requirements defined for certain Elements Important for Protection (EIP) and the analyses of the consequences of a reactivity accident. In February 2016, CEA also transmitted the stress tests report for the facility in its renovated configuration. The examination of these files and of the conclusions of the periodic safety review transmitted in 2015 will continue when CEA has provided the above-mentioned additional items.

ASN considers that the "worksite phase" baseline requirements implemented by CEA up until the end of the renovation work are on the whole in line with the facility's safety issues. ASN considers that the licensee's organisation is satisfactory for completion of the facility renovation work but in the future it will nonetheless remain attentive to the management of subcontracting. In 2017, ASN will remain vigilant with regard to the removal of unused radioactive sources from the facility, as well as to maintaining the defined requirements for the Activities and Elements Important for Protection (AIP/EIP) in accordance with the facility's safety case.

ÉOLE and Minerve reactors (Cadarache)

The ÉOLE and Minerve critical mock-ups are very low power reactors (less than 1 kW) used for neutron studies, in particular to qualify calculation systems, evaluate gamma or neutron attenuation in materials and acquire basic nuclear data.

The ÉOLE reactor (BNI 42), whose construction was authorised by the Decree of 23rd June 1965, is intended for neutron studies of light water reactor cores. It is able to reproduce a neutron flux representative of that of the power reactor cores, on a very small scale. The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses research centre to the Cadarache research centre was authorised by the Decree of 21st September 1977, is situated in the same hall as the ÉOLE reactor. It is primarily devoted to effective cross-section measurements.

Teaching and research activities continued in 2016, in particular with the "FLUOLE 2" programme, for which ÉOLE was authorised to operate at 1 kW. The experimental programmes should continue to run until the end of 2017, at which time the facilities will be finally shut down (see box below).

FOCUS

Shutdown of the ÉOLE and Minerve reactors (Cadarache)

The examination of the latest periodic safety review of these facilities confirmed their vulnerability to the seismic risk and in a resolution of 30th October 2014, ASN therefore made continued operation conditional upon seismic reinforcement and reduction of the radioactive source term.

CEA complied with the calendar for removal of fuels from storage and removed a very significant share of the radioactive materials, reducing the radiological impact in the event of an accident by 95%.

With regard to the seismic reinforcement of the facility, CEA indicated that the significant presence of asbestos and lead in numerous items which are to undergo this consolidation work entailed technical constraints making it impossible to complete the reinforcement work by the deadline of 31st December 2017. The decision was therefore taken not to initiate this work and to shut down the experimental programmes on that date. As this new strategy constitutes the cessation of the activities in the facilities, CEA sent the Minister responsible for Nuclear Safety a final shutdown notification in July 2016.

In September 2016, CEA asked for modification of certain prescriptions of the resolution of 30th October 2014 in order to perform a final series of experiments. On this occasion, ASN prescribed the transmission of the decommissioning file in July 2018.

Irradiation reactors

The Osiris reactor and its ISIS critical mock-up (Saclay)

The Osiris pool-type reactor (BNI 40) has an authorised power of 70 megawatts thermal (MWth). It was primarily intended for technological irradiation of structural materials and fuels for various power reactor technologies. It was also used for a number of industrial applications, in particular for the production of radionuclides for medical purposes. Its critical mock-up, the ISIS reactor, with a power of 700 kWth, is essentially used for training purposes today. These two reactors were authorised by a Decree dated 8th June 1965.

Given the old design of this facility by comparison with the best available techniques for protection against external hazards and for containment of materials in the event of an accident, the Osiris reactor was shut down at the end of 2015.

Pending its decommissioning authorisation, Operations to remove radioactive and dangerous materials and to Prepare for Decommissioning (OPDEM) began with an organisation that was appropriate to the status of the reactor. The programme of these OPDEM, presented by the licensee in 2015, was revised in 2016 at the request of ASN (see box below).

The inspections show that the facility is operated in conditions which must be more rigorous on certain optics (internal authorisation, management of fire loads, monitoring of fire sectoring conformity in particular). The main cause of the significant events is organisational failures, notably in communication between entities and in the assessment of the regulatory framework. More specifically, at the end of 2015, the storage within the BNI perimeter of high level sources intended for another facility led to the notification of a level 1 significant event in 2016.

In 2017, ASN will be vigilant with respect to licensee management of OPDEM and the baseline requirements, to the evaluation of the regulatory framework for the performance of new operations and to the information provided by the licensee. ASN notes that the deadline for submission of the decommissioning file, initially set at the end of 2016, has been pushed back by CEA to March 2019. The acceptability of this new deadline, which is late given the reactor shutdown date, is currently being examined by ASN.

FOCUS

Shutdown of the Osiris reactor (Saclay) and the beginning of decommissioning preparation operations

CEA finally shut the reactor down in December 2015. The Operations in Preparation for Decommissioning (OPDEM) began in 2016, more specifically with the beginning of removal of radioactive or dangerous materials present in the facility and the disassembly and removal of certain equipment. These operations must be continued within the framework of the baseline safety requirements authorised for operation of the facility and most of them will be covered by the CEA internal authorisations process. Some operations, linked to very limited actions involving irreversible disassembly of equipment items or the commissioning of new equipment for which additional justifications are required, will entail authorisation by ASN. The initial programme envisaged by CEA had to be modified because ASN considers that certain operations, more specifically linked to the disassembly of equipment contributing to the operation of the reactor and which are irreversible and of large scale, must be excluded from it and be a part of the decommissioning process.

Jules Horowitz Reactor (RJH) (Cadarache)

With the support of several partners from other countries, CEA is building a new facility to create a new research reactor. The RJH (BNI 172) will be able to carry out research activities, in particular to study the ageing of materials subjected to irradiation (activity similar to that of the Osiris reactor). It will also allow the production of artificial radionuclides intended for nuclear medicine. The RJH reactor represents significant developments concerning both the experiments it will be able to accommodate and safety.

The construction work on the facility, which began in 2009, continued in 2016. In 2016, CEA announced that it would be applying for a modification to the Creation Authorisation Decree, which currently makes provision for commissioning in 2019, to take account of the significant delays in the construction site. The civil engineering work on the reactor building was completed with pre-stressing of the building. The operations involved in lining the reactor cavity continued with the installation of the anchors and the beginning of welding of the stainless steel plates. The two safeguard buildings have been completed. Finally, the manufacture of reactor core elements is well-advanced and the assembly of these parts is in progress.

The inspections in 2016 mainly concerned the lining of the reactor cavity and the organisation of the construction site (notably monitoring of outside contractors), with regard to both procedures and follow-up of anomalies. ASN considers that CEA is sufficiently rigorous with respect to the risks and detrimental effects of the project.

ASN is also continuing to examine the applications submitted following the assessment of the preliminary safety report and in preparation for the review of the future commissioning authorisation application.

Neutron source reactors

Orphée reactor (Saclay)

The Orphée reactor (BNI 101) is a pool-type research reactor with an authorised power of 14 MWth, using heavy water as the moderator. It was authorised by the Decree of 8th March 1978 and its first divergence dates from 1980. It is equipped with nine horizontal channels, tangential to the core, enabling nineteen neutron beams to be used. These beams are used to conduct experiments in fields such as physics, biology and physical chemistry. The reactor also has ten vertical channels for the introduction of samples to be irradiated in order to produce radioisotopes or special materials and to carry out analysis by activation. The neutron radiography installation is used for non-destructive testing of certain components.

ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory.

Radiation protection provisions are well applied on the facility. The modifications internal authorisation process would appear to be well-managed. Attention is however required with regard to the appropriate requalification of the equipment after modification.

Finally, during an inspection, ASN found that most of the commitments and requests resulting from the last periodic safety review in 2009 had been cleared. A few particular technical justifications are still to be produced. In 2016, the licensee stated that it would not be carrying out some of the analyses to which it was committed, given the shutdown of the facility before 2020. ASN considers this approach to be acceptable provided that, in accordance with the regulations, CEA notifies the facility shutdown date.

Test reactors

Cabri reactor (Cadarache)

The Cabri reactor (BNI 24), created on 27th May 1964, is used for experimental programmes aimed at better understanding nuclear fuel behaviour in the event of a reactivity accident. The reactor is operated by CEA. Modifications to the facility were authorised in a Decree of 20th March 2006, in order to run new research programmes. The reactor's sodium loop was replaced by a water loop in order to study the behaviour of high burn-up fraction fuels in pressurised water reactor reactivity insertion accident situations.

2015 was marked by the first criticality of the modified reactor, authorised for start-up tests by ASN on 13th October 2015. 2016 was devoted to familiarisation with the renovated reactor by the operating teams and preparation for the research programme tests.

As in 2015, reactor operations led to emergency outages mainly due to the manual control by the shift crews on training duty and to the adjustment of certain systems. CEA continued the tests and more particularly verified the correct general operation and power increase of the reactor. It also carried out pressurised water loop equipment tests necessary for the research programme tests.

The inspections carried out by ASN in 2016 concerned equipment qualification, management of deviations and experience feedback; they did not reveal any deviation liable to compromise the continuation of the tests. In 2016, ASN issued a call for bids to select an expert other than IRSN, for examination of the start-up tests summary report in 2017.

In December 2015, CEA also presented its orientation file for the periodic safety review of the facility, for which the file should be submitted in November 2017. In 2016, ASN examined this file and informed CEA of its requests and observations to be incorporated into the periodic safety review.

Phébus reactor (Cadarache)

The Phébus reactor (BNI 92), the creation of which was authorised by the Decree of 5th July 1977, enabled tests to be performed concerning the severe accidents that could affect pressurised water reactors. It was finally shut down in 2010 following the "fission products" experimentation programme which started in 1988. CEA informed ASN in 2013 that it intended to shut down this BNI once and for all and in 2014 transmitted an updated file presenting the decommissioning preparation operations and the decommissioning plan. In 2015, CEA was authorised to begin the first operations to prepare for decommissioning, in this case the disassembly of cooling equipment outside the reactor building.

During the course of 2016, CEA also began to remove radioactive substances from its facility, along with effluents produced during the experiments. In accordance with the new regulatory requirements introduced by the Energy Transition for Green Growth Act 2015-992 of 17th August 2015 and with the licensee's undertakings, ASN expects the facility decommissioning file no later than in 2017. This file will be examined at the same time as the periodic safety review of the facility. During the course of 2016, the licensee thus added to its decommissioning plan and its review orientation file, in particular with regard to the management of radioactive substances.

Teaching reactor

ISIS reactor (Saclay)

With Osiris, this is one of the two reactors in BNI 40 (see Osiris reactor, page 457). ASN authorised the operation of this mock-up until 2019.

1.2.3 Laboratories

The irradiated materials and spent fuel assessment laboratories

These laboratories are investigative tools available to the nuclear licensees. From the safety viewpoint, these installations must meet the same standards and rules as the fuel cycle nuclear installations, but the safety approach also has to be proportionate to the specific risks presented.

Active Fuel Examination Laboratory (LECA) (Cadarache)

The LECA (BNI 55) was commissioned in 1964 and is a laboratory for both destructive and non-destructive examination of spent fuels from various nuclear power generating or experimental reactor series, and irradiated structures or instruments from these series. It is an ageing facility whose seismic resistance was partially reinforced beginning in 2010.

In 2014, CEA transmitted the file presenting the conclusions of the periodic safety review for the installation which it wishes to continue to operate on a long-term basis.

An in-depth examination was then initiated to assess whether the envisaged seismic reinforcements of the civil engineering structures were sufficient. It was presented to the Advisory Committee which met on 12th July 2016: this considered that the reinforcement measures proposed by CEA did not demonstrate the stability of the main building with regard to current seismic requirements and that the LECA should be shut down as rapidly as possible. ASN will issue a resolution on the continued operation of the facility in 2017.

In 2016, ASN carried out its first in-depth inspection of the LECA, which more particularly shows that CEA must revise the national process implemented for performance of the reviews.

The LECA extension Treatment, Clean-out and Reconditioning Station (STAR) (Cadarache)

The STAR facility (BNI 55) is a high-activity laboratory comprising shielded cells. It was designed for the stabilisation and reconditioning of irradiated fuel rods surplus to requirements with a view to storing them in the Cascad facility (see chapter 16). It also carries out destructive and non-destructive examinations on irradiated fuels. Its creation was authorised by the Decree of 4th September 1989 and its definitive commissioning was declared in 1999.

ASN regularly checks CEA's compliance with the commitments made after the periodic safety review completed in June 2009. Following this review, CEA in particular made a commitment to a project for redevelopment and for installation of new equipment, in particular for handling purposes. In May 2014 ASN prescribed the operating procedures associated with this project. CEA's delays led ASN to serve it with formal notice to finalise the STEP project before 30th April 2017; ASN will be vigilant regarding completion of the works within the prescribed time-frame.

Laboratory for Research and Experimental Fabrication of Advanced Nuclear Fuels (Lefca) (Cadarache)

The Lefca (BNI 123), commissioned in 1983, is a laboratory in charge of conducting studies on plutonium, uranium, actinides and their compounds in a variety of forms (alloys, ceramics, composites, metal, etc.) with a view to their applications in nuclear reactors. The Lefca carries out studies aimed at understanding the behaviour of these materials in the reactor and at various stages in the fuel cycle. It also produces devices for experimental irradiation designed to test the behaviour of these materials, as well as carrying out stabilisation and reconditioning of uranium and plutonium bearing materials.

In 2016, ASN completed the examination of the periodic safety review report for the facility, transmitted in December 2013. ASN will rule in 2017 on the continued operation of the facility. The first part of this examination took place in a specific context: in 2014, CEA announced that it would be transferring the Lefca R&D activities in 2017 to the Atalante facility and finally shutting it down by 2020.

Elsewhere, following a previous review, ASN issued a prescription for CEA on 29th June 2010 requiring it to ensure that a groundwater drainage system was operational before 30th September 2015 in order to prevent the risk of soil liquefaction in the event of an earthquake. Owing to the late transmission of the file in July 2015, CEA did not at first correctly assess the environmental impact of the system and commissioning could not be carried out within the allotted time. During an inspection, ASN nonetheless verified that it was technically ready and postponed commissioning to the end of 2017 without initiating any sanctions or enforcement measures.

With regard to the Lefca packaging activity, the acceptability of new materials is currently being examined by ASN. The use of the "pins" store for storage of new materials is also being investigated.

FUNDAMENTALS

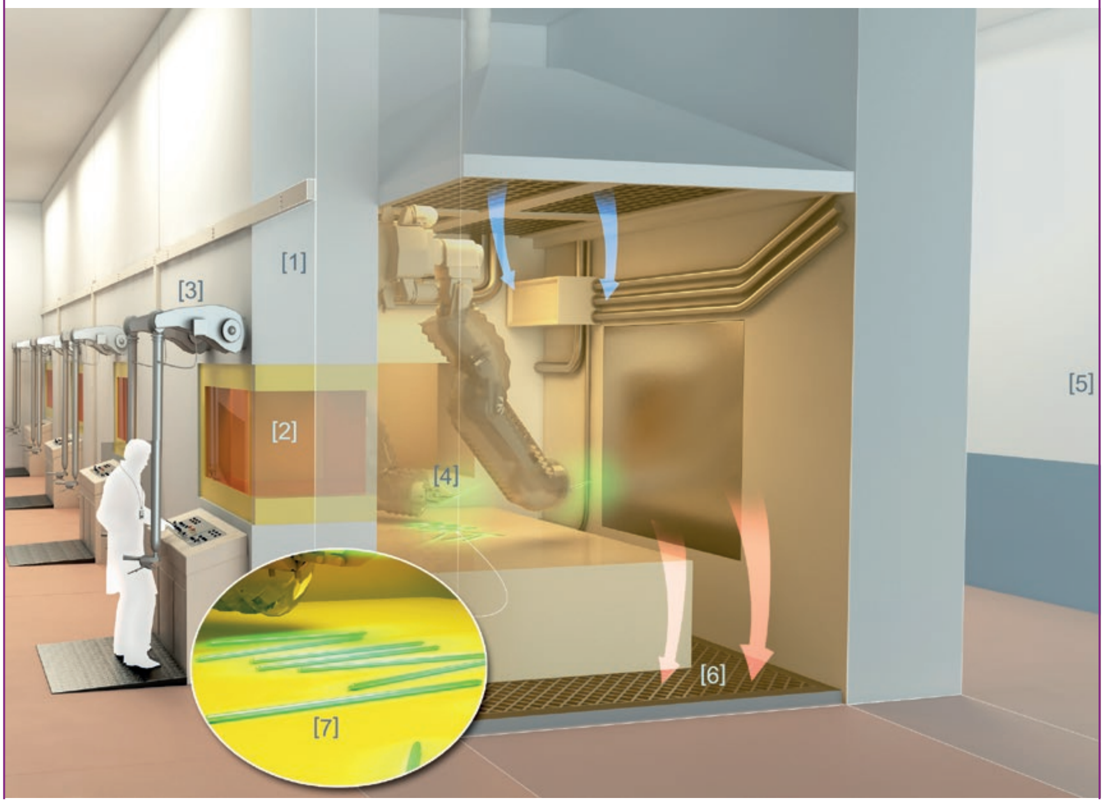
LECI, risks and prevention system of a hot laboratory

The main role of the LECI is assessment of irradiated materials from various nuclear facilities, research reactors in particular. The irradiated materials being assessed are handled by articulated arms in shielded cells.

The main safety issues for the facility are to limit exposure to ionising radiation, to contain the radioactive substances and to manage the criticality risk.

To limit these risks, constructive or organisational measures are implemented by CEA and regularly revised, more specifically during the periodic reviews. Following the last periodic review, ASN supplemented and on 30th November 2016 prescribed the most important deadlines of the plan envisaged by CEA to improve these provisions.

In principle, in a laboratory such as the LECI:
- Exposure to radiation is limited by the thickness of the walls [1] and windows [2] of the shielded cells in which the handling operations are carried out. The walls comprise a stainless steel box with lead plates. The personnel uses remote-manipulator arms [3] to handle the materials [4] in the cell. A Rear Zone (ZAR) [5] common to the shielded lines is used to transfer samples between shielded cells. This ZAR is also where packagings of radioactive substances are stored pending shipment.
- Containment of radioactive materials is guaranteed:
  - dynamically: each cell is equipped with extraction fans and extraction ducts [6], themselves fitted with filters,
  - statically by the walls of the shielded cells [1].
- Subcriticality is controlled by organisational measures:
  - materials management (accounting of the mass of fissile materials and hydrogenated materials liable to trigger a chain reaction) in each working unit,
  - fissile material packagings, which must be grouped according to a certain geometry [7].



Spent Fuel Testing Laboratory (LECI) (Saclay)

The LECI (BNI 50) was notified by CEA on 8th January 1968. An extension was authorised by decree in 2000. The role of the LECI is to study the properties of nuclear materials, whether or not irradiated. The LECI also has a role to provide support for the delicensing of the Saclay Centre.

ASN considers that the level of safety of the facility is satisfactory. ASN identifies two positive points in the inspections carried out in 2016: rigorous monitoring of commitments and the good upkeep of the facility. However, progress is required in the notification of significant events.

This facility also accommodates a shielded cell (Célimène) which has not been used since 1993. The examination of the periodic safety review, which began in December 2013, was on the whole satisfactory and gave rise to an improvement action plan that CEA has undertaken to implement. On 30th November 2016, ASN prescribed the most important aspects of this action plan, more particularly the reinforcement of the seismic resistance of building 625 and the decommissioning of the Célimène cell before 2025.

Research and development laboratories

Alpha facility and Laboratory for Transuranian Elements Analysis and Reprocessing Studies (Atalante) (Marcoule)

The main purpose of the Atalante facility (BNI 148), created in the 1980s, is to conduct research and development on the recycling of nuclear fuels, the management of ultimate waste and the exploration of new concepts for fourth generation nuclear systems.

In 2016, the safety level in Atalante was on the whole stable by comparison with the previous years. Given the variety and the numerous changes in the activities carried out in the facility, this level of safety is to a large extent based on operation in conformity with the baseline requirements. The inspections carried out in 2016 by ASN revealed insufficient handling of nonconformities with respect to integration of operating experience feedback: as the management of deviations is an activity important for protection, ASN asked for more rigorous identification of the defined requirements and corresponding technical checks. Several significant events affecting the containment safety function also took place this year.

The commissioning authorisation application for laboratories LN0 and L26 at Atalante as part of the TARRA project to transfer fuel R&D activities from Cadarache (Lefca) to Marcoule, transmitted in December 2015, is in the final review phase. The periodic safety review conclusions report transmitted at the end of 2016 will be examined by ASN in 2017.

1.2.4 Fissile material stores

Central Fissile Material Warehouse (MCMF) (Cadarache)

Built in the 1960s, the MCMF (BNI 53) is a storage warehouse for enriched uranium and plutonium. The main activities in the MCMF are reception, storage and shipment of non-irradiated fissile materials pending reprocessing, whether intended for use in the fuel cycle or temporarily without any specific purpose.

Given the inadequate seismic design of the facility, ASN asked CEA to remove the nuclear materials stored in it before 31st December 2017, the date on which the facility will be finally shut down. The notification of final shutdown was transmitted to the Minister responsible for Nuclear Safety and to ASN on 31st October 2016, accompanied by the facility's decommissioning plan. During its examination of this notification, ASN more particularly envisages setting the deadline for transmission of the decommissioning file.

In 2016, ASN forwarded an opinion on the orientation file of the periodic safety review for which the conclusions report should be transmitted to ASN and to the Minister responsible for Nuclear Safety in 2017. ASN notably formulated several requests concerning this review file and that for decommissioning of the facility.

The commissioning of the Magenta facility in 2011 meant that removal of materials from MCMF could continue. Removal from storage operations continued in 2016 within time-frames compatible with the ASN request and in compliance with CEA's major undertakings with regard to nuclear safety and radiation protection.

Magenta facility (Cadarache)

The Magenta facility (BNI 169), which replaces the MCMF, is dedicated to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received. Its creation was authorised in 2008 and its commissioning on 27th January 2011. The increase in activities in the facility, owing to the transfer of storage from Masurca, the MCMF, and ÉOLE-Minerve to Magenta, is taking place with a satisfactory level of safety, with the organisation of operations being efficient in the light of the current risks.

In 2016, CEA transmitted the updated safety analysis report which takes account of the requests expressed by ASN concerning alignment of the baseline safety requirements with the actual status of the facility. CEA should not in effect anticipate the authorisation to commission the glove boxes, for which it has not yet submitted an application to ASN.

FUNDAMENTALS

Poséidon, irradiator risks and prevention system

BNI 77 (Poséidon) is a "γ" irradiator. It is used to irradiate materials/components using very high level sealed sources of cobalt-60, with leaktight double envelope. These irradiations are used for studies and for qualification services for nuclear reactors, as well as for sterilisation for medical purposes.

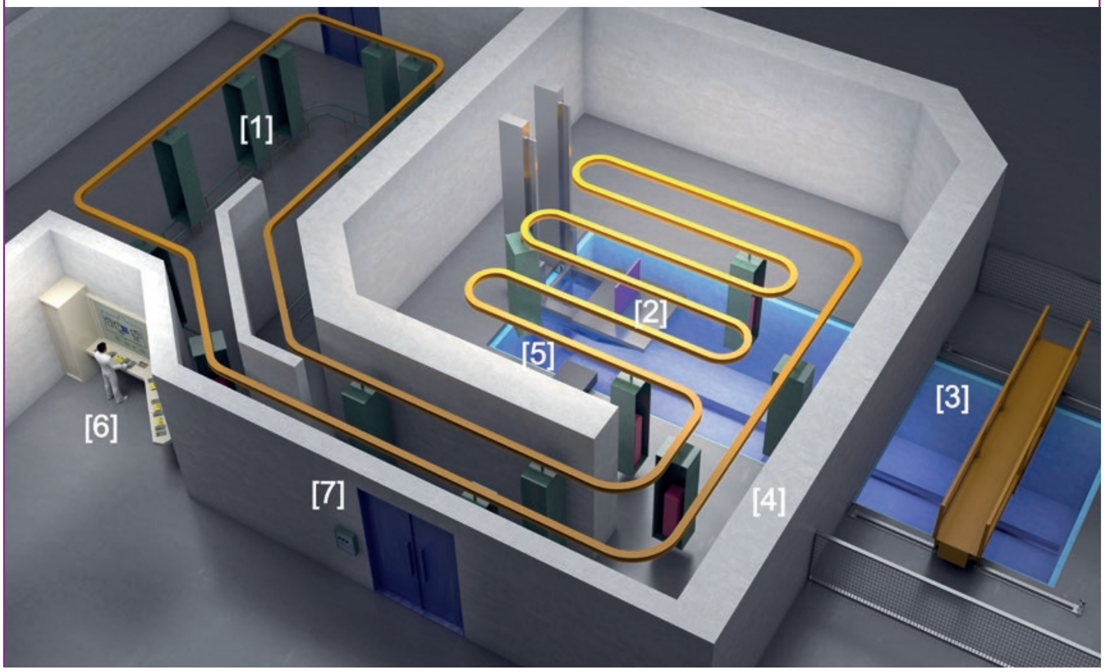
Conveyors [1] bring the materials/components into the pool. The sources are on a source-holder [2] at the bottom of the pool. This source-holder comes out of the pool to irradiate them. It is lowered again once the experiment is completed.

The main safety issues for the facility are to contain the radioactive substances, primarily by means of the double envelope of the cobalt-60 sources and to limit exposure to ionising radiation.

To limit these risks, constructive or organisational measures are implemented by CEA and regularly revised, more specifically during the periodic reviews. Following the last periodic safety review, ASN will supplement and in 2017 will prescribe the most important deadlines of the plan envisaged by CEA to improve these provisions.

The exposure to ionising radiation is limited by the radiological protections that are the height of water in the pool [3] and the thickness of the concrete walls of the bunker when the sources are taken from the pool [4]. The level of water in the pool is regularly checked [5]. No operator may enter the bunker when the sources are outside the pool. Access to the bunker is controlled by an access control system [7]. The installation is controlled from the control room [6] to which the information is relayed.

In addition, the irradiation of the air when the sources are out of the pool generates ozone. To limit the concentration of this gas, ventilation is installed above the area.



1.2.5 The Poséidon irradiator

The Poséidon facility (BNI 77) at Saclay, created by the Decree of 7th August 1972, is an irradiator consisting of a cobalt-60 source storage pool, partially topped by an irradiation bunker. The facility also features a submersible chamber and a test cell. R&D into the behaviour of materials under radiation is carried out in Poséidon. The main risk in the facility is that of exposure to ionising radiation owing to the presence of very high level sealed sources.

The facility was not inspected by ASN in 2016.

The examination of the periodic safety review, for which the complete file had been transmitted in 2013, continued in parallel with that of the stress tests. Following this review, CEA undertook to make modifications to the facility concerning the elimination of the common mode in the cabled lines and bunker access control. The safety files for these two changes are currently being reviewed by ASN. In 2017, ASN will prescribe the conditions for continued operation, more specifically with regard to the monitoring of structure ageing and the seismic reinforcement of certain elements.

Replacement of the very high level sources in Poséidon will continue until November 2017.

1.2.6 Waste and effluent storage and treatment facilities

The CEA waste and effluent storage and treatment facilities are addressed in chapter 16.

1.2.7 Installations undergoing decommissioning

The CEA facilities undergoing decommissioning, as well as the CEA decommissioning strategy, are covered in chapter 15.

1.3 Planned facilities

The purpose of the Astrid project (Advanced Sodium Technological Reactor for Industrial Demonstration), currently at the design phase, is to build a technology demonstrator for a possible Generation IV electricity generating reactor. This project is supported by CEA, in association with EDF and Areva. Astrid is a sodium-cooled fast neutron reactor, one of the six reactor technologies being studied for the Generation IV reactors. The first orientations envisaged for the design of Astrid were presented in a Safety Guidelines Document (DOrS) which was submitted to ASN in 2012 in advance of the regulatory procedures. Concerning this DOrS, in a letter in April 2014, ASN informed CEA of the demonstrations that would need to be provided in the next stage of the procedure, so that it could issue a position statement on the safety of the Astrid project. For ASN, this reactor must offer a level of safety at least equivalent to that of the EPR type reactors, incorporate the improvements resulting from the lessons learned from the Fukushima Daiichi accident and, as a prototype of a fourth generation plant series designed to provide significant safety gains, enable reinforced safety options and measures to be prepared and tested.

In the end, CEA did not submit the safety options file as initially planned at the end of 2015.

1.4 ASN's general assessment of CEA actions

The results of 2016 and ASN's assessment of each facility are detailed per region in chapter 8, in chapter 15 for the facilities being decommissioned and in chapter 16 for the waste processing and storage facilities.

ASN underlines the fact that the performance of numerous safety reviews associated with the preparation of the decommissioning files represents a major safety challenge, which will require significant resources on the part of CEA, in particular in the light of changes to the regulations. ASN will also be vigilant with regard to the actual initiation of the decommissioning operations on the facilities finally shutdown, in accordance with French regulations. In 2017 it will examine the updated decommissioning, post-operational clean-out and waste and materials management strategy at CEA.

ASN considers that the level of safety in the facilities operated by CEA is on the whole satisfactory, in particular the operation of its experimental reactors. ASN does however find that several CEA projects with an impact on safety have slipped and considers that CEA must reinforce its surveillance and its oversight of outside contractors in a context of large-scale subcontracting.

2. Non-CEA nuclear research installations

2.1 Large National Heavy Ion Accelerator

The Ganil (National Large Heavy Ion Accelerator) economic interest group was authorised by the Decree of 29th December 1980 to create an accelerator in Caen (BNI 113). This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. The intense, high-energy beams produce strong fields of ionising radiation, activating the materials in contact, which then emit radiation even after the beams have stopped. Irradiation thus constitutes the main risk at the Ganil.

In order to be able to produce exotic nuclei[1], the Ganil was authorised in 2012 to build phase 1 of the Spiral 2 project. ASN issued a partial commissioning license for phase 1 of this project on 30th October 2014. It continued to examine the phase 1 commissioning application for the Spiral 2 project submitted in

1. *The "exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in the Ganil for nuclear physics experiments on the origins and structure of matter.*

October 2013 and for which the final additions requested during the examination were produced at the end of May 2016.

Having observed delays in the implementation of several of the prescriptions of the 2015 resolution concerning the continued operation of the facility, ASN served the Ganil with formal notice to comply. In September 2016, it was informed of non-compliance with several prescriptions regarding the monitoring of discharges and the environment. In 2017, ASN will ensure compliance with these prescriptions. It considers that the resources engaged by the Ganil to meet the prescriptions or its commitments are not sufficient.

During an inspection carried out in 2016, ASN noted shortcomings in the organisation devoted to compliance with the commitments made by the licensee. Since then, the licensee states that it has corrected the deviations observed during the inspection and that it has strengthened its organisation to prevent them happening again. ASN considers that the deadlines for its prescriptions and the licensee commitments should be more closely followed.

In 2016, the Ganil modified its organisation by incorporating the resources of the Spiral 2 project and by continuing with a group dedicated to nuclear safety studies for ongoing and future projects. ASN will be attentive to the resources that the Ganil devotes to nuclear safety.

2.2 The High Flux Reactor (RHF) at the Laue-Langevin Institute

The RHF (BNI 67) in Grenoble, operated by the ILL, provides neutrons used for experiments in the fields of physics and biology. This reactor was authorised by the Decree of 19th June 1969, modified by the Decree of 5th December 1994, and has a maximum power of 58.3 MWth, operating continuously in 50-day cycles. The reactor core is cooled by heavy water contained in a reflective tank, which is itself immersed in a light water pool.

The RHF high-flux reactor, PCS3 walkway.

ASN considers that those technical aspects of RHF safety identified by ILL as priorities are managed satisfactorily. Therefore, within the context of lessons learned from the Fukushima Daiichi experience, ILL proposed an ambitious time-frame for the implementation of major reinforcements, which proceeded satisfactorily in 2016. In its resolution of 20th November 2016, ASN agreed to postpone the date for implementation of the final reinforcement, that is start-up of a groundwater circuit, now expected in 2017. This system would be able to cool the reactor from the groundwater aquifer in the event of the systems supplied by the Drac river being lost.

ASN has directed ILL to reinforce its organisation with respect to the requirements of the regulations. ASN observed that the licensee's current organisation does not enable it to meet all the regulatory requirements of the Order of 7th February 2012 concerning the management of deviations, detection of events and the Integrated Management System (IMS). ILL therefore submitted a modification of the organisation of its "safety" sector, authorised by ASN in 2016 (resolution of 5th September 2016). In order to implement this new organisation and given the forthcoming periodic safety review, ILL reinforced its safety team. ASN will be vigilant with respect to the implementation of this IMS in 2017, in accordance with ILL's commitments.

ASN has also directed ILL to analyse and make greater use of experience feedback to improve its organisation and its practices, in particular on the basis of notified significant events, observations and requests expressed by ASN following inspections, or on the occasion of the annual safety, environment and radiation protection reports. Moreover, two significant events concerning the failure to completely perform periodic tests in 2016 showed that greater anticipation is required on the part of the licensee concerning the re-running of tests which could not be performed in full.

With regard to radiation protection management, ASN noted that the licensee is correctly aware of the radiological implications of its facility and that, as indicated by the dosimetric reports, it satisfactorily optimises the doses received by the personnel.

Finally, the ILL must in 2017 send ASN the ten-yearly safety review file for the facility. Following its examination, ASN will issue a ruling on the continued operation of the facility.

2.3 European Organization for Nuclear Research (CERN) installations

The European Organization for Nuclear Research (CERN) is an international organisation whose role is to carry out purely scientific and fundamental research programmes concerning high energy particles. A tripartite agreement signed by France, Switzerland and CERN came into effect on 16th September 2011. The oversight of nuclear safety and radiation protection was previously managed through bilateral agreements.

In February 2016, a joint "Environmental monitoring" visit in accordance with the tripartite agreement of 16th September 2011 was held. During the visit to the measurement facilities, the representatives of ASN and the OFSP observed that the various topics were dealt with well. However, several requests were sent to CERN for additional information following this visit with regard to the quarterly reports, the performance of the radioactive substances sampling systems, the measurements of tritium emissions and the description of the maintenance and quality control operations performed per type of measurement station on the monitoring network.

In June 2016, the CERN presented the progress of the safety study for the future CERN-Medicis facility.

2.4 The ITER project

ITER (BNI 174) is an experimental installation, the purpose of which is scientific and technical demonstration of controlled thermonuclear fusion energy obtained with magnetic confinement of a deuterium-tritium plasma, during long-duration experiments with a significant power level (500 MWe for 400 s). This international project enjoys financial support from China, South Korea, India, Japan, Russia, the European Union and the United States, who make in-kind contributions by providing equipment for the project via the domestic agencies. The headquarters agreement between ITER and the French State was signed on 7th November 2007 and the creation of the BNI was authorised by Decree 2012-1248 of 9th November 2012. The resolution of 12th November 2013 sets prescriptions more specifically concerning the design and construction of the facility, in order to implement and supplement the requirements already defined by the authorisation decree.

2016 is marked in particular by the restructuring of the ITER organisation, with the appointment of a new director general in 2015 and the creation of project teams incorporating the domestic agencies. Following the considerable delays that have built up in recent years, ITER established a new design and construction schedule. The new ITER organisation which incorporates members of the domestic agencies into its teams, in particular those in charge of the civil engineering contracts, aims to improve the transmission and adoption of safety requirements by outside contractors.

The construction work on the facility continued in 2016, more specifically with the construction of the slab and the walls of level B1 (1st basement) of the tokamak complex, the end of construction of the assembly hall - with overhead cranes soon to be installed - and progress in the work to construct the other buildings and utilities. The manufacture and procurement of the equipment for the facility, more specifically for the vacuum chamber, the cryostat, the superconductor coils, the water detritiation system or the components of the cooling systems, have also progressed.

The five inspections carried out during the course of 2016 mainly concerned the monitoring of outside contractors, monitoring of design/construction and verification and handling of nonconformities. Despite the new organisation, ASN identified the persistence of difficulties experienced by ITER in monitoring the actual progress of the handling of deviations in its subcontracting chain. ASN recalled the licensee's responsibility with regard to the domestic agencies, in particular concerning compliance with the defined requirements. Given the shortcomings identified, ASN also asked for reinforced monitoring by the licensee of certain work packages under the responsibility of the European domestic agency, F4E.

In 2016, ASN authorised the lifting of a hold point for construction of the neutral beam injectors cell. ASN considers that the justifications and demonstrations required were provided, including for the two different designs envisaged for the vacuum chamber discharge line. Nonetheless, this authorisation in no away anticipates any ASN consent regarding a change to the design of the vacuum chamber discharge line, which should be the subject of a request from ITER in accordance with the relevant procedures. The examination of this hold point also leads to requests for additional information from ASN concerning the risks of contamination transfer between the interior of the vacuum chamber and the neutral beams injectors cell, which ITER will be required to address before commissioning of the facility.

In 2017, examination of the provisions concerning the electrical and I&C power supplies will continue, as well as with regard to the answers provided concerning the equipment of the tokamak vacuum chamber. ASN will be particularly vigilant concerning the quality of the demonstrations and justifications produced, in particular as part of the ongoing revision of the forecast schedule.

3. The other nuclear installations

3.1 Industrial ionisation installations

Irradiators sterilise medical devices, foodstuffs, pharmaceutical raw materials, etc., by irradiating them with gamma rays emitted from sealed cobalt-60 sources. The irradiation cells are made from reinforced concrete, designed to protect the environment. The sealed sources are either placed in the lowered position, stored in a pool under a layer of water which protects the workers in the cell, or are placed in the raised position to irradiate the items to be sterilised. The main risk in these facilities is irradiation of the personnel.

The Ionisos Group operates three industrial ionisation facilities located in Dagneux (BNI 68), Pouzauges (BNI 146) and Sablé-sur-Sarthe (BNI 154). ASN considers that the licensee must continue its efforts to detect deviations and ensure compliance with the deadlines set for the handover of files or requests for additional data. The three periodic safety reviews for the Ionisos facilities must be carried out no later than November 2017 and the licensee must also submit a stress tests report by this same deadline. The file for the first periodic safety review concerning the Sablé-sur-Sarthe facility was transmitted on 30th June 2015. This file is currently being examined by ASN and was the subject of a specific inspection at the end of 2016. Several change requests were submitted for these facilities. Examination of the files by ASN is in progress.

Synergy Health operates the Gammaster (BNI 147) irradiator in Marseille and Gammatec (BNI 170) on the Marcoule site. ASN considers that the level of safety and radiation protection in these installations is satisfactory. Improvements could however still be made in terms of radiation protection and the results of internal inspections must be written up in a more clearly defined format. ASN also considers that the licensee must continue its efforts to assimilate the regulations, particularly in the context of the Marcoule platform. Finally, ASN considers that the licensee must maintain sufficient human resources for operation of its facilities.

ASN inspection on the topic of fire in the CIS bio international artificial radionuclides production plant, February 2016.

3.2 The radio-pharmaceutical production facility operated by CIS bio international

CIS bio international is a key player on the French market for radiopharmaceutical products used for both diagnosis and therapy. Most of these radionuclides are produced in BNI 29 (UPRA) at Saclay. This facility also recovers used sealed sources which had been used for radiotherapy and for industrial irradiation. By Decree 2008-1320 of 15th December 2008, CIS bio international was authorised to succeed CEA as operator of BNI 29.

Despite the efforts made by CIS bio international to reinforce its integrated management system and human resources and despite a few improvements noted, ASN considers that these reinforcements remain insufficient for ensuring that lasting, tangible results are obtained. Operating rigour, the oversight and conformity of operations, the cross-functional nature of the organisation, compliance with the facility's baseline requirements, with resolutions and with the regulations, for implementation of modifications, must be reinforced.

Owing to the large number of undertakings made by CIS bio international following the review, but not complied with, ASN stipulated completion deadlines for them in February 2016. In 2016, ASN applied administrative enforcement measures for non-compliance with a prescription regarding the removal of radioactive materials.

Following an unannounced inspection in February 2016, ASN served CIS bio international with formal notice to comply with several requirements concerning control of the fire risk. CIS bio international complied with this formal notice. Finally, the performance of the fire reinforcement work is described in the box opposite.

The examination of the stress tests file submitted by CIS bio international will lead to oversight by ASN of emergency management in the event of an extreme situation in 2017.

BNI 29 should undergo a periodic safety review in 2017, for which a conclusions report shall be submitted no later than 31st July 2018. In preparation for this review, the licensee sent ASN an orientation file. ASN will be attentive to CIS bio international's compliance with the regulations, prescriptions and its commitments, to operating safety improvements and to the progress of the ongoing work.

3.3 Maintenance facilities

Two BNIs operated by Areva and EDF are devoted to nuclear maintenance activities in France.

FOCUS

Performance of fire work at CIS bio international

Following the periodic safety review of UPRA, ASN made continued operation of this facility dependent on the implementation of a fire risk management system in several fire sectors within the plant. This is essential, as the fire risk is the main risk identified in this facility.

As these prescriptions were not met, ASN served CIS bio international with formal notice to conform on 6th May 2014, in accordance with a schedule that is proportionate to the issues.

During inspections performed at each deadline in the formal notice, the ASN inspectors observed that the system prescribed had not been implemented in certain fire sectors.

Accordingly, on 3rd March 2015, ASN took measures to ensure that the UPRA licensee is obliged to deposit a bond with the public treasury corresponding to the value of the work to be performed for compliance with the ASN prescriptions.

The CIS bio international company appealed the formal notice and bond resolutions before the Council of State. By an Order of 11th May 2016, the Council of State rejected the appeals, considering in particular *"that these deadlines were justified by the safety concerns of the facility and the radiological consequences and took account of the nature of the work requested."*

During an inspection on 22nd May 2016, the ASN inspectors observed that a system complying with the ASN prescriptions had been implemented. CIS bio international also demonstrated that this system was operational, notably by an exercise involving actual triggering of the extinguishers.

In the light of the elements transmitted by CIS bio international and the findings of its inspectors, ASN concluded that its prescriptions had been met. It thus lifted the bond deposit measure resulting from its resolution of 3rd March 2015 in a resolution dated 19th July 2016.

The facility of the *Société de maintenance nucléaire* (Somanu) in Maubeuge

Authorised by the Decree of 18th October 1985, BNI 143, a subsidiary of Areva, specialises in the maintenance and appraisal of equipment coming from the primary cooling systems of EDF reactors.

ASN considers that even if the operation of the facility and the transparency of exchanges are on the whole satisfactory, the process to produce safety case studies in the facility is a laborious one. The licensee must therefore reorganise in order to better address ASN's requests and the commitments it has made, more specifically with respect to its periodic safety review filed at the end of 2011 and must reinforce corrective measures concerning compliance with the provisions of the BNI Order of 7th February 2012.

The examination of the applications for changes to the Creation Authorisation Decree and the water intake and effluent discharge resolutions has been suspended pending additional information from Somanu, for which ASN observes a significant delay.

The Clean-out and Uranium Recovery Facility (IARU) in Bollène

The activities of BNI 138, operated by Socatri, a subsidiary of Areva, can be divided into four sectors:
- repair and decontamination of equipment used in nuclear facilities (dismantling/reassembly, decontamination, mechanical work, maintenance for disposal or refurbishment);
- prior to discharge into the natural environment, treatment of radioactive and industrial liquid effluents from its activities and from the other facilities on the Tricastin platform, *via* the STEU (uranium bearing effluents treatment for recovery in diuranate form) and STEF (final treatment with production of metal hydroxide sludges) stations;
- processing and packaging (sorting, crushing, compacting, disposal, etc.) of radioactive waste for disposal in approved routes, including waste from the small producers (hospitals and laboratories) on behalf of the national radioactive waste management agency (Andra);
- storage and transport.

Before removal to approved routes, Socatri also stores contaminated items in containers, along with vessel covers on behalf of the EDF Tricastin Operational Hot Unit (BCOT).

ASN considers that the level of operational safety in Socatri improved in 2016. The licensee set up effective action plans to ensure better compliance with its baseline criticality requirements and with the design requirements of the equipment important for protection.

The undertakings made by the licensee following the periodic safety review of the facility are being gradually implemented. ASN remains vigilant regarding the successive updates of the facility's baseline safety requirements (safety analysis report and general operating rules) linked to these undertakings. More generally, ASN observes that the additional means allocated by the licensee following the periodic safety review have proven to be beneficial.

2016 will however have been marked by deviations concerning maintenance. ASN more specifically requires that the licensee implement reinforced checks on the retention areas for the dangerous or polluting substances present in the BNI.

Finally, the examination of the significant change request for the BNI Creation Authorisation Decree, more specifically licensing the creation of the new waste treatment unit called Trident (integrated treatment of Tricastin nuclear waste) is entering its final phase. The public inquiry was held from 6th June to 5th August 2016 and the licensee's file received a favourable opinion from the board of inquiry. ASN is also examining the authorisation file for the beginning of construction work on the unit.

Tricastin Operational Hot Unit (BCOT) in Bollène

BNI 157, operated by EDF, was authorised by Decree on 29th November 1993. This facility, also situated in Bollène, is intended for maintenance and storage of equipment and tools from PWR reactors, except for fuel elements.

At the beginning of 2016, the BCOT completed its first campaign to cut up the used control rod guide tubes from the PWR reactors operated by EDF. The experience feedback from this first campaign was transmitted to ASN and the results are on the whole satisfactory. The second campaign was started in mid-2016 and should extend to the first quarter of 2017. With regard to the old reactor vessel heads, their shipment to Andra was completed at the end of 2015.

The periodic safety review of the facility, submitted by EDF in 2010, was completed in 2011 and 2013. Owing to the priority given to the post-Fukushima actions on the facilities with the most serious potential consequences, ASN suspended the examination of this review. The examination resumed in 2015. ASN will oversee continued operation of the BCOT in 2017.

Finally, ASN considers that the level of safety of the BCOT is on the whole satisfactory. However, 2016 will have been marked by deviations in certain maintenance operations, which will lead ASN to pay particular attention to compliance with the periodic checks and tests on the equipment in this facility in 2017.

3.4 Inter-regional Fuel Warehouses (MIR)

EDF has two inter-regional fuel warehouses, on the Bugey site in the Ain département (BNI 102) and at Chinon in the Indre-et-Loire département (BNI 99). These facilities were respectively authorised by the Decrees of 2nd March 1978 amended, and 15th June 1978 amended. EDF uses them to store new nuclear fuel assemblies (only those made of uranium oxide of natural origin) pending loading into the reactor.

The level of safety in the MIR was satisfactory in 2016. The robustness of the organisation must however be reinforced in order to improve the management of the periodic tests required by the general operating rules. In accordance with the conclusions of the stress tests carried out on the MIR by EDF, the facilities were modified with the installation of cofferdams designed to prevent water from entering the facility and thus improve management of the earthquake induced flooding risk. The safety review files and the stress tests transmitted in 2015 were supplemented on 30th June 2016 at the request of ASN, which is currently examining these files.

4. Outlook

A wide variety of research and other facilities are regulated by ASN. ASN will continue to oversee the safety and radiation protection of these installations as a whole and compare practices per type of installation in order to choose the best ones and thus encourage operating experience feedback. ASN will also continue to develop a proportionate approach to the risks and detrimental effects of the installations, as classified by the resolution of 29th September 2015.

Examination of the numerous periodic safety reviews (see box page 453) which will be submitted in 2017 and the ASN position regarding the continued operation of the facilities concerned is one of the challenges for the coming years.

Concerning CEA

ASN considers that the "major commitments" approach implemented by CEA since 2006 is on the whole satisfactory. It will be attentive to the implementation of these commitments.

Generally speaking, ASN will remain vigilant to ensuring compliance with the commitments made by CEA, both for its facilities in service and those being decommissioned. Similarly, ASN will remain vigilant to ensuring that CEA performs exhaustive periodic safety reviews of its facilities so that the examination can be conducted in satisfactory conditions and so that the safety of the facilities benefits from the necessary improvements.

ASN will be particularly attentive to compliance with the deadlines for transmission of the decommissioning files for CEA's old facilities which have been or will shortly be shut down (in particular Phébus, Osiris, MCMF, Pégase, ÉOLE-Minerve). The Rapsodie reactor, the situation of which is described in chapter 15, is also concerned, as are the following waste processing facilities (chapter 16): the storage BNI (BNI 56) in Cadarache, the effluent treatment station (BNI 37) in Cadarache, the solid radioactive waste management zone (BNI 72) in Saclay. The drafting of all these decommissioning files and then performance of these decommissioning operations represent a major challenge for CEA, for which it must make preparations as early as possible. Finally, ASN will monitor the preparation work for the decommissioning of the Osiris reactor shut down in 2015.

In 2017, ASN intends to:
- continue with surveillance of the operations on the RJH construction site and prepare for examination of the future commissioning authorisation application;
- begin examining the significant modification authorisation application for Masurca and examine the safety review file completed by CEA;
- complete its examination of the periodic safety review files for the LEFCA and LECA facilities and decide on the conditions for their possible continued operation.

Concerning the other licensees

ASN will continue to pay particularly close attention to projects under construction, that is ITER and commissioning of the Ganil extension.

ASN will continue to examine the periodic safety review files for Ionisos.

ASN will finalise the examination of complete commissioning of the "hardened safety core" on the RHF operated by the ILL, several years ahead of the other licensees.

Finally, in 2017, ASN will maintain its close surveillance of the radio-pharmaceuticals production plant operated by CIS bio international, with regard to the following points:
- increased operational rigour and safety culture;
- performance of the prescribed work for continued operation of the plant following its last periodic safety review;
- post-operational clean-out work on the very-high level units shut down in the facility.

15

Safe decommissioning of basic nuclear installations

The term decommissioning covers all the technical and administrative activities carried out following the final shutdown of a nuclear facility in order to achieve a final predefined status in which all the hazardous and radioactive substances have been removed from the facility. These activities include removal of the radioactive materials and waste still present in the installation and disassembly of the equipment, components and facilities used during operation. The licensee can then proceed with post-operational clean-out of the premises, remediation of the soils, and possibly the destruction of civil engineering structures. The decommissioning operations thus lead to the treatment, packaging, removal and disposal of vast quantities of waste, whether radioactive or not. This phase in the life cycle of the facilities is characterised by rapid changes in the state of the facilities and changes in the nature of the risks.

In 2016, some thirty nuclear installations of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were shut down or undergoing decommissioning in France, which corresponds to about one third of the Basic Nuclear Installations (BNI) in operation other than the power reactors.

Decommissioning operations are usually long and costly undertakings involving the removal of massive amounts of waste and representing a real challenge for the licensees in terms of project management, maintaining skills currency and coordinating the various types of work which involve many specialised companies. The current size of the French nuclear fleet, of which the oldest plants and research installations are today definitively shut down or undergoing decommissioning, makes this stage in the life of an installation a major challenge for the future. Over the last few years, the Authorities concerned (ASN - Nuclear Safety Authority, ASND - Defence Nuclear Safety Authority, DGEC - General Directorate for Energy and the Climate) have enhanced coordination on this subject for which all the licensees must devote adequate resources.

The current regulations relative to BNI decommissioning are based on Act 2006-686 of 13th June 2006 relative to transparency and security in the nuclear field, now codified by the Decree of 2nd November 2007 and the Order of 7th February 2012. It has been supplemented by Act 2015-992 of 17th August 2015 relative to Energy Transition for Green Growth (TECV Act), also codified by the Ordinance of 10th February 2016 which led to the modification of the abovementioned Decree. ASN continued preparation of the regulatory framework and doctrine applicable to this phase of the BNI life cycle, more specifically by publishing several guides in September 2016.

2016 was marked by EDF's announcement of its change of decommissioning strategy for its first-generation Gas-Cooled Reactors (GCR): EDF indicated that it was going to have to push back their decommissioning by several decades on account of technical difficulties relative to the underwater decommissioning of Bugey 1, its first-in-series reactor. Another notable point in 2016 was the submission by CEA and Areva of decommissioning strategy and waste management files for their installations. These files will be assessed jointly by ASN and ASND, its defence counterpart, in 2018.

The year 2016 also saw the completion of the decommissioning files for four BNIs which were deemed sufficiently complete to undergo a public inquiry at the beginning of 2017. The decommissioning files in question concern BNI 93 Eurodif, BNI 105 Comurhex (Areva), BNI 94 AMI Chinon (EDF) and BNI 52 ATUE (CEA Cadarache). The Environmental Authority of the General Council for the Environment and Sustainable Development (CGEDD) issued an opinion on these files in 2016.

1. Technical and legal framework for decommissioning

1.1 Decommissioning risks

The decommissioning of an installation leads firstly to the production of very large volumes of waste given the usual method of managing operational waste, and the scale and associated difficulties must be appreciated as early as possible in the life of the installation (from the design stage if possible) in order to ensure safe decommissioning in as short a time frame as possible.

Smooth running of the decommissioning operations is thus governed by the availability of appropriate management routes for all the types of waste likely to be produced. When the availability of the final waste disposal outlets on the stated dates is called into question, the licensees must, with due caution, organise the facilities necessary for the interim storage of their waste pending opening of the corresponding disposal route. This point is moreover covered by a specific paragraph in the PNGMDR 2016-2018 (French National Radioactive Material and Waste Management Plan) (see chapter 16).

ASN also believes that management of the waste resulting from decommissioning operations is crucial for the smooth running of the decommissioning programmes (availability of disposal routes, management of waste streams). This subject receives particular attention when evaluating the overall decommissioning strategies and the waste management strategies established by EDF, Areva and CEA. The EDF strategy thus underwent an overall evaluation in 2015 and ASN issued a position statement in 2016 concerning EDF's change in strategy (see point 2.1.4); the Areva and CEA files submitted in 2016 will be assessed in 2018.

Furthermore, the massive decommissioning and post-operational clean-out of the old installations of the CEA and the first-generation plants of Areva (especially the plants that played a role in the French deterrence policy, such as the gaseous diffusion plants of the Pierrelatte Secret Basic Nuclear Installation (SBNI) at Tricastin and the UP1 plant of the Marcoule SBNI) is going to produce extremely large quantities of Very Low Level (VLL) waste. This massive production of waste, which was not anticipated during the installation operating phases and which is incompatible with the current capacities of the VLL disposal route, was addressed by a PNGMDR working group resulting in several lines of reflection relative to the possible recycling or on-site storage of this waste (see chapter 16).

The French policy for the management of very low level radioactive waste does not provide for release thresholds, but requires that it be managed via a specific route to guarantee its isolation and traceability. This policy is based on the waste zoning of the installations, which has often been established conservatively by the licensees for operational reasons and has been partly responsible for the difficulties mentioned during the work of the abovementioned PNGMDR working group. Nevertheless, this work conducted in collaboration with the licensees and stakeholders, shows that the French waste management policy with no release threshold remains appropriate for the decommissioning needs. A number of application points have been specified in ASN Guides No. 6, 14 and 24 published on 30th August 2016 and in the files of each installation. More specifically, those that generate very large volumes of VLL waste are examined at a very early stage (this is the case of BNI 93 Eurodif, see point 2.3.3).

1.2 The ASN doctrine concerning decommissioning

1.2.1 Immediate dismantling

Many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques, qualified personnel, personnel present during the operating phase, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc. Consequently, practices and regulations differ from one country to another.

In 2014, the International Atomic Energy Agency (IAEA) defined two possible decommissioning strategies for nuclear facilities following final shutdown:
- Deferred dismantling: the parts of the installation containing radioactive materials are maintained or placed in a safe state for several decades before actual decommissioning operations begin (the "conventional" parts of the installation can be decommissioned as soon as the installation is shut down).
- Immediate dismantling: decommissioning is started as soon as the installation is shut down, without a waiting period, although the decommissioning operations can extend over a long period of time.

The IAEA considers that safe enclosure (or entombment), which consists in placing the parts of the installation containing radioactive substances in a reinforced containment structure for a period that enables a sufficiently low level of radiological activity to be reached with a view to releasing the site, is no longer a possible decommissioning strategy, but may be justified in exceptional circumstances.

Today, in accordance with IAEA recommendations, French policy aims to ensure that BNI licensees adopt an immediate dismantling strategy.

This principle currently figures in the regulations applicable to BNIs (Order of 7th February 2012, the "BNI Order"). It has been included in the doctrine established by ASN for BNI decommissioning and delicensing since 2009 and has just been taken up at legislative level in the Energy Transition for Green Growth Act (TECV). This strategy moreover avoids placing the technical and financial burden of decommissioning on future generations. It also provides the benefit of having the knowledge and skills of the teams present during operation of the installation, which are vital during the first decommissioning operations.

The aim of the strategy adopted in France is that:
- The licensee prepares the decommissioning of its installation from the design stage.
- The licensee anticipates decommissioning and sends the decommissioning application file before it stops operating the installation.
- The decommissioning operations are carried out «in as short a time as possible» after shutting down the installation, a time which can vary from a few years to a few decades, depending on the complexity of the installation.

1.2.2 Complete clean-out

The decommissioning and post-operational clean-out operations for a nuclear installation must progressively lead to elimination of the radioactive substances resulting from the activation phenomena and/or of any contamination deposits or migrations, in both the structures of the installation premises and the ground of the site.

The structure clean-out operations are defined on the basis of the prior updating of the facility's waste zoning plan which identifies the areas in which the waste produced is, or could be, contaminated or activated. As work progresses (for example after cleaning the surfaces of a room using appropriate products), the "possible nuclear waste production areas" are downgraded to "conventional waste areas".

Pursuant to the provisions of Article 8.3.2 of the BNI Order, *"the final state reached on completion of decommissioning must be such that it prevents the risks or inconveniences that the site may represent for the interests mentioned in Article L. 593-1 of the Environment Code, in view more particularly of the projections for reuse of the site or buildings and the best post-operational cleanout and decommissioning methods available under economically acceptable conditions"*. In this context, ASN recommends, in accordance with its decommissioning policy developed in 2009, that the licensees deploy clean-out and decommissioning practices taking into account the best scientific and technical knowledge available at the time and under economically acceptable conditions, with the aim of achieving a final status in which all the hazardous and radioactive substances have been removed from the BNI. This is the reference approach according to ASN. Should it be difficult to apply this approach due to the nature of the contamination, ASN considers that the licensee must go as far as reasonably possible in the clean-out process. Whatever the case, the licensee must provide technical or economic elements proving that the reference approach cannot be applied and that the clean-out operations cannot be taken further under acceptable economic conditions using the best technical clean-out and decommissioning methods available.

In accordance with the general principles of radiation protection, the dosimetric impact of the site on the workers and public after decommissioning must be as low as possible. ASN therefore considers that the defining of a priori thresholds cannot be envisaged.

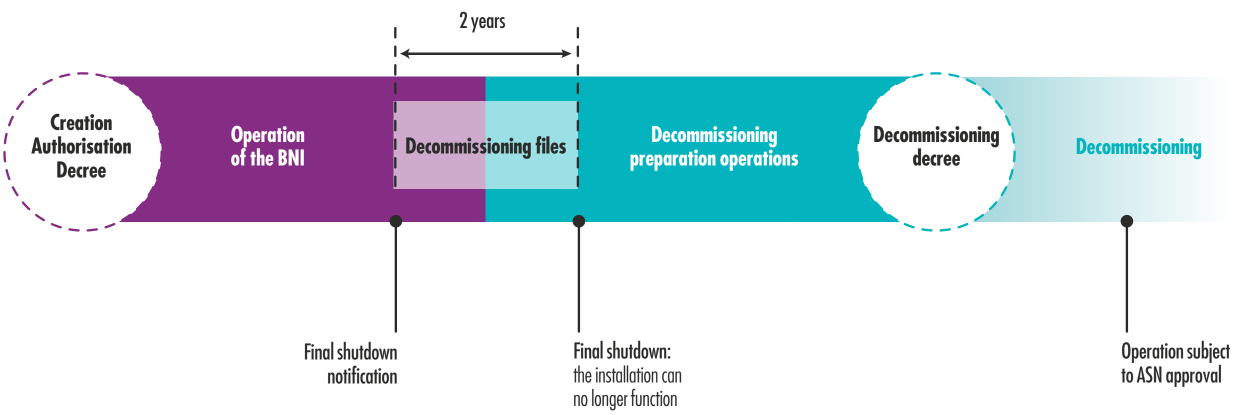
TECV Act

Changes brought by the TECV:
- When the licensee plans to definitively stop the operation of all or part of its installation, it must notify the Minister responsible for Nuclear Safety and ASN at least two years before the planned shutdown date, or as quickly as possible if the shutdown is implemented with shorter notice for reasons justified by the licensee. This notification is made known to the CLI (Local Information Committee) and made available to the public.
- The licensee is no longer authorised to operate the installation as from final shutdown of the installation.
- The licensee is obliged to submit its decommissioning file no later than two years after giving notification of its intention to definitively shut down its installation.
- Any installation that has been shut down for at least two years is considered to be definitively shut down and must be decommissioned (this period can however be extended to five years under special circumstances).

ASN contributed to the updating of the Decree of 2nd November 2007 relative to the BNI decommissioning procedures, and on 28th January 2016 it issued an opinion on the draft decree updating the procedures governing BNI final shutdown and decommissioning. Decree 2007-1557 amended introducing the abovementioned provisions was signed on 28th June 2016.

ASN has updated its Guide No. 6 on BNI decommissioning accordingly (available on *www.asn.fr*).

PHASES in the life of a BNI



More specifically, achieving a threshold with an exposure level leading to an annual dose of 300 microsieverts for the workers or the public does not, in principle, constitute an acceptable objective.

In 2016, ASN thus updated and published a technical guide relative to structure clean-out operations (Guide No. 14, available on *www.asn.fr*). The provisions of this Guide have already been implemented on numerous installations with diverse characteristics, such as research reactors, laboratories, fuel manufacturing plant, etc. ASN also published in 2016 a guide relative to the management of polluted soils in nuclear installations (Guide No. 24, available on *www.asn.fr*).

1.3 Decommissioning regulatory framework

From the moment a BNI is definitively shut down, it must be decommissioned and therefore changes its purpose with respect to that for which its creation was authorised, as the Creation Authorisation Decree specifies, among other things, the operating conditions of the installation. Furthermore, the decommissioning operations imply a change in the risks presented by the installation. Consequently, these operations cannot be carried out within the framework set by the Creation Authorisation Decree. The decommissioning of a nuclear installation is prescribed by a new decree issued after consulting ASN. This decree sets out, among other things, the main decommissioning steps, the decommissioning end date and the final state to be attained.

In order to avoid fragmentation of the decommissioning projects and improve their overall consistency, the decommissioning file must explicitly describe all the planned operations, from final shutdown to attainment of the targeted final state and, for each step, describe the nature and scale of the risks presented by the facility as well as the envisaged means of managing them. This file is subject to a public inquiry.

Given the fact that installation decommissioning operations are often very long, the decommissioning decree can stipulate that a number of steps will, when the time comes, be subject to prior approval of ASN on the basis of specific safety analysis files (previously called “hold points”).

The diagram above illustrates the corresponding regulatory procedure.

The licensee must prove in its decommissioning file that the decommissioning operations will be carried out in as short a time frame as possible.

The decommissioning phase may be preceded by a decommissioning preparation stage, provided for in the initial operating licence. This preparatory phase in particular allows removal of part of the radioactive and chemical substances as well as preparation for the decommissioning operations (readying of premises, preparation of worksites, training of teams, etc.). It is also during this preparatory phase that installation characterisation operations can be carried out: production of radiological maps, collection of pertinent data (operating history) with a view to decommissioning, etc. For example, the fuel of a nuclear reactor can be removed during this phase.

ASN will ensure that no irreversible decommissioning operations are carried out during this preparatory phase and that the duration of this phase does not exceed a few years. ASN recommends that the licensee informs the CLI of the planned operations in the decommissioning preparation phase, regularly informs the CLI of the progress of operations and present the results once they are completed.

As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as prescribed by the decommissioning decree.

The Environment Code provides that – as is the case for all other basic nuclear installations – the safety of a facility undergoing decommissioning be reviewed periodically, usually every 10 years. ASN's objective with these safety reviews is to ascertain that the installation complies with the provisions of its decommissioning decree and the associated safety and radiation protection requirements through to its delicensing by applying the principles of defence in depth specific to nuclear safety.

On completion of decommissioning, a nuclear facility can be delicensed by an ASN resolution approved by the Minister responsible for Nuclear Safety. It is then removed from the list of BNIs and is no longer subject to the BNI System. To support its delicensing application, the licensee must provide a dossier demonstrating that the envisaged final state has indeed been reached and describing the state of the site after decommissioning (analysis of the state of the soil and remaining buildings or equipment, etc.). Depending on the final state reached, ASN may make delicensing of a BNI subject to the putting in place of active institutional controls. These may set a certain number of restrictions on the use of the site and buildings (use limited to industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of excavation, etc.).

FOCUS

The ASN guides on final shutdown and decommissioning of BNIs, clean-out methodologies and management of soils polluted by the activities of a BNI

The new version of Guide No. 6 relative to the final shutdown, decommissioning and delicensing of BNIs was published in September 2016 and supersedes the July 2015 version:

- It integrates the legislative and regulatory modifications resulting from the TECV Act of 17th August 2015, the Ordinance of 10th February 2016 and Decree 2007-1557 of 2nd November 2007 amended by the Decree of 28th June 2016.
- It integrates the notions of complete decommissioning, initiated immediately after shutting down the installations, and it specifies the file submission time frames.
- It details the content of the decommissioning plan, emphasising the notions of initial and final status and the envisaged time frame for the decommissioning operations.
- It indicates the possibility of building new facilities to support decommissioning.
- It specifies the status of long-term installations that the licensee does not wish to decommission and introduces the possibility of separating a BNI into two BNIs or of keeping part of the installation in operation by regulating its decommissioning in a second phase.

The new version of Guide No. 14 relative to the post-operational clean-out of the structures in BNIs updates the version published in June 2010:

- It takes into account the BNI Order of 7th February 2012 and the resolution of 21st April 2015 on the management of waste and more specifically on the declassification of waste zoning.
- It takes into account Guide No. 24 on the management of polluted soils.
- It explains the notions of complete clean-out based on three lines of defence.

Guide No. 24 relative to the management of soils polluted by the activities of a BNI is based on Articles 3.3.6 and 3.3.7 of the ASN resolution relative to the environment which indicates that the licensee must periodically perform a chemical and radiological assessment of the environment of its installation; this assessment must include a soil diagnosis. If the soil diagnosis confirms the presence of pollution, the licensee must propose appropriate management measures that ASN must approve by examining the conformity of the licensee's approach with the following points:

- The proposed management approach is based on a conceptual scheme established on the basis of the diagnosis and including a precise description of the impacts and issues associated with the studied situation.
- If it is technically possible, the site must be completely remediated, even if the exposure of persons induced by the pollution appears limited.
- The objective is to render the state of the soils compatible with any subsequent use (established, envisaged, feasible); if compatibility with all uses cannot be achieved, the licensee must demonstrate that remediation has been taken as far as possible under acceptable technical and economic conditions.
- Soil remediation by excavation is based on a soil removal plan which takes up the concept of waste zoning.
- On completion of the work, a report demonstrating achievement of the objectives must be drawn up: this is followed by definitive declassification of the waste zoning or the implementation of active institutional controls.

1.4 The financing of decommissioning and radioactive waste management

1.4.1 The legislative and regulatory provisions

Articles L. 594-1 to L. 594-14 of the Environment Code define the system for ring-fencing funds to meet the costs of decommissioning nuclear facilities and managing the spent fuel and the radioactive waste. This system is clarified by Decree 2007-243 of 23rd February 2007 amended and the Order of 21st March 2007 concerning the securing of financing of nuclear costs.

It aims to secure the funding for nuclear costs in compliance with the "polluter-pays" principle. It is therefore up to the nuclear licensees to take charge of this financing by setting up a dedicated portfolio of assets capable of meeting the expected costs. They are obliged to submit three-yearly reports and annual update notices to the Government. Provisioning is ensured under direct control of the State, which analyses the situation of the licensees and can prescribe measures should it be found to be insufficient or inappropriate. In any case, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

These costs are divided into five categories:
- decommissioning costs, except for long-term management of radioactive waste packages;
- spent fuel management costs, except for long-term management of radioactive waste packages;
- cost of Retrieving and Packaging legacy Waste (RCD), except for long-term management of radioactive waste packages;
- costs of long-term management of radioactive waste packages;
- cost of surveillance following disposal facility closure.

The costs involved must be assessed using a method based on an analysis of the options that could be reasonably envisaged for the operation, on a conservative choice of a reference strategy, on consideration of residual technical uncertainties and performance contingencies, and on consideration of operating experience feedback.

An agreement signed between ASN and the General Directorate for Energy and Climate (DGEC) whereby ASN ensures the surveillance of these long-term costs, defines:
- the conditions in which ASN produces the opinions it is required to issue pursuant to Article 12, paragraph 4 of the above-mentioned Decree of 23rd February 2007, on the consistency of the strategies for decommissioning and management of spent fuels and radioactive waste;
- the conditions in which the DGEC can call on ASN expertise pursuant to Article 15, paragraph 2 of the same Decree.

1.4.2 Review of the reports submitted by the licensees

On 26th May 2016, ASN gave the DGEC its opinion on the 2015 updates notes provided by the licenses. In this opinion it pointed out the importance of regularly reassessing the hypotheses used by the licensees to determine the amounts to provision for. ASN recommended that the amounts provisioned by Areva for the La Hague site be audited.

ASN underlined, as in the preceding years, the lack of detail in the EDF report, which only presents the hypotheses from a broad angle. Such an approach does not allow precise validation of the chosen hypotheses. ASN reminded EDF of the studies required in the context of the PNGMDR concerning the recycling of URE and MOX fuels and the calendar associated with the creation of new spent fuel storage capacities, the cost of which must be integrated in the waste management costs.

Lastly, the BNI licensees transmitted the three-yearly reports during 2016 and they are currently being examined.

1.5 Lessons learned from the Fukushima Daiichi accident

To take into account the lessons learned from the nuclear accident that occurred at the Fukushima Daiichi nuclear power plant in Japan, ASN asked the BNI licensees to carry out stress tests on their installations, including those undergoing decommissioning.

With regard to EDF, the stress test reports for the BNIs undergoing decommissioning (Bugey 1, Chinon A1, A2 and A3, Saint-Laurent-des-Eaux A1 and A2, Chooz A, Superphénix, Brennilis) and the Fuel Evacuation Facility (APEC) (Creys-Malville) were submitted on 15th September 2012. ASN gave its conclusions on 10th October 2014. It considered that the procedure followed complied with the specifications and asked for further information relative to the seismic risk in the APEC and the Gas-Cooled Reactors (GCRs), and the flood risk in the GCRs. EDF has committed itself to taking several of these demands into account.

With regard to the CEA installations, the Plutonium Technology Facility (ATPu) (Cadarache) currently undergoing decommissioning was the subject of the ASN resolution No. 2012-DC-0296 of 26th June 2012 setting out additional requirements in the light of the conclusions of the stress tests. In addition to the generic requirements, ASN asked CEA to keep up to date the estimated quantities of fissile materials present in each area within the ATPu. ASN did not however consider it necessary to set "hardened safety core" requirements for this BNI (see chapter 12, point 3.1).

ASN resolution of 26th June 2012, issued subsequent to the transmission on 15th September 2011 of the stress tests report for the Phénix reactor (Marcoule), sets out additional requirements to reinforce the robustness of the installation against extreme situations, notably by establishing a "hardened safety core". The ASN resolution of 8th January 2015 also sets additional prescriptions specifying the requirements applicable to the "hardened safety core" of the Phénix reactor and the management of emergency situations.

ASN has not issued prescriptions for the Rapsodie reactor (Cadarache), for which the report was issued on 13th September 2012. Nevertheless, CEA has undertaken to review the scenario of a sodium-water reaction induced by rainfall occurring further to an extreme earthquake having caused severe structural failure of the BNI buildings. At the request of ASN, the corresponding study was handed over in late 2014 and did not give rise to additional prescriptions insofar as the sodium tanks still present in the installation at the time of the study were transferred before the end of 2016 to BNI 71 Phénix in Marcoule for treatment.

The report concerning the Irradiated Materials Facility (AMI) operated by EDF at Chinon was submitted on 6th June 2014. ASN considered on 10th July 2015 that the measures adopted by EDF to mitigate the consequences of an accident situation associated with extreme external hazards, such as those taken into consideration for the stress tests, were satisfactory, subject to removal in the short term of the radiological inventory present in the installation.

The experience feedback from the Fukushima Daiichi accident will be taken into account for the facilities of lesser importance later on, notably during the next periodic safety reviews for the Procédé and Support BNIs (Fontenay-aux-Roses).

The installations whose decommissioning work is sufficiently far advanced, or whose potential source term is very low and for which delicensing is very close, are not concerned by the stress tests.

1.6 The international action of ASN in the area of decommissioning

ASN participated in various international actions relating to decommissioning in 2016.

It contributed in particular to the WENRA "Working Group on Waste and Decommissioning" (WGWD) which in June 2013 published a report identifying the reference safety levels applicable to the decommissioning of nuclear installations. These reference safety levels must be transposed into the national regulations of each of the WENRA member countries. Publication of the BNI Order of 7th February 2012 allowed a number of these safety levels to be transposed, relating to safety management in particular, but other measures still have to be specified in ASN resolutions, notably the resolutions relative to the studies of waste management in the installations and to decommissioning, currently under preparation.

ASN is also a member of the International Decommissioning Network (IDN) coordinated by the IAEA and as such keeps itself informed of the international projects. It has contributed in particular since 2012 to the CIDER (Constraints to Implementing Decommissioning and Environmental Remediation) Project, which aims to identify and develop aids to overcome the difficulties that member countries can encounter in site decommissioning and rehabilitation projects.

ASN also participates in Nuclear Energy Agency (NEA) working groups addressing the decommissioning of nuclear installations, particularly the ISOE (Information System on Occupational Exposure) working group which focuses more specifically on radiation protection issues, and the WPDD (Working Party on Decommissioning and Dismantling).

ASN takes part in bilateral exchanges between safety authorities on subjects relating to decommissioning and legacy situations (particularly the retrieval and packaging of legacy waste and polluted sites and soils), the scale of which is growing on the international scene. In 2016, ASN more specifically met the NRC (Nuclear Regulatory Commission, United States), the CSN (*Consejo de Seguridad Nuclear*, Spain), the NRA (Nuclear Regulation Authority, Japan), the ONR (Office for Nuclear Regulation, United Kingdom) and the NLSO (Nuclear Licensing and Safety Office, Israel).

2. Situation of nuclear installations undergoing decommissioning in 2016

Some thirty installations are currently being decommissioned in France (see map opposite).

2.1 EDF nuclear installations

2.1.1 The decommissioning strategy of EDF

The first decommissioning strategy for EDF reactors in shut down status was transmitted in 2001 at the request of ASN. This strategy has been updated regularly to adjust the decommissioning schedule for the shutdown of EDF reactors, to incorporate the complementary studies requested by ASN and to integrate elements concerning the future decommissioning of the reactor fleet in service. However, the updates did not call into question either the decommissioning scenarios or the pace of decommissioning. In March 2016, EDF informed ASN of a complete change in strategy for its Gas-Cooled Reactors (GCRs) which pushes back their decommissioning by several decades (see box below).

On the other hand, the decommissioning strategy for the other reactors, namely Brennilis, Chooz A and Creys-Malville, has not been significantly modified.

ASN has asked EDF to submit several files to demonstrate that this change still meets the regulatory requirements which demand that decommissioning be carried out in the shortest time possible and to examine this new strategy with respect to the safety requirements applicable to these installations. These files are to be submitted by the end of March 2017 and end of December 2017. ASN will make a statement on this new strategy for the GCRs at that time.

2.1.2 Internal authorisations

The system of internal authorisations is governed by the Decree of 2nd November 2007 and the ASN resolution of 11th July 2008. The aim of implementing a system of internal authorisations in basic nuclear installations is to consolidate the prime responsibility of the operator with regard to nuclear safety and radiation protection. For operations of minor importance it introduces flexibility in the updating of the baseline safety requirements of the facilities, whose state changes rapidly during decommissioning. ASN authorised EDF's internal authorisations system relating primarily to reactors undergoing decommissioning through its resolution of 15th April 2014. Following publication of the Decree of 28th June 2016 amending the Decree of 2nd November 2007, ASN must define the criteria under which modifications can be notified without necessitating the consent of ASN. This resolution will replace the resolution of 15th April 2014.

2.1.3 The Brennilis NPP

The Brennilis NPP on the Monts d'Arrée site (BNI 162), called EL4-D, is an industrial prototype heavy water moderator nuclear power reactor cooled with carbon dioxide which was definitively shut down in 1985. EDF has been the nuclear operator since 2010. Partial decommissioning operations were carried out from 1997 to mid-2007 (plugging systems, dismantling certain heavy water and carbon dioxide systems and electromechanical components, demolition of non-nuclear buildings, etc.). A Decree of 27th July 2011 authorised part of the decommissioning operations with the exception of decommissioning of the reactor unit. The Decree of 16th November 2016 extended the time frame for carrying out the decommissioning operations authorised by the Decree of 27th July 2011, and more specifically:
- decommissioning of the heat exchangers, halted since 23rd September 2015 due to a fire;
- clean-out and demolition of the effluent treatment station.

These operations are to be completed before 28th July 2018.

This same Decree, promulgated after obtaining ASN's opinion, stipulates that EDF must submit a complete decommissioning file for the installation before 31st July 2018.

FOCUS

EDF announced a change in decommissioning strategy for the first-generation Gas-Cooled Reactors (GCR)

In March 2016, during its hearing by the ASN Commission, EDF informed ASN of a complete change in decommissioning strategy for its GCRs.

EDF indicated that it was facing serious technical difficulties in decommissioning the reactors «under water» as initially planned, and would have to change technique and decommission them "in air".

This change comes with modifications in the order of reactor decommissioning and the planning and scheduling principle.

The decommissioning principle based on opening the reactor pressure vessels and extracting the graphite blocks in series proposed by EDF in the initial strategy has been abandoned: EDF wants to finish complete decommissioning of one reactor before starting to decommission the others in order to have experience feedback from a full cycle.

EDF stated that it will nevertheless decommission all the installations peripheral to the pressure vessels of all the reactors within the next fifteen years.

This new strategy means that the decommissioning of certain reactors will be pushed back by several decades with respect to the strategy announced by EDF in 2001 and updated in 2013.

ASN will give an opinion on this strategy as of 2018.

During 2016, EDF continued firstly the operations to clean and rehabilitate the equipment present in the reactor containment following the September 2015 fire on the heat exchanger decommissioning worksite, and secondly decommissioning of the effluent treatment station.

The major challenges in 2017 will concern finalising decommissioning of the heat exchangers and effluent treatment station, and performing the periodic safety review, for which the conclusions are expected at the end of 2018.

To this end, ASN will examine the periodic safety review guidance file submitted at the end of 2016.

2.1.4 The Gas-Cooled Reactors

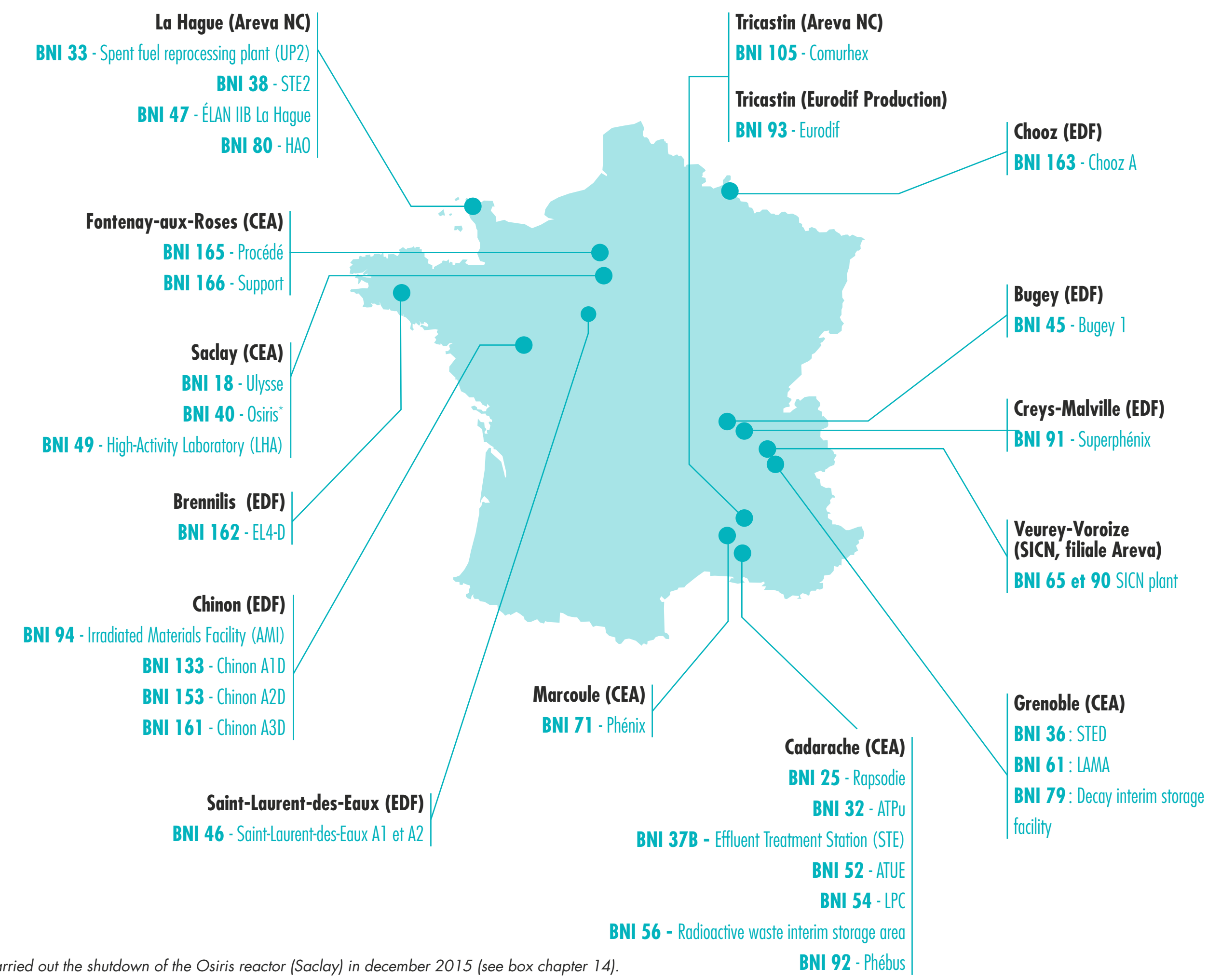
Bugey 1, Chinon A1, A2 and A3, Saint-Laurent-des-Eaux A1 and A2 constitute the Gas-Cooled Reactors (GCR). These first-generation reactors functioned with natural uranium as the fuel and graphite as the moderator. They were cooled by gas. The last reactor of this type to be shut down was Bugey 1 in 1994.

There are two types of GCR: "integrated" reactors, whose heat exchangers are situated beneath the reactor core inside the pressure vessel, and "non-integrated" reactors whose heat exchangers are situated on either side of the reactor pressure vessel.

Bugey 1 reactor (BNI 45)

The Bugey 1 reactor is an "integrated" GCR. EDF wants to change its decommissioning strategy and push back the end-of-decommissioning date for the Bugey 1 reactor by about fifty years with respect to the initial date. The Bugey 1 reactor was to be the first EDF GCR to be decommissioned. On reception of the requested files, ASN will examine the admissibility of this new EDF strategy for the decommissioning of its GCRs (see point 2.1.1).

INSTALLATIONS definitively shut down or in the process of decommissioning as at 31st December 2016



* *CEA carried out the shutdown of the Osiris reactor (Saclay) in december 2015 (see box chapter 14).*

Complete decommissioning of the installation, for which final shutdown became effective in 1994, was authorised by Decree of 18th November 2008. The corresponding scenario involved decommissioning the reactor pressure vessel "under water". If there is a change of scenario ("in air") as envisaged by EDF, a new decree will be necessary (see point 2.1.1).

ASN considers that decommissioning of the Bugey 1 reactor is proceeding under satisfactorily safe conditions. The licensee has a robust organisation and monitors the decommissioning equipment and work with rigour.

In 2017, EDF will prepare the operations to extract of the operational waste from the reactor pressure vessel, authorised by ASN in 2016 under certain conditions.

In 2017, ASN will examine the periodic safety review guidance file submitted by Bugey 1, for which the conclusions report must be submitted before the end of 2018.

Chinon A1, A2 and A3 reactors (BNIs 133, 153 and 161)

The Chinon A1, A2 and A3 reactors are "non-integrated" GCRs. They were shut down in 1973, 1985 and 1990 respectively.

EDF has changed decommissioning strategy and pushed back the date of end of decommissioning of the Chinon A reactors. These reactors were to be last to be decommissioned, but the new strategy would lead to one of these reactors being decommissioned first (Chinon A2 or A3). This is because the decommissioning of a "non-integrated" GCR would purportedly present fewer difficulties than that of an "integrated" GCR. On reception of the requested files, ASN will examine the admissibility of this new EDF strategy for the decommissioning of its GCRs (see point 2.1.1).

Reactors A1 and A2 were partially decommissioned and transformed into storage facilities for their own equipment (Chinon A1 D and Chinon A2 D). These operations were authorised by the Decrees of 11th October 1982 and 7th February 1991 respectively. Chinon A1 D is currently partially decommissioned and has been set up as a museum since 1986. Chinon A2 D is also partially decommissioned and accommodates the Intra EIG (Economic Interest Grouping) (robots and machines for intervening on accident-stricken nuclear installations). The amending of the Decree of 2nd November 2007 has led ASN to prescribe the submission of the decommissioning files for the Chinon A1 D and A2 D reactors. The corresponding ASN resolution has undergone consultation by the licensee.

The complete decommissioning of the Chinon A3 reactor was authorised by the Decree of 18th May 2010 with an "under water" decommissioning scenario. The change of scenario envisaged by EDF will necessitate a new decommissioning decree. Decommissioning of the Chinon A3 reactor heat exchangers (first step in the decommissioning of the installation) started a few years ago. This work, however, has been temporarily halted due to the discovery of asbestos in certain parts of the heat exchangers.

Handling a UI container on the Chinon A2 site.

Removal of the components of the previously decommissioned Chinon A2 systems is under preparation following the first tests. The chemically polluted soils are going to be decontaminated. Measures to reinforce monitoring of the ground waters and complementary characterisations of the gaseous discharges are in progress, in accordance with the regulatory provisions.

Given this context, ASN will be attentive to the execution in the short term of the actions, whether ongoing or just started, to operating rigour and to the monitoring of outside contractors.

Lastly, ASN will check the periodic safety review for the Chinon A1 and Chinon A2 reactors, for which the conclusions report is expected at the end of 2017.

Saint-Laurent-des-Eaux A1 and A2 reactors (BNI 46)

Complete decommissioning of the facility, which comprises two reactors whose final shutdown was declared in 1990 and 1992 respectively, was authorised by the Decree of 18th May 2010. The prescriptions regulating the water intakes and effluent discharges are set by ASN resolutions published in 2015.

F UNDAMENTALS

The risks associated with Gas-Cooled Reactors (GCR)

The EDF GCRs, which have been shut down for several decades, were designed and built in accordance with the safety requirements of the time. These reactors were not initially built to function over a very long time scale.

Nowadays, the most significant safety issues concern:
- the behaviour of the pressure vessels in the event of an earthquake;
- the resistance of the internal structures that support the graphite bricks of the «integrated» reactors, in normal and earthquake situations.

Several factors can effectively call into question the resistance of the reactor, such as the ageing of materials (anti-seismic pads) or the corrosion of steel structures.

For the abovementioned subjects, the behaviour of EDF's GCRs had been considered acceptable from an immediate dismantling viewpoint, which might not be the case with deferred dismantling.

Moreover, since 2006, the French National Agency for Radioactive Waste Management (Andra) has been tasked with creating a disposal facility for the low-level long-lived graphite waste from the GCRs. The choice of site for the disposal facility has posed many problems and the date of creation of the facility has still not been decided. Consequently, as a result of the foreseeable delays, the decommissioning waste dispatch rates have been reviewed and the creation of an interim storage facility for graphic waste has become plausible, which makes the decommissioning operations more complex for EDF.

Lastly, the loss of knowledge concerning operation of the GCRs, which is already quite substantial for these installations, can make decommissioning even more difficult. EDF effectively plans to place the installations in safe condition pending decommissioning of the reactor pressure vessel, which will take place several decades later.

EDF wants to change decommissioning strategy, which would push back the end of decommissioning of the Saint-Laurent-des-Eaux A reactors to 2100.

On reception of the requested files, ASN will examine the admissibility of this new strategy proposed by EDF for the decommissioning of its GCRs (see point 2.1.1).

Pending decommissioning of the pressure vessel of the reactors, other operations are performed outside the pressure vessel or to prepare for its decommissioning.

Consequently, several liquid and solid waste removal operations took place in 2016. However, all the worksites (emptying of tanks, characterisation of sludge, removal of the source term from the Saint-Laurent-des-Eaux A2 pool) were halted following the discovery of internal contamination of persons who had worked on worksites presenting an alpha contamination risk.

EDF identified the possible causes of the internal contaminations and defined corrective measures to prevent this recurring. During the next inspections ASN shall check that these measures have been implemented with rigour. ASN shall verify in particular the standard of EDF's monitoring of outside contractors, as a deficiency in this respect was one of the causes of the event.

Lastly, ASN will check the periodic safety review for the Saint-Laurent-des-Eaux reactors A1 and A2, for which the conclusions report is expected at the end of 2017.

2.1.5 Chooz A reactor

The reactor of the Ardennes NPP (BNI 163) was the first pressurised water reactor built in France. It was shut down in 1991. Its decommissioning foreshadowed the future decommissioning of pressurised water reactors, the technology of the French nuclear power reactors currently in operation.

Within the context of partial decommissioning of the reactor, the Decree of 19th March 1999 authorised the modification of the existing facility to convert it into a storage facility - called CNA-D - for its own equipment left on site. Its complete decommissioning was authorised by Decree of 27th September 2007.

After decommissioning the steam generators and the primary system, ASN, through its resolution of 3rd March 2014, authorised decommissioning of the reactor vessel.

In 2016, the reactor vessel decommissioning work began with opening of the vessel head and continued with preparation for flooding the vessel in order to cut it up.

The decommissioning work on all the equipment still present in the auxiliary cavern bunkers has started and is being carried out mainly by tele-operation using a robotic arm.

With regard to the environment, radiation protection and nuclear safety, ASN considers that the decommissioning operations are being carried out satisfactorily.

The licensee will have to be attentive to maintain its level of safety and radiation protection, particularly during phases of concomitant activities[1] and the associated lifting or handling operations.

Lastly, ASN will check the periodic safety review for the Chooz A reactor, for which the conclusions report is to be submitted in September 2017.

2.1.6 The Superphénix reactor and the Fuel Evacuation Facility (APEC)

The Superphénix fast neutron reactor (BNI 91), a sodium-cooled industrial prototype, is located at Creys-Malville. It was definitively shut down in 1997. This installation is associated with another BNI, the Fuel Evacuation Facility (APEC, BNI 141), which consists primarily of a storage pool in which the spent fuel removed from the Superphénix reactor vessel is stored, and storage for packages of soda concrete from the Sodium Treatment Installation (TNA).

ASN considers that the safety of the Superphénix reactor decommissioning operations and of APEC operation is satisfactorily ensured.

Further to several findings of liquid in retention structures during ASN inspections, EDF was asked in 2015 to set up an organisational structure enabling it to remove and treat as rapidly as possible the hazardous substances that could accumulate in the retention structures. During an unannounced inspection early in 2016 ASN found that detection and treatment of the tightness defects in the retention structures could be further improved. Furthermore, in 2016 the licensee notified three significant environment-related events that pointed to poor management of the retention structures. Further to these events and the ASN inspection findings, the licensee carried out several actions to ensure the tightness of the retention structures and to improve its system of managing and operating them. In 2017, ASN will ascertain that this new organisation enables the licensee to comply with the regulatory requirements in effect.

In 2016, the licensee notified four significant events relating to safety which occurred in the performance of periodic tests or installation modification work. Three of the four events led to unserviceability of equipment required to be serviceable by the general operating rules. ASN therefore expects to see an improvement in this area in 2017.

An ASN inspection also revealed that the licensee had to improve the traceability of the operations relating to the lockout/tagout of components important for protection of the interests mentioned in Article L.593-1 of the Environment Code.

EDF performed the periodic safety review on the two installations. EDF sent the files and conclusions reports to ASN late December 2015 for BNI 141 and late March 2016 for BNI 91, within the deadlines prescribed in their respective authorisation decrees. ASN started the technical examination of the safety review file of BNI 141 at the end of 2016, and will start that of BNI 91 early in 2017.

2.1.7 Irradiated Material Facility

The Irradiated Material Facility (AMI), which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This installation (BNI 94) is not yet undergoing decommissioning even though it is shut down. It was intended essentially for performing examinations and expert appraisals on activated or contaminated materials from Pressurised Water Reactors (PWR).

2016 is the first year in which there are no expert appraisal activities, as all these activities were transferred in 2015 to a new facility on the site which is not classified as a BNI, the "Lidec" (Integrated laboratory of the CEIDRE [Centre for Expert appraisals and Inspection in pRoduction and opEration]).

With decommissioning of the installation in view, the activities at AMI essentially concern decommissioning preparation operations and surveillance.

The decommissioning file was submitted in June 2013. At the end of 2014, ASN asked EDF for further information concerning the state of the installation in 2018 (projected

ASN inspection of the AMI electrical system at Chinon, 2016.

1. *Concomitant activities: different activities conducted simultaneously by several employees over a limited period in the same place.*

time frame for publishing the decommissioning decree). This additional information was provided by the licensee in 2016 and deemed satisfactory; consequently, the decommissioning file will be made available for public inquiry at the beginning of 2017.

As part of the decommissioning preparation operations, specific provisions are implemented for the packaging and storage of some of the waste. The waste in question is legacy waste for which appropriate management routes are not yet available. ASN will be attentive to the legacy waste retrieval and packaging operations, given the lateness accumulated over the last few years.

Operation of the AMI is marred by a few deficiencies in the monitoring of outside contractors and in operational management. The integration of experience feedback and the assessment of deviations must be improved. In a context in which the organisation of the facility will change significantly in 2017, ASN will be particularly attentive to the licensee's compliance with the facility's baseline requirements and to operating rigour.

ASN will monitor performance of the periodic safety review of the installation for which the conclusions are expected in 2017.

2.2 CEA installations

ASN and ASND (Defence Nuclear Safety Authority) have noted that the decommissioning operations and the retrieval and packaging of CEA legacy waste are significantly behind schedule, the forecast duration of the decommissioning and legacy waste retrieval operations has been very significantly increased (about fifteen years for the Fontenay-aux-Roses installations and for the UP1 plant of the Marcoule SBNI (Secret Basic Nuclear Installation), and there is considerable lateness in the transmission of decommissioning files. Consequently, ASN and ASND have asked CEA to present in 2016 the new decommissioning strategy envisaged by CEA for all the BNIs and individual installations situated inside SBNIs. ASN and ASND have asked CEA to draw up decommissioning programmes for the next fifteen years based on ranked priorities of safety, radiation protection and environmental protection, taking particular account of the total potential activity of the radioactive and hazardous substances present in each installation.

ASN and ASND have therefore asked CEA to conduct an overall review of the nuclear installation decommissioning strategy and the management of CEA's radioactive waste. This review more specifically concerns the prioritisation of operations, human resources and the effectiveness of the organisational set-ups to achieve them and the appropriateness of the financial resources allocated to these operations. ASN and ASND have also asked CEA to increase the human resources assigned to the decommissioning operations and to the organisation of its decommissioning and waste management programmes. Lastly, they have asked CEA to review the budget resources assigned to decommissioning operations.

2.2.1 The Fontenay-aux-Roses Centre

Created in 1946, the Fontenay-aux-Roses site - CEA's first research centre - is continuing to move away from nuclear activities and towards research into the life sciences.

The CEA Fontenay-aux-Roses Centre comprises two BNIs, namely Procédé (BNI 165) and Support (BNI 166). BNI 165 accommodated the research and development activities on nuclear fuel reprocessing, transuranium elements, radioactive waste and the examination of irradiated fuels. These activities were stopped in the years 1980-1990. BNI 166 is a facility for the characterisation, treatment, reconditioning and storage of legacy radioactive waste and waste from the decommissioning of BNI 165.

The Procédé installation (BNI 165) and Support installation (BNI 166)

The decommissioning of these two installations was authorised by two Decrees of 30th June 2006. The initial planned duration of the decommissioning operations was about ten years. CEA has informed ASN that due to the strong presumptions of radioactive contamination underneath one of the buildings and unforeseen difficulties, the decommissioning operations will be extended at least until 2023 for the Procédé installation and 2029 for the Support installation. CEA submitted an authorisation application file in June 2015 to modify the Decrees of 30th June 2006, particularly with regard to the decommissioning deadlines and the final state. The Minister responsible for Nuclear Safety has referred the matter to ASN which considered that the first versions of these files were not admissible for reasons relating primarily to waste management.

The year 2016 also witnessed significant advances in the revising of the On-site Emergency Plan (PUI) and in the preparation of the prescriptions governing effluent discharges and transfers and monitoring of the environment around the CEA Fontenay-aux-Roses BNIs.

Despite the undeniable efforts of the CEA teams in place, ASN considers that the level of safety of the Fontenay-aux-Roses BNIs is still not entirely satisfactory. The reason is that a significant number of prolonged stoppages of the ventilation systems ensuring dynamic containment and faults in alarm or measurement data transfers occurred in BNI 165 in 2016, as well as two events linked to the heating of electrical components. ASN considers that the difficulties in diagnosing and remedying these situations raise questions and that control of the fire risk remains an issue.

The planned organisation for the management of decommissioning projects, such as it was understood during the in-depth inspection on decommissioning management in 2016, does not enable decommissioning - soil remediation included - to be carried out within controlled times while at the same time ensuring optimum conditions of safety and radiation protection. This inspection also revealed that the operating rigour of the waste storage facilities was not always satisfactory, even though progress has been made since 2015.

ASN also noted that the system for internal authorisation of minor modifications is managed satisfactorily by the Centre.

Lastly, ASN considers that CEA has taken measure of the recurrent deviations associated with the organisation of subcontracting by planning for the redistribution of services by activity. ASN will be particularly attentive to the monitoring of outside contractors once these future contracts have been put in place. The CEA must increase the field presence of its personnel in this respect.

2.2.2 The Grenoble Centre

The Grenoble Centre was inaugurated in January 1959. Activities associated with the development of nuclear reactors were carried out there before being gradually transferred to other CEA centres in the 1980's. Now the Grenoble Centre conducts its research and development in the fields of renewable energies, health and microtechnology. In 2002 the CEA Centre in Grenoble launched a site delicensing programme.

The site housed six nuclear facilities which were gradually shut down and entered the decommissioning phase with a view to their ultimate delicensing. Delicensing of the Siloette reactor was declared in 2007, that of the Mélusine reactor in 2011 and that of the Siloé reactor in January 2015.

ASN considers that the safety of the decommissioning and post-operational clean-out of the installations in the Grenoble Centre was on the whole satisfactory in 2016.

Radioactive Effluent and Solid Waste Treatment Station (STED) and Decay Storage Facility (BNIs 36 and 79)

The final shutdown and decommissioning operations of the STED (BNI 36) and the interim radioactive waste decay storage facility (BNI 79) were authorised by the Decree of 18th September 2008 which prescribed a term of 8 years for the completion of decommissioning activities.

All the buildings have been destroyed in compliance with the above Decree. The main operations still to be carried out concern decontamination of the soil.

The technical discussions between ASN and CEA concerning remediation of the soil of the STED (Effluent and Waste Treatment Plant) continued in 2016. ASN asked CEA to continue the remediation operations that can be technically achieved for an economically acceptable cost.

Active Material Analysis Laboratory (LAMA) (BNI 61)

This laboratory conducted post-irradiation studies of uranium and plutonium based nuclear fuels and structural materials from nuclear reactors until 2002. Decommissioning of the LAMA was authorised by Decree on 18th September 2008.

In accordance with the provisions of this Decree, CEA carried out the decommissioning of BNI 61 (LAMA) from 2008 to 2015.

In 2016, CEA sent a delicensing application for the installation, including a document relative to the diagnosis of the state of the soil. Within six months following completion of decommissioning, CEA also sent ASN a report presenting the experience feedback from the decommissioning operations and elements demonstrating achievement of the desired end-state.

Considering that the clean-out objectives had been achieved, in 2016 ASN initiated the procedures for informing and consulting the stakeholders prior to delicensing of the installation.

2.2.3 The Cadarache Centre installations undergoing decommissioning

Rapsodie reactor and Fuel Assembly Shearing Laboratory (LDAC) (BNI 25)

The experimental reactor Rapsodie is the first sodium-cooled fast neutron reactor built in France. It functioned until 1978. A reactor vessel sealing defect led to its final shutdown in 1983.

Decommissioning operations have been undertaken since then but were partly stopped further to a fatal accident (explosion) that occurred in 1994 when washing out a sodium tank. At present, the core has been unloaded, the fuel evacuated from the installation, the fluids and radioactive components have been removed and the reactor vessel contained. The reactor pool has been emptied, partially cleaned out and decommissioned. In addition, 23 tonnes of sodium are stored and must be removed to the CEA Marcoule Centre for treatment.

The CEA transmitted its complete decommissioning authorisation application to ASN in December 2014 and the periodic safety review file for the installation in May 2015. Additional requests were made by the Minister responsible for Nuclear Safety in the October 2015. The licensee responded to these requests in 2016. The technical examination was started and will continue in 2017.

The operations carried out by the CEA at present mainly involve removing waste containing sodium. The measures taken by CEA to ensure removal of all the waste containing sodium still present in the installation by 2018 are also closely monitored by ASN.

The purpose of the LDAC, located within the Rapsodie BNI, was to perform inspections and examinations on irradiated fuels from the fast-neutron reactors. This laboratory has been shut down since 1997 and partially cleaned out. The licensee wants to carry out decommissioning preparation operations. These operations are currently being examined by ASN. Its decommissioning is included in the decommissioning project for the entire BNI.

The ventilation of building 206 was affected by a significant event in 2016. Analysis of the event led the licensee to install a slaving system between the redundant ventilation systems to prevent such a situation recurring.

Enriched Uranium Processing Facilities (ATUEs) (BNI 52)

Until 1995, the ATUEs converted uranium hexafluoride from the enrichment plants into sinterable oxide, and ensured the chemical reprocessing of waste from the manufacture of fuel elements. The facility included an incinerator for slightly contaminated organic liquids. Production in the facilities ended in July 1995 and the incinerator was shut down at the end of 1997.

The installation's final shutdown and decommissioning authorisation Decree of 8th February 2006 prescribed work completion in 2011. After having observed that the decommissioning operations were stopped and that CEA had not followed up its request to submit a new authorisation application file in order to complete the decommissioning, ASN gave CEA formal notice on 6th June 2013 to submit a new file. In February 2014 CEA submitted a new application for authorisation to complete the decommissioning and clean-out operations. The Environmental Authority gave its opinion on this file in late 2016. ASN's technical examination will continue in 2017, with the public inquiry among other things.

ASN has also observed shortcomings in the management of the decommissioning waste streams and their storage and a loss of tightness of the buildings. ASN considers that the licensee must remedy this situation definitively in 2017, and improve its monitoring of the last containment barrier, that is to say the buildings.

The Plutonium Technology Facility (ATPu) (BNI 32) and the Chemical Purification Laboratory (LPC) (BNI 54)

The ATPu produced plutonium-based fuel elements initially intended for fast neutron or experimental reactors and then, as of the 1990s, for pressurised water reactors using MOX fuel. The LPC's activities were associated with those of the ATPu: physical-chemical checks and metallurgical examinations, treatment of effluents and contaminated waste. The two facilities were shut down in 2003.

CEA is the nuclear licensee for these facilities. Since 1994 Areva NC has been the industrial operator responsible for operation of the facilities and for their decommissioning until CEA took over this latter activity completely in the second half of 2016.

Decommissioning of the two facilities, authorised by the two Decrees of 6th March 2009 and governed by the resolutions of 26th October 2010, continued in 2016 with a large volume of operations, resulting in a significant reduction in the source term. The licensee made modification notifications for certain operations such as the sorting, reconditioning and transfer of metal fuel scraps, and changing of the organisation concerning conditions for maintaining sub-criticality, which ASN has examined.

With regard to the cryogenic treatment unit, the decommissioning operations authorised by ASN resolution of 20th October 2011 are in progress.

ASN has kept close track of implementation of the measures taken by CEA further to the compliance notice resolution of 19th February 2013 concerning monitoring of Areva NC and management of the skills associated with decommissioning safety, and the organisation put in place by the operator appears to be effective on the whole.

A significant event involving the internal exposure of a worker of an outside contractor was however notified on 3rd June 2016. An ASN inspection verified the steps taken and analyses carried out to understand the circumstances of the event. Some uncertainties regarding the circumstances of the event subsisted, but the licensee's analysis enabled a realistic explanation that was compatible with the medical findings and the work performed by the employee concerned to be submitted to the inspectors. The event was rated level 1 on the INES scale.

ASN will remain attentive to the situation of these two BNIs in 2017 with regard to social, organisational and human factors, particularly when the CEA takes over the decommissioning activities on departure of the industrial operator, and will ensure that the observed progress is maintained over the long term.

2.2.4 The Saclay Centre installations undergoing decommissioning

The decommissioning operations carried out on the site concern two BNIs in final shutdown state and three BNIs in operation but with sections that have stopped their activity and on which preparatory operations for decommissioning are being carried out. They also concern two ICPEs (Installations Classified on Environmental Protection grounds), EL2 and EL3, which were previously BNIs but which have not been completely dismantled due to the absence of a disposal route for low-level long-lived waste. Their delicensing in the 1980's from BNI status to ICPE status, in compliance with the regulations of that time, would not be possible today.

High-Activity Laboratory (LHA) (BNI 49)

The LHA comprises three buildings housing several laboratories which were intended for research into or the production of various radionuclides. On completion of the decommissioning and clean-out work authorised by Decree of 18th September 2008, only two laboratories currently in operation should ultimately remain under the ICPE System. These two laboratories are the laboratory for chemical and radiological characterisation of effluents and waste, and the packaging and storage facility for the recovery of sources that are surplus to requirements.

ASN considers that the level of safety of BNI 49 undergoing decommissioning is satisfactory. The post-operational clean-out of the cells continued in 2016.

Despite the good progress of the decommissioning operations, treatment of the radioactive contamination of the soils in certain interior courtyards will not be able to be carried out before the 18th September 2018 deadline set by the LHA decommissioning authorisation decree. ASN will therefore be attentive to the submission in 2017 of a file applying for a change in this deadline and giving reasons justifying the requested extension.

The in-depth inspection on decommissioning management carried out in the Saclay Centre showed that shortcomings in the management of the streams and storage of decommissioning waste persisted. ASN considers that the licensee must correct this situation definitively in 2017.

The operations scheduled for 2017 are the decommissioning of the main manifolds and the last filtration level, and continuation of cell clean-out. These operations will necessitate the setting up of numerous worksite containment systems. ASN will be attentive to compliance with the operating rules for these containment systems.

Ulysse reactor (BNI 18)

Ulysse was the first French university reactor. The facility has been definitively shut down since February 2007 and has contained no fuel since 2008. The final shutdown and decommissioning authorisation decree for the BNI was published on 18th August 2014 and provides for a five-year decommissioning period.

BNI 18 is an installation presenting limited safety risks.

The installation is ageing and modifications have been introduced to allow its future decommissioning (appropriate ventilation, specific electrical switchboard, procurement of gantry, etc.). Unnecessary items have been removed (batteries, documentation, etc.). CEA began conventional decommissioning of the equipment inside the installation in 2016, more specifically the «horizontal cemetery» operational waste storage facilities. Dismantling of the pool has fallen behind schedule following the discovery of a lens of water (small but constant quantity coming from perched water tables) behind one of the pool walls.

The decommissioning operations will start in 2017. ASN will be attentive to the follow-ups to the discovery of a lens of water (small but persistent quantity of water coming from perched water tables) and to any delays it could induce in the installation's projected decommissioning programme for which the set completion date is 18th August 2019.

2.2.5 The Marcoule Centre installations undergoing decommissioning

Phénix NPP (BNI 71)

The Phénix reactor, built and operated by CEA, is a sodium-cooled fast neutron reactor demonstrator. It was definitively shut down in 2009.

The year 2016 saw the publishing of the Decree of 2nd June 2016 instructing CEA to proceed with the decommissioning operations. The examination report for the decommissioning authorisation application and the periodic safety review file for the BNI were handed over to the Minister of the Environment, Energy and Sea in August 2016 and gave rise to ASN resolution of 7th July 2016 which supplements the provisions of the Decree of 2nd June 2016.

This resolution details the prescriptions relative to decommissioning and the periodic safety review of the BNI and obliges updating of the BNI baseline safety requirements and its On-site Emergency Plan (PUI). It also defines the expected content of the commissioning authorisation application file for the future NOAH facility whose purpose will be to transform the sodium from the Phénix and other CEA installations into sodium hydroxide.

The licensee continued the construction of the NOAH building in 2016 and has prepared the premises that will accommodate the inactive and the slightly contaminated sodium-containing waste respectively in the electricity production building emptied of its equipment, and in the building housing the steam generators which no longer contain any sodium.

The inspections carried out by ASN in 2016, which focused chiefly on the monitoring of outside contractors, the meeting of commitments and construction of the NOAH building did not reveal any deviations that could call into question the continuation of decommissioning of the reactor.

2.3 Areva installations

The situation of the UP2-400 complex is described in chapter 13. This complex comprises the former spent fuel reprocessing plant UP2-400 (BNI 33) and the associated units, shut down since 2004, namely the Effluent Treatment Plant STE2A (BNI 38), the Oxide High Activity Facility HAO (BNI 80), and the ELAN IIB installation (BNI 47), which manufactured caesium-137 and strontium-90 sources until 1973.

2.3.1 The UP2-400 spent fuel reprocessing plant and associated facilities

The HAO (High Activity Oxide) Facility (BNI 80)

BNI 80 ensured the first stages of the reprocessing of spent oxide nuclear fuels: reception, storage then shearing and dissolution. The dissolution solutions produced in BNI 80 were then transferred to the UP2-400 industrial plant in which the subsequent reprocessing operations took place.

BNI 80 comprises five facilities:
- HAO North, fuel unloading and storage site;
- HAO South, in which the shearing and dissolution operations were carried out;
- the filtration building, which accommodates the filtration system for the pool of the HAO South facility;

In-depth inspection by ASN in the HAO facility, La Hague, October 2016.

- the HAO silo, in which are stored the hulls and end-pieces in bulk, fines coming essentially from shearing, resins and technological waste resulting from operation of the HAO facility from 1976 to 1997;
- the SOC (Organised Storage of Hulls) comprising three pools in which the drums containing the hulls and end-pieces are stored.

Decommissioning of the HAO was authorised by Decree of 31st July 2009.

The Waste Retrieval and Packaging (RCD) project currently under way in the HAO silo and in the SOC (see chapter 13, point 1.2.4), represents the first hold point in the decommissioning of the installation. The civil engineering work for the construction of the retrieval and packaging unit authorised by the ASN resolution of 10th June 2014 continued in 2016. The licensee is going to install the equipment of this unit in 2017.

Furthermore, BNI 80 has undergone a periodic safety review which ASN will finish examining in the first quarter 2017.

The UP2-400 (BNI 33) plant, the effluent treatment plant STE2 (BNI 38) and the ÉLAN IIB installation (BNI 47)

In October 2008, Areva NC submitted three final shutdown and decommissioning authorisation applications for BNI 33 (UP2-400), BNI 38 (STE2 and AT1 facility) and BNI 47 (ELAN IIB).

On completion of the technical examination of the files, ASN considered that the measures defined by Areva NC for the decommissioning of BNIs 33 and 38 showed nothing unacceptable with regard to safety, radiation protection or waste and effluent management. Nevertheless, this examination did reveal the necessity for the licensee to provide a large number of additional studies. Consequently, only those operations for which the information in the safety cases was considered sufficient could be authorised for BNIs 33 and 38.

The three Decrees authorising the start of the final shutdown and decommissioning operations for the three BNIs date from 8th November 2013. The Decrees concerning BNIs 33 and 38 only authorise partial decommissioning, whereas the Decree concerning BNI 47 authorises complete decommissioning of the installation.

In accordance with the Decrees for BNIs 33 and 38, Areva submitted new complete decommissioning application files for BNIs 33 and 38 in July 2015. It also submitted the periodic safety review files for BNIs 33, 38 and 47. Concomitant examination of the periodic safety review files and the decommissioning files will allow the compatibility of the ageing control measures with the decommissioning strategy envisaged by the licensee - particularly the projected duration of the decommissioning project as a whole - to be checked.

The licensee has started the decommissioning operations in BNI 33 and decommissioning preparation work in BNIs 38 and 47. ASN notes that the difficulties encountered on the decommissioning worksites are mainly associated with the uncertainties regarding the initial states and the presence of asbestos. The licensee is endeavouring to define action plans to control the drifts in schedule that could result from this.

With regard more particularly to retrieval of the legacy waste on the La Hague site, which constitutes a major safety risk, ASN conducted an in-depth inspection in October 2016 which focused on the licensee's organisation and the progress of the top priority projects. ASN noted that although efforts had been made to allow certain operations not to fall even further behind schedule, blocking points could seriously hinder the progress of other operations. ASN also noted that the first retrieval deadline prescribed by the resolution of 9th December 2014, which concerns the waste from silo 130, had not been met, even though the efforts devoted to these waste retrieval operations merit being underlined, which has not been the case for all the projects.

ASN will be particularly attentive to the analysis of the situations of the various projects in order to identify lines for improvement that will enable the regulatory deadlines to be met, including those of the resolution of 9th December 2014, which are of major importance for the safety of these old installations.

2.3.2 Comurhex plant at Tricastin

Operated by Areva NC, the Comurhex plant (BNI 105) mainly produced uranium hexafluoride (UF_6) for the fabrication of nuclear fuel. Alongside this main activity, BNI 105 produced various fluorinated products such as chlorine trifluoride.

The production of UF_6 from natural uranium was carried out in a part of the plant subject to ICPE regulations, while the production of UF_6 from reprocessed uranium was carried out in a part of the plant constituting a BNI. This part, BNI 105, which was definitively shut down in 2009, essentially comprises two units:
- the 2000 unit, which transformed reprocessed uranyl nitrate $UO_2(NO_3)_2$ into uranium tetrafluoride (UF_4) or uranium sesquioxide (U_3O_8);
- the 2450 unit, which transformed the UF_4 from the 2000 unit into UF_6. This UF_6 was intended to enrich the reprocessed uranium for the manufacture of fuel.

Areva NC filed a decommissioning decree application in February 2014. The technical examination was completed in May 2016 and the Environmental Authority of the CGEDD (General Council for the Environment and Sustainable Development) issued its opinion on the file in September 2016. The examination will continue in 2017, the year in which the public inquiry will be held.

Events led more specifically to deficiencies in the containment of nuclear materials or chemicals with immediate corrective actions and no significant consequences on site personnel or the environment. The ASN inspections showed that these events resulted from organisational shortcomings. In 2017, ASN will be attentive to the corrective measures adopted by the licensees to maintain a satisfactory level of safety.

2.3.3 Eurodif plant at Tricastin

The Eurodif Production facility (BNI 93), licensed in 1977, consisted primarily of a plant for separating the isotopes of uranium using the gaseous diffusion process, with a nominal annual capacity of 10.8 million separative work units.

Following stoppage of its production in May 2012, Eurodif Production was authorised in May 2013 to implement the operations of the Eurodif project for intensive rinsing followed by «air-filling» («Prisme» operation), which consisted in repeatedly rinsing the gaseous diffusion circuits with chlorine trifluoride (ClF_3), a toxic and hazardous substance which allowed the extraction of virtually all the residual uranium deposited in the barriers[2].

In accordance with the Decree of 24th May 2013, the licensee filed its final shutdown and decommissioning application for the installation in March 2015. Examination of its admissibility revealed that further information was required before the examination could proceed. These clarification requests concern general aspects in the decommissioning strategy adopted by Eurodif Production, more particularly in the management of radioactive waste and the description of the initial and final states of the installation. The Environmental Authority issued its opinion on 23rd November 2016. The examination will continue in 2017, the year in which the public inquiry will be held.

The decommissioning challenges concern the volume of Very Low-Level (VLL) waste produced (including 180,000 tonnes of metallic VLL waste) and the reduction in the decommissioning time frame which must be as short as possible (currently estimated at 30 years).

2. *The Eurodif plant used the process of gaseous diffusion through a cascade of diffusers. Further to the production stoppage in 2012, decommissioning preparation operations have been undertaken: these operations (baptised «Prisme») consist firstly in intensive rinsing with ClF_3 to extract the large majority of the residual uranium from the equipment and secondly in injecting moist air to cause a hydrolysis chemical reaction in order to extract the gaseous effluents.*

The last stages of the Prisme operation (air-filling of the cascade), which began at the end of 2015, will be completed by the end of 2016.

More specifically, the rinsing and air-filling of the DPR facility and the U annexe are finished. The majority of the source term has been removed and the installations shall be kept under surveillance until the first decommissioning operations commence.

ASN notes a deterioration in the control of radiation protection and safety in 2016, tasks which have been delegated to the Tricastin site. As licensee of BNI 93, Eurodif must maintain control over the activities it delegates and ultimately remain responsible for the safety and radiation protection of all the facilities of the BNI.

In 2017, ASN will ensure that the transition to this intermediate phase is carried out in strict compliance with the authorisations it issues. Alongside this, ASN will be particularly attentive to ensuring that Eurodif maintains operating rigour in all its facilities despite the reorganisation of the Tricastin platform, and maintains a safety culture that is appropriate for this particular situation.

ASN will also ensure that Eurodif continues to make progress in the areas other than decommissioning (removal of operational waste, treatment of environmental liabilities, etc.).

2.3.4 SICN plant in Veurey-Voroize

The former nuclear fuel fabrication plant of Veurey-Voroize, operated by the *Société Industrielle de Combustible Nucléaire* (SICN, Areva Group) consists of two nuclear facilities, BNIs 65 and 90. Fuel fabrication activities were definitively stopped in the early 2000's. The Decrees authorising the decommissioning operations date from 15th February 2006. The decommissioning work has now been completed.

The site nevertheless displays residual contamination of the soil and groundwater, the impact of which is acceptable for its envisaged future use (industrial). ASN has therefore asked the licensee to submit, as a prerequisite to delicensing, an application for the implementation of active institutional controls designed to restrict the use of the soil and groundwater and to guarantee that the land usage remains compatible with the state of the site. SICN submitted this file to the Isère *département* Prefecture in March 2014, and the delicensing application file for the two BNIs to ASN. Delicensing will not be able to be declared until these active institutional controls have been effectively put in place by the Prefect of the *Isère département*, at the end of the examination procedure which includes a public inquiry.

3. Outlook

ASN's key actions in 2017 will concern the monitoring of decommissioning and waste management project progress, and especially the retrieval and packaging of the legacy waste of CEA and Areva, where the delays are particularly detrimental to the safety of the sites concerned. The strategy files submitted by these two licensees in June and December 2016 respectively shall undergo in-depth examination.

ASN will also make a position statement on EDF's request to change the decommissioning strategy for its first-generation GCRs.

The periodic safety reviews of the installations undergoing decommissioning, for which the majority of the conclusions files will be submitted by the licensees in 2017, will be the subject of attentive examinations tailored to the risks and inconveniences these installations represent.

Lastly, in order to clarify the decommissioning and waste management regulations updated by the Ordinance of February 2016, ASN will continue to develop new guides in these areas as well as in the area of polluted sites and soils in the BNIs.

Thus in 2017, ASN plans to:
- examine and implement actions with respect to the decommissioning strategy of EDF and more particularly the decommissioning of the GCRs;
- continue examining the decommissioning strategies of Areva and CEA;
- finalise the examination of the licensees' three-yearly reports in view of producing an ASN resolution for the DGEC;
- continue examining the decommissioning files for the AMI (Chinon), Comurhex and Eurodif (Tricastin), UP2-400 and STE2 (La Hague), ATUE and Rapsodie (Cadarache), and the Procédé and Support BNIs (Fontenay-aux-Roses);
- initiate or continue the periodic safety reviews of the abovementioned installations;
- continue the examination of decommissioning files for the solid radioactive waste management zone installation (Saclay) and initiate the periodic safety review of the installation;
- examine the periodic safety review files of Superphénix and APEC;
- finish examining the delicensing application for the LAMA and STED in Grenoble and the SICN in Veurey-Voroise;
- clarify, through the production of a joint ASN-IRSN guide, the structuring and the requirements associated with the BNI decommissioning plans;
- start drafting guides developing specific points stemming from Guides No. 14 and No. 24 relative to the management of contaminated soil, and in particular a guide concerning radioactivity measurements in order to verify achievement of the remediation objectives for a site;
- continue capitalising on international decommissioning experience feedback by participating in the work of WENRA, the IAEA and the NEA.

APPENDIX

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2016

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
IDE Fontenay-aux-Roses (FAR)	(former BNI 10)	Reactor (500 kWth)	1960	1981	1987: removed from BNI list	Decommissioned
Triton FAR	(former BNI 10)	Reactor (6.5 MWth)	1959	1982	1987: removed from BNI list and classified as ICPE	Decommissioned
ZOÉ FAR	(former BNI 11)	Reactor (250 kWth)	1948	1975	1978: removed from BNI list and classified as ICPE	Confined (museum)
Minerve FAR	(former BNI 12)	Reactor (0.1 kWth)	1959	1976	1977: removed from BNI list	Dismantled at FAR and reassembled at Cadarache
EL2 Saclay	(former BNI 13)	Reactor (2.8 MWth)	1952	1965	Removed from BNI list	Partially decommissioned, remaining parts confined
EL3 Saclay	(former BNI 14)	Reactor (18 MWth)	1957	1979	1988: removed from BNI list and classified as ICPE	Partially decommissioned, remaining parts confined
Peggy Cadarache	(former BNI 23)	Reactor (1 kWth)	1961	1975	1976: removed from BNI list	Decommissioned
César Cadarache	(former BNI 26)	Reactor (10 kWth)	1964	1974	1978: removed from BNI list	Decommissioned
Marius Cadarache	(former BNI 27)	Reactor (0.4 kWth)	1960 at Marcoule, 1964 at Cadarache	1983	1987: removed from BNI list	Decommissioned
Le Bouchet	(former BNI 30)	Ore processing	1953	1970	Removed from BNI list	Decommissioned
Gueugnon	(former BNI 31)	Ore processing	1965	1980	Removed from BNI list	Decommissioned
STED FAR	BNI 34	Processing of liquids and solid waste	Before 1964	2006	2006: removed from BNI list	Integrated into BNI 166
Harmonie Cadarache	(former BNI 41)	Reactor (1 kWth)	1965	1996	2009: removed from BNI list	Destruction of the ancillaries building
ALS	(former BNI 43)	Accelerator	1958	1996	2006: removed from BNI list	Cleaned out Institutional controls (**)
Saturne	(former BNI 48)	Accelerator	1966	1997	2005: removed from BNI list	Cleaned out Institutional controls (**)
Attila* FAR	(former BNI 57)	Reprocessing pilot	1968	1975	2006: removed from BNI list	Integrated into BNI 165 and 166
LCPu FAR	(former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: removed from BNI list	Integrated into BNI 165 and 166
BAT 19 FAR	(former BNI 58)	Plutonium metallurgy	1968	1984	1984: removed from BNI list	Decommissioned
RM2 FAR	(former BNI 59)	Radio-metallurgy	1968	1982	2006: removed from BNI list	Integrated into BNI 165 and 166
LCAC Grenoble	(former BNI 60)	Fuels analysis	1975	1984	1997: removed from BNI list	Decommissioned
STEDs FAR	(former BNI 73)	Radioactive waste decay storage	1989		2006: removed from BNI list	Integrated into BNI 166
ARAC Saclay	(former BNI 81)	Fabrication of fuel assemblies	1981	1995	1999: removed from BNI list	Cleaned-out
IRCA	(former BNI 121)	Irradiator	1983	1996	2006: removed from BNI list	Cleaned out Institutional controls (**)
FBFC Pierrelatte	(former BNI 131)	Fuel fabrication	1990	1998	2003: removed from BNI list	Cleaned out Institutional controls (**)
SNCS Osmanville	(former BNI 152)	Ioniser	1983	1995	2002: removed from BNI list	Cleaned out Institutional controls (**)

APPENDIX

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2016

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Miramas uranium warehouse	(former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: removed from BNI list	Cleaned out Institutional controls (**)
Siloette Grenoble	(former BNI 21)	Reactor (100 kWth)	1964	2002	2007: removed from BNI list	Cleaned out Institutional controls (**)
Melusine Grenoble	(former BNI 19)	Reactor (8 MWth)	1958	1988	2011: removed from BNI list	Assaini
Strasbourg university reactor	(former BNI 44)	Reactor (100 kWth)	1967	1997	2012: removed from BNI list	Cleaned out Institutional controls (**)
Siloé Grenoble	(former BNI 20)	Reactor (35 MWth)	1963	2005	2015: removed from BNI list	Cleaned out Institutional controls (**)
Chooz AD (formerly-Chooz A)	163 (former BNIs 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Chinon A1D (formerly-Chinon A1)	133 (former BNI 5)	Reactor (300 MWth)	1963	1973	1982: Chinon A1 confinement decree and creation of the Chinon A1 D storage BNI	Partially decommissioned, remaining parts confined Integrated in BNI. Decommissioning file to submit
Chinon A2 D (formerly-Chinon A2)	153 (former BNI 6)	Reactor (865 MWth)	1965	1985	1991: partial decommissioning decree for Chinon A2 and creation of the Chinon A2 D	Partially decommissioned, remaining parts confined Integrated in BNI. Decommissioning file to submit
Chinon A3 D (formerly-Chinon A3)	161 (former BNI 7)	Reactor (1,360 MWth)	1966	1990	2010: decommissioning decree	Decommissioning in process
Rapsodie Cadarache	25	Reactor (40 MWth)	1967	1983		Preparation for decommissioning
EL4-D (formerly-EL4 Brennilis)	162 (former BNI 28)	Reactor (250 MWth)	1966	1985	1996: decree ordering decommissioning and creation of the EL-4D storage BNI 2006: final shutdown and decommissioning (MAD-DEM) decree 2007: decision of the *Conseil d'État* (State Council) cancelling the 2006 decree 2011: partial decommissioning decree	Partially decommissioned, remaining parts confined Integrated in BNI. Decommissioning in process Decommissioning file to submit
Spent fuel reprocessing plant (UP2) (La Hague)	33	Transformation of radioactive substances	1964	2004	2013: partial MAD-DEM decree	Decommissioning in process
STE2 (La Hague)	38	Effluent treatment facility	1964	2004	2013: partial MAD-DEM decree	Decommissioning in process
STED and high level waste storage unit (Grenoble)	36 and 79	Waste treatment and storage facility	1964/1972	2008	2008: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Bugey 1	45	Reactor (1,920 MWth)	1972	1994	2008: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Saint-Laurent A1	46	Reactor (1,662 MWth)	1969	1990	2010: decommissioning decree	Decommissioning in process
Saint-Laurent A2	46	Reactor (1 801 MWth)	1971	1992	2010: decommissioning decree	Decommissioning in process

LIST of Basic Nuclear Installations delicensed and undergoing decommissioning as at 31st December 2016

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
ÉLAN IIB La Hague	47	Manufacture of caesium-137 sources	1970	1973	2013: decommissioning decree	Decommissioning in process
High Activity Laboratory (LHA) Saclay	49	Laboratory	1960	1996	2008: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
ATUE Cadarache	52	Uranium processing	1963	1997	2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
LAMA Grenoble	61	Laboratory	1968	2002	2008: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
SICN Veurey-Voroize	65 et 90	Fuel fabrication Plant	1963	2000	2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
HAO (High Level Oxide) Facility (La Hague)	80	Transformation of radioactive substances	1974	2004	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
ATPu Cadarache	32	Fuel fabrication Plant	1962	2003	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
LPC Cadarache	54	Laboratory	1966	2003	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Superphénix Creys-Malville	91	Reactor (3,000 MWth)	1985	1997	2009: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Comurhex Tricastin	105	Uranium chemical transformation plant	1979	2009		Preparation for final shutdown
LURE	(former BNI 106)	Particle accelerators	From 1956 to 1987	2008	2015: removed from BNI list	Cleaned out institutional controls (***)
Procédé FAR	165	Grouping of former research installations (BNI 57 and 59) concerning reprocessing processes	2006		2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Support FAR	166	Grouping of former installations (BNI 34 and 73) for packaging and treating waste and effluents	2006		2006: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Ulysse Saclay	18	Reactor (100 kW)	1967	2007	2014: final shutdown and decommissioning (MAD-DEM) decree	Decommissioning in process
Phénix Marcoule	71	Reactor (536 MWth)	1973	2009	2016: decommissioning decree	Decommissioning in process

** Attila: reprocessing pilot located in a unit of BNI 57*
*** Institutional controls*
**** Active institutional controls*

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Radioactive waste and contaminated sites and soils


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This chapter presents the role and actions of ASN, the French Nuclear Safety Authority, in the management of radioactive waste and the management of sites contaminated by radioactive substances. It describes in particular the steps taken to define and determine the main radioactive waste management routes and the controls carried out by ASN with respect to nuclear safety and radiation protection in facilities involved in the management of this waste.

The term radioactive waste implies radioactive substances for which no subsequent use is planned or envisaged. These substances can come from both nuclear and non-nuclear activities in which the radioactivity naturally contained in substances, which are not used for their radioactive properties, may have been concentrated by the processes employed.

A site contaminated by radioactive substances is any site, either abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site can present risks for health and the environment. Contamination by radioactive substances can result from industrial, craft, medical or research activities.

2016 saw the finalising of the PNGMDR (French National Plan for Radioactive Materials and Waste Management) 2016-2018. This three-yearly plan presents the rules of the radioactive substances management policy nationwide, identifies new needs and determines the objectives to be achieved, more specifically in terms of studies and research to create new management solutions. It was transmitted to Parliament at the beginning of 2017. Decree 2017-231 and the Order of 23rd February 2017 set out the prescriptions.

2016 also saw the submission by Andra, the French national agency for radioactive waste management, of the safety options dossier for the deep geological repository - *Cigéo* - and ASN is currently examining this dossier. Areva has submitted to ASN and ASND, the Defence Nuclear Safety Authority (ASND), as requested by the two Authorities, its file covering the waste management and decommissioning strategy for its installations. The two Authorities will give a joint opinion on this file after examining it.

Lastly, in 2016, ASN published Guide No. 23 on the drawing up and modification of the waste zoning plan for Basic Nuclear Installations (BNI) in order to facilitate application of the regulations governing the operational management of radioactive waste in the installations.

1. Radioactive waste

Radioactive waste must be managed in accordance with specific procedures. Pursuant to the provisions of the Environment Code, the producers of spent fuel and radioactive waste are responsible for these substances, without prejudice to the liability of those who hold these substances in their role as persons or entities responsible for nuclear activities. Moreover, waste producers must pursue the objective of minimising the volume and harmfulness of their waste, both before production, by appropriate design and operation of the facilities and after production, by appropriate sorting, treatment and packaging.

The different forms of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their physical and chemical form (scrap metal, rubble, oils, etc.).

Two main parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity, which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time. A distinction is therefore made between very low, low, intermediate and high level waste on the one hand and, on the other hand, very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

Each type of waste requires the implementation of an appropriate and safe management solution in order to control the risks it represents, particularly the radiological risk.

1.1 Radioactive waste management regulatory framework

Radioactive waste management falls within the general waste management framework defined in Book V, Part IV, Chapter I of the Environment Code and its implementing decrees. Particular provisions concerning radioactive waste were introduced first by Act 91-1381 of 30th December 1991 on research into radioactive waste management, and then by Planning Act 2006-739 of 28th June 2006 on sustainable management of radioactive waste, called the "Waste Act", which gives a legislative framework to management of all radioactive materials and waste (these Acts are extensively codified in Book V, Part IV, Chapter II of the Environment Code).

This Waste Act has set a new calendar for research into High and Intermediate-Level, Long-Lived (HL and IL-LL) waste and a clear legal framework for ring-fencing the funds needed for decommissioning and for the management of radioactive waste. It also provides for the drafting of the PNGMDR, which prescribes a periodic assessment and the defining of the prospects for the radioactive substance management policy. It also increases the missions of Andra. Finally, it prohibits the disposal in France of foreign waste by providing for the adoption of rules specifying the conditions for the return of waste resulting from the reprocessing in France of spent fuel and waste from abroad.

This framework was amended in 2016 with the publication of the Ordinance of 10th February 2016 which made it possible to:
- transpose Council Directive 2011/70/Euratom of 19th July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste;
- modify existing legislation to adapt it to the provisions of this Directive without calling into question Article L. 542-2 of the Environment Code which prohibits the disposal in France of radioactive waste from foreign countries and of radioactive waste from the reprocessing of spent fuel and treatment of radioactive waste from abroad, and to detail the conditions of application of this prohibition;
- define a procedure for the administrative authority to re-qualify materials as radioactive waste;
- reinforce the existing administrative and criminal penalties and provide for new penalties in the event of disregard of the provisions applicable to radioactive waste and spent fuel or in the event of a breach of the said provisions.

Among these provisions, ASN notes the importance of defining a procedure for the administrative authority to re-qualify materials as radioactive waste.

1.1.1 Production of radioactive waste in installations regulated by ASN

ASN does not regulate all the activities associated with radioactive waste management. Activities associated with national defence are regulated by ASND. Furthermore, some radioactive waste management facilities that do not fulfil the conditions defined in Decree 2007-830 of 11th May 2007 relative to the BNI nomenclature can have the status of ICPE (Installations Classified on Environmental Protection grounds) in which case they are placed under the control of the Prefects. They can also be licensed by ASN under the Public Health Code.

Decree 2014-996 of 2nd September 2014 defines the attribution of competences with regard to the oversight of installations which manage radioactive substances. Thus the licensing of radioactive substances in sealed form (called «sealed sources») is now governed solely by the Public Health Code and is therefore regulated by ASN. The licensing of non-sealed radioactive substances and of radioactive waste, however, is governed by the Environment Code if the volume present in the facility exceeds $10m^3$, and by the Public Health Code if not.

Production of radioactive waste in the BNIs

In France, the management of radioactive waste in BNIs is governed in particular by the Order of 7th February 2012 setting the general rules relative to BNIs, of which Part VI concerns waste management.

A noteworthy characteristic of the French regulations is that there are no clearance levels[1]. In concrete terms, application of this doctrine leads, in BNIs, to the establishment of a waste zoning plan which identifies the zones in which the waste produced is or could be contaminated or activated. As a protective measure, the waste produced in these zones is managed as if it was radioactive and must be directed to specific routes. Waste from other parts of the installation, once confirmed as being free of radioactivity, is sent to authorised routes dedicated to the management of hazardous, non-hazardous or inert waste, depending on its properties.

The regulations also require licensees to conduct waste studies, indicating the targets with regard to prevention, reduction at source, harmfulness of the waste and the means implemented to reduce waste volumes and harmfulness through sorting and appropriate treatment and packaging.

1. *Activity thresholds below which it would be possible to consider that very low-level waste produced in a nuclear facility could be managed in a conventional disposal route without a requirement for traceability.*

ASN resolution of 21st April 2015 relative to the waste management study and the assessment of the waste produced in the BNIs details the provisions of the BNI Order of 7th February 2012, particularly concerning:

- the content of the waste management study, which must be submitted when a BNI is commissioned and kept up to date throughout its operation;
- the procedures for drawing up and managing the waste zoning plan;
- the content of the annual waste management assessment which each installation must transmit to ASN.

Production of radioactive waste by a nuclear activity authorised under the Public Health Code

Article R. 1333-12 of Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities related to medicine, human biology, or biomedical research that involve a risk of exposure to ionising radiation must be examined and approved by the public authorities. ASN resolution 2008-DC-0095 of 29th January 2008 lays out the technical rules applicable for the disposal of effluents and waste contaminated or potentially contaminated by radionuclides owing to a nuclear activity. ASN published a guide (Guide No. 18) to the application of this resolution in January 2012.

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Guide No. 23 on the drawing up and modification of the waste zoning plan for BNIs

In September 2016 ASN published an application guide (Guide No. 23) for its resolution of 21st April 2015 with regard to the drawing up and modification of the waste zoning plan for basic nuclear installations.

This Guide sets out the methods of establishing waste zoning based on a distinction between potential nuclear waste production zones and conventional waste zones and encourages the licensees to define zone sub-categories allowing the implementation of radiological controls that are proportionate to the risks presented by each of these sub-categories and to anticipate the problems associated with the installation decommissioning phase.

The Guide also details the methods of implementing waste zoning declassifications or reclassifications.

1.1.2 The national inventory of radioactive materials and waste

Article L. 542-12 of the Environment Code assigns Andra the duty of *«establishing, updating every three years and publishing the inventory of radioactive materials and waste present France, along with their location on the national territory»*.

The last issue of the national inventory of radioactive materials and waste was published in June 2015. It presents in particular information relative to the quantities, the nature and the location of the radioactive materials and waste at the end of 2013 and projections for the end of 2020 and the end of 2030. A prospective exercise was also conducted considering two contrasting scenarios for France's long-term energy policy. This inventory is a source of information for the PNGMDR.

ASN sits on the steering committee that supervises the exercise.

1.1.3 The French National Plan for the Management of Radioactive Materials and Waste

Article L.542-1-2 of the Environment Code, as clarified by Ordinance 2016-128 of 10th February 2016, requires the production of a National Radioactive Materials and Waste Management Plan (PNGMDR) which is revised every three years and serves to *«review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, specify the necessary capacity of these facilities and the storage durations and, for radioactive waste for which there is as yet no final management solution, to determine the objectives to be met.»* This plan is produced by a pluralistic working group co-chaired by ASN and the Ministry responsible for Energy and is revised every three years. The main provisions of the plan are set by Decree.

In application of Article L. 122-4 of the Environment Code, the analysis of the environmental impacts of the PNGMDR is now the subject of an environmental report drawn up concomitantly with this plan.

With a view to establishing the PNGMDR 2016-2018, ASN issued seven opinions to the Government on various subjects relating to the management of radioactive materials and waste:

- evaluation of the reusable nature of radioactive materials;
- management of temporary or legacy situations;
- management of Very Low-Level (VLL) and Low- and Intermediate-Level, Short-Lived (LL/ILW-SL) waste;
- management of radioactive waste that requires specific work;
- evaluation of the impact of uranium mine tailings and management of former uranium mining sites;
- management of Low-Level, Long-Lived (LLW-LL) waste;
- management of High and Intermediate-Level, Long-Lived (HL/ILW-LL) waste.

The consultations for the draft PNGMDR 2016-2018 took place throughout 2016: the Environmental Authority of the CGEDD (General Council for the Environment and Sustainable Development) issued an opinion on the Plan and its environmental report on 20th July 2016, and these documents were subject to public consultation in October, along with the draft decree and order establishing the prescriptions of the PNGMDR 2016-2018. ASN issued its opinion on these draft prescriptions for the PNGMDR on 13th December 2016. ASN emphasised in particular the importance of the provisions of these texts which allow the pursuit of the in-depth work on the structuring of management routes for radioactive materials and waste and on the need to define the application framework for the various provisions (regulatory systems applicable to the installations or PNGMDR), to inform the safety Authorities of the possibilities and conditions envisaged by the licensees for recycling the various materials, to seek out in priority the possibilities of recycling VLL materials in the nuclear sector and of being consulted for an opinion on Andra's proposed composition of the *Cigéo* reserves inventory.

The PNGMDR 2016-2018 was submitted to Parliament at the beginning of 2017, then made public. The Decree and Order of 23rd February 2017 set out respectively the prescriptions of the Environment Code and the studies to conduct in the coming years.

The plan is accompanied by a concise and educational summary for the general public presenting an overview of the management of radioactive materials and waste and the main recommendations.

1.2 ASN's role in the radioactive waste management system

The public Authorities, and ASN in particular, are attentive to the fact that there must be an operational management route for all radioactive waste and that each step of waste management is carried out under safe conditions. ASN thus considers that the development of management routes appropriate to each waste category is of vital importance and that any delay in the search for long-term waste disposal solutions will increase the volume and size of the storage areas in the facilities and the inherent risks. ASN takes care, particularly within the framework of the PNGMDR but also by regularly assessing the licensees' waste management strategy, to ensure that the system made up by all these routes is optimised through an overall and coherent approach to management. This approach must take into account all the issues relating to safety, radiation protection, traceability, volume minimisation and harmfulness of the waste.

Finally, ASN considers that this management approach must be conducted in a manner that is transparent for the public and involves all the stakeholders. The PNGMDR is thus developed within a pluralistic working group co-chaired by ASN and the General Directorate for Energy and Climate (DGEC) as described in chapter 2. ASN also publishes the PNGMDR, its synthesis, the minutes of the abovementioned working group's meetings, the studies required by the plan and the associated ASN opinions on its website.

1.2.1 Oversight of the BNIs

With regard to radioactive waste management, ASN's oversight and inspection activities aim at verifying on the one hand correct application of the waste management regulations on the production sites and on the other hand the safety of the facilities dedicated to radioactive waste management (waste treatment, packaging, storage and disposal facilities).

These activities are described in this chapter as well as in chapters 8 and 13.

1.2.2 Oversight of the packaging of waste packages

Regulations

The BNI Order of 7th February 2012 defines the requirements associated with waste packaging. Producers of radioactive waste are instructed to package their waste taking into account the requirements associated with their subsequent management, and more particularly their acceptance at the disposal facilities.

ASN has written a draft resolution specifying the requirements regarding waste packaging for disposal and the conditions of acceptance of waste packages in the disposal BNIs. This text was made available for consultation in 2015. The resolution should be published in 2017.

Production of waste packages intended for existing disposal facilities

The waste package producers prepare an approval application file based on the acceptance specifications of the disposal facility that is to receive the packages. Andra delivers an approval formalising its agreement on the package manufacturing process and the quality of the packages. Andra verifies the conformity of the packages with the delivered approvals by means of audits and monitoring actions on the package producers' premises and on the packages received at its facilities.

Waste packages intended for projected disposal facilities

With regard to disposal facilities currently being studied, the waste acceptance specifications have of course not yet been defined. Andra therefore cannot issue approvals to govern the production of packages for LLW-LL, HLW or ILW-LL waste.

Under these conditions, the production of waste packages for a disposal facility currently being studied is subject to ASN authorisation on the basis of a file called "packaging baseline requirement". This file must demonstrate that the packages display no unacceptable behaviour under the disposal conditions on the basis of existing knowledge and the currently known requirements of the disposal facilities being studied.

This provision also avoids delaying waste retrieval and packaging operations.

Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks that the licensee correctly applies the requirements of the approval and has a satisfactory command of the packaging processes. For waste packages intended for disposal facilities still being studied, ASN applies particular vigilance to ensuring that the packages comply with the conditions of the issued authorisations.

ASN also ensures through inspections that Andra takes the necessary measures to verify the quality of the packages accepted in its disposal facilities. This is because ASN considers that Andra's role in the approvals issuing process and in monitoring waste package producers is vital in guaranteeing the package quality necessary to comply with the safety case of the waste repositories.

1.2.3 Developing recommendations for sustainable waste management

ASN issues opinions on the studies submitted in application of the Decree setting the requirements of the PNGMDR. ASN also gives the Government its recommendations concerning the disposal projects for long-lived radioactive waste.

1.2.4 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue statutory resolutions. Thus, the provisions of the BNI Order of 7th February 2012 which concern the management of radioactive waste have been set out in ASN resolutions on the subjects of waste management in BNIs and the packaging of waste, resolutions which have undergone public consultation and are awaiting publication. Other ASN resolutions may detail, among other things, the prescriptions applicable to the storage of radioactive waste and to the facilities intended for its disposal.

Lastly, ASN is consulted for its opinion on draft regulatory texts relative to radioactive waste management.

More generally, ASN issues requirements relative to the management of waste from the BNIs. These requirements are set out in ASN resolutions which are subject to public consultation and published on its website.

1.2.5 Evaluation of the nuclear financial costs

The regulatory framework designed to ring-fence the financing of nuclear facility decommissioning costs or, for radioactive waste disposal facilities, the final shutdown, maintenance and monitoring costs, in addition to the cost of managing spent fuel and radioactive waste, is described in chapter 15 (see point 1.4).

1.2.6 ASN's international action in the area of waste

ASN participates in the work of WENRA (Western European Nuclear Regulators' Association) aiming at harmonising nuclear safety practices in Europe by defining "reference safety levels" which must be transposed into the national regulations of its member countries. In this respect, the WGWD (Working Group on Waste and Decommissioning) is tasked with developing reference levels for the management of radioactive waste and spent fuel. Following the work already carried out on storage, disposal and decommissioning, ASN participated in the development of reference levels for the packaging of radioactive waste in 2016. A plan of action has been drawn up for transposition of the levels which have not been transposed to date. ASN resolutions will detail the provisions of the Order of 7th February 2012 defining the general regulations applicable to BNIs.

ASN also tracks the transposition of the reference levels in the WENRA member countries, which they present at the follow-up meetings. ASN participates in the International Atomic Energy Agency's (IAEA) Waste Safety Standards Committee (WASSC), whose role is to draft the international standards, particularly concerning the management of radioactive waste. It also takes part in the work of ENSREG (European Nuclear Safety Regulators Group) group 2 which is responsible for subjects relative to radioactive waste management.

ASN also participates in projects of a technical nature with the European Union (SITEX) and IAEA (GEOSAF, HIDRA).

In 2017, ASN will coordinate the authoring of the French national report on the implementation of the obligations of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management which France will send to the IAEA in October 2017. This report will present the implementation of the obligations of the Joint Convention by all the French actors concerned. It also details the developments in the European and French regulatory frameworks, in the spent fuel and radioactive waste management policies, and the issues raised by the decommissioning of nuclear facilities. The report also specifies the new steps taken by France to integrate the lessons learned from the Fukushima Daiichi accident. It will be examined in May 2018 in Vienna.

ASN's international actions are presented more generally in chapter 7.

1.3 Long-term management solutions for radioactive waste

1.3.1 Disposal of Very-Low-Level (VLL) waste

Cires (Industrial Centre for Nuclear Waste Collection, Storage and Disposal), located in the towns of Morvilliers and La Chaise in the Aube *département* and operated by Andra, includes a disposal facility for Very-Low-Level (VLL) waste. This facility, which has ICPE status, has been operational since August 2003.

At the end of 2016, the volume of waste in the Cires repository was about 328,000 m^3, or 50.5% of the authorised capacity (650,000 m^3). The latest production estimates for VLL waste indicate that the needs will exceed the capacity planned for when the centre was designed. However, the annual VLL waste production streams have been lower than projected in the last few years.

In 2015, under the PNGMDR 2013-2015, Andra submitted a comprehensive industrial scheme meeting the needs for new VLL waste disposal capacity. ASN examined this scheme and gave the Government an opinion on VLL waste management on 18th February 2016.

In this opinion, ASN considers that Andra and the waste producers must continue their efforts to reduce the quantity of VLL waste, particularly by optimising its production and densification. ASN also considers that consolidation of the VLL waste production projections is a vital step in guiding future choices in the overall optimisation of the management route. ASN also considers that the absence of clearance levels for the management of contaminated, activated or potentially activated waste must remain the cornerstone of VLL waste management in France and that reuse of VLL waste is a practice which must not become commonplace and could only be permitted as a waiver under certain conditions, first and foremost in the nuclear sector[2].

2. *A pluralistic working group (ASN, licensees, government departments, associations, etc.), mandated by ASN and the DGEC under the PNGMDR, has identified potential conditions of reuse of VLL waste. The report submitted in 2015 is available on the ASN website.*

ASN considers moreover that the possibilities for reusing VLL waste within the nuclear sector must be fully exploited before turning to other outlets if necessary.

As authorised disposal capacities are expected to have been reached by 2025-2030, ASN considers that Andra must examine the possibility and conditions of increasing the volume capacity of Cires without changing its ground coverage area and, subject to these conditions being favourable, filing the corresponding modification (or extension) application as soon as possible.

ASN considers that a second VLL waste disposal facility will ultimately be necessary to maintain the availability of disposal capacities for this waste. ASN also considers that VLL waste producers must engage in an approach that allows an in-depth examination of the feasibility of creating disposal facilities appropriate for certain types of VLL waste on their sites.

1.3.2 Disposal of Low and Intermediate-Level, Short-Lived (LL/ILW-SL) waste

The majority of LL/ILW-SL waste is placed in surface disposal facilities operated by Andra. Once these facilities are closed, they are subject to monitoring during an "oversight phase" set by convention at 300 years. The facility safety case – which is updated periodically, including during the oversight phase – must show that at the end of this phase the residual activity contained in the waste is such that human and environmental exposure levels are acceptable, even in the event of a significant loss of the containment properties of the facility.

There are two such repositories in France.

The Manche repository - BNI 66

The Manche waste Disposal Facility (CSM), which was commissioned in 1969, was the first radioactive waste repository operated in France. 527,225 m^3 of waste packages are emplaced in it. The CSM stopped accepting waste in July 1994.

In application of Decree 2016-846 of 28th June 2016, the CSM is no longer considered to be in monitoring phase but in operation until the long-term cover has been definitively put in place. An ASN resolution will specify the duration of the operations in question and the minimum duration of the CSM monitoring phase.

ASN considers that the state and the operation of the facilities are satisfactory. Andra must continue its efforts to reinforce the stability of the cover and to eliminate the residual infiltrations of water into the repository at the edge of the membrane. An interim review of the work on the repository cover was presented in 2015. ASN has requested additional technical information.

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The decommissioning of radioactive waste disposal facilities

The new legislative provisions resulting from transposition of the "Waste" Directive of 19th July 2011 have introduced a definition of the notion of closure in Article L. 542-1-1 of the Environment Code and a new definition of decommissioning for disposal facilities in Article L. 593-31.

In effect, the Ordinance of 10th February 2016 introducing various provisions relating to nuclear activities supplements Article L. 542-1-1 of the Environment Code by defining the closure of a radioactive waste disposal facility as *"completion of all the operations resulting from the emplacement of radioactive waste in the facility, including the last engineering structures or other work required to ensure long-term control of the risks and inconveniences that the facility presents for the interests mentioned in article L. 593-1."* This Ordinance also specifies the provisions of Article L. 593-31 of the above Code which now states that in the particular case of facilities devoted to radioactive waste disposal, *"decommissioning means all operations carried out after final shutdown in preparation for closure of the facility, and closure itself"*.

Decree 2016-846 of 28th June 2016 relative to the modification, final shutdown and decommissioning of BNIs and subcontracting, indicates the conditions of application of these new legislative provisions by modifying Article 42 of Decree 2007-1557 of 2nd November 2007. It stipulates more specifically that *"closure of the facility devoted to radioactive waste disposal and its entry into monitoring phase are subject to the prior consent of the ASN [...]"*.

These new definitions thus provide a clearer "end of life" framework for disposal facilities by indicating the links between final shutdown (stopping reception of waste), the decommissioning phase (closure preparation operations, including more specifically putting in place the long-term cover in the case of a surface disposal facility), closure of the facility and its entry into monitoring phase.

This information will more specifically enable the characteristics of the long-term cover to be examined.

Reminder: the tritium concentrations in the ground and surface waters in the vicinity of the CSM are measured regularly in order to monitor the tritium contamination of the water table, discovered in 1976 further to the disposal of waste containing high concentrations of tritium (waste retrieved between 1976 and 1978).

In 2016, the association Greenpeace France filed a complaint on this subject. A judicial investigation is in progress.

The Aube repository - BNI 149

Authorised by the Decree of 4th September 1989, the Aube repository (CSA) took over from the Manche repository (CMS), benefiting from the experience gained with it. This facility, situated in Soulaines-Dhuys, has a disposal capacity of one million cubic metres of LL/IL-SL waste. The operations authorised on the facility include waste packaging by injection of mortar into 5 m^3 or 10 m^3 metal crates, or by compacting 200-litre drums.

At the end of 2016, the volume of waste in the repository was about 316 m^3, or 31.6% of the authorised capacity. According to the estimations made by Andra in 2015 for the PNGMDR 2013-2015, the CSA could be filled to capacity by 2060.

In 2016, Andra continued the modification work on the package inspection facility aiming to give the site more efficient means for checking the quality of the packages received at the CSA. The commissioning of this facility, planned for early 2017, will require an ASN authorisation. Construction of the disposal structures of section 9, for which ASN has given its agreement, continued in 2016.

In 2016, ASN also authorised the CSA to accept non-standard packages originating from the decommissioning of the Superphénix installation at Creys-Malville.

ASN considers that the CSA is operated satisfactorily, in line with previous years.

Andra sent ASN the periodic safety review file for the CSA in August 2016. The examination of this file will focus in particular on evaluating the safety of the facility with regard to the planned development of its activities over the next ten years.

1.3.3 Management of High and Intermediate-Level, Long-Lived (HL/ILW-LL) waste

The "Waste" Act of 28th June 2006 states that research into the management of HL/ILW-LL waste should be pursued in three complementary directions: separation and transmutation of long-lived radioactive elements, storage, and reversible disposal in a deep geological repository, in continuity with the Act of 30th December 1991. ASN considers that studies in these three directions are on the whole proceeding satisfactorily.

Separation/Transmutation

Separation/transmutation processes aim to isolate and then transform long-lived radionuclides in radioactive waste into shorter-lived radionuclides or even stable elements. The transmutation of the minor actinides contained in the waste could have an impact on the size of the disposal facility, by reducing both the heating power of the packages placed in it and the repository inventory. However, the impact of the disposal facility on the biosphere, which originates essentially from the mobility of the fission and activation products, would not be significantly reduced.

Under the PNGMDR, during 2015 CEA submitted an interim assessment report on the industrial prospects of the separation/transmutation processes. On 25th February 2016, ASN issued another opinion on this file, in line with its opinion of 4th July 2013.

ASN considers that the expected gains from the transmutation of minor actinides in terms of safety, radiation protection and waste management do not appear to be decisive, particularly given the resulting constraints on the fuel cycle facilities, the reactors and the transport operations, which would involve highly radioactive materials at all stages of the fuel cycle. ASN also considers that these gains do not eliminate the need for a deep disposal facility and would only be tangible on the assumption of a nuclear fleet operating for more than one hundred years with a level of production sufficient to maintain overall consistency with the characteristics of the fuel cycle facilities.

Storage

The Waste Act states that storage studies must be carried out by Andra so that *"no later than 2015, new storage facilities can be created or existing facilities modified to meet the needs, particularly in terms of capacity and duration"*. The needs to extend or create storage facilities must be anticipated and listed. Uncertainties subsist with regard to the schedule for commissioning a deep geological disposal facility, the delivery time frames that Andra will adopt, and the acceptability of certain waste packages. ASN is thus attentive to ensuring that the holders of HL/IL-LL waste have storage facilities with sufficient margins on storage capacities and possible storage times.

To verify the robustness of these margins, the opinion issued by ASN on 25th February 2016 asked that waste producers study the consequences of postponing the date of *Cigéo* commissioning by several years beyond the planned date of 2030. This will allow the identification of any threshold effects in terms of future storage requirements or extensions to the operating duration of ageing storage facilities. ASN moreover considers that the PNGMDR should keep track of the filling status of storage facilities.

Andra is tasked with gathering and capitalising on experience feedback from the construction and operation of existing facilities or those being developed. It is also tasked with conducting research on the behaviour of the materials used to construct the storage structures and package materials as well as monitoring techniques. Andra has been set the objective of optimising the durability, the monitoring, the heat removal and, if necessary, the versatility of these storage facilities.

The PNGMDR 2013-2015 required Andra to produce, after consultation with Areva, CEA and EDF, recommendations for the design of storage facilities to complement the disposal process.

Analysis of the documents communicated by Andra shows that no significant progress can be expected from further detailing the engineering design of future storage facilities in a generic context. Nevertheless, these studies have allowed the identification of several guidelines which must be followed when designing new storage facilities or when the licensees conduct their periodic safety reviews.

Lastly, Andra indicates that it has stopped its research into near-surface disposal facilities due notably to the management of groundwater, which is extremely complex - particularly with regard to ventilation management when exothermic waste is involved - and less flexible. The insufficient degree of technical detail of the document submitted by Andra does not however allow a ruling on the appropriateness of definitive abandonment of the near-surface storage facility design option. ASN thus considers in its opinion of 25th February 2016 that Andra must detail, for the PNGMDR 2016-2018, the technical and economic elements allowing a comparison of the advantages and drawbacks of near-surface storage facilities compared with above-ground or partially buried facilities, particularly in terms of robustness and safety with respect to external hazards.

Reversible deep geological disposal

The deep geological disposal studies fit into the guidelines of Article L. 542-1-2 of the Environment Code, namely that *"after storage, ultimate radioactive waste which, for nuclear safety or radiation protection reasons, cannot be disposed of on the surface or at shallow depth, shall be disposed of in a deep geological repository"*.

Underground laboratory of Meuse/Haute-Marne: rigid design drift.

The Waste Act assigns Andra the task of designing a deep geological disposal facility, which is considered to be a BNI and therefore subject to ASN oversight.

The principle of this type of disposal

Deep geological disposal of radioactive waste consists in placing packages of radioactive waste – without the intention of retrieving them – in an underground facility situated in a deep geological formation whose characteristics ensure the containment of the radioactive substances present in the waste. Such a disposal facility– unlike storage facilities – must be designed such that long-term safety is ensured passively, that is to say without depending on human actions (such as monitoring or maintenance activities) which require oversight, the durability of which cannot be guaranteed beyond a limited period of time. Lastly, the depth of the disposal structures must be such that they cannot be significantly affected by the expected external natural phenomena (erosion, climate change, earthquakes, etc.) or by "normal" human activities.

Under these conditions, in its opinion of 1st February 2006, ASN considers deep geological disposal to be an *"unavoidable definitive management solution"*.

In 1991 ASN published Basic Safety Rule RFS III-2-f defining the objectives to be set in the design and works phases for final disposal of radioactive waste in deep geological formations, in order to ensure safety after the operational life of the repository. In 2008 it published an update of this document which became Safety Guide No.1.

Underground laboratory of Meuse/Haute-Marne

Studies on deep geological disposal necessitate research and experiments in an underground laboratory. Andra has been operating such an underground laboratory within the Bure municipality since 1999. A fatal accident caused by a structural collapse occurred in 2016. A judicial inquiry is in progress.

ASN issues recommendations concerning the research and experiments, and ascertains through follow-up inspections that they are carried out using processes that guarantee the quality of the results.

FOCUS

International review of the *Cigéo* Safety Options Dossier (DOS) organised by the IAEA

Given that the *Cigéo* deep geological repository for radioactive waste project is unique in France, ASN wanted the examination of the DOS to be conducted as an international peer review. ASN asked the IAEA to organise an international peer review of this dossier by experts from foreign Nuclear Safety Authorities.

This review was held in France from 7th to 15th November 2016. The seven experts involved in the review, internationally acknowledged in their area of competence and led by Jussi Heinonen, Director of Nuclear Waste and Materials Regulation at STUK (*Säteilyturvakeskus*), the Finnish Nuclear Safety Authority, submitted their conclusions to ASN on 15th November.

The experts examined the DOS submitted by Andra against standards established by the IAEA. ASN asked the IAEA to examine in particular the research and development programme in relation to the development of the project, Andra's plans for *Cigéo* monitoring, and the defining of scenarios for safety in operation and over the long term.

The review experts underlined the quality of the discussions they had with Andra during the review. These discussions and the analysis of the documents in the DOS led the experts to make several observations, suggestions and recommendations. These converge with some requests made by ASN on a number of subjects such as the link between the research and development programme and the industrial development or the monitoring of the repository. They will be examined attentively in the next stages of examination of the *Cigéo* project DOS, on which ASN will give its opinion in Summer 2017.

FOCUS

ASN's position on reversibility

In the context of the discussions on the bill relative to deep geological disposal, which should, among other things, detail the notion of reversibility, ASN issued an opinion on deep geological disposal reversibility on 31st May 2016. ASN set down the following principles in this opinion:

"The principle of reversibility implies two requirements:
- ***a requirement for adaptability:*** *: the facility must be able to adapt to take into account:*
  - *experience feedback and scientific progress (which would for example lead to changes in the industrial processes used),*
  - *possible changes in energy policy or industrial choices (for example leading to direct disposal of spent fuels or closure operations that are deferred for varying periods of time). The adaptability inventory defined in the above-mentioned opinion of 10th February 2015* must be presented as of the creation authorisation application,*
- ***a retrievability requirement:*** *it must be possible to remove the waste from the disposal facility:*
  - *over a period governed by the Act;*
  - *in controlled conditions of safety and radiation protection, including in the case of degradation of the structures and the waste packages."*

These two notions of adaptability and retrievability have been taken up in Act 2016-1015 of 25th July 2016 which supplements Article L. 542-10-1 of the Environment Code to define the notion of reversibility. This is now defined as *"the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive nature of the construction, the adaptability of the design and the operational flexibility of placing radioactive waste in a deep geological repository which can integrate technological progress and adapt to possible changes in waste inventory following a change in energy policy for example. It includes the possibility of retrieving waste packages from the repository under conditions and during a period of time that are consistent with the operating strategy and the closure of the repository".*

As for the ASN requests concerning the necessity for an adaptability inventory to be presented as soon as the creation authorisation application is submitted, they have been taken up in the implementing decree for the PNGMDR 2016-2018.

The regulatory framework governing waste retrievability will have to be specified. ASN will make a position statement on this subject on completion of the examination of the *Cigéo* project safety options dossier.

** ASN Opinion 2015-AV-0227 of 10th February 2015 concerning the evaluation of the costs of the Cigéo radioactive waste deep geological disposal project;* "ASN considers it necessary to define an umbrella inventory, baptised «adaptability inventory» presenting a broader vision and covering possible changes in waste inventory resulting from future decisions in terms of energy or industrial policy, and the redirecting to geological disposal of certain types of waste which would be unacceptable in near-surface disposal."

Technical instructions

Under the Act of 30th December 1991 through until 2006, and then under the Waste Act and the PNGMDR, Andra has carried out studies and submitted reports and files on deep geological repository. These studies and reports have been examined by ASN - referring in particular to the Safety Guide of 2008 - and it has issued an opinion on them.

ASN has thus primarily examined the overall files submitted by Andra in 2005 and at the end of 2009. It gave the Government its opinion on these files on 1st February 2006 and 26th July 2011.

Andra is continuing its work and ASN examines the files submitted to it to measure the progress of the studies and work carried out.

ASN issued a position statement:
- in 2013, on the documents produced between 2009 and 2013 - the year of the public debate, and on the intermediate design milestone at the outline stage presented by Andra in 2012;
- in 2014, on the safety components of the closure structures and the expected content of the safety options dossier for the facility;
- in 2015, on the control of operating risks and the cost of the project.

In 2016, ASN examined the file submitted by Andra entitled Components Development Plan. ASN once again underlined the need for Andra to make sure that the research and development work is well coordinated with the planned project development phases in order to ensure the availability of the data necessary for the facility's safety case. ASN has asked Andra to update its *Cigéo* project schedule, as the current project does not include margins to cover potential unforeseeable events and uncertainties concerning project time frames. ASN informed Andra of its observations in a letter dated 20th June 2016 so that they could be taken into account in the future creation authorisation application file.

The authorisation process

The examination of a creation authorisation application for a deep geological disposal facility has not been started. It will begin when Andra files such an application, which at present is planned for mid-2018. The conditions for creating a reversible deep geological repository for HL and IL-LL radioactive waste are detailed in Act 2016-1015 of 25th July 2016. Some proposals made by Andra's Board of Directors further to the conclusions of the public debate have been implemented, such as the setting up of an industrial pilot before operating the facility at industrial rates. The Board of Directors of Andra also decided to submit a Safety Options Dossier[3] for the *Cigéo* repository project to ASN before applying for the facility creation authorisation.

ASN welcomed this decision which is in keeping with the stepwise development promoted in the ASN Safety Guide relative to radioactive waste disposal in deep geological formations, and informed Andra of its expectations regarding the content of this dossier by letter dated 19th December 2014.

Examination of the dossier submitted by Andra started in Spring 2016.

The cost of the project

In accordance with the procedure stipulated in Article L. 542-12 of the Environment Code, after consideration of ASN's opinion of 10th February 2015 and the comments of the radioactive waste producers, the Minister responsible for Energy issued an Order on 15th January 2016 setting the reference cost of the *Cigéo* disposal project *"at €25 billion under the economic conditions prevailing on 31st December 2011, the year in which the cost evaluation work began». This Order also specifies that the cost must be updated regularly and «at least at the key stages of project development (creation authorisation, commissioning, end of the «industrial pilot phase», periodic safety reviews), in accordance with the opinion of ASN."*

3. *Article 6 of the Decree of 2nd November 2007 stipulates that* "any person who plans operating a BNI can, before initiating the creation authorisation procedure provided for by Article 29 of Act 2006-686 of 13th June 2006, ask ASN for an opinion on all or part of the options it has chosen to ensure the safety of that installation. ASN, through an opinion rendered and published under conditions determined by ASN, indicates the extent to which the safety options presented by the applicant are appropriate for preventing or mitigating the risks for the interests mentioned in I of Article 28 of the Act of 13th June 2006, given the prevailing technical and economic conditions. It may indicate the additional studies and justifications that will be required for a prospective creation authorisation application. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Ministers responsible for nuclear safety."

1.3.4 Low-level long-lived waste management

Low-Level Long-Lived (LLW-LL) Waste comprises two main categories: graphite waste resulting from the operation of the Gas-Cooled Reactor (GCR) nuclear power plants, and radium-bearing waste, from the radium industry and its offshoots. Other types of waste fall into this category such as certain bituminised effluents, substances containing radium, uranium and thorium with low specific activity, as well as certain spent sealed radioactive sources.

FOCUS

ASN opinion on Andra's interim report on the Low-Level Long-Lived (LLW-LL) Waste disposal project

In its opinion of 29th March 2016 on the interim report submitted by Andra, ASN considers that it will be difficult to demonstrate the feasibility - in the investigated area - of a disposal facility for all the LLW-LL waste considered in the file. As Andra is pursuing its geological investigations on the site of the municipal federation of Soulaines, ASN considers that it must indicate the proportion of the LLW-LL waste that could be emplaced on the studied site by verifying, in particular, the quality of the layers of clay situated above and below the disposal facility. In this context, ASN asks Andra to submit a report presenting the technical and safety options for this disposal facility by mid-2019. ASN also considers it necessary for Andra, in collaboration with the producers of LLW-LL waste, to submit an industrial scheme for the management of LLW-LL before the end of 2019:

- covering all LLW-LL waste, and more specifically the graphite and LLW-LL bitumen waste, the waste produced as from 2019 by the Areva NC Malvési plant and radium-bearing waste,
- taking into account all the management solutions and the projected waste production time frames and the implementation of these solutions. The search for a second near-surface disposal site for LLW-LL waste, based more specifically on the recommendations of the HCTISN (French High Committee for Transparency and Information on Nuclear Security) of 7th October 2011.

In a letter dated 19th July 2016, ASN also indicated the points in Andra's file necessary for the future examinations and which required further development, such as the LLW-LL disposal design hypotheses, an evaluation of disposal facility safety in operation and after closure, the quality and performance of the chosen geological formation and consolidation of the waste inventory likely to be disposed of on the studied site.

The PNGMDR 2013-2015 required the various players involved to carry out studies (characterisation and waste treatment possibilities, geological investigations on a site identified by Andra, design studies and preliminary safety analyses) so that in 2016 the State can specify guidelines for the management of LLW-LL waste.

The holders of LLW-LL waste have thus progressed in the characterisation of their waste and in the processing possibilities, particularly with regard to graphite waste and some types of bitumen-solidified waste. More specifically, the radiological inventory for chlorine-36 and iodine-129 has been considerably reduced.

As part of the PNGMDR, Andra submitted a report in July 2015 containing:
- proposals of choices of management scenarios for graphite and bituminous waste, notably with the possibility of reinitiating the search for a site for an "intact cover disposal" type repository or not;
- a feasibility file for the project for a "reworked cover disposal.[4]" type disposal facility, the types of waste to be placed in it and the schedule for its deployment.

1.4 The radioactive waste management strategies of the nuclear licensees

ASN requires that licensees define a management strategy for all the radioactive waste produced in their facilities and it periodically evaluates this strategy.

These management strategies can be based on facilities specific to each licensee but also on facilities operated by other licensees (Andra and Socodei), described earlier.

The waste management procedures adopted by the three main waste producers are presented below.

1.4.1 CEA waste management

Types of waste produced by CEA

CEA operates diverse installations covering all the activities associated with the nuclear cycle, ranging from laboratories and plants involved in research on the fuel cycle to experimental reactors.

CEA also carries out numerous decommissioning operations.

4. Reworked cover disposal is disposal at shallow depth achieved by open-cast excavation of a layer with a clayey or marly component to reach the storage level. Once filled, the vaults are covered by a layer of compacted clay followed by a protective layer of planted vegetation reconstituting the site's natural level.

Consequently, the types of waste produced by CEA are varied and include more specifically:
- standard waste resulting from operation of the research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and packaging projects (sodium, magnesium and mercury-bearing waste);
- decommissioning waste following the final shutdown and decommissioning of facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also varied: presence of alpha emitters in activities relating to fuel cycle research, beta-gamma emitters for operational waste from the experimental reactors.

CEA has specific facilities for managing this waste (processing, packaging and storage). It should be noted that some of these facilities are shared between all the CEA centres, such as the liquid effluent treatment station in Marcoule or the solid waste treatment station in Cadarache.

The issues and implications

The two main issues for CEA with regard to radioactive waste management are:
- bringing new waste processing and storage facilities on-line or renovating existing ones within a time frame compatible with its commitments to shut down old installations whose level of safety no longer complies with current requirements;
- the management of legacy waste retrieval and packaging projects

ASN notes the difficulty CEA has in fully managing these two issues and conducting all the associated projects, especially decommissioning projects, at the same time.

ASN's opinion on CEA's waste management strategy

ASN's last examination of CEA's strategy, which was concluded in 2012, showed that waste management on the whole had improved since the previous examination in 1999. CEA's organisation and the implementation of management tools must enable it to evaluate the movements of waste produced in the coming years and in particular to forecast storage and transport packaging needs.

Nevertheless, given the diversity of the projects and the corresponding waste produced, ASN has observed disparities in the quality of results, particularly with regard to the management of long-lived intermediate-level solid waste and low or intermediate-level liquid waste. CEA has still not defined its strategy for managing the solid radioactive waste produced on the Saclay site following the shutdown of BNI 72 (see page 512).

More particularly, the very significant increases in the projected duration of decommissioning operations along with the quantity, non-standard nature and difficulty in characterising certain substances or waste that will be removed from storage or produced during the decommissioning operations led ASN and ASND to jointly ask CEA to conduct an overall review in 2016 of its decommissioning and radioactive materials and waste management strategies for the next fifteen years. This report was received in December 2016 and will be examined by ASN and ASND so that the two authorities can have an overall view of the subject and establish a joint position on CEA's strategy.

Facilities operated by CEA to support this strategy

Facilities under construction

- **Diadem - BNI 177**

After having provided a safety options dossier in November 2007, in April 2012 CEA submitted an authorisation application file for the creation of the BNI 177, called Diadem and situated in the CEA Marcoule centre (Gard *département*). This creation was authorised by Decree 2016-793 of 14th June 2016, further to the opinion of ASN dated 12 November 2015.

Diadem is intended for the storage on the Marcoule centre of containers of radioactive waste emitting beta or gamma rays or with high levels of alpha emitters. It has been designed to function for at least fifty years.

Diadem occupies an important position in CEA's management strategy for ILW-LL and LL/ILW-SL radioactive waste. Its entry into service will allow the decommissioning of some of its installations, especially the Phénix reactor (BNI 71), and the retrieval and packaging of legacy waste held by CEA (at the Fontenay-aux-Roses Centre in particular) to be carried out.

Since the start of the worksite at the end of 2014, ASN has carried out inspections to check the quality of construction of the structure and verify that commitments made by CEA following the technical examination of the BNI creation authorisation application file have been met. These inspections have shown that this worksite is proceeding under satisfactory conditions.

At the end of 2016 the civil engineering work was almost finished and ASN considers that the construction phase commitments (hydrology, geology, excavations, drainages and concreting) have been satisfied.

FOCUS

Creation of the Diadem BNI

Creation of the BNI was authorised by Decree 2016-793 of 14th June 2016. In addition to the general information on the BNI, its creation authorisation decree stipulates:
- the duration of waste storage in the facility;
- the specifications for acceptance of radioactive waste packages in the facility;
- the waste package monitoring requirements; the monitoring programme put in place by CEA must allow the evolution of the content of certain packages containing potentially degradable radioactive waste, especially organo-halogenated compounds, to be monitored;
- the availability of a facility, in addition to Diadem, authorised to handle nonconforming waste packages;
- the civil engineering monitoring requirements.

In order to check the content of the commissioning authorisation application file that CEA plans filing for this facility in 2017, ASN has supplemented the provisions of the Decree of 14th June 2016 by resolution Codep-CLG-2016-044832 of 17th November 2016. The prescriptions of this resolution concern the radioactive waste packages and the safety of the facility, focusing in particular on:
- the margins or the assessment of the facility design-basis margins, particularly with respect to external hazards;
- integration in the safety baseline requirements and in the licensee's integrated management system of requirements relative to elements involved in demonstrating the control of risks and inconveniences;
- updating the design-basis study for the on-site emergency plan;
- taking into account the conclusions of the stress tests carried out to draw the lessons from the Fukushima Daiichi accident, particularly relative to defining a «hardened safety core» for the facility.

CEA has not yet defined the definitive packaging procedures that will be adopted to adapt the waste packaging to the acceptance specifications of the receiving disposal facilities. These procedures should be taken into account to optimise the initial packaging of the waste that will be stored in Diadem. CEA must study these procedures following a schedule to be defined before the facility is commissioned.

Diadem construction site, November 2016.

Installations in operation

On the Cadarache site

• **Agate facility (BNI 171)**

The function of the Agate facility, which was authorized by Decree 2009-332 of 25th March 2009, is to concentrate, through evaporation, radioactive aqueous liquid effluents chiefly containing beta- and gamma-emitting radionuclides. The resulting concentrates must then be conditioned in the liquid effluents treatment station of Marcoule.

ASN authorised commissioning of this facility on 29th April 2014. An end-of-start-up file incorporating experience feedback from the facility's first year of operation was communicated by CEA on 30th October 2015. Examination of this file is reaching completion.

Although the measures for monitoring outside contractors need to be improved, ASN considers that the organisational set-up, which takes good account of the Social, Organizational and Human Factors (SOHF), can ensure a satisfactory level of safety. The inspections and periodic tests, particularly those concerning system sealing, must be improved.

• **Cedra facility (BNI 164)**

The purpose of the Cedra facility, which was authorised by Decree 2004-1043 of 4th October 2004, is to process Intermediate-Level, Long-Lived Waste (ILW-LL) and store packages of low and medium irradiating waste pending the creation of an appropriate disposal route. The package storage duration is limited to fifty years.

ASN authorised commissioning of the first section of the storage facility for Low-Irradiating (LI) Waste (two storage halls) and Medium Irradiating (MI) Waste (one storage hall) in April 2006.

At the end of December 2016, the filling rate was 38% for the LI halls and 31% for the MI hall. According to CEA's projections, the LI halls should be filled to capacity as of 2029 and the MI hall by 2027, but this latter time frame is highly dependent on the rate of removal of waste from BNI 56.

The monitoring cell commissioning file was approved by ASN on 6th January 2016.

CEA submitted the periodic safety review guidance file to ASN in June 2016. It will submit the safety review conclusions file in November 2017. In its resolution 2014-DC-0450 of 22nd July 2014, ASN specified that the periodic safety review must address all authorised sections, not just those that are built. This resolution also requires CEA to define, at the same time as the periodic safety review, the projected construction schedule for the sections not yet built and, if applicable, to indicate whether in the short term it renounces building the waste processing section and consequently requests the modification of its Creation Authorisation Decree (DAC). CEA has chosen this latter option and plans submitting a DAC modification request before submitting the periodic safety review file.

In the periodic safety review, ASN will be particularly attentive to the scope and method adopted by CEA to review the conformity of the installation and the stored packages in particular. 2016 was effectively marked by significant event notifications concerning noncompliance with package acceptance specifications and the dropping of an MI bin, an event that had already occurred in 2012.

ASN considers that operating rigour at Cedra must be improved.

An annexe ("cold" building for equipment storage) should be put into service in the near future.

- **Cascad facility (BNI 22)**

The Cascad facility, authorised by a Decree of 4th September 1989 modifying the Pégase facility and operated since 1990, is dedicated to the dry storage of spent fuel canisters in wells.

Unlike Pégase, from which all radioactive substances must be removed as soon as possible, Cascad is a long-term storage site for which the SSE[5] resistance has been verified. Completion of the safety improvement actions resulting from the periodic safety review of 2007 formed the subject of summary notes communicated in 2016.

Through resolution CODEP-DRC-2014-026017 of 8th July 2014, ASN authorised a further ten years of storage for the spent fuels already present in the facility. This resolution is without prejudice to the conclusions of the facility's next periodic safety review for which the file shall be submitted in November 2017, the same deadline as for Pégase. CEA submitted the periodic safety review guidance file in March 2016.

In June 2016, 84.5% of the storage wells were occupied. With regard to the change in the source term over the next ten years, CEA considers that the Cascad wells will reach 91% capacity in 2026 (provided that the fuel from Phénix is removed before 2023).

ASN has asked CEA, in the context of updating its radioactive material and waste management strategy, to give reasons for abandoning or maintaining the construction of the second section provided for in Article 2 of the Decree of 4th September 1989 and, if applicable, to submit a DAC modification request.

After 2018, CEA plans starting the uncoupling work to separate Pégase and Cascad with a view to continuing operation of Cascad and decommissioning Pégase. The safety options associated with the separation of these two facilities and defining their respective perimeters must be presented in the periodic safety review file.

ASN's opinion on the safety of operation of the Cascad facility is generally positive.

- **Chicade (BNI 156)**

Chicade (BNI 156) (chemistry, waste characterisation) is a facility for research and development on low and intermediate level waste. This work mainly concerns:
- the destructive and non-destructive characterisation of radioactive objects, waste sample packages and irradiating objects;
- the development and qualification of nuclear measurement systems;
- the development and implementation of chemical and radiochemical analysis methods;
- the assessment and monitoring of waste packaged by the waste producers.

Creation of the facility was authorised by the Decree of 29th March 1993 and its definitive commissioning was authorised in 2003.

CEA is considering extending the facility's activities (waste packaging) in 7 to 10 years' time. ASN considers that CEA must ensure that the facility is appropriately dimensioned to be able to operate with the envisaged extensions.

CEA has put back submittal of the facility's periodic safety review report - initially planned for mid-2016 - until 2017. ASN will be particularly attentive to the earthquake hazard analysis for the LLW building and the methods of increasing its resistance.

CEA has also informed ASN of its intention to apply for a gaseous discharge authorisation at the end of 2018.

On the Saclay site

- **Stella facility (BNI 35)**

BNI 35, declared by CEA by letter on 27th May 1964, is dedicated to the treatment of radioactive liquid effluents. By Decree 2004-25 of 8th January 2004, CEA was authorised to create an extension in the BNI, called Stella, for the purpose of treating and packaging low-level short-lived aqueous effluents from the Saclay centre. These effluents are concentrated by evaporation then immobilised in a cementitious matrix in order to produce packages acceptable by Andra's surface waste disposal centres.

The concentration process was put into service in 2010, but the appearance of cracks in the first packages led ASN to limit the packaging operations. CEA has thus only packaged certain effluents coming from one of the installation's tanks that contains 40 m^3 of concentrates. ASN does however note a positive trend in the discussions between CEA and Andra for the examination of the package approval requests. It nevertheless remains attentive to the progress of the approval file for the 12H package, for which CEA must mobilise the necessary resources. Should this examination not be concluded within the regulatory time, the cementation process used could be called into question.

During the preparation for the renovation work on the roof of hall 97of the facility, CEA has observed a weakness in the behaviour over time of the walls of the structure of this hall which houses the facility's front-end tanks. Pending further investigations, CEA stopped the BNI from accepting effluents from other facilities in September 2016. Other unforeseeable events also led to worksite stoppages in 2016. ASN

5. *SSE: Safe Shutdown Earthquake as defined in the Basic Safety Rule (RFS) of 31st May 2001 relative to determining the seismic risk for the safety of surface BNIs.*

is attentive to the development of these situations and more specifically to any impacts they might have on the safety of the facility, on the legacy effluent retrieval programmes and the on management of the Saclay centre's liquid waste. Given this situation, CEA must monitor the safety of this facility particularly closely.

Renovation or shutdown of old facilities

On the Cadarache site

- **Solid waste Treatment Station (STD) - BNI 37-A and Effluent Treatment Station (STE) - BNI 37-B**

BNI 37 of CEA Cadarache historically comprised the Effluent Treatment Station (STE) and the Waste Treatment Station (STD). The STE definitively stopped functioning on 1st January 2014. Continuation of operation of the STD over the long term necessitates renovation work which was prescribed on completion of its second periodic safety review.

The STD and the STE were registered as BNI 37-A and 37-B respectively on 5th July 2015. The registrations were made after defining the perimeters of these two BNIs by Orders of the Minister responsible for Nuclear Safety on 9th June 2015. The registration resolutions for these two BNIs act as a Creation Authorisation Decree.

ASN considers that safety management on these facilities must be improved.

Further to persistent shortcomings in the management of deviations on BNIs 37-A and 37-B, ASN gave CEA formal notice on 5th July 2016 to put in place an organisation designed to better detect deviations, analyse them, define appropriate corrective actions, implement them and measure their effectiveness in order to comply with the BNI Order.

The observed malfunctions concern more specifically management of the periodic checks and tests, the conditions of waste storage in the facility, equipment lockouts/tag-outs and management of the fire risk.

On 7th December 2016 the ASN inspectors examined compliance with this formal notice. ASN considers that the corrective actions conducted on these facilities are satisfactory. The progress must nevertheless be maintained over the long term and improved rigour of operation of the STE is still expected.

- **Solid Waste Treatment Station (STD) - BNI 37-A**

At present, the STD is CEA's only civil BNI licensed for packaging ILW-LL radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository (*Cigéo* project).

ASN has analysed the report presenting the conclusions of the second periodic safety review of the STD. Transmitted by the CEA in March 2012, this report is based on the licensee's desire to continue operating the STD for a minimum period of ten years. It explains in particular the safety options in the renovation of the facility. In May 2014 CEA undertook to implement improvements in the safety of the facility in the short term, particularly with regard to control of the containment or radioactive substances, fire protection and earthquake resistance.

Pending completion of the renovation work, through its resolution CODEP-CLG-2016-015866 of 18th April 2016, ASN issued prescriptions relative to conservative operating measures to be put in place before the end of 2016, concerning more specifically the limiting of quantities of radioactive substances in the facility and fire protection. The prescriptions also concern the renovation work, particularly increasing the earthquake resistance of the waste treatment zones and the protective measures against fire and flooding and their completion deadline in 2021.

On completion of its analysis, in view of the commitments made by the licensee and provided it carries out the renovation work without delay, ASN considers that overall the licensee's conformity review and periodic safety review are acceptable.

Pursuant to Article 6.7 of the BNI Order of 7th February 2012 which stipulates that the packaging of waste intended for radioactive waste disposal facilities under study is subject to ASN approval, CEA filed a packaging approval application at the end of 2015 for packages 500 L MI and 870 L alpha-Pu FI of BNI 37-A which is currently being examined.

- **Effluent Treatment Station (BNI 37-B)**

The STE stopped operating on 1st January 2014. It has been functionally replaced by the Agate facility which entered service in 2014. CEA sent ASN the periodic safety review guidance file on 14th June 2016. The periodic safety review file should be submitted to ASN in November 2017.

CEA planned submitting the STE decommissioning file in 2017 at the same time as the safety review file. CEA has now pushed back submission of this file until 2021. As the STE has been stopped since 1st January 2014, its shutdown can be considered definitive since 1st January 2016 in accordance with the provisions of Act 2015-992 relative to the Energy Transition for Green Growth Act of 17th August 2015. In application of Article L. 593-24 of the Environment Code, ASN will set the time frame for submitting the decommissioning in 2017.

The analysis of the historical data on the radiological state of the soils is in progress. The investigation campaign on the tanks is continuing and samples are scheduled to be taken in 2017.

Spent fuel and legacy waste and effluents recovery operations

On the Saclay site

• **Solid radioactive waste management zone (BNI 72)**

BNI 72, which was authorised by Decree on 14th June 1971, serves for waste storage and packaging as well as waste retrieval from small-scale nuclear activities[6] (sources, scintillating liquids, ion exchange resins) and storage of radioactive sources.

For several years now the licensee has been having difficulty in significantly improving the tracking of and compliance with the prescriptions set by ASN and the commitments made during the periodic safety review or after inspections. ASN has asked CEA to put in place the appropriate organisation and means, particularly the means necessary for decommissioning the facility. This is because following the examination of the last periodic safety review file for the facility in 2009, CEA undertook to shut down the facility's waste treatment units within ten years and to remove, within this same lapse of time, the waste stored in the pool and the storage blocks.

ASN notes that these retrieval and packaging projects necessitate substantial technical and human resources and verifies, through periodic meetings with the licensee, the progress of these projects and CEA's compliance with its commitments. ASN does note some improvements, notably the implementation of a procedure that has enabled CEA to prioritise the accomplishing of its commitments according to the stakes they represent. CEA has for example started removing the facility's waste, spent fuel and sources from storage. The ongoing emptying of storage block 116 has been disturbed several times by the discovery of content that did not correspond to what was expected.

ASN notes that the ongoing removal from storage operations continue to be technically well managed but are falling behind schedule. Several operations, such as draining of the water potentially contained in the spent fuel cans, have not started. Compliance with certain deadlines prescribed by ASN seems compromised, which should lead CEA in 2017 to request a modification of the resolution of 2010. ASN shall be attentive to the justification of the new time frames requested and the plan of action proposed by CEA to complete the removal from storage operations in a schedule compatible with maintaining the facility in suitably safe conditions.

ASN considers that the safety of the facility on the whole remains acceptable. The organisational means necessary in the short term have been put in place. CEA must nevertheless be vigilant to the follow-ups to the deterioration of an element of the facility's ventilation system and the deficiencies in monitoring the gaseous effluents discharged at the outlets which have been the cause of significant events.

CEA declared the shutdown of BNI 72 for 31st December 2017. The decommissioning authorisation application file submitted in December 2015 and currently being examined by ASN has displayed numerous shortcomings. The required complementary information is expected in 2017 and will include details and the safety case for the operations planned over the next ten years (removal from storage operations - EPOC in particular).

With the prospect of scheduled final shutdown and decommissioning of BNI 72, ASN will be attentive to the proposed organisation and the means deployed by CEA for the future treatment of solid waste from the Saclay site as a whole.

• **Liquid effluent management zone (BNI 35)**

The Decree of 8th January 2004 authorising the creation of Stella (see above) required CEA to remove old effluents stored in the MA500 and HA4 tanks of BNI 35 within ten years. CEA was unable to meet this deadline due to technical difficulties in the retrieval and packaging of this waste. Indeed, only half of the initial source term had been removed (19,256 gigabecquerels in 2004) as at 8th January 2014. ASN does nevertheless note that all the radioactive organic effluents contained in tank HA4, which presented the greatest safety risks, had been removed by the end of 2013.

Through resolution 2014-DC-0441 of 15th July 2014, ASN prescribed new retrieval deadlines for these effluents and obliged CEA to have them removed by the end of 2018, with intermediate milestones at the end of 2014, 2015 and 2016.

CEA continued these removal operations in 2016. Drainage of the last tank must be completed before the end of 2018.

On the Cadarache site

• **Radioactive waste storage area (BNI 56)**

BNI 56, which was declared in January 1968, is used for storing solid radioactive waste.

The installation comprises six pits, five trenches, three pools and hangars containing primarily Intermediate-Level, Long-Lived Waste (ILW-LL) from the operation or decommissioning of the CEA's installations which cannot be disposed of at the CSA repository. The installation also comprises storage areas of legacy Very Low Level (VLL) waste compatible with disposal at the Cires facility.

6. *Small-scale nuclear activities represent all activities using ionising radiation but not covered by the BNI regime. Small-scale nuclear activities concern many fields such as medicine (radiology, radiotherapy, nuclear medicine), human biology, research and industry.*

The waste present on the installation must be retrieved as soon as possible, packaged and stored in appropriate facilities (Cedra in particular). Retrieval of the waste from the pits and trenches requires the deployment of new procedures. The VLL legacy waste is characterised and packaged at the Starc ICPE, then transferred to the Cires repository.

CEA will also transmit the report presenting the conclusions of the installation's periodic safety review to ASN in March 2017. The procedure for registering the BNI perimeter of the installation shall be carried out in parallel with the safety review. CEA plans to submit the installation decommissioning file at the end of 2017.

ASN considers that significant improvements have been made in safety management at this installation over the last few years. It nevertheless notes delays in the waste retrieval and packaging projects linked to project management and the development of retrieval solutions that take into account all the requirements concerned. CEA was unable to meet its commitment to retrieve the waste from pits 5 and 6 of BNI 56 in 2016 (see chapter 14).

- **Pégase (BNI 22)**

The Pégase reactor entered service on the Cadarache site in 1964 and was operated for about ten years. By Decree on 17th September 1980, CEA was authorised to reuse the Pégase facilities to store radioactive substances, particularly spent fuel elements in a pool.

The preceding periodic safety review of 2003 concluded that the earthquake resistance of the main building was not guaranteed. Due to the scale of the necessary reinforcement work and the corresponding costs, CEA decided to end the storage activities and in 2004 it undertook to remove all stored material from the facility by the end of 2010. Since that date the quantity of radioactive substances present in the facility has fallen significantly. CEA has nevertheless asked for the removal-from-storage completion deadline to be pushed back several times. More specifically, in 2015 CEA asked that the deadline for removing the radioactive substances from the Pégase pool be pushed back from 2015 to 2025.

The work to remove the 2,714 drums of plutonium-bearing waste stored in Pégase was completed at the end of 2013. ASN then considered that a major milestone had been crossed and that CEA should continue retrieval of the fuel elements stored in the pool.

The work to remove the non-araldited surplus-to-requirements fuel cans ended on 16th November 2016. The category of four of these cans was changed to araldited in 2016, bringing the number of araldited fuel cans stored in the pool to 119. Their removal from storage necessitates the finalising of a treatment process currently under development in the STAR facility (BNI 55).

The other radioactive substances and items to be removed comprise beryllium reflector elements, boron carbide absorbing elements and irradiating materials from decommissioning of the Pégase reactor.

CEA submitted the periodic safety review guidance file for Pégase at the end of March 2016. CEA plans starting the work to separate Pégase and Cascad after 2018 (see page 509). The safety options associated with this separation and the defining of the respective perimeters of the two facilities shall be presented in the periodic safety review file that CEA will submit in November 2017.

The examination of CEA's request to push back the deadline for removal of the radioactive substances from the Pégase pool led to the creation of a resolution aiming to subject the removal from storage operations to requirements until ASN has finished examining the periodic safety review file. ASN has also prescribed that provisions be made to limit the risks associated with potential dewatering of the pool in the event of an earthquake. Lastly, CEA plans submitting the Pégase decommissioning file in 2019.

ASN's assessment of the operating safety of BNI 22 is positive on the whole and it considers that a further major milestone was crossed at the end of 2016 with removal of the non-araldited surplus-to-requirements fuel cans. It will remain attentive regarding compliance with the schedule for removing the other radioactive substances from the Pégase pool.

1.4.2 Areva waste management

ASN's opinion on Areva's waste management strategy

The spent fuel reprocessing plant at La Hague produces most of Areva's radioactive waste. The waste on the La Hague site comprises on the one hand waste resulting from reprocessing of the spent fuel, which generally comes from nuclear power plants but also from research reactors, and on the other, waste resulting from operation of the various facilities on the site. Most of this waste remains the property of the licensees who have their spent fuel reprocessed (whether French or foreign).

Areva's Tricastin site also produces waste associated with the front end activities of the cycle, essentially contaminated by alpha emitters.

Mid-2016 Areva submitted to ASN and ASND a file presenting the decommissioning and waste management strategy for the group as a whole and its practical application on the La Hague and Tricastin sites. This file is currently being examined. The last review of

Areva's waste management strategy dates back to 2005 and only focused on Areva NC La Hague.

The issues and implications

The main issues relating to the management of waste from the licensee Areva concern:
- the safety of the facilities for storing the legacy waste present on the La Hague site, which requires planning for and implementing appropriate retrieval and storage solutions. ASN has effectively observed recurrent lateness in the retrieval of legacy waste at La Hague (see chapter 13);
- the defining of solutions for waste packaging, in particular for legacy waste.

As concerns this second point, Article L. 542-1-3 of the Environment Code requires that IL-LL waste produced before 2015 be packaged no later than the end of 2030. ASN therefore reminded Areva of the need to define and finalise solutions for packaging this waste within a time frame enabling the 2030 deadline to be met. These solutions will require the prior approval of ASN in accordance with the provisions of Article 6.7 of the BNI Order of 7th February 2012 (see point 1.2.2).

Within the framework of the waste retrieval and packaging operations, Areva NC is examining packaging solutions that necessitate the development of new processes, particularly for the following IL-LL waste:
- the sludge from the STE2 facility;
- the alpha technological waste coming primarily from the La Hague and MELOX plants, which is not suitable for surface disposal.

For other types of IL-LL waste resulting from the waste retrieval and packaging operations, Areva NC is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Part of the associated packaging baseline requirements are currently being examined by ASN.

Facilities operated by Areva

The waste management strategy of Areva is based essentially on the La Hague site. This site is presented in chapter 13 covering fuel cycle installations.

- **Ecrin (BNI 175)**

The Areva NC plant on the Malvési site transforms the concentrates from the uranium mines into uranium tetrafluoride. The transformation process produces liquid effluents containing nitrated sludge loaded with natural uranium. These effluents are settled and evaporated in ponds. The sludge is stored in ponds and the supernatant is evaporated in evaporation ponds.

The entire plant is subject to the Seveso high-threshold ICPE System.

The Ecrin facility was authorised by Decree of 20th July 2015 for the storage of radioactive waste for a period of thirty years with a volume of waste not exceeding 400,000 m^3 and total radiological activity of less than 120 terabecquerels.

It comprises two sludge storage ponds (B1 et B2) for sludge from the Areva NC plant on the Malvési site. These ponds alone are subject to the BNI System due to the presence of traces of artificial radioisotopes from the processing of reprocessed uranium from the Marcoule site. Ponds B1 and B2 have not been used for the settling of liquid effluents since the B2 pond embankment failed in 2004 (utilisation prohibited by Prefectural Order). Once commissioned, BNI 175 situated on the site of ponds B1 and B2 will also contain the solid residues from the Malvési site's ponds B5 and B6, which will be emptied when the facility enters service. Ponds B1 and B2 and their content will be covered with a bituminous cover.

The Ecrin facility commissioning authorisation application was submitted by Areva NC on 15th October 2015. It was supplemented by Areva NC on 2nd June 2016 and is currently being examined by ASN.

ASN will focus particular attention on the stability of the embankments and their earthquake resistance, and on the safety of the work involved in the transfer of the sludge, the filling of the compartment and the laying of the bituminous cover.

Within the framework of the PNGMDR, ASN asked Areva to study the different long-term disposal options for the waste contained in the Ecrin BNI. The studies provided by Areva are currently being studied.

1.4.3 EDF waste management

EDF waste management strategy

The waste produced by EDF Nuclear Power Plants (NPP) is activated waste (from reactor cores) and waste resulting from their operation and maintenance. Some legacy waste and waste resulting from ongoing decommissioning operations can be added to this. EDF is also the owner, for the share attributed to it, of HL and IL-LL waste resulting from spent fuel reprocessing in the Areva NC La Hague plant.

Activated waste

This waste notably comprises control rod assemblies and poison rod assemblies used for reactor operation. This is IL-LL waste that is produced in small quantities. This waste is currently stored in the NPP pools pending transfer to the ICEDA facility.

Operational and maintenance waste

Some of the waste is processed by the Centraco facility in Marcoule in order to reduce the volume of ultimate waste. The other types of operational and maintenance waste are packaged on the production site then shipped to the CSA or Cires repositories for disposal (see points 1.3.1 and 1.3.2). This waste contains beta and gamma emitters, and few or no alpha emitters.

At the end of 2013, EDF submitted a file presenting its waste management strategy. This file was examined by the competent Advisory Committees of Experts in 2015.

The issues and implications

The main issues related to the EDF waste management strategy concern:

- the management of legacy waste. This primarily concerns structural waste (graphite sleeves) from the graphite-moderated gas-cooled reactor fuels. This waste could be disposed of in a repository for LLW-LL (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the gas-cooled reactors currently being decommissioned.
- changes linked to the fuel cycle. EDF's fuel use policy (see chapter 12) has consequences for the fuel cycle installations (see chapter 13) and for the quantity and nature of the waste produced. This subject was examined by the Advisory Committee of Experts for Nuclear Reactors and the Advisory Committee of Experts for Laboratories and Plants on 30th June 2010. Following this examination, in its letter of 5th May 2011, ASN asked EDF to implement a more rigorous policy for managing its storage capacity for substances before their disposal, treatment or reprocessing (see chapter 13). More specifically with regard to waste, EDF must for example ensure that the available packaging containers can meet the disposal needs.

Facilities operated by EDF to support this strategy

- **ICEDA (BNI 173)**

The purpose of the ICEDA facility, authorised by Decree 2010-402 of 23rd April 2010, will be to process and store activated waste from operation of the EDF installations and from the decommissioning of the first-generation reactors and of the Creys-Malville NPP. The facility is designed for a service life of fifty years.

ICEDA must ensure the quality of the package packaging operations, maintain the packages in a state of conservation such that they can be managed in complete safety during the storage time, ensure their retrieval with standard operating resources at the end of storage and their compatibility with the planned subsequent management conditions. The facility is also responsible for archiving the characteristics of each package, namely their place of origin, nature and radiological content. The main risks and inconveniences associated with the facility are the dispersion of radioactive substances and hazardous substances, the release of heat, the radiolysis of waste and the exposure of persons to ionising radiation.

The construction site was suspended in January 2012 for more than three years due to cancellation of the building permit by the appeal court of Lyon. Work resumed in April 2015.

Building work on the facility continued in 2016. The worksite suspension resulted in commissioning of the facility, which EDF had initially scheduled for early 2014, falling behind schedule.

The ICEDA commissioning authorisation application file was submitted to ASN in July 2016 with commissioning planned for 2017 after conducting the prior functional tests. Pursuant to the examination of this file, ASN asked for complementary technical information concerning the safety case, the defining of Elements Important for Protection (EIP) and Activities Important for Protection (AIP), the start-up tests, waste management and the operating documents.

The inspection carried out in 2016 on a random basis to check that the construction work was going as planned and to verify EDF's surveillance actions was found to be satisfactory on the whole, but ASN considers that EDF must improve its management of EIPs and hot work permits.

ASN plans to perform several inspections between now and facility commissioning to check management of the EIPs and AIPs and to monitor the equipment and system tests.

ICEDA construction worksite, 2016.

In 2016, ASN also began examining the application file for approving the packaging of ILW-LL waste in C1PGSP packages in the ICEDA facility, submitted by EDF in November 2015 and supplemented at the request of ASN in May 2016.

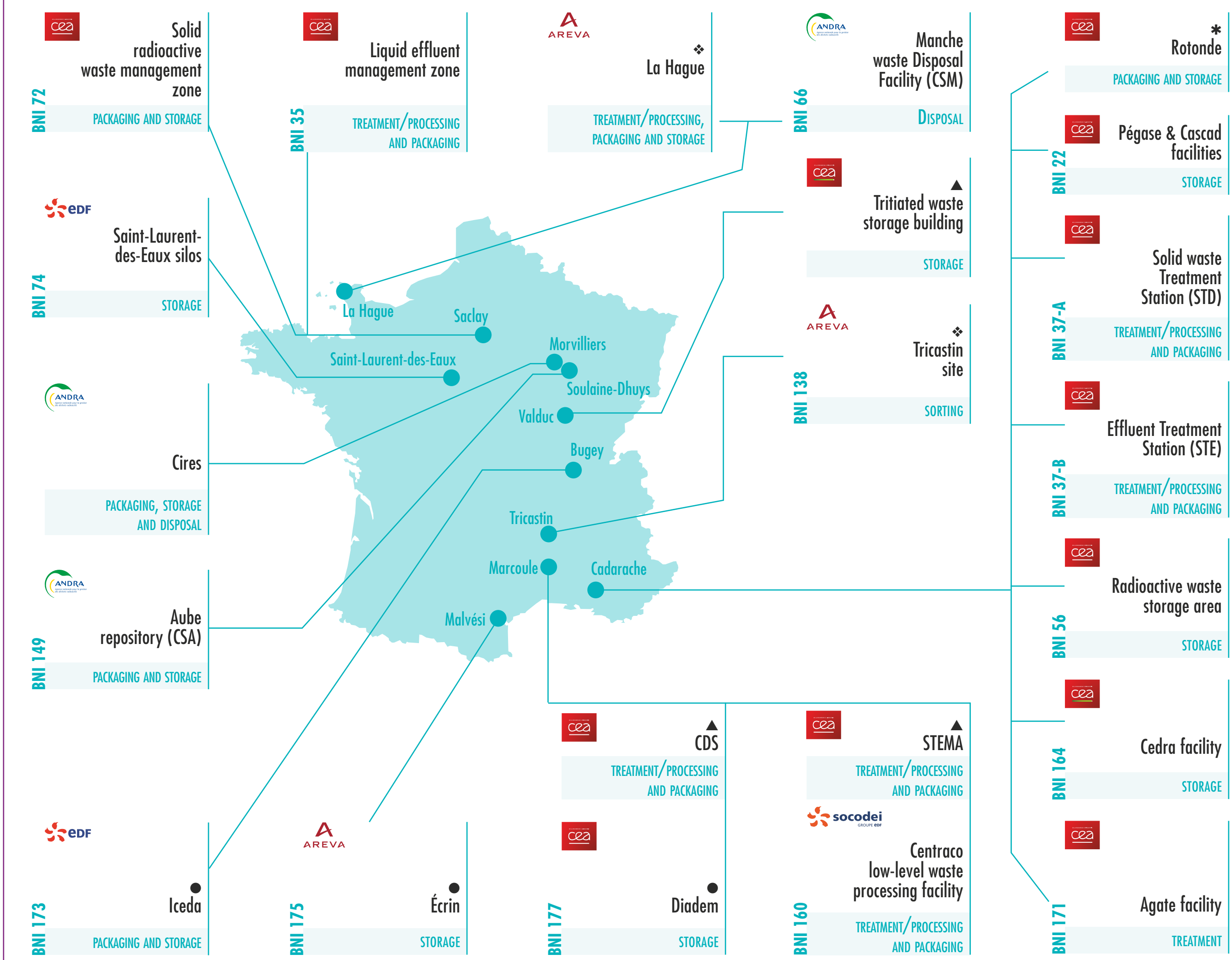
- **Saint-Laurent-des-Eaux silos (BNI 74)**

The installation, which was authorised by the Decree of 14th June 1971, comprises two silos which are used to store irradiated graphite sleeves (LLW-LL) from the operation of the graphite-moderated gas-cooled reactors of Saint-Laurent A. The static containment of this waste is ensured by the concrete structures of the silo bunkers which are sealed by a steel liner. In 2010, EDF installed a geotechnical containment around the silos, reinforcing control of the risk of dissemination of radioactive substances, which is the main risk presented by the installation.

Operation is limited to surveillance and maintenance measures (inspections and radiological monitoring of the silos, checking there is no water ingress, checking relative humidity, dose rates in the vicinity of the silos, the activity of the water table, monitoring the condition of civil engineering structures). These actions are on the whole performed satisfactorily.

In 2015, ASN completed its examination of the commitments made by EDF following the periodic safety review of the installation which ended in 2014. ASN considers that nothing calls operation of the BNI into question provided that the dates of waste removal from the silos are respected, but it is waiting for additional studies from EDF which must be transmitted as part of the periodic safety review conclusions file. The additional studies primarily concern the seismic risk and surveillance of the condition of the civil engineering structures.

THE MAIN FACILITIES involved in radioactive waste management



● Waiting for commissioning * Comes under the status of ICPE ❖ See chapter 13 on the nuclear fuel cycle
■ Creation Autorisation Decree (DAC) pending ▲ Comes under the status of SBNI

The file concerning the stress tests conducted as part of the Fukushima Daiichi accident experience feedback process, submitted at the end of 2015 is currently being examined by ASN.

In the context of its new decommissioning strategy for the Gas-Cooled Reactors (GCR) presented to ASN and the local information committee in 2016, EDF announced its decision to start removing the graphite from the silos without waiting for the graphite waste disposal route to become available. To this end EDF is considering creating a new facility for storing sleeves on the Saint-Laurent-des-Eaux site and submitting a decommissioning file in 2019 with a view to starting the emptying of the silos in 2027.

1.4.4 Socodei melting/incineration facility

The Centraco low-level waste processing facility (BNI 160), located in Codolet near the Marcoule site (Gard *département*), is operated by Socodei, a subsidiary of EDF.

The purpose of the Centraco plant is to sort, decontaminate, reuse, treat and package - particularly by reducing their volume - waste and effluents with low levels of radioactivity. The waste is then routed to the Andra CSA repository.

The facility comprises:
- a melting unit melting a maximum of 3,500 tonnes of metallic waste per year;
- an incineration unit incinerating a maximum of 3,000 tonnes of solid waste and 2,000 tonnes of liquid waste per year;
- storage areas for ash and clinkers, liquid wastes, leaching effluents and metallic waste;
- a maintenance unit.

The incineration and melting units returned to nominal operation in 2016. The incineration unit was subject to a major technical outage in 2015, while the melting unit, which had been shut down since the September 2011 accident, was authorised to restart operation by ASN resolution CODEP-DRC-2015-013495 of 9th April 2015.

ASN resolution of 16th December 2008 governing operation of the BNI was modified by the ASN Chairman's resolution of 22nd June 2016. This change allowed regulatory changes applicable since 2008 to be integrated and the treatment capacity of BNI 160 to be extended, as requested by the licensee in 2015. Furthermore, the prescriptions concerning the conditions of water intakes and consumption and the discharge of effluents from the facility into the environment were revised by ASN resolution of 1st March 2016.

On 6th September 2016 ASN issued a favourable opinion on the modification of the Order of 19th August 2016 aiming to integrate BNI 160 in the list of sites benefiting from reduced financial liability.

ASN considers that the current organisation of the facility is conducive to safe operation of the installations. Consequently, ASN has ended the tightened monitoring which had been implemented since 2009.

1.5 Management of waste from small-scale nuclear activities

1.5.1 Management of waste from non-BNI nuclear activities

The issues and implications

The use of unsealed sources in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory equipment used to prepare sources, medical equipment used for administration, remains from meals served (uneaten foodstuffs, containers, cutlery) to patients who have received injections for diagnostic or therapeutic purposes, etc. Radioactive liquid effluents also come from source preparation as well as from patients who eliminate the administered radioactivity by natural routes.

The diversity of waste from small-scale nuclear activities, the large number of establishments producing it and the radiation protection issues involved have led the public authorities to regulate the management of the waste produced by these activities.

Management of disused sealed sources considered as waste

Sealed sources are used for medical, industrial, research and veterinary applications (see chapters 9 and 10). When they reach end of life, and if their suppliers do not envisage their reuse in any way, they are considered as radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in particular, must take into consideration the dual constraint of concentrated activity and a potentially attractive nature in the event of human intrusion after loss of the memory of a disposal facility. This dual constraint therefore limits the types of sources that can be accepted in disposal facilities, especially surface facilities.

As required by the PNGMDR 2013-2015, CEA (acting as secretary of a working group led jointly by the DGPR - General Directorate for Risk Prevention, and the DGEC - General Directorate for Energy and Climate) submitted a synthesis report of the group's work to the Government at the end of 2014, covering:
- continuation of Andra's study of the conditions of acceptance of these sealed sources in disposal facilities;
- consolidated batching of disused sealed sources in order to determine a reference solution for each batch;
- with regard to the existing disposal centres, Andra's assessment of the conditions for acceptance of disused sealed sources, if necessary modifying the acceptance specifications but without compromising the safety of the disposal centres;
- a study of the requirements in terms of treatment and packaging facilities to enable them to be accepted in existing or planned disposal centres;
- a study of the requirements in terms of interim storage facilities;
- optimised technical and economic planning of the conditions for acceptance and elimination of disused sealed sources in the light of the availability of processing, storage and disposal facilities and transport constraints.

Furthermore, Decree 2015-231 of 27th February 2015 enables holders of disused sealed sources to call upon not only the initial source supplier but also any licensed supplier or - as a last resort - Andra, to manage these sources. These provisions should bring a reduction in the costs of collecting disused sources and provide a recovery route in all situations.

Management by Andra of waste from non-BNI nuclear activities

Article L. 542-12 of the Environment Code entrusts Andra with a public service mission for waste produced by small-scale nuclear activities. Yet until 2012 Andra was not equipped with its own facilities for the management of waste from small-scale nuclear activities. Consequently, Andra made agreements with other nuclear licensees, and CEA in particular, which stores waste on the Saclay site.

Andra started reconfiguring the route in 2012 by creating at Cires, situated in the municipalities of Morvilliers and La Chaise, a collection centre and a storage facility for waste from small producers other than nuclear power plants. Nevertheless, the tritiated solid waste shall be managed in a storage facility operated by CEA and pooled with the waste from ITER (Intermed project).

However, the delays in the ITER project schedule are impacting the Intermed project schedule and the management strategy for tritiated waste from small producers. In its opinion of 24th November 2016, ASN asked CEA to take into account the shift in the projected date of Intermed commissioning in the studies to compare tritiated waste management solutions carried out for the PNGMDR and to define, before 31st December 2017, a revised strategy for the storage of tritiated waste from installations other than ITER.

ASN considers that the approach adopted by Andra will be sufficient to meet the duties entrusted to it under Article L. 542- 12 of the Environment Code and that this must be continued.

1.5.2 Management of waste containing enhanced natural radioactivity

Some professional activities using raw materials which naturally contain radionuclides but which are not used for their radioactive properties, may lead to an increase in specific activity in the resulting products, residues or waste. This is known as technologically enhanced natural radioactivity. The majority of these activities are (or were) regulated by the ICPE System and are listed by the Order of 25th May 2005 concerning professional activities involving raw materials that naturally contain radionuclides and which are not used for their radioactive properties.

Waste containing enhanced natural radioactivity can be accepted in various types of facilities, depending on its specific activity:
- in a waste disposal facility authorised by prefectural order if the conditions of acceptance provided for in the Circular of 25th July 2006 relative to classified installations "Acceptance of waste containing enhanced or concentrated natural radioactivity in the waste disposal facilities" are fulfilled;
- in the very low level waste disposal facility, Cires;
- in a storage facility. Some of this waste is waiting for a disposal route, in particular the commissioning of a disposal centre for long-lived, low level waste.

Four waste disposal facilities are authorised by prefectural order to receive waste containing enhanced natural radioactivity, namely the hazardous waste disposal facilities of:
- Villeparisis in Ile-de-France, authorised until 31st December 2020, for an annual capacity of 250,000 tonnes per year (t/year);
- Bellegarde in Languedoc-Roussillon, authorised until 4th February 2029, for an annual capacity of 250,000 t/ year until 2018 and 105,000 t/year beyond this;
- Champteussé-sur-Baconne in Pays de la Loire, authorised until 2049, for an annual capacity of 55,000 t/year;
- Argences in Basse-Normandie, authorised until 2023, for an annual capacity of 30,000 t/year.

The PNGMDR 2013-2015 required the implementation of regulatory changes in order to improve knowledge of the deposits of enhanced naturally radioactive waste and improve its traceability.

The transposition of Directive 2013/59/Euratom of 5th December 2013 setting the basic standards for radiation protection provides for a reinforcement of the provisions applicable to radiation of natural origin, and notably to human activities involving the presence of natural sources of radiation that lead to a notable increase in the exposure of workers or the public. The activities of industries involving enhanced natural radioactivity are therefore concerned. The scope of application of the reinforcements will extend to substances, products and materials that naturally contain radionuclides (potassium-40 and chains of uranium-238 and 235 and of thorium-232) at a level necessitating radiation protection verification. The currently applicable regulations concerning activities involving enhanced natural radioactivity shall therefore be modified and supplemented in 2017 within the framework of this transposition.

1.5.3 Management of mining residues and mining waste rock from former uranium mines

Uranium mines were worked in France between 1948 and 2001, producing 76,000 tons of uranium. Exploration, mining and processing work was carried out on about 250 sites in France spread over 27 *départements*. Ore processing was carried out in 8 plants. The former uranium mines are now almost all under the responsibility of Areva Mines.

The working of uranium mines produced two categories of products:
- mining waste rock, that is to say the rocks excavated to gain access to the ore; the quantity of mining waste rock extracted is estimated at about 167 million tonnes;
- static or dynamic processing tailings, which are the products remaining after extraction of the uranium from the ore. In France, these tailings represent 50 million tonnes spread over 17 disposal sites. These sites are ICPEs and their environmental impact is monitored.

The regulatory context

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code.

The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE nomenclature.

Furthermore, the Minister responsible for the Environment and the ASN Chairman issued a Circular on 22nd July 2009 defining a plan of action relative to the management of the former uranium mines comprising the following lines of work:
- monitor the former mining sites;
- improve understanding of the environmental and health impact of the former uranium mines and their surveillance;
- manage the mining waste rock (better identify the uses and reduce impacts if necessary);
- reinforce information and consultation.

Most of the mining waste rock remains on the site where it was produced (mine in-fill, redevelopment work or spoil heaps). Nonetheless, 1 to 2% of the mining waste rock may have been used as backfill, in earthworks or for road beds in public places situated near the mining sites. Although the transfer of waste rock to the public domain has been traced since 1984, knowledge of transfers prior to 1984 remains incomplete. ASN and the Ministry responsible for the Environment, in the framework of the action plan of the Circular of 22nd July 2009, asked Areva Mines to inventory the mining waste rock reused in the public domain in order to verify compatibility of the uses and to reduce the impacts if necessary.

Areva Mines has thus deployed a plan of action comprising three broad phases:
- aerial overflight around the former French mining sites to identify radiological singularities;
- inspection on the ground of areas identified in the overflight to confirm the presence of waste rock;
- treatment of areas of interest incompatible with the land usage.

The second phase of this action plan was completed in 2014. The Ministry responsible for Risk Prevention defined the procedures for managing cases of confirmed presence of mining waste rock in its Instruction to Prefects of 8th August 2013. The resulting inventory maps are provisional maps submitted for public consultation. Members of the public are asked to communicate their observations to correct or supplement the maps on the basis of their memory of the utilisations of waste rock, where applicable. The definitive maps are associated with remediation action proposals if necessary. Some work has already been carried out on priority sites in 2015 and 2016, that is to say sites where the calculation of the added annual effective dose excluding radon due to the presence of waste rock on generic scenarios exceeds the value of 0.6 millisieverts per year (mSv/year) on the basis of a radiological impact study. All these operations are under the administrative surveillance of the Prefect, on the basis of proposals from the Regional Directorate for the Environment, Planning and Housing (Dreal). ASN provides assistance for the radiation protection of workers and the public and the management routes. In this context it encourages the complete clean-out of the sites when this is technically possible and asks that any other procedure implemented be justified with regard to this strategy. Furthermore, it is particularly vigilant to cases that could result in the exposure of persons, particularly to radon, in order to identify and deal with any cases similar to that of the house in Bessines-sur-Gartempe. Lastly, it ensures that the actions are carried out in complete transparency with maximum involvement of the local actors.

The long-term behaviour of the mining residue disposal sites

Redevelopment of the uranium processing tailings disposal sites consisted in placing a solid cover over the tailings to provide a protective barrier to limit the risks of intrusion, erosion, dispersion of the stored products and the risks of external and internal (radon) exposure of the surrounding populations.

The studies submitted for the PNGMDR 2013-2015, based on ASN opinion of 11th October 2012, have provided greater insight into:
- the strategy chosen for the changes in the treatment of water collected from former mining sites;
- a doctrine for assessing the long-term integrity of the embankments surrounding tailings disposal sites;
- the comparison of the surveillance data and the results of modelling to improve the relevance of the monitoring systems and evaluation of the long-term dosimetric impact of the tailings disposal sites;
- the evaluation of the long-term dosimetric impact of the mining waste rock piles and the mining waste rock in the public domain in relation to the results obtained in the context of the Circular of 22nd July 2009;
- transport of uranium from the waste rock piles to the environment;
- the mechanisms governing the mobility of uranium and radium within uranium-bearing mining tailings.

These various studies have to be continued under the next two waste management plans, PNGMDR 2016-2018 and 2019-2021, as requested in ASN opinion of 9th February 2016 in order to:
- supplement the studies of the long-term evolution of processing residues and mining waste rock;
- supplement the method of evaluating the long-term resistance of embankments;
- study the possibilities of upgrading or shutting down the water treatment stations and ultimately proposing concrete risk- and impact-reduction actions on the various sites.

With regard to mining waste rock, sites containing waste rock outside the perimeter of the former uranium mining sites must continue to be treated. The consultation process must also be continued with the stakeholders on all these subjects, within the framework of the PNMGDR as well as at the local level.

Alongside this, and beyond the studies submitted for the PNGMDR, ASN is concerned by Areva's decision to withdraw its redevelopment project for the Bois Noirs - Limouzat site. This position seems to reflect a more general opting out by the company with regard to questions relating to the former uranium mining sites.

Long-term management of the former mining sites

ASN is contributing to a technical guide on the management of former uranium mining sites that is currently being prepared under the coordination of the Ministry responsible for the Environment. It shall more particularly respond to several recommendations resulting from the report of the Limousin Pluralistic Expert Group (GEP) of September 2010: it will address the administrative status of the sites, the procedures for stopping mining work and the requirements in terms of redevelopment in the long-term perspective.

The Pluralistic Expert Group, involvement and informing of the stakeholders

Set up in 2005, the Limousin Pluralistic Expert Group (GEP) submitted a first report containing its recommendations for the short-, medium- and long-term management of former uranium mining sites in France to the Minister responsible for the Environment and to the Chairman of ASN in September 2010. ASN and the Ministry responsible for the Environment are thus engaged in a plan of action dedicated to the implementation of these recommendations.

A second report was submitted to the Minister in 2013; it presents the results drawn from the presentation of the GEP's conclusions and recommendations to the local and national consultative bodies and an evaluation of the implementation of its recommendations. The GEP considers its involvement to have brought positive results and notes that its recommendations remain fully relevant. ASN and the Ministry responsible for the Environment have proposed the creation of a network of experts from the site monitoring commissions who would be assigned expert appraisal missions on questions of both local and national scope where justified by the societal aspect.

ASN is continuing its involvement in the steering committee for the national inventory of uranium mining sites, baptised Mimausa (Memory and impact of uranium mines: summary and archives, available on *www.irsn.fr*). This mining site inventory was updated in winter 2016. It will ultimately be supplemented by a mining waste rock inventory.

2. Management of sites and soils contaminated by radioactivity

A site contaminated by radioactive substances is defined as any site, whether abandoned or in operation, on which natural or artificial radioactive substances have been or are employed or stored in conditions such that the site may constitute a hazard for health and the environment.

Contamination by radioactive substances can result from industrial, craft, medical or research activities involving radioactive substances. It can concern the places where these activities are carried out, but also their immediate or more remote vicinity. The activities concerned are generally either «nuclear activities» as defined by the Public Health Code, or activities concerned by enhanced natural radioactivity, as covered by the Order of 25th May 2005.

However, most of the sites contaminated by radioactive substances and today requiring management in fact concern past industrial activities, dating back to a time when radioactive hazards were not perceived in the same way as at present. The main industrial sectors from which the radioactive contamination identified today originated are: radium extraction for medical and para-pharmaceutical needs, from the early 20th century up to the end of the 1930s; the manufacture and application of luminescent radioactive paint for night vision and the industries working ores such as monazite or zircons. Sites contaminated by radioactive substances are managed on a case-by-case basis, requiring a precise diagnosis of the site and the contamination.

Several inventories of contaminated sites are available to the public and are complementary: Andra's national inventory, which is updated every 3 years and comprises the sites identified as contaminated by radioactive substances (the June 2015 edition is available on *www.andra.fr*) as well as the databases accessible from the web portal of the Ministry responsible for the Environment (*www.sites-pollues.ecologie.gouv.fr*) and dedicated to contaminated sites and soils.

Article L.125-6 of the Environment Code, amended on 26th March 2014, provides for the State to create Soil Information Sectors (SIS) in the light of the information at its disposal. These sectors must comprise land areas in which the knowledge of soil contamination justifies (particularly in the case of change of use) carrying out soil analyses and taking contamination management measures to preserve safety, public health and the environment. Decree 2015-1353 of 26th October 2015 defines the conditions of application.

The Regional Directorates for the Environment, Planning and Housing (Dreal) coordinate the SIS development process under the authority of the Prefects. The ASN regional divisions contribute to the process by naming the sites they know to be contaminated by radioactive substances. Ultimately these sites are to be registered in the urban planning documents.

The SIS development process is progressive and is not intended to be exhaustive. The approach is limited by the State's knowledge of soil contamination, the quality of data from relatively old analyses carried out applying methodologies and standards which have changed over time, and the quality and precision with which the sites concerned are geolocated.

For further information: *www.developpement-durable.gouv.fr/Elaboration-des-secteurs-d.html*

In October 2012, ASN finalised its doctrine specifying the fundamental principles it has adopted for the management of sites contaminated by radioactive substances. Assuming that, depending on the characteristics of the site, this procedure would be difficult to apply, it is in any case necessary to go as far as reasonably possible in the clean-out process and to provide elements, whether technical or economic, proving that the clean-out operations cannot be taken further and are compatible with the actual or planned use of the site.

The ASN doctrine defines the measures to take if complete clean-out is not achieved.

ASN also considers that the management of contaminated sites requires public involvement in the choice of solution to adopt, in order to create a climate of trust and minimise conflicts.

ASN also points out that in application of the "polluter-pays" principle written into the Environment Code, those responsible for the contamination finance the operations to rehabilitate the contaminated site and to remove the waste resulting from these operations. If the responsible entities default, Andra, on account of its public service remit and by public requisition, ensures the rehabilitation of radioactive contaminated sites.

2.1 Regulatory framework

In reference to Article L. 542-12 of the Environment Code (see point 1.5.1), Andra receives a State subsidy to help fund its assigned missions of general interest. The French National Funding Commission for Radioactive Matters (CNAR) was set up within Andra in 2007. It is chaired by the Director-General of Andra and includes representatives of the Ministries responsible for the Environment, Energy and Health, of ASN, of the French Institute of Radiation Protection and Nuclear Safety (IRSN), of the Association of Mayors of France, of environmental defence associations and qualified personalities.

The commission met four times in 2016, more specifically to decide on the allocation of public funds for the management of contaminated sites considered priorities, such as a clock making site in Charquemont, the Isotopchim site in Ganagobie, two sites in Champlay and Pargny-sur Saulx, sites owned by the municipalities of Bordeaux, Nogent-sur-Marne and Colombes and the Radium Diagnosis operation.

The Circular of 17th November 2008 of the Minister responsible for the Environment relative to the management of certain radioactive wastes and sites with radioactive contamination describes the applicable procedure for the management of contaminated radioactive sites governed by the ICPE regime and the Public Health Code, whether the party responsible

TECV Act

A System of active Institutional Controls (SUP) governing the management of land, constructions or structures that could cause human exposure to the harmful effects of ionising radiation and justifying radiation protection control and coming under the Public Health Code is currently being defined.

By Ordinance of 10th February 2016, the Government created a system of active institutional controls relating to radioactive substances, as already exists for the ICPEs and BNIs, when radioactive substances subsist on a plot of land or in a building (due to contamination by radioactive substances, after decontamination or in the presence of naturally radioactive materials) in order to maintain a record that will serve with regard to future uses and to define, if necessary, restrictions on use or prescriptions governing future development or demolition work.

is solvent or in default. Whatever the case, the Prefect relies on the opinion of the classified installations inspectorate, of ASN and the ARS (Regional Health Agency), to approve the site rehabilitation project, and issues a prefectural order to govern implementation of the rehabilitation measures. ASN may thus be called upon by the services of the Prefectures and the classified installations inspectors to give its opinion on the clean-out objectives of a site. The Ministry responsible for the Environment started updating this Circular in 2015. ASN is involved in this work.

The framework applicable to sites and soils contaminated by radioactive substances must be modified to transpose Directive 2013/59/Euratom of 5th December 2013, which sets basic radiation protection standards. At the end of 2016, the Ministry of the Environment, Energy and the Sea presented a project that integrates these particular contaminated sites and soils to a greater extent in the general framework applicable to all contaminated sites and soils. When contamination is caused by an installation that is subject to special policing (BNI, ICPE or nuclear activity governed by the Public Health Code), the sites are managed under the same oversight system. In other cases, the draft decree maintains a special status for radioactive contamination by giving the Prefect, not the Mayor, responsibility for overseeing management of the contaminated site. ASN stated that it was in favour of this reform on condition that, in the latter case, the Prefect always consulted ASN for its opinion before making any decisions.

Chapter 8 details the various demands concerning contaminated sites and soils to which the ASN regional divisions responded.

2.2 The Radium Diagnosis operation

In October 2010, the State decided to carry out diagnoses in order to detect and if necessary treat any radium contamination resulting from past activities. Discovered by Pierre and Marie Curie in 1898, radium has been used in certain medical (the first cancer treatments) and craft activities (clock-making until the 1950s, due to its property of radioluminescence, and the manufacture of lightning arresters and cosmetic products).

These medical or craft activities have left traces of radium on certain sites. The diagnosis of the sites having accommodated an activity that used radium is a continuation of the many actions engaged by the State in recent years, such as the rehabilitation of sites on which research and radium extraction activities were carried out at the beginning of the 20th century, or the retrieval of radioactive objects from private households, etc.

This operation is free of charge for the occupants of the places concerned: the diagnosis consists in taking systematic measurements to detect the presence of any traces of radium or confirm the absence of radium. These measurements are performed by a team of IRSN specialists, accompanied by an ASN coordinator who contacts the occupant beforehand to explain the operation. On completion of the diagnosis, the occupants are informed verbally of the results, with subsequent written confirmation by letter. If traces of contamination are detected, rehabilitation operations are performed by Andra free of charge, with the agreement of the property owners. Ultimately, each person concerned is given a certificate guaranteeing the results of the operation.

New addresses were added to the initial list as the diagnosis operation progressed, with more than 160 sites in France being concerned at the end of 2014.

In 2016, 36 sites in Ile-de France and one site in Annemasse had been examined. The Annemasse site was diagnosed before the operation was launched in the Rhône-Alpes region, at the owner's request because a real estate transaction was envisaged in the near future.

Eight of the 36 sites in Ile-de-France were excluded outright because the buildings are too recent with respect to the period of potential manipulation of radium to be able to display any radioactive contamination.

IRSN has carried out more than 430 diagnoses since the operation began; in effect, the majority of the sites involve either one building with many apartments or several individual plots. The fact that the occupants were informed and that the operation was free of charge were vital factors in obtaining the occupants' agreement. There were only nine diagnosis refusals.

These diagnoses led to twenty-five rehabilitation and renovation operations (twenty-one in Ile-de-France and four in Annemasse).

More than five years after the start of the operation, experience feedback shows that it is relatively well accepted by the occupants and environmental protection associations. The vast majority of the premises diagnosed are free of radiological contamination. The contamination levels recorded are low and confirm that there is no health risk; the maximum dosimetry received is less than 2.4 mSv/ year (added value), which is approximately the same order of magnitude as the dose received per year by the French population from naturally occurring sources of radioactivity.

The engagement of further diagnosis operations has been suspended in Ile-de-France since March 2014 at the request of the Ministry responsible for the Environment, in order more specifically to modify the conditions of performance of the operation. ASN would like the diagnoses to resume rapidly in order to finalise the operation in Ile-de-France and start diagnoses in other regions. ASN considers moreover that ambitious treatment targets must be maintained for the contaminated sites. The funding allocated to the CNAR to treat these sites was reduced in 2016.

2.3 ASN's international action in the management of contaminated sites and soils

ASN has participated since 2012 in the meetings of the International Working Forum on Regulatory Supervision of Legacy Sites[7] (RSLS) organised by the International Atomic Energy Agency (IAEA). The aim of this forum is to promote interchanges between the various organisations responsible for regulating and monitoring "legacy sites" in order to identify the sites' needs in terms of management and means for preventing the creation of future "legacy sites". In 2017, the IAEA plans publishing a «Techdoc» technical document tracing back the interchanges between the countries.

Moreover, ASN contributes to the work carried out under the CIDER project (Constraints to Implementing Decommissioning and Environmental Remediation programmes) initiated in 2012 by the IAEA. This project aims to identify the main difficulties that contracting parties can encounter, particularly in site rehabilitation, and propose aids to overcome them.

In 2015, ASN continued its collaboration with the United States Environmental Protection Agency (US-EPA), tasked with managing the "Superfund" programme to protect American citizens against the risks associated with sites polluted by abandoned or unmonitored hazardous waste and particularly sites contaminated by radioactive substances.

3. Outlook

ASN considers that the French radioactive waste management system, built around a specific legislative and regulatory framework, a National Plan for Radioactive Materials and Waste Management (PNGMDR) and an Agency for management of radioactive waste independent of the waste producers (Andra), is capable of regulating and implementing a structured and coherent national waste management policy. ASN considers that there must eventually be safe management for all waste, more specifically by means of a disposal solution. ASN will monitor the progress of the studies submitted under the PNGMDR 2016-2018, more specifically within the PNGMDR working group that it co-chairs with the DGEC.

The regulations concerning the management of radioactive waste

In 2017, ASN will finalise the resolution concerning the packaging of radioactive waste. It will draw up draft resolutions concerning radioactive waste disposal and storage installations. These draft texts will be subject to consultation by the stakeholders and the public.

ASN will also be vigilant in ensuring that the work to transpose Directive 2013/59/Euratom of 5th December 2013, setting basic radiation protection standards, does not compromise the French policy in which there are no clearance levels for waste from BNIs, while reinforcing the monitoring of waste containing technologically enhanced naturally occurring radioactivity.

Licensee waste management strategies

In 2017, ASN will continue to closely monitor the legacy waste and spent fuel retrieval and packaging operations, focusing on those presenting the most significant implications for safety.

ASN and ASND are assessing the waste management strategy submitted by Areva in mid-2016 and they will issue their conclusions in 2018.

In 2017, ASN will be particularly attentive to ensuring that CEA meets its commitments concerning its old facilities which no longer comply with current safety requirements. ASN will also keep track of the progress of the CEA's strategic waste management projects (Diadem,

7. International forum on the regulations for sites contaminated by radionuclides, presenting a risk for health and/or the environment and which are a subject of concern for the Authorities.

BNI 37-A, solid and liquid waste management on the Saclay site) and the preparation of the decommissioning files for the old storage facilities (BNI 56, Pégase, BNI 37-B).

Low-Level, Long-Lived Waste (LLW-LL)

With regard to LLW-LL, ASN considers it essential to make progress in setting up management solutions. The analysis of the file submitted by Andra in 2015 under the PNGMDR has shown that it will be difficult to demonstrate the feasibility - in the investigated area - of a disposal facility for all the LLW-LL waste. In its opinion of 29th March 2016, ASN asked Andra to submit by mid-2019, under the PNGMDR, a report presenting the technical and safety options for this disposal facility and an industrial scheme for managing the LLW-LL waste established through consultation with the producers of this waste.

Depending on the results of this report, the waste producers will, if necessary, have to firstly create new storage capacity to avoid delaying decommissioning operations, and secondly speed up the deployment of alternative strategies if their waste is not compatible with the Andra project.

In 2017, ASN will start revising the Safety Guide relative to the disposal of low-level long-lived radioactive waste.

HLW and ILW-LL waste

With regard to the *Cigéo* disposal project for HLW and ILW-LL waste, 2017 will see the issuing of ASN's opinion on the *Cigéo* safety options dossier submitted by Andra in 2016. This dossier includes the project's safety options, the technical retrievability options, a preliminary version of the waste acceptance specifications and a project development plan. It constitutes the first overall safety file for the facility since 2009. It more specifically underwent an international peer review under the aegis of IAEA in November 2016. The opinion of ASN, based on a study of the safety options dossier by the competent advisory committees of experts and on the report of the IAEA experts, will indicate its expectations regarding the content of the *Cigéo* creation authorisation application that Andra plans submitting in mid-2018.

ASN underlines the importance it attaches to the progress the waste producers must make in the packaging of their waste, particularly waste resulting from waste retrieval and packaging operations. ASN considers that this preliminary version of the *Cigéo* waste acceptance specifications drafted by Andra will enable requirements concerning the future waste packages to be detailed.

The *Cigéo* project is entering the industrial phase. Andra must coordinate firstly the industrial development of its facility which must satisfy the need to accommodate all waste which for safety reasons cannot be disposed of in above-ground facilities, and secondly the preparation of its nuclear safety case in compliance with the requirements of the Environment Code and the BNI System.

Management of the former uranium mining sites and polluted sites and soils

With regard to the former uranium mining sites, in 2017 ASN will endeavour to address the requests of the Dreals (Regional Directorates for the Environment, Planning and Housing) regarding the Areva Mines action plan for the management of mining waste rock. It will focus more specifically on the management of potentially sensitive cases, in particular with regard to the radon risk. It will aim to ensure that the measures are taken in complete transparency and with the involvement of local stakeholders and it will continue its work in collaboration with the Ministry responsible for the Environment.

With regard to contaminated sites and soils, in 2017 ASN will continue its analysis of the contaminated site remediation projects, on the basis of the principles of its doctrine published in October 2012. ASN will work with the Ministry responsible for the Environment on overhauling the Circular of 17th November 2008 relative the management of certain types of radioactive waste and of sites contaminated by radioactive substances, and on the draft decree for the transposition of Directive 2013/59/Euratom on which it will issue an opinion in early 2017. ASN will also maintain its role in the operational coordination of the Radium Diagnosis operation in collaboration with the administrations concerned and the other stakeholders.

ASN will also continue its involvement in international work on these topics, in particular within IAEA, ENSREG and WENRA, as well as bilaterally with its counterparts.

List of Basic Nuclear Installations as at 31st december 2016

To regulate all civil nuclear activities and installations in France, ASN has set up a regional organization comprising 11 regional divisions based in Bordeaux, Caen, Châlons-en-Champagne, Dijon, Lille, Lyon, Marseille, Nantes, Orléans, Paris and Strasbourg.

The Paris division also covers the french overseas *départements* and collectivities. The Caen and Orléans divisions are responsible for BNI regulation in the Brittany and Ile-de-France regions respectively.

A BNI is one which, by its very nature or owing to the quantity or activity of the radioactive substances it contains, is subject to specific regulatory arrangements as defined by the TSN Act of 13th June 2006 (codified in Books I and V of the Environment Code by Order 2012-6 of 5th January 2012). These installations must be authorised by decree issued following a public inquiry and an ASN opinion. Their design, construction, operation and decommissioning are all regulated.

The following are BNIs:
1. Nuclear reactors;
2. Large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels or the treatment, storage or disposal of radioactive waste;
3. Large installations containing radioactive or fissile substances;
4. Large particle accelerators;
5. Deep geological repositories for radioactive waste.

With the exception of nuclear reactors and the possible future deep geological repositories for radioactive waste, which are all BNIs, Decree 2007-830 of 11th May 2007 relative to the nomenclature of basic nuclear installations sets the threshold for entry into the BNI System for each category.

For technical or legal reasons, the concept of a basic nuclear installation can cover a number of different physical situations: for example in a nuclear power plant, each reactor may be considered as a separate BNI, or a given BNI might in fact consist of two reactors. Similarly, a fuel cycle plant or a CEA centre can comprise several BNIs. These different configurations do not alter the regulatory conditions in any way.

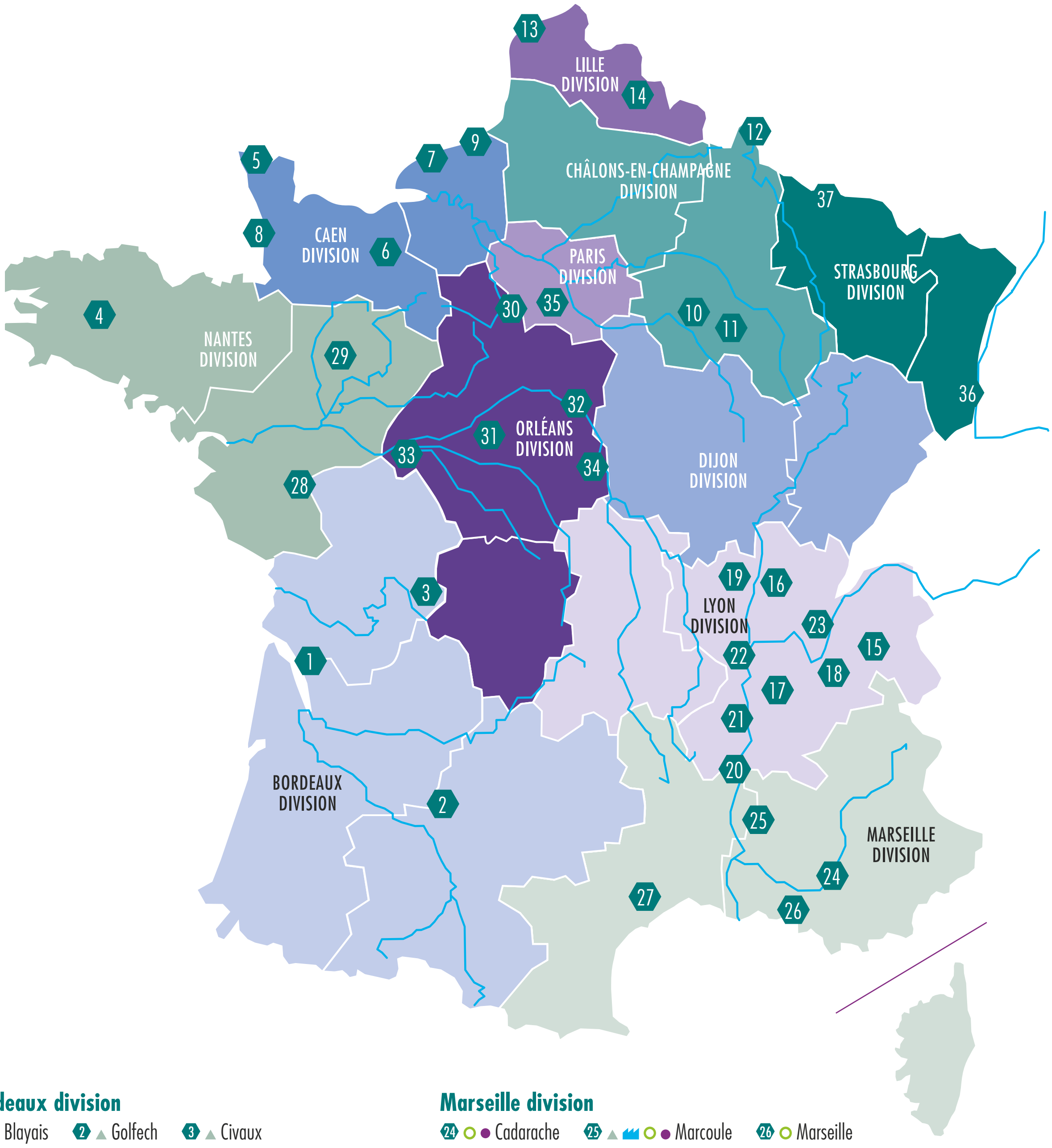
The following are subject to the BNI System:
- facilities under construction, provided that they are the subject of a Creation Authorisation Decree;
- facilities in operation;
- facilities shut down or undergoing decommissioning, until they are delicensed by ASN.

As at 31st December 2016, there were 127 BNIs (legal entities).

The notified BNIs are those which existed prior to the publication of Decree 63-1228 of 11th December 1963 concerning nuclear facilities and for which neither said Decree nor the TSN Act of 13th June required authorisation but simply notification on the basis of the acquired rights (see Articles 33 and 62 of the TSN Act, codified in Articles L. 593-35 and L. 593-36 of the Environment Code).

The missing BNI numbers correspond to facilities that figured in previous issues of the list, but which no longer constitute BNIs further to their delicensing (see chapter 15) or their licensing as new basic nuclear installations.

SITES REGULATED by the ASN regional divisions



Bordeaux division

1 ▲ Blayais 2 ▲ Golfech 3 ▲ Civaux

Caen division

4 ▲ Brennilis 5 🏭 ■ La Hague 6 ● Caen 7 ▲ Paluel
8 ▲ Flamanville 9 ▲ Penly

Châlons-en-Champagne division

10 ▲ Nogent-sur-Seine 11 ■ Soulaines-Dhuys 12 ▲ Chooz

Lille division

13 ▲ Gravelines 14 ○ Maubeuge

Lyon division

15 ○ ● Grenoble 16 ▲ ○ Bugey 17 🏭 Romans-sur-Isère
18 🏭 Veurey-Voroize 19 ○ Dagneux 20 ▲ 🏭 ○ Tricastin
21 ▲ Cruas-Meysse 22 ▲ Saint-Alban 23 ○ ▲ Creys-Malville

Marseille division

24 ○ ● Cadarache 25 ▲ 🏭 ○ ● Marcoule 26 ○ Marseille
27 ○ Narbonne

Nantes division

28 ○ Pouzauges 29 ○ Sablé-sur-Sarthe

Orléans division

30 ● Saclay 31 ○ ▲ Saint-Laurent-des-Eaux
32 ▲ Dampierre-en-Burly 33 ▲ ○ Chinon
34 ▲ Belleville-sur-Loire 35 ● Fontenay-aux-Roses

Strasbourg division

36 ▲ Fessenheim 37 ▲ Cattenom

Type of installation

▲ Nuclear power plant
🏭 Factory
● Research installations
■ Disposal of waste
○ Others

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LOCATION OF INSTALLATIONS REGULATED BY THE BORDEAUX DIVISION				
1 BLAYAIS	BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	86
1 BLAYAIS	BLAYAIS NUCLEAR POWER PLANT (reactors 3 and 4) 33820 Saint-Ciers-sur-Gironde	EDF	Reactors	110
2 GOLFECH	GOLFECH NUCLEAR POWER PLANT (reactor 1) 82400 Golfech	EDF	Reactor	135
2 GOLFECH	GOLFECH NUCLEAR POWER PLANT (reactor 2) 82400 Golfech	EDF	Reactor	142
3 CIVAUX	CIVAUX NUCLEAR POWER PLANT (reactor 1) BP 1 86320 Civaux	EDF	Reactor	158
3 CIVAUX	CIVAUX NUCLEAR POWER PLANT (reactor 2) BP 1 86320 Civaux	EDF	Reactor	159
LOCATION OF INSTALLATIONS REGULATED BY THE CAEN DIVISION				
4 BRENNILIS	MONTS D'ARRÉE EL4D 29218 Huelgoat	EDF	Reactor (decommissioning in progress)	162
5 LA HAGUE	SPENT FUEL REPROCESSING PLANT (UP2-400) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	33
5 LA HAGUE	EFFLUENT AND SOLID WASTE TREATMENT STATION (STE2) AND SPENT NUCLEAR FUELS REPROCESSING FACILITY (AT1) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	38
5 LA HAGUE	ELAN IIB FACILITY 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	47
5 LA HAGUE	MANCHE WASTE REPOSITORY (CSM) 50448 Beaumont-Hague	ANDRA	Disposal of radioactive substances (under surveillance)	66
5 LA HAGUE	HAO (HIGH LEVEL OXIDE) FACILITY 50107 Cherbourg	AREVA NC	Transformation of radioactive substances (decommissioning in progress)	80
5 LA HAGUE	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP3-A) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances	116
5 LA HAGUE	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances	117
5 LA HAGUE	LIQUID EFFLUENT AND SOLID WASTE TREATMENT STATION (STE3) 50107 Cherbourg	AREVA NC	Transformation of radioactive substances	118
6 CAEN	NATIONAL LARGE HEAVY ION ACCELERATOR (GANIL) 14021 Caen Cedex	GIE GANIL	Particle accelerator	113
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 1) 76450 Cany-Barville	EDF	Reactor	103
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 2) 76450 Cany-Barville	EDF	Reactor	104
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 3) 76450 Cany - Barville	EDF	Reactor	114
7 PALUEL	PALUEL NUCLEAR POWER PLANT (reactor 4) 76450 Cany- Barville	EDF	Reactor	115
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) 50340 Flamanville	EDF	Reactor	108
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) 50340 Flamanville	EDF	Reactor	109
8 FLAMANVILLE	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 - EPR) 50340 Flamanville	EDF	Reactor	167
9 PENLY	PENLY NUCLEAR POWER PLANT (reactor 1) 76370 Neuville-lès-Dieppe	EDF	Reactor	136
9 PENLY	PENLY NUCLEAR POWER PLANT (reactor 2) 76370 Neuville-lès-Dieppe	EDF	Reactor	140

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LOCATION OF INSTALLATIONS REGULATED BY THE CHÂLONS-EN-CHAMPAGNE DIVISION				
10 NOGENT-SUR-SEINE	NOGENT-SUR-SEINE POWER PLANT (reactor 1) 10400 Nogent-sur-Seine	EDF	Reactor	129
10 NOGENT-SUR-SEINE	NOGENT-SUR-SEINE POWER PLANT (reactor 2) 10400 Nogent-sur-Seine	EDF	Reactor	130
11 SOULAINES-DHUYS	AUBE WASTE REPOSITORY (CSA) 10200 Bar-sur-Aube	ANDRA	Radioactive waste surface repository	149
12 CHOOZ	CHOOZ B NUCLEAR POWER PLANT (reactor 1) 08600 Givet	EDF	Reactor	139
12 CHOOZ	CHOOZ B NUCLEAR POWER PLANT (reactor 2) 08600 Givet	EDF	Reactor	144
12 CHOOZ	ARDENNES NUCLEAR POWER PLANT CNA-D 08600 Givet	EDF	Reactor (decommissioning in progress)	163
LOCATION OF INSTALLATIONS REGULATED BY THE LILLE DIVISION				
13 GRAVELINES	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines	EDF	Reactors	96
13 GRAVELINES	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines	EDF	Reactors	97
13 GRAVELINES	GRAVELINES NUCLEAR POWER PLANT (reactors 5 and 6) 59820 Gravelines	EDF	Reactors	122
14 MAUBEUGE	NUCLEAR MAINTENANCE FACILITY (SOMANU) 59600 Maubeuge	SOMANU	Nuclear maintenance	143
LOCATION OF INSTALLATIONS REGULATED BY THE LYON DIVISION				
15 GRENOBLE	EFFLUENT AND SOLID WASTE TREATMENT STATION (STED) 38041 Grenoble Cedex	CEA	Transformation of radioactive substances (decommissioning in progress)	36
15 GRENOBLE	ACTIVE MATERIALS ANALYSIS LABORATORY (LAMA) 38041 Grenoble Cedex	CEA	Utilisation of radioactive substances (decommissioning in progress)	61
15 GRENOBLE	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex	Max von Laue Paul Langevin Institute	Reactor	67
15 GRENOBLE	DECAY INTERIM STORAGE FACILITY (STD) 38041 Grenoble Cedex	CEA	Storage of radioactive substances (decommissioning in progress)	79
16 BUGEY	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 - 01155 Lagnieu Cedex	EDF	Reactor (decommissioning in progress)	45
16 BUGEY	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 - 01155 Lagnieu Cedex	EDF	Reactors	78
16 BUGEY	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 - 01155 Lagnieu Cedex	EDF	Reactors	89
16 BUGEY	BUGEY INTER-REGIONAL WAREHOUSE (MIR) BP 60120 - 01155 Lagnieu Cedex	EDF	Storage of new fuel	102
16 BUGEY	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA)) 01120 Saint Vulbas	EDF	Packaging and interim storage of radioactive substances	173
17 ROMANS-SUR-ISÈRE	NUCLEAR FUELS FABRICATION UNIT (CERCA) 26104 Romans-sur-Isère	AREVA NP	Fabrication of radioactive substances	63
17 ROMANS-SUR-ISÈRE	NUCLEAR FUELS FABRICATION UNIT (FBFC) 26104 Romans-sur-Isère	AREVA NP	Fabrication of radioactive substances	98
18 VEUREY-VOROIZE	NUCLEAR FUELS FABRICATION PLANT 38113 Veurey-Voroize	SICN	Fabrication of radioactive substances (decommissioning in progress)	65
18 VEUREY-VOROIZE	PELLET FABRICATION FACILITY 38113 Veurey-Voroize	SICN	Fabrication of radioactive substances (decommissioning in progress)	90
19 DAGNEUX	DAGNEUX IONISATION PLANT Z.I. Les Chartinières 01120 Dagneux	IONISOS	Utilisation of radioactive substances	68
20 TRICASTIN	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	87
20 TRICASTIN	TRICASTIN NUCLEAR POWER PLANT (reactors 3 and 4) 26130 Saint-Paul-Trois-Châteaux	EDF	Reactors	88

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
20 TRICASTIN	GEORGES BESSE PLANT FOR URANIUM ISOTOPE SEPARATION BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex	EURODIF PRODUCTION	Transformation of radioactive substances	93
20 TRICASTIN	URANIUM HEXAFLUORIDE PREPARATION PLANT (COMURHEX) 26130 Saint-Paul-Trois-Châteaux	AREVA NC	Transformation of radioactive substances	105
20 TRICASTIN	URANIUM CLEAN-UP AND RECOVERY FACILITY (IARU) 26130 Saint-Paul-Trois-Châteaux	SOCATRI	Factory	138
20 TRICASTIN	TU5 AND W FUEL CYCLE PLANTS BP 16 - 26701 Pierrelatte	AREVA NC	Transformation of radioactive substances	155
20 TRICASTIN	TRICASTIN OPERATIONAL HOT UNIT (BCOT) BP 127 - 84504 Bollène Cedex	EDF	Nuclear maintenance	157
20 TRICASTIN	GEORGES BESSE II PLANT FOR CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES (GB II) 26702 Pierrelatte Cedex	SET	Transformation of radioactive substances	168
20 TRICASTIN	AREVA TRICASTIN ANALYSIS LABORATORY (ATLAS) 26700 Pierrelatte	AREVA NC	Laboratory for the utilisation of radioactive substances	176
20 TRICASTIN	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARD 26700 Pierrelatte	AREVA NC	Storage of radioactive materials	178
21 CRUAS-MEYSSE	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas	EDF	Reactors	111
21 CRUAS-MEYSSE	CRUAS-MEYSSE NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas	EDF	Reactors	112
22 SAINT-ALBAN	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon	EDF	Reactor	119
22 SAINT-ALBAN	SAINT-ALBAN/SAINT-MAURICE NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon	EDF	Reactor	120
23 CREYS-MALVILLE	SUPERPHENIX REACTOR 38510 Morestel	EDF	Reactor (decommissioning in progress)	91
23 CREYS-MALVILLE	FUEL STORAGE FACILITY 38510 Morestel	EDF	Storage of radioactive substances	141
LOCATION OF INSTALLATIONS REGULATED BY THE MARSEILLE DIVISION				
24 CADARACHE	TEMPORARY DISPOSAL FACILITY (PEGASE) AND SPENT NUCLEAR FUEL DRY STORAGE INSTALLATION (CASCAD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	22
24 CADARACHE	CABRI 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	24
24 CADARACHE	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	25
24 CADARACHE	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication or transformation of radioactive substances (decommissioning in progress)	32
24 CADARACHE	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances	37-A
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24 CADARACHE	MASURCA 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	39
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24 CADARACHE	ENRICHED URANIUM PROCESSING FACILITY (ATUE) 13115 Saint-Paul-lez-Durance Cedex	CEA	Fabrication of radioactive substances (decommissioning in progress)	52
24 CADARACHE	ENRICHED URANIUM AND PLUTONIUM WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	53
24 CADARACHE	CHEMICAL PURIFICATION LABORATORY (LPC) 13115 Saint-Paul-lez-Durance Cedex	CEA	Transformation of radioactive substances (decommissioning in progress)	54
24 CADARACHE	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL REPROCESSING, CLEAN-OUT AND REPACKAGING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex	CEA	Utilisation of radioactive substances	55

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
24 CADARACHE	SOLID RADIOACTIVE WASTE STORAGE YARD 13115 Saint-Paul-lez-Durance Cedex	CEA	Storage of radioactive substances	56
24 CADARACHE	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	92
24 CADARACHE	MINERVE 13115 Saint-Paul-lez-Durance Cedex	CEA	Reactor	95
24 CADARACHE	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex	CEA	Utilisation of radioactive substances	123
24 CADARACHE	CHICADE BP 1 - 13108 Saint-Paul-lez-Durance Cedex	CEA	R&D laboratory	156
24 CADARACHE	CEDRA 13115 Saint-Paul-lez-Durance Cedex	CEA	Packaging and interim storage of radioactive substances	164
24 CADARACHE	MAGENTA 13115 Saint-Paul-lez Durance Cedex	CEA	Reception and shipment of nuclear materials	169
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24 CADARACHE	ITER 13115 Saint-Paul-lez-Durance Cedex	International organisation ITER	Nuclear fusion reaction experiments with tritium and deuterium and deuterium plasmas	174
25 MARCOULE	PHÉNIX 30205 Bagnols-sur-Cèze	CEA	Reactor	71
25 MARCOULE	ATALANTE 30200 Chusclan	CEA	R&D laboratory and study of actinides production	148
25 MARCOULE	NUCLEAR FUELS FABRICATION PLANT (MELOX) BP 2 - 30200 Chusclan	AREVA NC	Fabrication of radioactive substances	151
25 MARCOULE	CENTRACO 30200 Codolet	SOCODEI	Radioactive waste and effluent processing	160
25 MARCOULE	DIADEM 30200 Chusclan	CEA	Storage of solid radioactive waste	177
25 MARCOULE	GAMMATEC 30200 Chusclan	Synergy Health Marseille	Ionisation treatment of materials, products and equipment, for industrial purposes and for research and development	170
26 MARSEILLE	GAMMASTER IONISATION PLANT 13323 Marseille Cedex 14	Synergy Health Marseille	Ionisation installation	147
27 NARBONNE	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) (MALVÉSI) 11100 Narbonne	AREVA NC	Storage of radioactive substances	175
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30 SACLAY	ULYSSE (Saclay) 91191 Gif-sur-Yvette Cedex	CEA	Reactor (decommissioning in progress)	18
30 SACLAY	ARTIFICIAL RADIONUCLIDES PRODUCTION FACILITY (UPRA) 91191 Gif-sur-Yvette Cedex	CIS Bio International	Fabrication or transformation of radioactive substances	29
30 SACLAY	LIQUID EFFLUENT MANAGEMENT ZONE (STELLA) 91191 Gif-sur-Yvette Cedex	CEA	Transformation of radioactive substances	35
30 SACLAY	OSIRIS-ISIS 91191 Gif-sur-Yvette Cedex	CEA	Reactors	40
30 SACLAY	HIGH-ACTIVITY LABORATORY (LHA) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances (decommissioning in progress)	49
30 SACLAY	SPENT FUEL TEST LABORATORY (LECI) 91191 Gif-sur-Yvette Cedex	CEA	Utilisation of radioactive substances	50

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
30 SACLAY	SOLID RADIOACTIVE WASTE MANAGEMENT ZONE (ZGDS) 91191 Gif-sur-Yvette Cedex	CEA	Storage and packaging of radioactive substances	72
30 SACLAY	POSEIDON IRRADIATION FACILITIES 91191 Gif-sur-Yvette Cedex	CEA	Ionisation installations	77
30 SACLAY	ORPHÉE 91191 Gif-sur-Yvette Cedex	CEA	Reactor	101
31 SAINT-LAURENT-DES-EAUX	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors A1 and A2) 41220 La Ferté-Saint-Cyr	EDF	Reactors (decommissioning in progress)	46
31 SAINT-LAURENT-DES-EAUX	IRRADIATED GRAPHITE SLEEVE STORAGE SILOS 41220 La Ferté-Saint-Cyr	EDF	Storage of radioactive substances	74
31 SAINT-LAURENT-DES-EAUX	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors B1 and B2) 41220 La Ferté-Saint-Cyr	EDF	Reactors	100
32 DAMPIERRE-EN-BURLY	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 1 and 2) 45570 Ouzouer-sur-Loire	EDF	Reactors	84
32 DAMPIERRE-EN-BURLY	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 3 and 4) 45570 Ouzouer-sur-Loire	EDF	Reactors	85
33 CHINON	IRRADIATED MATERIAL FACILITY (AMI) 37420 Avoine	EDF	Utilisation of radioactive substances	94
33 CHINON	CHINON INTER-REGIONAL WAREHOUSE (MIR) 37420 Avoine	EDF	Storage of new fuel	99
33 CHINON	CHINON NUCLEAR POWER PLANT (reactors B1 and B2) 37420 Avoine	EDF	Reactors	107
33 CHINON	CHINON NUCLEAR POWER PLANT (reactors B3 and B4) 37420 Avoine	EDF	Reactors	132
33 CHINON	CHINON A1D 37420 Avoine	EDF	Reactor (decommissioning in progress)	133
33 CHINON	CHINON A2 D 37420 Avoine	EDF	Reactor (decommissioning in progress)	153
33 CHINON	CHINON A3 D 37420 Avoine	EDF	Reactor (decommissioning in progress)	161
34 BELLEVILLE-SUR-LOIRE	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 1) 18240 Léré	EDF	Reactor	127
34 BELLEVILLE-SUR-LOIRE	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 2) 18240 Léré	EDF	Reactor	128
35 FONTENAY-AUX-ROSES	PROCÉDÉ 92265 Fontenay-aux-Roses Cedex	CEA	Research installation (decommissioning in progress)	165
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36 FESSENHEIM	FESSENHEIM NUCLEAR POWER PLANT (reactors 1 and 2) 68740 Fessenheim	EDF	Reactors	75
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37 CATTENOM	CATTENOM NUCLEAR POWER PLANT (reactor 3) 57570 Cattenom	EDF	Reactor	126
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