

Abstracts

ASN REPORT

on the state of nuclear safety
and radiation protection in France in |2014|



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The ASN (Nuclear Safety Authority) Report on the state of nuclear safety and radiation protection in France in 2014.

This report is specified in 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.

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IMPROVING NUCLEAR SAFETY AND RADIATION PROTECTION: A DUTY AS IMPORTANT AS EVER



FROM LEFT TO RIGHT:

Philippe JAMET - Commissioner
Margot TIRMARCHE - Commissioner
Pierre-Franck CHEVET - Chairman
Jean-Jacques DUMONT - Commissioner
Philippe CHAUMET-RIFFAUD - Commissioner

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Montrouge, 3rd March 2015

014 was generally in line with previous years in terms of nuclear safety and radiation protection.

The situation is on the whole relatively satisfactory, but we cannot afford to rest on our laurels. The scale of the challenges and the expectations of society mean that the nuclear safety and radiation protection requirements must be gradually tightened, in the light of accident analysis, increasing scientific knowledge and technological developments.

“*This principle of reinforced safety and radiation protection applies to all facilities, including those which have been in service for many decades.*”

This concern is apparent internationally. In this respect, 2014 was a significant year:

- the European directives on nuclear safety and radiation protection were significantly reinforced;
- a coordinated approach to the management of emergency situations was proposed by all the European safety and radiation protection regulators.

This principle of reinforced nuclear safety and radiation protection applies to all facilities, including those which have been in service for many decades. The problems encountered in certain facilities in 2014 (CIS bio international, Osiris, FBFC, etc.) illustrate the problems involved in implementing this principle. Similarly, the possible continued operation of the nuclear power plants (NPPs) beyond forty years and the numerous periodic safety reviews initiated on research and fuel cycle facilities means that major and complex work will be required as of 2015.

This year 2015 will also be marked by:

- the beginning of examination of the Flamanville EPR NPP commissioning file;
- continued work to limit the doses resulting from public exposure to radon;
- continued work to ensure improved management of the exposure of patients and health care professionals, particularly in diagnostic radiology and during interventional procedures.

REINFORCED SAFETY REQUIREMENTS

In accordance with the European Nuclear Safety Directive and the recommendations of WENRA (Western European Nuclear Regulators Association), ASN is demanding continuous progress in the safety of the nuclear facilities, whether new-build or existing installations, the safety of which is periodically reassessed.

Learning the lessons of the Fukushima Daiichi disaster is part of this process. Following the stress tests, ASN required that the nuclear facilities be made more resistant to extreme natural hazards and that additional safety structures and equipment (hardened safety core) be installed. In early 2015, ASN completed the definition of all the requirements concerning

this hardened safety core. A first series of material and organisational improvements have already been made. Considerable work still has to be done however. It will extend beyond 2020.

The major challenges for the coming years will be to analyse the proposals from the licensees concerning this work and to monitor its performance.

The nuclear facilities are subject to periodic safety reviews every ten years. Their continued operation depends on a demonstration of their conformity with the safety requirements applicable to them and on the implementation of improvements in line with the level of safety of the most recent facilities. This approach has already been used for the EDF reactors and for some facilities of the French Alternative Energies and Atomic Energy Commission (CEA) and Areva. The next few years will be marked by a significant increase in the number of fuel cycle and research facilities to be examined. These facilities are often ageing and some of them will be undergoing their first review. Difficult safety issues will need to be addressed.

ASN will also continue to assess the possibility of the EDF reactors continuing to operate beyond their fourth periodic safety review. As things currently stand, this is not a foregone conclusion. The first periodic safety review concerned will take place in 2020. The schedule is thus a very tight one, given the complexity of the questions to be dealt with and the importance and scale of the corresponding challenges.

Examination of the Flamanville 3 EPR NPP commissioning application will begin in 2015. As this is the first third-generation reactor to be built in France, this commissioning process is of particular importance. The commissioning is scheduled by EDF for 2017 and will entail the deployment of considerable human and financial resources by ASN and by the French Institute for Radiation Protection and Nuclear Safety (IRSN).

Difficulties were once again observed in 2014 in the field of nuclear pressure equipment, both for the manufacturing and assembly operations and in the implementation of the new applicable regulatory provisions. These in particular concern the primary and secondary systems of the EPR reactor and the replacement steam generators, notably those of Le Blayais NPP reactor 3. Some of these deviations entailed large-scale repairs and the development of more effective inspection methods. ASN thus asked Areva and EDF for more extensive safety justifications prior to installation of the steam generators and the restart of reactor 3 at the Le Blayais NPP. More generally, long-term solutions must be implemented to ensure compliance with the regulations in this field.

MEDICAL RADIATION PROTECTION NEEDS TO BE MORE EFFECTIVE

Medical radiation protection remains a priority for ASN. Its work in this field will follow on from that performed in previous years. The main challenges will be to manage the doses delivered to patients in imaging and radiotherapy, and the exposure of health professionals in the operating theatres.

In France, medical imaging for diagnostic purposes is the second most important source of exposure of the population to ionising radiation after naturally occurring radiation. This exposure is continuing to rise as a result of the increased utilisation of certain radiological examinations. The largest contribution by far is from computed tomography. Optimum management of exposure entails strict application of the justification principle: the use of ionising radiation must be reserved for those cases in which non-irradiating techniques such as magnetic resonance imaging (MRI) or ultrasonography are unsuitable. The optimisation principle must also be used to obtain the necessary diagnostic image quality, while minimising patient exposure as far as possible. The main priorities in this field are to reinforce medical physics resources and facilitate access to MRI techniques.

In the field of radiotherapy, four incidents rated level 2 on the ASN-SFRO scale concerning excessive irradiation or doses erroneously delivered to patients were recorded by ASN in 2014. This field requires compliance with particularly rigorous quality assurance procedures, owing to the scale of the doses delivered and the precision of the areas to be irradiated during treatment. The technologies used are also changing extremely fast and if they are to be correctly assimilated by the staff, then sufficient numbers of medical physicists and dosimetrists are required.

Two incidents concerning doses received by physicians during imaging interventions were rated level 2 on the INES scale by ASN in 2014. More generally, and in particular when fluoroscopy-guided procedures are carried out in the operating theatres, interventional radiology inspections show the need to draft and follow operating procedures, ensure a higher level of initial and on-going training of all those involved, increase the involvement by medical physicists and persons competent in radiation protection and, finally, create a true radiation protection culture that is shared by all the personnel.

GROWING EUROPEAN HARMONISATION

ASN continues to play an important role in the European organisations, in particular WENRA, HERCA (Heads of the European Radiological protection Competent Authorities) and ENSREG (European Nuclear Safety Regulators Group). The

goals are to harmonise nuclear safety and radiation protection requirements, to promote the independence of the regulators and to act transparently, while communicating with all aspects of society.

Significant European radiation protection and nuclear safety directives have been published or revised since 2013 and their implementation in the coming years implies considerable work:

- in 2015, ASN will continue to coordinate the work to transpose directive 2013/59 /Euratom of 5th December 2013 into French law, specifying the basic radiation protection standards. The first texts will primarily concern: extension of the scope of regulatory oversight to industrial activities using naturally radioactive materials, the implementation of specific management of exposure resulting from an accident, special measures for chronic exposure situations (contaminated sites, exposure to radon, etc.), and reinforcement of the notion of a graduated approach to regulatory oversight according to the stakes involved;
- for several years now, ASN has been involved in the radon action plan in France and in 2014 organised an international seminar on management of the radon risk, in particular in the home;
- a revision of the “nuclear safety” directive was adopted by the Council of Ministers in July 2014. It explains the general safety objectives to be met by nuclear facilities. It introduces a mandatory periodic safety review of each facility at least every ten years and the performance of coordinated Europe-wide examinations on specific safety topics, similar to the post-Fukushima Daiichi stress tests. The obligations to inform the public and the stakeholders are also reinforced.

These improvements to the European safety approach are to be compared with the difficulties being experienced with advancing the situation internationally in these fields.

The radioactive releases from a severe nuclear accident in a European country could affect several other countries in Europe. In a situation such as this, harmonisation of emergency situation management would be essential for effective population protection measures. A significant milestone was reached on this subject in 2014. The European radiation protection and nuclear safety authorities, grouped together within HERCA and WENRA, adopted recommendations for harmonising immediate population protection measures and the associated perimeters in the various European countries affected by radioactive releases. A wide range of accidents is considered, including the most severe, comparable to that at Fukushima Daiichi nuclear power plant. In each State, dialogue is now required with the authorities in charge of civil protection so that these recommendations can be implemented. This approach, which is vital to protecting the populations in the event of a severe nuclear accident, is a priority for ASN.

At the request of the Prime Minister, ASN will in 2015 continue to coordinate the work of the Steering Committee for managing the post-accident phase of a nuclear accident or radiological emergency situation (CODIRPA) on the management of post-accident situations. It will share the results with its European partners, with a view to eventual harmonisation.

REINFORCED SAFETY OVERSIGHT

In 2014, the ASN Commission issued two opinions underlining the need to reinforce the State's oversight system to deal with unprecedented nuclear safety and radiation protection issues, such as the aftermath of the Fukushima Daiichi disaster, the generalised adoption of safety reassessments for all nuclear facilities, the possible continued operation of EDF reactors beyond their fourth periodic safety review, monitoring the commissioning of the Flamanville EPR NPP and the safety assessment of the radioactive waste disposal projects.

The need for this reinforcement was confirmed by the audit of the French nuclear safety and radiation protection oversight system in 2014, carried out by an international team of experts under the supervision of the International Atomic Energy Agency.

The green growth energy transition bill also provides for an expansion of the roles and prerogatives of ASN concerning stakeholder information and participation in decisions and the orientation of research into nuclear safety and radiation protection. It also makes provision for the possibility of giving ASN additional powers of sanction.

ASN and IRSN benefited from relatively favourable budget decisions for the period 2015-2017. ASN appreciates the efforts made by the Government in a particularly difficult context. It would however point out that these temporary, limited measures cannot guarantee the long-term financing required for performance of its duties. Reform is therefore required if ASN and IRSN are to be given appropriate financing suitable for the challenges involved, derived both from the State budget and from an annual contribution by the nuclear licensees, to be set by Parliament. The 2015 Budget act opens the door to this possibility.

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 hazards involved in 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*



0 HFA 216 PD
Porte ordinaire

PRESEI

SOUDE



ACIDE SULFURIQUE

MORPHOLINE



**MEZ
ORTE !**

Station
deminéralisation
Local Lits Mélangés
0 SDA 107 DE
0 SDB 107 DE
0 SDC 107 DE

asn

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 authorisations, with the exception of major authorisations for basic nuclear installations, such as creation and decommissioning. ASN also issues the licenses provided for in the Public Health Code concerning small-scale nuclear activities and issues authorisations 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 monitoring, 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 monitors and regulates 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.

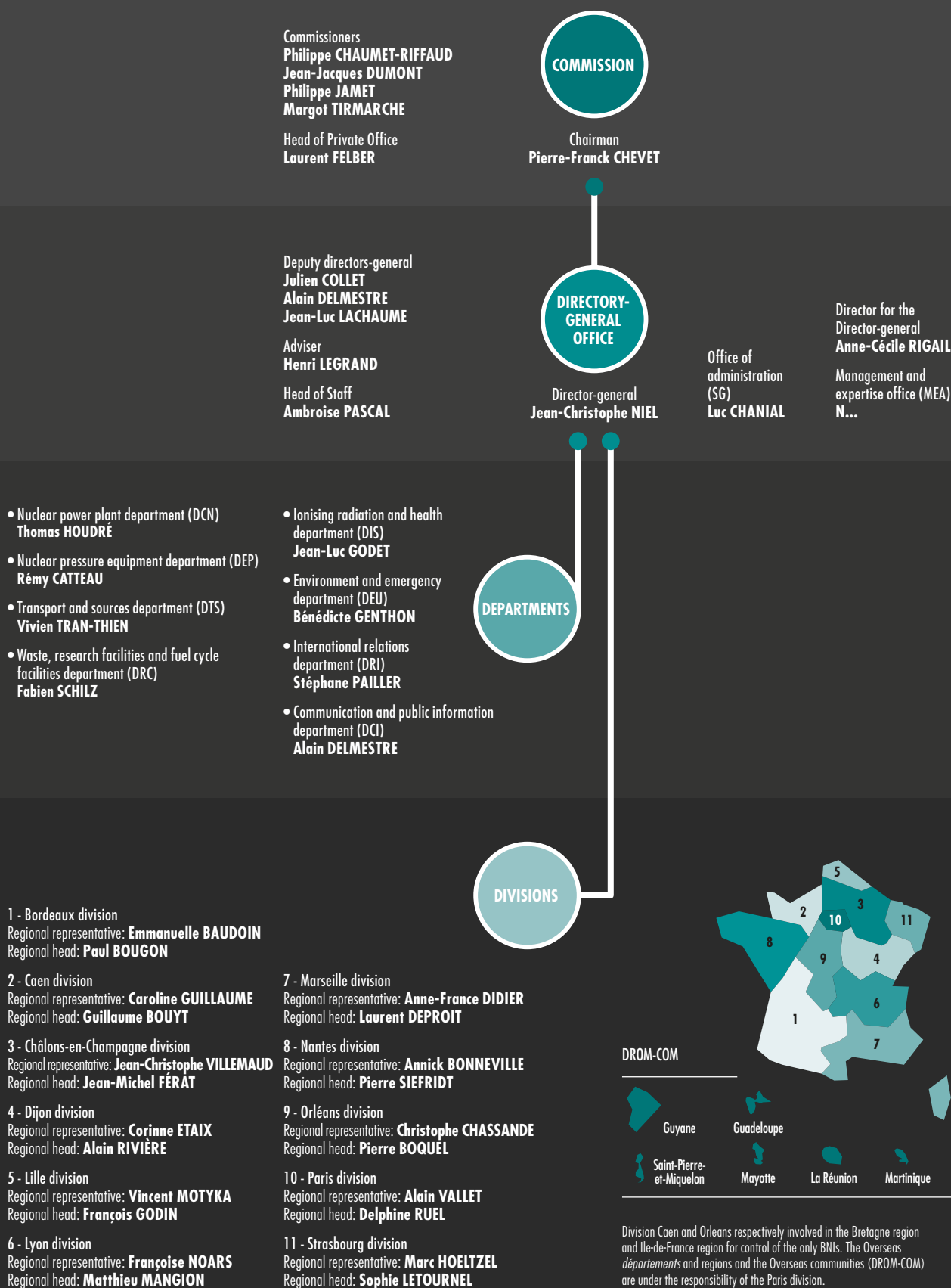
THE HELP OF EXPERTS

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 (GPE).

KEY FIGURES

474	staff members	3,170	licenses
82 %	management	21	press conferences
273	inspectors	90	information notices
2,170	inspections of nuclear facilities, of shipments of radioactive substances, of the medical, industrial and research sectors, of approved organisations	26	press releases
14,850	inspection follow-up letters available on www.asn.fr as at 31st December 2014	7	accident simulation exercises
448	technical opinions sent to ASN by IRSN	79.95	million euros total budget for ASN
23	Advisory Committee meetings	84	million euros IRSN budget devoted to expert appraisal work on behalf of ASN

ASN organisation chart - March 2015



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	Jean-Jacques DUMONT Commissioner	Philippe JAMET Commissioner	Margot TIRMARCHE Commissioner
DATE APPOINTED				
12 November 2012 for 6 years	10 December 2014 for 6 years	15 December 2010 for 6 years	15 December 2010 for 6 years	12 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 2014

71

sessions

27

opinions

85

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*¹, who is in charge of protecting the general public, and supervise the operations carried out to safeguard the facility on the site.

¹ Administrative region headed by a Prefect

ASN'S MAJOR ACHIEVEMENTS IN 2014



Jean-Christophe NIEL
Director-general

Montrouge, 3rd March 2015

In the editorial of its 2013 report, the Commission underlined that the regulation and monitoring of nuclear safety and radiation protection is a major responsibility for ASN, which it strives to carry out in complete independence, with stringency, competence and transparency.

A few figures illustrate the density of our activity during the course of 2014 in dealing with this issue and meeting the particularly high expectations of society in this field:

- 2,170 inspections, including the first in-depth inspection of a medical establishment, the Pitié-Salpêtrière Hospital;
- 4 level 2 events and 136 level 1 events on the INES scale applicable to nuclear activities;
- 4 level 2 events and 117 level 1 events on the ASN-SFRO scale applicable to radiation protection of patients;
- 24 violation reports;

- 71 sessions by the Commission, 85 resolutions issued and 27 opinions delivered;
- 6 draft regulatory resolutions and 151 draft individual decisions, with an influence on the environment, submitted to the public for consultation;
- 23 Advisory Committee of Experts meetings;
- 90 information notices and 26 press releases;
- 7 national level nuclear emergency exercises.

As of 31st December 2014, the ASN workforce stood at 474.

Over and above these figures, let us take a look at the main events which marked this year.

THE STRESS TESTS INITIATED IN THE WAKE OF THE FUKUSHIMA DAIICHI ACCIDENT

ASN regularly mentioned that complete analysis of the lessons learned from the Fukushima Daiichi accident would take many years. This feedback would lead to a significant tightening of the requirements applying to nuclear facilities and to major changes in the management of radiological emergency situations.

Following the Fukushima Daiichi accident, ASN thus asked the licensees to identify the equipment enabling the nuclear facilities to withstand extreme situations. This equipment constitutes the “hardened safety core”. On 21st January 2014, it determined the level of seismic hazard the EDF NPPs should be able to withstand. On this same occasion, it also indicated that in the management of such a situation, reactor cooling and heat removal should preferably be by means of the steam generators and that the tightness of the containment should be preserved for as long as possible. In late 2014, as a result of ASN prescriptions, the Nuclear Rapid Intervention Force (FARN) was in a position to intervene simultaneously on four damaged reactors on a given site.

From 22nd October to 21st November 2014, ASN submitted draft resolutions to the public for consultation concerning the additional prescriptions applicable to the “hardened safety core” for the Areva and CEA facilities. These prescriptions more specifically define the hazards to be considered for this “hardened safety core” as well as the associated design requirements. The corresponding resolutions were approved in January 2015.

REVISION OF THE EUROPEAN “NUCLEAR SAFETY” DIRECTIVE

From a regulatory viewpoint, the significant event in 2014 was the approval of the revision of the European “nuclear safety” directive. ASN considers that this revision, initiated following the Fukushima Daiichi accident, represents substantial improvements by comparison with the previous version. The revised directive in particular highlights the principles of “defence in depth” and “safety culture” and the safety objectives

for the nuclear facilities promoted by WENRA (Western European Nuclear Regulators Association). It makes a safety reassessment of each nuclear facility mandatory at least every ten years, and requires examination by the European counterparts on specific safety topics every six years, along the same lines as the stress tests. Finally, it reinforces stakeholder information.

At a national level, ASN continued to develop the regulations applicable to nuclear facilities, in particular by taking decisions concerning management of the criticality risk in BNIs or the shutdown and restart of PWR reactors.

“ In 2014, ASN was particularly attentive to the situation of certain nuclear facilities.

”

PERIODIC SAFETY REVIEWS OF NUCLEAR FACILITIES

In accordance with the Environment Code, all French nuclear facilities must undergo a ten-yearly periodic safety review. On this occasion, the facility's conformity with its baseline safety requirements is checked. Improvements must be made to bring it closer into line with the best safety standards. This approach was recognised as being best practice by the European countries following the Fukushima Daiichi accident and was integrated into the revised European nuclear safety directive, approved in June 2014.

In 2014, ASN issued prescriptions concerning the continued operation of Dampierre-en-Burly reactor 1 beyond its third periodic safety review and Nogent-sur-Seine reactors 1 and 2, Cattenom 2 and 3, Saint-Alban/Saint-Maurice 1 and 2 and Penly 1 beyond their second periodic safety reviews. The 900 MWe reactors will for their part be entering the period of their fourth periodic safety review. Detailed technical exchanges were held between EDF, IRSN and ASN, through four seminars concerning the conformity of the facilities, their ageing and their obsolescence, the safety of fuel storage, internal and external hazards and the prevention and mitigation of severe accidents.

Finally, in 2014, ASN also issued prescriptions concerning the operation beyond their periodic safety review of several Areva facilities (Mélox – Mox fuel fabrication plant at Marcoule and IARU – Tricastin site clean-up and uranium recovery facility) and CEA facilities (Eole and Minerve reactors in Cadarache). This was the first

periodic safety review for these facilities, which were not subject to this process prior to the TSN act of 2006.

In 2014, ASN was particularly attentive to the situation of certain nuclear facilities.

This was more specifically the case of the Le Blayais NPP, where EDF will replace the three steam generators for reactor 3, owing to the degree of wear on their tube bundles. After examination of the design and manufacture of the new steam generators built by Areva, ASN observed that Areva had not provided all the necessary safety justifications. Accordingly, prior to the installation and then commissioning of the new steam generators in November 2014, the ASN Chairman asked Areva and EDF to provide these safety justifications, in particular with regard to the mechanical stresses for the design of the equipment, the mechanical properties of certain materials, the representativeness of the calculation methods for verifying the mechanical strength of the equipment, or the ability of the inspection methods to detect potential defects.

ASN also placed Areva's FBFC facility under close surveillance. This decision was taken further to the worrying observations regarding safety management, operational rigorousness, in particular concerning management of the criticality risk, and project management. The ASN Commission summoned the senior management of the facility in February 2014 and a meeting was organised with all the management on the site in May. ASN will issue a position statement following analysis of the action plan drawn up by FBFC and the in-depth inspection performed in November 2014.

In 2008, given the risks presented by the Osiris experimental reactor which entered into service 50 years ago in Saclay in the Paris area, and on the basis of the undertakings made by CEA, ASN prescribed shutdown of this reactor in 2015. In accordance with ASN's position, published in the summer of 2014, the Government confirmed that the reactor would be shut down in late 2015. ASN notified the various parties concerned as of 2009 about the international and national issues associated with the production of radiopharmaceuticals by experimental reactors.

The CIS bio international radiopharmaceuticals manufacturing facility, located in the Paris area, was also the subject of particularly close attention. The safety analysis of the facility and the detection of serious fire risk shortcomings, led ASN in 2013 to require that the licensee install automatic fire extinguishing systems. Faced with its tardiness in performing this work, despite formal notice to comply with its prescriptions, ASN initiated a process to require the deposit of a sum corresponding to the required work in September 2014. Notwithstanding the nuclear safety implications, the licensee nonetheless intends to challenge this ASN resolution before the Council of State.

Finally, the ASN Commission reminded the Chairman of Areva of the importance of recovering and packaging the legacy waste at La Hague as rapidly as possible. A draft ASN resolution outlining and prioritising the recovery of legacy waste based on the safety implications of the storage facilities was presented for public consultation in August and September 2014. The resolution was published in January 2015.

THE ISSUES AND IMPLICATIONS OF SMALL-SCALE NUCLEAR ACTIVITIES

Even if no level 2 incident was recorded in 2014 on nuclear installations, this was not the case with small scale nuclear activities, in which four level 2 incidents were identified during the course of the year. Even if no pertinent conclusions can be drawn from the fluctuations in a small number of annual events, ASN nonetheless remains attentive to ensuring that the most serious events are the subject of detailed analysis, so that the necessary lessons can be learned, although without neglecting to analyse medium-term trends.

Thus an analysis of the significant radiation protection events (SRE) notified between 2007 and 2013 led ASN to alert the interventional radiology players to several points in 2014. It in particular pointed out the need to conduct an assessment of the risks for patients and professionals, to identify the procedures entailing a risk and to define the procedures for monitoring the patients at risk. It also recalled the need for medical physicists and persons competent in radiation protection, the importance of training personnel in the radiation protection of both workers and patients and in the use of equipment and, finally, the need to anticipate technical and organisational changes. Over the coming years, ASN will be maintaining interventional radiology as one of its inspection priorities.

In 2014, ASN published the summary of the inspections carried out in the 217 nuclear medicine units in France between 2009 and 2011. Although the state of radiation protection is considered to be satisfactory on the whole, progress is still required concerning personnel training in the radiation protection of patients and workers, the performance of workplace studies for all the personnel, internal quality checks and the exhaustiveness of the waste and effluents management plans.

With regard to the regulations, the new directive setting basic radiation protection standards was published on 5th December 2013. France has four years in which to transpose this new directive into national law. Even if the French regulations had already anticipated the tightening of certain prescriptions, in particular in the field of radiotherapy and the management of unsealed radioactive sources, changes to the legislation (system of qualification of medical physicists) or to the regulations (twelve month dose limit for the lens of the eye reduced to 20 millisieverts per year, modification of the persons competent in radiation protection (PCR)

system, reduction in the radon reference level from 400 Bq/m³ to 300 Bq/m³) are nonetheless required. ASN has been and will remain involved in this process.

2014 saw the signing of a framework collaboration agreement between ASN and the French national cancer institute (INCa). This agreement more particularly concerns the medical uses of ionising radiation, the cancerous pathologies actually or potentially attributable to nuclear activities, whether medical or industrial in origin, or exposure of the population to ionising radiation of natural origin, more specifically that linked to radon.

In 2014, ASN published a summary of the inspections carried out by its inspectors in 2012 in 47 “equine” veterinary radiology structures. This branch of veterinary medicine has the most significant potential implications for radiation protection, notably owing to the power and conditions of use of the equipment designed for large sized animals. Although the practices in the field were on the whole found to be good (presence of in-house PCR, optimisation of the diagnostic performance conditions), several areas for improvement were identified (operational dosimetry of workers, internal radiation protection checks, radiological zoning, etc.).

In 2014, it also updated and published information on the radioactive substance transport traffic. A public consultation was opened concerning draft guidelines to clarify what should be included in the management plans for radioactive substance transport incidents and accidents drawn up by those involved in this sector (carriers, consignors, etc.).

ASN also reminded those in possession of ionisation chamber smoke detectors that they must be registered by 31st December 2014. In 2011, two resolutions were issued to deal with the withdrawal from service of the seven million detectors installed nationwide in France. These detectors containing radioactive sources can no longer be justified in terms of radiation protection, given that alternatives exist. This system plans, guides and organises the removal, maintenance or recovery operations.

Finally, in autumn 2014, ASN and the Norwegian radiation protection authority jointly organised a seminar on national strategies to reduce radon exposure of the population and the associated risks of lung cancer. Twenty European countries, the World Health Organisation, the International Atomic Energy Agency (IAEA), the United States, Canada and Russia were present. Radon is a public health problem which requires coordinated management, involving all sectors of society and a broad range of tools (regulations, incentives, information, etc.). Although national strategies may differ from one country to another, owing to the specific conditions linked in particular to the local geological conditions or the number of people living in the areas with a high risk of radon exposure, all are based on a shared goal of reducing average radon concentrations.

THE WORKING OF THE FRENCH SYSTEM FOR THE OVERSIGHT OF NUCLEAR SAFETY AND RADIATION PROTECTION

In November 2014, the French system for the oversight of nuclear safety and radiation protection was assessed by a team of twenty-nine international experts under the supervision of IAEA. In 2006, ASN hosted the first IRRS (Integrated Regulatory Review Service) mission concerning all the activities of a safety regulator. This audit is the result of the European nuclear safety directive which requires a peer review mission every ten years. The team identified best practices such as stakeholder involvement, the independence of the ASN commissioners and personnel, the coordination between the oversight organisations involved in emergency planning. The mission also identified a number of points worthy of particular attention or improvement, in particular the regulatory framework for monitoring medical exposure, the system used by ASN for assessing and modifying its regulatory framework, or the human and financial means available to ASN for the performance of its duties. IAEA's final report was transmitted to France in the first quarter of 2015 and posted on the ASN website.

In order to issue its resolutions, ASN relies on the technical services of IRSN and on the opinions and recommendations of its seven Advisory Committees of Experts (GPE), five of which concern nuclear safety and two radiation protection. They comprise members from various expert organisations (including IRSN), university research laboratories, associations or licensees. Foreign experts from the safety regulators of other countries input their international experience. In 2014, ASN decided to reinforce the independence of the expertise on which it relies and the transparency of the process of drafting its resolutions and decisions.

To do this, new procedures for the selection and nomination of the members of the Advisory Committees of Experts were adopted in order to open them up more broadly to civil society.

To conclude, I would like to underline the commitment and professionalism of the ASN personnel, whose everyday efforts in the field are advancing nuclear safety and radiation protection. The quality of our resolutions and our actions is built on their commitment and on the unfailing assistance of IRSN and our Advisory Committees.

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 processed for their radioactive, fissile or fertile properties, as well as interventions in the event of a radiological risk following an accident or a contamination event. 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. Many uncertainties and unknown factors nonetheless persist, in particular with regard to high-dose radiopathologies, the effects of low doses or the effects on non-human species.

EXPOSURE TO IONISING RADIATION IN FRANCE

The entire French population is potentially exposed to ionising radiation, but to differing extents,

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 3.7 millisieverts (mSv) per year in 2010, varying by a factor of 2 to 5 depending on the location. The sources of this exposure are as follows:

- for about 1 mSv/year, naturally occurring radioactivity excluding radon, including 0.5 mSv/year for radiation of telluric origin, 0.3 mSv/year for cosmic radiation and 0.2 mSv/year for internal exposure from food;
- for about 1.4 mSv/year, 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 2011-2015 national action plan is currently being drawn up. In 2014, ASN organised a European seminar on national radon risk management programmes;
- for about 1.6 mSv/year (estimation for 2012), radiological diagnostic examinations were up by comparison with 2007 (1.3 mSv/year in 2007) owing to an increase in the number of computed tomography procedures and improved awareness of practices. Particular attention must therefore be given to management of the doses delivered to the patients;
- representing 0.03 mSv/year, the other artificial sources of exposure: past airborne nuclear tests, accidents affecting facilities, releases from nuclear installations.

Workers in nuclear activities undergo specific monitoring (more than 350,000 individuals in 2013); the annual dose remained lower than 1 mSv (annual effective dose limit for the public) for more than 96% of the workforce monitored; the number of times the limit of 20 mSv (regulatory limit for nuclear workers) was exceeded dropped significantly (9 cases in 2013); the same applies to the collective dose (drop of about 43% since 1996) whereas the population monitored has increased by about 50%. 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, 85% are between 1 mSv per year and 5 mSv per year, while 15% are below 1 mSv per year.

OUTLOOK

ASN will be particularly attentive to following up the recommendations expected in 2015 from a pluralistic working group on individual monitoring of the exposure of workers to ionising radiation.

With regard to radon, the third national plan, to be adopted in 2015, should compensate for the shortcomings of the previous plan regarding strategic management, which led to a lack of visibility of priority areas on the new map, but also regarding information of the public and elected officials and the radon screening strategy in existing homes.

With regard to the regular increase in doses delivered to patients through medical imaging procedures, ASN will reinforce the steps it initiated in

2011 to maintain the mobilisation of the health authorities and health professionals at all levels. The deployment of strategic management involving the health authorities, to support the intended actions of the Cancer 3 plan, would appear to be essential.

02 THE PRINCIPLES AND PLAYERS IN REGULATING NUCLEAR SAFETY, RADIATION PROTECTION AND ENVIRONMENTAL 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 principles involved are the prevention principle (anticipation of any environmental threat through rules and measures taking account of the “best available techniques at an economically acceptable cost”), the “polluter-pays” principle (the polluter responsible for the environmental damage bears the cost of pollution prevention and remediation), the precautionary principle (the lack of certainty, in the light of current scientific and technical knowledge,



must not delay the adoption of proportionate preventive measures), the participation principle (the populations must take part in determining public decisions), the justification principle (a nuclear activity can only be carried out if justified by the advantages it offers by comparison with its inherent exposure risks), the optimisation principle (exposure to ionising radiation must be kept as low as is reasonably achievable), the limitation principle (the regulations set limits for an individual's exposure to ionising radiation resulting from a nuclear activity except for medical or biomedical research purposes) and the principle of the nuclear licensee's responsibility for the safety of its installation.

THE NUCLEAR ACTIVITY REGULATORS

The current French organisation for the regulation of nuclear safety and radiation protection was established by the 13th June 2006 act on transparency and security in the nuclear field (TSN act) codified in the Environment Code; this regulation is primarily the responsibility of the Government and ASN, within the legislative framework defined by and under the control of Parliament.

Parliament regularly monitors the regulation of nuclear safety and radiation protection, in particular through its special commissions, which conduct hearings, or the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST), which has issued a number of reports on this subject and to which ASN presents its annual report on nuclear safety and radiation protection in France.

On the advice of ASN, the Government defines the general regulations for nuclear safety and radiation protection. Also on the advice of ASN, it takes key individual decisions concerning BNIs (creation or decommissioning authorisation, closure in the event

of an unacceptable risk, etc.). It is responsible for civil protection in an emergency.

In the current governmental organisation, the Minister for Ecology, Sustainable Development and Energy is responsible for nuclear safety and, together with the Minister for Social Affairs and Health, for radiation protection.

In the *départements*, the Prefects, as representatives of the State, are the guarantors of public order and have a particular role to play in the event of an emergency, given that they are in charge of population protection measures. The Prefect also takes part in the various procedures concerning the nuclear installations in his *département*, overseeing local consultations and providing the Ministers or ASN with his recommendations as applicable.

ASN is an independent administrative Authority created by the TSN act. It is responsible for regulating nuclear safety and radiation protection and contributes to informing the populations on these subjects. It sends the Government proposals for regulatory texts and is consulted on the texts prepared by the Ministers. It clarifies the regulations by issuing statutory resolutions which are then sent to the competent Ministers for approval. 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. ASN contributes to France's European and international actions. It alerts and informs the Authorities of third-party States in the event of a radiological emergency and in turn receives alerts and information from them. Finally, it provides its assistance for management of radiological emergencies.

In technical matters, ASN relies on the expertise provided by IRSN and by the Advisory Committees of Experts (GPE) that it has set up, the composition of which was

renewed in 2014 with the aim of achieving diversification.

It also convenes pluralistic working groups enabling all the stakeholders to contribute to drafting doctrines and action plans and monitor their implementation. These groups look more specifically at social, organisational and human factors, the management of post-accident situations or the management of waste and radioactive materials (group set up with the Ministry in charge of these questions).

ASN has made a commitment to research, to identify areas of knowledge essential for medium and long-term expertise. 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 nominates the Chairman and two Commissioners) and by the President of the Senate and the President of the National Assembly (who each nominate one Commissioner).

ASN has headquarters and eleven regional divisions around the country. On 31st December 2014, its total workforce stood at 474 employees. In 2014, the ASN budget stood at €79.95 million. In addition, IRSN receives €84 million for the technical support it provides to ASN; these credits include a State subsidy and the revenue from a tax paid by the licensees of the large nuclear facilities.

In total, the State's budget for transparency and the regulation of nuclear safety and radiation protection amounted to €174.7 million in 2014.

These credits are at present divided among five budget programmes, which obscures the overall clarity of the cost of regulation and also leads to problems with budgetary preparation, the settling of budget allocation conflicts and execution.

ASN has a multi-year strategic plan. The current plan covers the period 2013-2015.

CONSULTATIVE BODIES

The organisation of nuclear security and transparency also involves a number of consultative bodies, in particular the High Committee for Transparency and Information on Nuclear Security, an information, consultation and debating body for the risks related to nuclear activities and the impact of these activities on human health, the environment and nuclear security. One could also mention the High Council for public health, a scientific and technical consultative body reporting to the Minister for Health, which contributes to defining the multi-year public health objectives, evaluates the attainment of national public health objectives

and contributes to their annual monitoring, along with various commissions tasked with giving an opinion on draft regulatory texts (High Council for the prevention of technological risks concerning certain texts applicable to BNIs, Central Committee for pressure equipment for those concerning pressure equipment and so on).

Faced with a number of unprecedented challenges (“post-Fukushima Daiichi” measures, ageing of facilities and application for extended NPP operation, EPR commissioning, initial periodic safety reviews for about fifty facilities, continuous rise in radiation doses delivered to patients, etc.), ASN considered that it was essential to effect a significant increase in the human and financial resources of both itself and IRSN. It recognises the efforts made by the Government

in 2014 in an extremely difficult budgetary context (addition of thirty staff over three years), but it considers that this is insufficient to meet the needs and thus requests a reform of the financing of the regulation and monitoring of nuclear safety and radiation protection, expert appraisal and information concerning nuclear safety and radiation protection, by means of an annual contribution from the nuclear licensees to be determined by Parliament.

03 REGULATIONS

The legal framework for radiation protection is based on international norms, standards and recommendations issued by various organisations, more specifically the International Commission on Radiological Protection (ICRP), an NGO which publishes recommendations about protection against ionising radiation (the latest recommendations appear in the 2007 ICRP publication 103), the International Atomic Energy Agency (IAEA) which regularly publishes and revises nuclear safety and radiation protection standards, and the International Organisation for Standardisation (ISO) which publishes international technical standards.

At a European level, under the Euratom Treaty, various directives set basic rules for radiation



protection, nuclear safety and the management of radioactive waste and spent fuel; these directives are binding on all the member States.

With regard to radiation protection, a process to merge and revise the directives led on 5th December 2013

to the adoption of Council directive 2013/59/Euratom, which sets out basic standards for health protection against the dangers resulting from exposure to ionising radiation, published on 17th January 2014.

With regard to nuclear safety, the European Council of Ministers on 8th July 2014 adopted a revision of Council Directive 2009/71/Euratom of 25th June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

ASN actively contributed to the adoption of these two directives.

Nationally, the legal framework for nuclear activities has been extensively overhauled in recent years. The main texts are contained in the Public Health Code and the Environment Code. 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.

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 created a system of authorisation or notification for the manufacture, possession, distribution (including import and export), and utilisation of radionuclides or products or devices containing them. Licences are issued by ASN and notifications are filed with the ASN regional divisions.

The general rules applicable to small-scale nuclear facilities are the subject of ASN statutory resolutions. On 23rd October 2014, ASN thus adopted resolution 2014-DC-0463 concerning minimum technical rules for the design, operation and maintenance of in vivo nuclear medicine facilities.

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.

Activities leading to increased ionising radiation of natural origin materials: certain professional activities which cannot be defined as “nuclear activities” can lead to a significant increase in the exposure to ionising radiation on the part of the workers and, to a lesser extent, the neighbouring populations. This in particular concerns activities which utilise raw materials, construction materials or industrial residues containing natural radionuclides not used for their radioactive, fissile or fertile properties (phosphate extraction and phosphate-based fertiliser manufacturing industries, dye industries, in particular those using titanium oxide and those utilising rare earth ores such as monazite). The radiation protection measures required in this field are based on a precise identification of the activities, an estimation of the impact of exposure for the persons concerned, the implementation of corrective measures to reduce this exposure, if necessary, and to monitor it. They are regulated by the Labour Code and the Public Health Code.

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 man and the environment, whether or not radioactive in nature. It in particular requires that the creation or decommissioning of a BNI be authorised by a decree issued on the advice of ASN and that ASN authorise start-up of the installation and stipulate requirements regarding its design and operation with respect to protection of the population and the environment.

ASN is carrying out work to overhaul the general technical regulations for BNIs, together with the Ministry responsible for the environment; this led to the publication of the Order of 7th February 2012 setting the general rules for BNIs. Most of the provisions of this order entered into force on 1st July 2013. In the next few years it will be supplemented by about fifteen ASN statutory resolutions. In 2014, ASN thus adopted four resolutions concerning the management of fire risks, physical modifications to BNIs, NPP PWR shutdown and restart and management of the criticality risks. This system is supplemented by ASN guides, which are not legally binding and which present ASN policy; seventeen guides have so far been published.

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 deployed in the event of an incident or accident. The consignor is responsible for implementing these lines of defence.

The regulations concerning the transport of radioactive materials have a particularly international flavour. They 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".

Within this legal framework, ASN is responsible for approving package models for the most hazardous shipments.

Contaminated sites and soils: 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 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.

OUTLOOK

The green growth energy transition bill, which should be adopted in the first half of 2015, will lead to significant progress in the regulation and monitoring of nuclear safety

and radiation protection. ASN will contribute to finalising the texts (ordinances and decrees) implementing this act.

04 REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

In France, the party responsible for a nuclear activity is first in line for ensuring the safety of that activity. They cannot delegate this responsibility, and must ensure permanent surveillance of their installations. On behalf of the State, ASN is responsible for regulating nuclear activities.

Regulation and monitoring of nuclear activities is a fundamental duty of ASN. The aim is to verify that all parties responsible for a nuclear activity, in particular the licensees of nuclear facilities, 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 against the risks associated with nuclear activities.

Inspection is the key means of monitoring available to ASN.



It involves an ASN inspector travelling to a site being inspected. 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 and published on www.asn.fr. Any deviations found during the inspection can lead to administrative or penal sanctions.

ASN has a broad vision of monitoring and regulation, encompassing material, organisational and human aspects. Its actions take the tangible form of resolutions, prescriptions,

inspection follow-up documents and assessments of nuclear safety and radiation protection in each sector of activity.

SIGNIFICANT EVENTS

2,170 inspections were carried out in 2014 by the 273 ASN inspectors.

In 2014, ASN was notified of:

- 1,114 significant events concerning nuclear safety, radiation protection and the environment in BNIs; 971 of these events were rated on the INES scale (872 events rated level 0 and 99 events rated level 1). Ten significant events were rated as “generic events” including 3 at level 1 on the INES scale;
- 63 significant events concerning the transport of radioactive substances, including 3 events rated level 1 on the INES scale;
- 650 significant events concerning radiation protection in small-scale nuclear activities, including 195 rated on the INES scale (of which 34 were level 1 events and 4 were level 2 events).

In 2014, as a result of violations observed, the ASN inspectors (nuclear safety inspectors, labour inspectors and radiation protection inspectors) transmitted 24 violation reports to the public prosecutor's offices, nine of which were related to labour inspections in the NPPs.

ASN took administrative action (formal notice, suspension, etc.) against 18 licensees and managers of nuclear activities. In 2014, for the first time, ASN in particular initiated two procedures requiring the deposit of funds to cover the performance of work, against the Cis bio international company.

OUTLOOK

In 2015, ASN scheduled 1,850 inspections on BNIs, radioactive substances transport operations, activities employing ionising radiation, organisations and laboratories it has approved and activities involving pressure equipment. Continuing the

approach used in 2014, ASN will as a priority inspect the high-stake activities, taking account of experience feedback.

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

It will propose changes to the sanctions policy, pursuant to the provisions of the green growth energy transition bill.

In the field of pollution prevention and mitigation of impacts and detrimental effects, after finalising the regulatory overhaul of the BNI system, with the publication of ASN resolution 2013-DC-0360 of 16th July 2013 concerning the control of nuisances and the health and environmental impact of BNIs, which supplements Title IV of the ministerial order of 7th February 2012 setting the general rules applicable to BNIs, ASN will ensure the effective implementation of the new provisions by the licensees and will analyse the initial feedback obtained. ASN will publish the resolution modifying the approval process for environmental radioactivity monitoring laboratories, currently defined by ASN resolution 2008-DC-0099 of 29th April 2008. Work will be started on updating the website of the national environmental radioactivity monitoring network and work on self-monitoring by the licensees will be continued.

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. An accident can never be completely ruled out and the necessary provisions for dealing with and managing a radiological emergency situation must be planned, tested and regularly revised.

ASN has four main duties in the management of these situations, with the support of IRSN:

- to ensure and verify the soundness of the steps taken by the licensee;
- to advise the Government and its local representatives;
- to take part in information of the public and the media;
- to act as competent Authority within the framework of the international conventions.

The emergency plans relative to accidents occurring at a BNI define the measures necessary to protect the site personnel, the general public and the environment, and to control the accident.

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 in constant contact with IRSN, whose task is to issue position statements to advise the Prefect, who is director of the emergency response operations;



- a communications 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.

ASN is supported by IRSN's emergency technical centre.

In the event of a severe accident, an interministerial crisis committee is set up with the participation of ASN.

SIGNIFICANT EVENTS

The "Major nuclear or radiological accident" national response plan

This was published in February 2014 and covers all types of emergency situations, supplementing the existing local planning arrangements (PUI – on-site emergency plan and PPI – off-site emergency plan). It clarifies the organisation of the national response in the event of a nuclear accident.

This plan anticipates the possible consequences of an accident so that they can be mitigated and more rapidly assessed. It also includes elements of post-accident policy established by the CODIRPA, the international nature of emergency situations and the mutual assistance possibilities in the case of an event.

CODIRPA

Pursuant to the interministerial directive of 7th April 2005, ASN set up the CODIRPA in June 2005. Post-accident management of a nuclear accident is a complex subject involving numerous aspects and many players. The assessment must benefit from a pluralistic structure which in particular involves all the stakeholders.

CODIRPA policy covering the exit from the emergency phase and the transition and long-term phases was transmitted by ASN to the Prime Minister in November 2012, accompanied by an opinion from the ASN Commission, published on www.asn.fr and widely distributed locally, nationally and internationally.

In 2014, the CODIRPA continued its work concerning the lessons learned from post-accident management in the aftermath of

the Fukushima Daiichi disaster. The studies carried out hitherto on accidents of a moderate scale should more specifically be extended to the management of severe accidents.

In this context, three areas for focus were proposed:

- test and supplement the policy elements with respect to the different accident situations;
- assist with regional implementation of the elements of post-accident management;
- take part in international work carried out on the post-accident theme, share and integrate its results.

The new duties of the CODIRPA were officially laid out in a letter from the Prime Minister on 29th October 2014, giving ASN a new mandate for a five-year period.

The cost of the nuclear risk

Following on from the work done by the CODIRPA, ASN organised a pluralistic study seminar on the cost of the nuclear risk, on 24th October 2014.

HERCA/WENRA approach

HERCA (Heads of the European Radiological protection Competent Authorities) and WENRA (Western European Nuclear Regulators Association) adopted a joint position on 22nd October 2014 concerning the management of emergency situations and their transboundary coordination, in particular the rapid transmission of information between the countries concerned and consistency between the recommendations issued for protection of the populations. The principle is to align the population protection measures in neighbouring countries with those decided on by the country in which the accident occurred.

In Europe:

- evacuation should be prepared up to 5 km around nuclear power plants, and sheltering

and ingestion of iodine thyroid blocking (ITB) 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 ITB up to 100 km.

Each of the European nuclear safety and radiation protection authorities will be initiating discussions with their respective national civil protection authorities with a view to implementing the recommended measures.

National nuclear and radiological emergency exercises

ASN, together with the General Secretariat for Defence and National Security, the General Directorate for civil security and emergency management and the Defence Nuclear Safety Authority, took part in implementing the 2014 programme of national nuclear and radiological emergency exercises concerning BNIs and radioactive substance transport operations.

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. 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, more specifically testing the time needed to mobilise all the parties concerned.

OUTLOOK

ASN is actively contributing to the review process currently being carried out by the public authorities following the Fukushima Daiichi accident, concerning the national radiological emergency response organisation. ASN will actively participate in the work to implement the “Major nuclear or radiological accident” national response plan and will in particular call on the

assistance of the Ministry of the Interior and the offices of the Prefects on the occasion of the publication of the regional implementation guide.

In 2015, ASN will continue with the European initiatives taken with a view to transboundary harmonisation of actions 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 HERCA/WENRA approach.

In 2015, ASN will ensure that these emergency exercises also have an educational and informative dimension by extensively involving the populations in their preparation and implementing international relations aspects.

In 2015, ASN will oversee the preparation of the campaign to inform the populations living around the NPPs with regard to the protection measures and the distribution of stable iodine tablets which will take place in early 2016.

06 FROM INFORMATION TO TRANSPARENCY AND PUBLIC PARTICIPATION

“Transparency in the nuclear field consists in the set of provisions adopted to ensure the public’s right to reliable and accessible information on nuclear security” (Article L.125-12 of the Environment Code which codifies Article 1 of the TSN act).

ASN is responsible for the correct implementation of the requirements of the TSN act, particularly those concerning transparency. ASN considers that nuclear subjects are everyone’s business and that all citizens should be able to reach their own opinions.

ASN oversees application of the TSN act by the stakeholders and is particularly attentive to verifying that the nuclear licensees meet their obligations regarding transparency. The licensees are required to release to anyone who so requests the information in their possession concerning the risks involved in their activities and the safety or radiation protection measures taken by them to prevent or mitigate these risks.

ASN also focuses on ensuring participation by civil society in subjects related to nuclear safety and radiation protection, in the spirit of the Aarhus Convention which encourages consultation of the public and the stakeholders and the transparency of information. It supports steps in favour of transparency by the Local Information Committees (CLI) and the HCTISN.

Each year ASN presents its Report on the state of nuclear safety and radiation protection in France to Parliament and develops its relations with the members of parliament and the local elected officials.



SIGNIFICANT EVENTS

The ASN Report on the State of Nuclear Safety and Radiation Protection in France in 2013 was presented to Parliament on 15th April. It led to more than twenty national and regional press conferences.

The new format of *Contrôle* magazine was launched in March 2014 with number 197 concerning the new BNI regulations. It was an opportunity for those concerned by their implementation to give their opinions. Number 198 deals with continued reactor operations beyond 40 years, the radon risk and the fire risk. *Contrôle* magazine is a technical review and is now divided into three separate sections: “Analyse” (analysis), “Retour d’expérience” (feedback) and “En question” (focus).

The www.asn.fr website is the main source of information for the general public. This year, the www.asn.fr website attracted nearly 540,000 visitors. In 2014, ASN reorganised the content of the site to make it even easier for the various audiences to find the information they were looking for.

On 21st March 2014, ASN organised a seminar for the nuclear licensees, with the presence of

CLI members (300 participants) to present the new regulations applicable to BNIs. This national seminar was followed by a first regional discussion seminar in Caen with the nuclear licensees of Normandy and Brittany.

In 2014, ASN was regularly summoned to attend Parliamentary hearings on its activities and on the various bills concerning nuclear safety and radiation protection. For the second year, ASN took part in the Mayors and Local Authorities Exhibition in November 2014, where it received nearly 300 visitors on a variety of topics, notably the operating lifetime of the nuclear power plants and their monitoring, the management of emergency situations, the radon risk in the home and the means of preventing it, radiation protection of the population and of patients.

In 2014, ASN and IRSN completed their preparation of a travelling educational exhibition designed to inform the general public about the risks linked to ionising radiation. The exhibition was presented to the public in about fifteen high schools and in the ASN information centre. The aim of the exhibition is to be presented primarily in communities within off-site emergency plans (PPI)

zones, in the regions concerned by the radon risk, in schools, medical facilities, etc.

ASN's public information centre received nearly 300 visitors during the exhibition entitled "*La sûreté nucléaire? Question centrale!*" (Nuclear Safety? The core of the matter) designed by ASN and IRSN, to present the principles and effects of radioactivity and understand how a nuclear power plant functions and is monitored.

In partnership with the National Association of local information committees and commissions (Anccli), ASN organised the 26th CLI conference, which attracted about 200 participants on 10th December 2014 in Paris. After the "topical questions", with presentations by ASN and the Anccli, two round-table sessions addressed the topics of "Continued operation of the nuclear reactors beyond their 4th periodic safety review" and "Population protection measures in the event of a

nuclear accident: towards European harmonisation?"

In October 2014, ASN and the Drôme *département* General Council organised the first inter-CLI discussion seminar, bringing together 150 participants from all the CLIs in the Rhone valley.

OUTLOOK

For 2015, ASN will actively contribute to implementing steps to reinforce nuclear transparency in accordance with the requirements of the green growth energy transition bill.

It will reinforce transparency on the subjects under its responsibility, together with the other players and stakeholders.

ASN will develop its general public information measures, in order to make the technical subjects presented to them clearer and more accessible. ASN will continue to suggest that the

public contribute to draft regulatory texts, by submitting their opinion on www.asn.fr.

ASN will coordinate preparations for the 2016 information and iodine tablets distribution campaign intended for the populations living around the nuclear power plants.

ASN will continue its exchanges with the elected officials and stakeholders. An inter-CLI meeting for the Val de Loire area is thus planned for 2015.

ASN will continue to support CLI activities. It will continue its actions with respect to the Government and Parliament, to ensure that the CLIs are given the resources they need.

ASN considers that the HCTISN plays an important consultation role at the national level. It regretted the interruption of its work in 2014 and hopes that the HCTISN will rapidly resume working in 2015.

07 INTERNATIONAL RELATIONS



ASN devotes considerable resources to 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 area for ASN's international actions, in which it aims to contribute to the construction of two areas, one dealing with the topic of nuclear safety and the safe

management of waste and spent fuels and the other with the topic of radiation protection.

ASN actively contributed to the revision of the European nuclear safety directive. This was adopted on 8th July 2014 and makes provision for greater powers and independence on the part of the national safety regulators, sets ambitious safety objectives and establishes a European system of peer reviews. It also sets up national periodic safety assessments and provisions concerning preparedness for emergency response interventions. It also reinforces transparency and improves education and training. ASN considers that these new measures significantly strengthen the European community framework

for oversight of the safety of nuclear installations.

The European associations of nuclear regulatory authorities (WENRA) and radiation protection authorities (HERCA) created a joint working group in January 2014, which proposed “reflex” response measures to be taken in the event of a severe accident in which the authorities have very little information about the condition of the facility affected, as was the case for the accident in the Fukushima Daiichi NPP.

In the field of radiation protection, ASN coordinated the work involved in transposing the revision of the directive concerning basic radiation protection standards of 5th December 2013.

Outside Europe, numerous international initiatives on the harmonisation of regulations and practices have been made, more specifically under the supervision of IAEA and the OECD Nuclear Energy Agency (NEA). ASN actively participates in the work of the IAEA Commission of Safety Standards (CSS) which draws up international standards for nuclear safety and radiation protection. It was the originator of a scale for rating radiation protection events involving patients, ASN-SFRO scale which was presented to all countries in October 2014. ASN also takes part in the cooperative MDEP (Multinational Design Evaluation Programme) for new reactors, in particular in the work of the group dedicated to the EPR.

As in previous years, 2014 was marked by intense activity by the international organisations regarding the implications of the accident which struck the Fukushima Daiichi NPP in 2011. ASN played a major role in this work and recalled that it is essential to learn all possible lessons, both regarding technical and organisational and human aspects. At a European level, the safety regulators updated their action plans established following the stress tests.

ASN considers that the peer reviews of the nuclear safety and radiation protection regulators are an essential lever in achieving improvement and international harmonisation. Since 2009, the member states of the European Union have been required to undergo this periodic peer review of their organisation regarding nuclear safety. After receiving the first IRRS (Integrated Regulatory Review Service) mission concerning all the activities of a safety regulator in 2006, ASN hosted a second mission in November 2014. On this occasion, twenty-nine foreign auditors examined the French nuclear safety regulation and monitoring system.

ASN has signed bilateral cooperation agreements with many countries. It thus maintains close relations with the main countries equipped with nuclear reactors or looking to acquire them and with countries interested in radiation protection and emergency situation management issues. It pays particularly close attention to relations with France's neighbours. For many years, ASN has also been promoting personnel exchanges with its foreign counterparts and opens up its Advisory Committees of Experts to foreign representatives.

In 2014, ASN continued to be approached by countries wishing to benefit from its assistance in the regulation of nuclear safety and radiation protection. 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. ASN replies to these approaches through bilateral programmes with the safety regulator of the country concerned, or through international instruments such as the Instrument for Nuclear Safety Cooperation (INSC) – with projects under way in China and Vietnam for example – or IAEA's Regulatory Cooperation Forum (RCF).

Finally, France is a contracting party to four international agreements aimed at preventing accidents linked

to the use of nuclear energy and at mitigating their consequences. In 2014, the sixth review meeting of the Convention on Nuclear Safety was held in Vienna and was chaired by André-Claude Lacoste, the former Chairman of ASN.

OUTLOOK

In 2015, ASN will be aiming to promote a high level of safety internationally for new and existing reactors, making full use of the lessons learned from the Fukushima Daiichi accident. It will continue its work to reinforce the safety objectives of reactors worldwide. ASN will take part in the second peer review of the national plans resulting from the reactor stress tests carried out in 2012, concluding with a seminar organised by ENSREG (European Nuclear Safety Regulators Group) in April 2015.

The collaboration between HERCA and WENRA on the management of emergency situations will continue in 2015 and will involve national emergency preparedness authorities, so that a European approach to preparedness for emergency situations can be defined.

ASN will continue its work to develop the European approach to radiation protection. ASN will continue its involvement in radiation protection and will continue to put across its message concerning the need to limit patient doses in medical imaging and to optimise doses in general. It will remain active on the subject of radon and will discuss its practices in this respect with its counterparts.

Finally, ASN will maintain its policy of cooperation, by continuing the various forms of exchanges with its foreign counterparts.

08 REGIONAL OVERVIEW OF NUCLEAR SAFETY AND RADIATION PROTECTION



This chapter sets out the nuclear safety and radiation protection situation observed locally by ASN's eleven regional divisions.

Summary sheets present the BNIs and small-scale nuclear facilities (medical, industrial and research) and the local actions particularly representative of ASN's work in the regions.

09 MEDICAL USES OF IONISING RADIATION



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, 217 nuclear medicine units using unsealed sources for in vivo or in vitro diagnostics and for internal radiotherapy, plus 175 external radiotherapy centres equipped with 452 treatment devices, handling some 175,000 patients every year.

For more than a century, medicine has made use of sources of ionising radiation, both for diagnostic purposes and for therapy. While their benefits and usefulness have long been medically proven, these techniques contribute significantly to the exposure of the population 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. According to IRSN, 222,975 people working in the medical and veterinary fields were the subject of dosimetric exposure monitoring in 2013. Medical radiology concerns about 52% of the medical personnel exposed. More than 98% of the health professionals monitored in 2013 received an annual effective dose below 1 mSv. The annual effective dose limit of 20 mSv was exceeded on six occasions.

The activities presenting the highest risk from the radiation protection standpoint require authorisation. In 2014, ASN issued 681 authorisations, including 363 in computed tomography, 163 in nuclear medicine, 110 in external radiotherapy, 36 in brachytherapy and 9 for blood product irradiators.

In 2014, ASN produced a situation report on computed tomography radiation protection, on the basis of the inspections performed in 2013,

along with a report of external radiotherapy on the basis of the inspections performed in 2012 and 2013.

SIGNIFICANT RADIATION PROTECTION EVENTS (SRE)

In 2014, the number of SRE notified to ASN in the medical field is close to that of 2013 and stands at 557. However, there is a downward trend in the number of SRE notified in radiotherapy, with a drop of about 23% in external radiotherapy. For workers, the 40 SRE concern all activity sectors. For patients, 55% of the 302 SRE notified come from radiotherapy units. These events, which have no serious consequences for the health of the patients, were rated level 1 (117) and 2 (3) on the ASN-SFRO scale. 134 events concerned nuclear medicine. 133 concerned the medical exposure of women unaware of their pregnancy. The number of events concerning radioactive effluent leaks from nuclear medicine units rose in 2014.

The incident notices are published on www.asn.fr.

The events notified to ASN in 2014 show that the consequences with the most significance in radiation protection terms concern:

- for workers, primarily interventional radiology;
- for patients, interventional radiology during complex and lengthy procedures, but also nuclear medicine, with errors in the administration of radiopharmaceuticals;
- for the public and the environment, leaks from effluent containment devices in nuclear medicine.

For interventional radiology, the experience feedback from the SRE notified to ASN underlines the need to make greater use of and give greater resources to persons with competence for radiation protection and medical physicists, to develop the training of professionals who are not specialists in ionising radiation and to adopt approaches to manage the quality, safety and evaluation of professional practices.

So that information about a significant event notified to ASN is rapidly available, the Feedback information sheet, a new feedback tool intended for the professionals, was produced by ASN in 2014.

THE RADIATION PROTECTION SITUATION IN RADIOTHERAPY

Since 2012, radiotherapy centres are inspected every two years. An inspection frequency of one year is however maintained for centres showing potential signs of vulnerability or in which major changes have occurred in terms of human resources or organisation, or which adopt new techniques.

At the request of ASN, at the end of 2014, the Advisory Committee of Experts for radiation protection for the medical and forensic applications of ionising radiation worked on the conditions for implementing high-precision irradiation techniques in radiotherapy. ASN will adopt a position on this subject in 2015, on the basis of its opinion.

The ASN inspections performed in 2013 confirm the positive trend with regard to the increase in human resources for medical radiation physics. All the centres now have more than one equivalent full time medical physicist.

All the centres have implemented a patient treatment safety and quality management system, although the progress of this implementation varies greatly from one centre to another.

To encourage the use of risk analysis by the departments, ASN identified the difficulties encountered and in 2015 will be issuing recommendations on this subject.

THE RADIATION PROTECTION SITUATION IN NUCLEAR MEDICINE

In 2014, ASN continued to inspect nuclear medicine units and updated the rules applicable to their layout. Compliance with the regulatory obligations was considered to be on the whole satisfactory, in particular with

respect to the designation and definition of the duties of the person competent in radiation protection (PCR), the implementation of appropriate dosimetry and the performance of external radiation protection checks. Efforts are still required concerning risk assessment, radiation protection training of the personnel and the performance of internal inspections. Radiation protection training of the patients remains a weak point.

In 2015, ASN will issue recommendations on the conditions for discharge of radionuclide-contaminated effluents into the public sewerage system.

THE RADIATION PROTECTION SITUATION IN CONVENTIONAL RADIOLOGY AND COMPUTED TOMOGRAPHY

In 2012, computed tomography procedures accounted for 71% of the mean effective dose received by the population, although they only represent 10% of the volume. It should be noted that for a sample of about 600,000 individuals covered by health insurance, analysis of the effective doses for this population shows that 70% of them received less than 1 mSv, 18% between 1 and 10 mSv, 11% between 10 and 50 mSv and 1% more than 50 mSv. In 2013 and 2014, this field remains an inspection priority.

In 2013, the inspection of the 96 computed tomography facilities (10% of the total) confirmed a better assimilation of worker radiation protection than patient radiation protection along with the persistence of the shortcomings previously identified with regard to application of the optimisation principle, analysis of the workstations, radiation protection training refresher courses and monitoring by operational dosimetry

In 2014, ASN contributed to ensuring that the guide to medical imaging best practices was available on smartphone and tablet to enable those referring patients for radiological examinations (general

practitioners, specialists and emergency doctors) to better apply the justification principle.

At a European level, within HERCA, ASN met scanner manufacturers in order to improve the equipment optimisation tools and European medical societies and international organisations to look at the justification of imaging examinations utilising ionising radiation.

THE RADIATION PROTECTION SITUATION IN INTERVENTIONAL RADIOLOGY

The monitoring and regulation of radiation protection in interventional radiology is also a national priority for ASN.

In 2015, ASN will be publishing a national summary of the inspections performed over the period 2010 to 2012. The 2013 inspections have

already confirmed that the radiation protection of professionals is better assured in fixed installations than in operating theatres and that workplace environment studies, in particular concerning the doses at the extremities and lens of the eye, dosimetric monitoring and professional training must be reinforced.

At the initiative of ASN, the French National Authority for Health (HAS) published recommendations in 2014 for monitoring patients having undergone interventional radiology procedures that could lead to effects on tissues.

Finally, ASN considers that devices for estimating the dose of radiation delivered should be installed on all the radiology equipment in service.

Even if ASN notes improvements in the units and awareness on the part of the professionals, it nonetheless

considers that, as in 2013, the urgent measures it has been recommending for several years (more medical physicists, user training, quality assurance, auditing of professional practices, PCR resources, training of professionals in the radiation protection of patients, publication of guides of best practice by learned societies) are not always adequately implemented.

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. ASN must therefore adapt its efforts to their radiation protection issues 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.

REGULATION

In 2014, the list of installations classified on environmental protection grounds (ICPE) was changed, which meant that some facilities previously authorised by the Environment Code to possess and utilise radioactive substances are now regulated by ASN under the Public Health Code. Henceforth, only facilities holding radioactive substances in an unsealed form in quantities exceeding 10m³ are subject to the ICPE system (excluding the medical sector and particle accelerators).

In accordance with the simplification process and the graduated approach to radiological risks and potential consequences, ASN has drawn up and implemented licensing

application forms specific to each activity and available on www.asn.fr.

With regard to the application of the ban on the intentional addition of radionuclides in consumer goods and construction products, two ministerial decisions were the subject of an order in 2014: a waiver on the ban on the addition of radionuclides for the use of ampoules and refusal of a waiver for the addition of radionuclides in watches. ASN issued a favourable opinion on the draft orders and recalled the principle of the justification of activities comprising a risk of human exposure to ionising radiation.

With regard to the design of the facilities, ASN resolution 2013-DC-0349 of 4th June 2013, setting the minimum technical rules for the design of facilities in which X-rays are present, entered into force on 1st January 2014.

Finally, although the subject of monitoring the protection of radioactive sources against malicious acts has been the subject of interministerial discussions since 2008, France has not yet defined the obligations to be implemented to protect sources against malicious acts nor has it designated an authority with the legal capacity to carry out this regulation. In 2014, ASN brought this subject to the attention of Parliament through the review of the green growth energy transition bill. At the same time, ASN continued its preparations for rapid and efficient performance of this new mission.

AUTHORISATION

In 2014, 60 licensing or license renewal applications from suppliers of sources or devices containing sources were examined by ASN and 58 inspections were performed at these suppliers'. With regard to the users of sources, ASN examined and notified 225 new licenses, 1,015 license renewals or updates and revoked 398 licenses. Finally, with regard to the users of electrical

generators of ionising radiation, ASN granted 206 licenses and 229 license renewals in 2014 and issued 500 notification certificates.

CONTROL

Two incidents rated level 2 on the INES scale occurred in 2014: an employee working on a defective gamma radiography device at the Latresne welding institute was irradiated and received a single dose higher than the annual regulation limit, and non-compliance with zone entry rules led to significant exposure of a worker during an X-ray inspection in the Nantes centre of the DCNS industrial group.

In 2014, the ASN radiation protection inspectors sent the public prosecutors three violation reports concerning veterinary surgeons, three concerning lead detection devices and three concerning industrial radiology. ASN also adopted three resolutions for formal notification in the industrial field.

ASN also noted several incidents linked to failure of the shutter on certain devices. Analysis of these particular incidents enabled the origin of the failure of this part to be identified and ASN asked the supplier to take preventive measures as part of the annual maintenance of the devices.

Most source blockage incidents were correctly managed. However, poor practices led ASN to send further reminders to the professionals regarding the correct practices resulting from the radiation protection regulations applicable to gamma radiography.

At the same time, ASN organised technical meetings with the stakeholders to define standard scenarios for loss of source control, define technical recovery solutions and best practices in the event of an incident. The conclusions of this working group should be published in early 2015.

With regard to the monitoring of cyclotrons, ASN noted an incident in 2014 concerning pressure control faults in shielded enclosures.

In 2014, ASN completed deployment of the system for remote-declaration of construction site schedules for industrial radiography contractors.

Finally, despite the improvement in the administrative situation of the veterinary structures, certain best practices observed in the field and the strong commitment by the profession to harmonise practices nationally, ASN remains vigilant with regard to the activities performed on large animals and outside specialised veterinary facilities. In this field, areas for improvement have been identified with regard to operational dosimetry monitoring of workers, internal radiation protection checks, radiological zoning and radiation protection of outside persons participating in radiological diagnostics.

11

TRANSPORT OF RADIOACTIVE SUBSTANCES



About 980,000 packages of radioactive substances are carried in 770,000 shipments annually in France, representing a very small percentage of the hazardous goods traffic. 88% of the packages transported are intended for the health, non-nuclear industry or research sectors. The medical sector alone accounts for 31% of the packages transported and the nuclear industry 12% (for example, 389 annual shipments of new fuel, 220 of spent fuel, about 50 for MOX fuels and about 100 for plutonium oxide powder).

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. The consignor is responsible for package safety.

ASN ensures correct application of the regulations concerning the safe transport of radioactive and fissile substances for civil uses. This safety must not be confused with security, or physical protection, which is the prevention of theft or misappropriation of nuclear materials (usable for making weapons), for which ASN is not responsible. 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 from fire, mechanical impact, water ingress into the packaging (leading to a criticality risk), chemical reaction between package components, etc. 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.

SIGNIFICANT EVENTS

In 2014, ASN urged the carriers of radiopharmaceutical products to make efforts to optimise radiation

protection. A study requested from IRSN by ASN in 2013 showed that exposure of the drivers working for radiopharmaceutical package carriers over the past five years was higher than the average of workers exposed in France, with significant variations from one company to another.

Dangerous goods transport operations can take place on private roads within BNIs. These operations are subject to the provisions of the order of 7th February 2012. In 2014, several BNIs thus sent ASN revisions of their baseline safety requirements to take account of on-site transports. ASN analysed the on-site transport procedures for the site of La Hague and requested modification of the on-site transport packages for hulls and end-pieces resulting from the cutting up of spent fuel and of waste containers.

In 2014, in response to frequently asked questions, ASN drew up an information sheet on the transport of radioactive substances, intended for the general public and available on www.asn.fr.

In 2014, ASN issued 41 approval certificates. Most of these certificates concern prolongations or extensions of certificates already granted and two certificates concerned new package models. Eighteen of these certificates concern the transport of new or spent nuclear fuels.

In 2014, ASN carried out 113 inspections in radioactive substance transport (all sectors considered).

Half of these inspections concern shipments and carriers. They reveal incomplete familiarity with the regulations, especially in the medical sector. ASN pays particular attention to surveillance of the contractors, who are frequently called on.

In early 2014, ASN more specifically carried out two inspections on the drop tests for the new TN G3 spent fuel shipment packaging, which by 2020 should be replacing the TN 12/2 and TN 13/2 – for which ASN decided not to renew the approval. ASN also inspected the manufacture of new package models for the transport of vitrified waste and spent fuels from research or power reactors respectively. For these latter, the inspection was carried out jointly with the Swiss safety regulator.

In 2014, ASN carried out several inspections on transport package maintenance, in particular for the transport of MOX fuel and radioactive liquid effluents.

In 2014, ASN continued inspections on packages that do not require approval. These inspections show that the ASN recommendations expressed in its guide concerning these packages are beginning to be taken into account. There are still inadequacies, in particular as regards the demonstration of package compliance with the regulations.

ASN also carried out three inspections in 2014 in the railway sector, more specifically in collaboration with the French rail safety institution (Établissement français de sécurité ferroviaire). The follow-up letters to these inspections are available on www.asn.fr.

In 2014, 63 events rated level 0, and 3 events rated level 1 on the INES scale were notified to ASN. More than half of the events are notified by the industrial stakeholders in the nuclear cycle (EDF and Areva in particular). Nearly one quarter of the events concern radioactive pharmaceutical products. The conventional industry and research sectors notify very few transport events, probably owing to the lack of notification by the professionals in the small-scale nuclear sector.

In 2014, ASN took part in two emergency exercises involving a shipment of radioactive substances, one concerning a shipment of depleted uranium, the other – jointly with Belgium – a shipment of uranium hexafluoride.

In 2014, ASN submitted a guide to the drafting of emergency plans for public consultation. The guide was published in December 2014.

OUTLOOK

The actions undertaken in 2014 will be pursued in 2015 and particular attention will be given to compliance with the regulatory requirements of the order of 7th February 2012 concerning on-site transports, packages not requiring ASN approval, the manufacture and maintenance of packagings and analysis of the lessons learned from the Fukushima Daiichi accident with regard to transport.

12 EDF NUCLEAR POWER PLANTS (NPPs)

The 58 electricity generating reactors operated by EDF are at the heart of the nuclear industry in France. ASN imposes stringent safety requirements on these facilities, the regulation and monitoring of which mobilises nearly 200 of its staff and as many IRSN experts on a daily basis.

ASN has developed an integrated approach to regulation, covering not only the design of new facilities, their construction, modification and the integration of operating experience feedback, but also social, organisational and human factors,



radiation protection, environmental protection, worker safety and the application of social laws.

SIGNIFICANT EVENTS

Continued operation of the nuclear power plants

In accordance with the Environment Code, EDF must carry out a periodic safety review of its reactors every ten years. This review consists, on the one hand, of a detailed check on designs and equipment and, on the other, of a reassessment of the safety of the reactors by comparison with the most recent facilities and international best practices. On this occasion, EDF corrects the deviations detected and identifies the modifications it intends to make to reinforce reactor safety. On a case by case basis, ASN then decides on the continued operation of each reactor, if necessary issuing additional prescriptions designed to strengthen safety.

In late 2014, all of the 1300 MWe reactors had undergone their second ten-yearly outage inspections. ASN has not identified any element that would compromise EDF's ability to manage the safety of these reactors until the next periodic safety review.

In February 2015, ASN ruled on the orientations of the periodic safety review associated with the second ten-yearly outages of the 1450 MWe reactors. On this occasion, it recalled that the safety objectives to be considered for the review of these reactors must be defined with reference to those set for the fourth ten-yearly outage inspections of the 900 MWe reactors.

Experience feedback from the Fukushima Daiichi accident

Following the accident at Fukushima Daiichi, ASN considered that stress tests needed to be carried out on French civil nuclear facilities in order to take account of the experience feedback from the accident. Further to these stress tests, ASN issued a range of resolutions in 2012,

requiring EDF to take additional steps to reinforce the robustness of the NPPs to extreme situations, more specifically:

- a "hardened safety core" able to perform vital safety functions in the event of hazards or unforeseen circumstances exceeding those adopted for the general design of the facility;
- deployment of the "Nuclear Rapid Intervention Force" (FARN) proposed by EDF, a national emergency system involving specialised crews and equipment, capable of intervening on an affected site within less than 24 hours;
- reinforced measures to reduce the risk of uncovering of the spent fuel in the reactor fuel storage pits.

After analysis by IRSN and the Advisory Committee of Experts for Reactors (GPR) of the EDF proposal for the "hardened safety core" and having collated the comments from the public, ASN issued further resolutions on 21st January 2014 clarifying the components of this "hardened safety core" and the requirements applicable to their design and implementation.

Regulation of construction of the EPR in Flamanville

The Creation Authorisation Decree for the Flamanville 3 EPR was signed in April 2007 and construction work began in September 2007. The next regulatory step is ASN authorisation for reactor commissioning, for which EDF intends to submit its application in the spring of 2015. With this in mind and as of 2007, ASN initiated the review of certain topics requiring detailed examination and a check on the detailed design of the most important systems.

At the same time, ASN oversees the construction of the reactor through inspections and the examination of documents. Twenty-one inspections concerned the organisation of the project, the equipment assembly activities and the initial start-up tests. ASN also checked

the manufacture of the nuclear pressure equipment intended for the main primary and secondary systems. Finally, the ASN labour inspectors carried out inspections on construction site safety and the fight against illegal labour.

Replacement of reactor 3 steam generators in the Le Blayais NPP

After examining the design and the manufacture of the new steam generators intended for reactor 3 at the Le Blayais NPP, ASN found that not all the required safety justifications had been provided. On 24th November 2014, ASN therefore asked Areva and EDF to provide additional safety justifications prior to installation and start-up of the new steam generators.

ASN ASSESSMENTS

Nuclear power plants

ASN considers that 2014 was relatively satisfactory in terms of nuclear safety and radiation protection in the NPPs, marked by improved management of reactor outages.

Management of operations is on the whole satisfactory. However, several activities were the origin of significant events in 2014. Their underlying causes lay in insufficient preparation, inadequate management of tag-outs or erroneous application or interpretation of operating documents. ASN considers that the operating documentation drafting process needs to be improved, with closer involvement of the end-users.

Although some improvements are visible with respect to 2013, efforts must be continued with regard to planning, preparation, periodic testing and interpretation of the results obtained. Although the shortcomings in the reference documentation partly explain the deviations observed in 2014, the skills of the players concerned are not always able to prevent their effects, despite the improvements made

by EDF to the personnel training programmes and the implementation of a tutoring system for young recruits. EDF must continue to strengthen the jobs and skills management system.

The emergency management inspections carried out in 2014 confirmed that the sites had correctly assimilated the new PUI. However, these inspections did show that the management of emergency situations could be improved, more specifically with regard to the management of the mobile equipment used in an emergency situation and the corrective measures identified during the emergency exercises. The emergency response organisation was revised, notably with the integration of the FARN.

In terms of the organisation and internal training of the players involved in the processing of deviations, considerable progress was made by the NPPs in 2014, even if problems still exist with the implementation of and compliance with the baseline requirements issued by the EDF head office departments. The sites must continue their efforts, in particular with regard to the identification and traceability of the deviations detected. EDF has made undertakings, by means of a more detailed and more reactive review of deviations, to reinforce the assessment of their safety implications, in order to better identify and then prioritise the additional measures to be taken.

EDF has implemented a specific multi-year action plan designed to reinforce the management of activities scheduled and carried out during maintenance outages of nuclear power generating reactors. This action plan has in fact enabled the licensee to carry out more serene management of the preparation and performance phases. However, EDF's efforts must be continued over the long-term, more particularly with respect to work organisation, the preparation of certain activities, schedule compliance and coordination of the worksites.

In 2014, the condition of the first barrier and its management were on the whole stable but certain points could nonetheless be improved. 2014 was marked by the significant increase in the control rod cluster drop times for reactor 2 at the Nogent NPP, linked to the deformation of the fuel assemblies, entailing shutdown of the reactor before the end of its normal operating cycle, as well as the separation of a control rod in reactor 3 at the Tricastin NPP, which was not detected for more than one complete reactor operating cycle. ASN considers that particular attention must be paid to these points.

EDF's management of the second containment barrier is moving towards a satisfactory situation with the preventive strategy deployed in the programmes for replacement of the steam generators and the operations to keep their secondary parts clean.

By comparison with 2013, the number of events concerning the third barrier fell, in particular on the sites with an officer in charge of the "containment" function. Nonetheless, improvements are still expected with regard to the condition of the containment and the third barrier, more specifically concerning management of containment breaches in connection with the performance of work. The tests on the 900 MWe reactor containments performed in 2014 brought to light no particular problems liable to compromise their operation for a further ten years. On the other hand, ASN remains vigilant with respect to the double-wall containments of the 1300 and 1450 MWe reactors, which are not lined with a complete metal liner. It issued a ruling on this subject in June 2014 on the advice of the GPR and will be attentive to compliance with the undertakings that EDF made on this occasion.

The skills and qualifications management in place at the plants is on the whole satisfactory and the management processes

well documented and coherent. Training programmes are, generally, 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.

Inadequacies at certain plants were however still observed by ASN during inspections, concerning forecast management of jobs and skills, even if considerable investments are being made by EDF for hiring and training, in order to anticipate the renewal of skills following the retirement of current staff. At some plants, the workforce in certain disciplines is insufficient and may lead to overwork, which is prejudicial to safety, and to problems in ensuring that young recruits are accompanied by more experienced tutors.

Given the scale of retirements expected in the coming years and the considerable work to be performed by EDF, ASN considers that EDF's recruitment and training efforts need to be continued.

In the NPPs, ASN plays a labour inspection role. Improvements were observed with respect to daily and weekly rest periods, to the consideration of certain risks, such as those linked to welding fumes. EDF also announced the broadening of the duties of the "zone managers" to all conventional worker safety aspects, which is a positive move.

Progress is still expected in the field of managing multi-contractor activity and the use of subcontractors. ASN also asked EDF to improve the distribution of operating experience feedback and good practices between the sites.

Generally speaking, ASN considers that the radiation protection organisation defined and implemented is on the whole satisfactory. The collective dose in 2014 fell by comparison with 2013. This drop is partly because of progress in implementing the Alara principle and improved management of the duration of reactor maintenance

outages. Management of industrial radiography work is improving, even if there are still weaknesses in the preparation of these operations.

The organisation in terms of management of nuisances and the impact of NPPs on the environment is considered to be satisfactory at most plants, in particular through the implementation of structures that guarantee application of the regulatory requirements. However, contractor monitoring was felt to be insufficient and the plants do not all integrate operating experience feedback to the same extent. Improvements are also expected regarding the conformity of the facilities, the implementation of the maintenance programmes and waste management on the sites.

The ASN assessment of each NPP is detailed in chapter 8 of the report. Some plants stand out in this general assessment:

- with regard to nuclear safety: Saint-Laurent-des-Eaux;
- in the field of radiation protection: Chinon, Civaux, Golfech, Saint-Alban/Saint-Maurice, Saint-Laurent-des-Eaux;
- in the environmental field: Bugey, Dampierre-en-Burly, Saint-Laurent-des-Eaux.

Other NPPs are on the contrary under-performing with respect to at least one topic:

- with regard to nuclear safety: Bugey, Chinon;
- in the field of radiation protection: Bugey, Cattenom;
- in the environmental field: Belleville-sur-Loire, Cattenom, Chinon, Cruas Meyssse.

Nuclear pressure equipment manufacturers

The order of 12th December 2005 concerning nuclear pressure equipment introduced a significant tightening up of the justification and monitoring of the design and manufacture of this equipment. It requires that the equipment manufacturers provide more justifications and demonstrations

than before, in order to give stronger guarantees concerning the quality of this equipment.

The justifications and demonstrations provided by the manufacturers for new nuclear pressure equipment conformity assessments are still regularly unsatisfactory. ASN thus asked the manufacturers to modify their practices in order to bring them into line with the regulatory requirements.

OUTLOOK

In early 2015, ASN will rule on the generic aspects of the continued operation of 1300 MWe reactors beyond thirty years. It will then monitor the third ten-yearly outage inspection of Paluel NPP reactor 2. This third ten-yearly outage inspection will be the first carried out on a 1300 MWe reactor. Finally, ASN should be issuing its guidelines for the fourth periodic safety review of the 900 MWe reactors by the end of 2015.

Monitoring the implementation of the material and organisational measures prescribed following the Fukushima Daiichi accident will remain a priority for ASN. It will in particular examine the modifications made for the installation of additional generating sets and new emergency response centres. It will check EDF's ability to activate mobile response resources on the Gravelines site, the only French plant comprising six reactors.

In 2015, the Flamanville 3 EPR commissioning authorisation application will also be examined. The construction checks and EPR start-up tests will continue at a sustained rate.

13

NUCLEAR FUEL CYCLE INSTALLATIONS

The fuel cycle comprises the fabrication of the fuel and its subsequent reprocessing after it has been used, in order to extract the elements that are reusable in the nuclear reactors.

The main plants in the cycle – Comurhex, Areva NC Pierrelatte, Eurodif, Georges Besse II, FBFC, Melox, Areva NC La Hague – are part of the Areva group. These plants include facilities which have BNI status.



SIGNIFICANT EVENTS

The Comurhex II uranium conversion project is experiencing delays. These delays led Areva NC to ask ASN to allow continued operation of the former ICPE plants beyond July 2015. ASN is satisfied with Areva's replacement of the existing conversion units by a more modern and safer plant. It does however consider that continued operation would only be conceivable provided that the level of safety in the facilities is improved and that their shutdown date is compatible with the urban development programme around BNI 105. Based on the lessons learned from the Fukushima Daiichi accident, strengthening the safety of these facilities is also necessary. ASN will adopt a position in the first half of 2015.

With regard to the uranium enrichment activities, more specifically the Eurodif plant which has now been shut down, Areva carried on with rinsing of the circuits using chlorine trifluoride (ClF_3), as part of the Prisme project. The licensee will submit a Final Shutdown and Decommissioning (MAD-DEM) application for the installation before 31st March 2015, so that this new phase can begin at the end of the rinsing operations. In parallel with the Eurodif shutdown,

the Georges Besse II plant, comprising two enrichment units, is gradually being brought on line. In a resolution dated 7th October 2014, ASN thus authorised start-up of the reception, sampling and packaging unit called REC II. ASN considered that the level of safety of the Georges Besse II plant was satisfactory in 2014.

With regard to the fuel fabrication activities on the FBFC site in Romans-sur-Isère, ASN asked the licensee to implement an ambitious plan of action to improve the safety of the facility and compensate for the observed lack of rigour in operations and safety management. ASN thus placed the licensee under heightened surveillance. FBFC met the first deadlines of the action plan transmitted. The results of the in-depth inspection conducted in November 2014 and concerning operational rigorousness is on the whole positive with regard to the steps taken by the licensee. However, the reorganisation and the actions examined by ASN were relatively recent. ASN will thus check that this positive trend is maintained in the long term.

With regard to the back-end of the cycle, the most significant point is the 9th December 2014 resolution concerning legacy waste recovery and packaging (RCD)

on the La Hague site. Indeed, the recovery of this waste is monitored particularly closely by ASN, mainly because of the significant safety and radiation protection implications associated with it. This resolution therefore aims more specifically to regulate the progress and performance of this programme according to the safety implications of the operations. ASN will be particularly attentive to compliance with the deadlines concerning the RCD programme.

ASSESSMENT AND OUTLOOK

Cross-disciplinary aspects

ASN will be initiating a new process for examining safety and radiation protection management in the Areva group on the basis of the answers to the first examination phase which ended in 2011. It will notify Areva of its requirements, with a view to an examination in 2018.

ASN will be particularly attentive to the implementation of the internal authorisation systems approved in 2014 for the Tricastin and Melox sites, in addition to that already in place at La Hague.

ASN will continue to monitor the additional safety measures requested following the stress tests.

Fuel cycle consistency

In 2015, ASN will continue to monitor the “Cycle impact” file and its annual updates. ASN will in particular focus on monitoring the level of occupancy of the spent fuel underwater storage facilities (Areva and EDF). ASN in particular considers that saturation of the storage facilities for radioactive substances and wastes must be anticipated, in particular the spent fuel storage pools (pools at La Hague and fuel building pools of EDF reactors). ASN also wants Areva and EDF rapidly to define a management strategy going beyond 2030.

Tricastin site

ASN will continue to monitor the reorganisation of the Tricastin platform to ensure that these major organisational changes have no impact on the safety of the various BNIs on the site.

ASN will be vigilant in ensuring that the decommissioning authorisation application for the Eurodif plant, to be submitted before the end of March 2015, gives a detailed description and justification of the operations necessary for the decommissioning and post-operational clean-out of the facility.

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 2015 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.

La Hague site

For the La Hague plants, ASN considers that efforts must be continued for the recovery and packaging of legacy waste on the site in order to meet the prescribed deadlines. As part of the periodic safety reviews of the facilities, the adoption of an approach to identify elements important for safety and protection (EIP) at the operational level and improvements to the general operating rules for these plants will continue in 2015. The conclusions of the periodic safety review for the UP3-A plant will be the subject of an ASN resolution and a report to the Minister responsible for nuclear safety.

With regard to future changes to the processes in the La Hague facility, ASN attaches particular importance to replacement of the R7 evaporator and to the TCP project. The first will improve the availability of the facility's evaporator capacity, while the second will make it possible to process several particular fuel assemblies and thus postpone saturation of the storage ponds. Analysis of the event observed on the evaporators in the R2 unit should also be a priority for the licensee.

ASN will also be vigilant in ensuring that all the fuels received by the Areva NC plant are intended for processing in accordance with the plant's authorisation decrees.

14 NUCLEAR RESEARCH AND MISCELLANEOUS INDUSTRIAL FACILITIES

Nuclear research and miscellaneous industrial facilities, not directly linked to the nuclear power industry, are operated by the Alternative Energies and Atomic Energy Commission (CEA), for the civil part, and by a few other research organisations or industrial firms for commercial activities such as the production of radiopharmaceuticals, industrial ionisation or maintenance. The variety of activities covered and their past history explain the wide diversity of facilities concerned.

SIGNIFICANT EVENTS

Generic subjects on which ASN focused in 2014 were:

- the continued integration of experience feedback from the Fukushima Daiichi accident;
- the progress of CEA's major commitments;
- periodic safety reviews of CEA installations.

During the course of 2014, ASN called the CEA to hearings concerning:

- the progress of its strategic plan, in particular in terms of the creation, commissioning, final shutdown and decommissioning of its facilities;
- the Jules Horowitz reactor (JHR) and Astrid reactor projects;
- the tritium contamination incident in the buildings of the 2M Process company in Saint-Maur-des-Fossés.

In its opinion of 25th July 2014, ASN recalled that it was not in favour of continued operation of the Osiris facility beyond 2015 owing to the current level of safety of this reactor. This position already appeared in its 2008 resolution, which duly noted CEA's undertaking to cease activities at Osiris by the end of 2015. Reactor shutdown at the end



of 2015 has since been confirmed by the Government and CEA transmitted the updated facility decommissioning plan in late 2014. CEA must also transmit a decommissioning authorisation application file in 2016.

For facilities other than those operated by CEA, ASN is concerned by the situation of the radiopharmaceuticals production facility operated by CIS bio international on the Saclay site.

ASN considers that CIS bio international is still demonstrating considerable difficulty in managing large-scale operations and that safety performance must make significant progress.

Further to the previous periodic safety review, ASN in 2013 prescribed measures that included reinforcing fire risk management, in particular through the installation of automatic fire extinguishing systems in various parts of the facility containing radioactive materials. The licensee's tardiness in initiating the work and complying with these prescriptions led ASN to issue several violation reports and serve formal notice on the licensee on several occasions, followed by procedures to ensure the deposit of funds corresponding to the cost

of the work. CIS bio international is challenging these decisions and has appealed. ASN considers that CIS bio international must take all necessary steps to perform this conformity work concerning the fire risk within the prescribed time.

ASN also considers that the licensee must in particular improve the performance of many actions defined in the BNI's periodic safety review, in order to meet the deadlines to which it is committed in order to improve the plant's level of safety. A large amount of work to improve safety, which has been in progress for several years, is still not completed.

In 2015, ASN will therefore maintain heightened surveillance and monitoring of the facility.

ASSESSMENT AND OUTLOOK

A wide variety of research and other facilities are monitored 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 its work to develop a proportionate approach when considering the issues involved in the facilities.

With regard to the stress tests, ASN will ensure compliance with the deadlines prescribed in its resolutions of 26th June 2012 and 8th January 2015. ASN will issue a position statement in 2015 for the final facilities of batch 2 without a hardened safety core and will examine the stress test reports for the batch 3 facilities received in 2014.

Concerning CEA

ASN considers that the “major commitments” approach, implemented by CEA since 2006, is on the whole satisfactory and should be continued and enhanced, more specifically by the adoption of new “major commitments” by CEA.

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 ASN can conduct its examination 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 authorisation application files for CEA's old facilities which have been or will shortly be shut down. 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 CEA's preparations for final shutdown of the Osiris reactor at the end of 2015.

In 2015, ASN intends to:

- continue with surveillance of the operations on the RJH construction site and prepare for examination of the future commissioning authorisation application;
- rule on restart of the Cabri reactor;
- begin examination of the significant modification authorisation application for Masurca;

- complete examination of the periodic safety review files for the LECI, Poséidon, LEFCA facilities and issue a position statement on their possible continued operation;
- continue to examine the periodic safety review files for the LECA and Masurca facilities;
- prepare to examine the options file for the Astrid facility, after issuing its conclusions in 2014 on the main safety orientations of the project.

Concerning the other licensees

ASN intends to continue to pay particularly close attention to ongoing projects, that is ITER and the Ganil extension.

ASN will complete its examination of the periodic safety review files for the Ganil, BCOT and Somanu facilities and will decide on the conditions for their possible continued operation. ASN will continue to examine the periodic safety review files for Ionisos and will initiate that of the MIR inter-regional fuel warehouses.

Finally, in 2015, 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 work prescribed for continued operation of the plant following its last periodic safety review;
- compliance with the undertakings made by the licensee in respect of the periodic safety review and not as yet honoured.

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 predetermined final condition in which all the dangerous and radioactive substances have been removed. In 2014, about thirty nuclear facilities of all types were shut down or undergoing decommissioning in France.

POLICY AND REGULATIONS

In 2014, AIEA recognised two possible strategies for decommissioning nuclear facilities following their final shutdown: immediate dismantling and deferred dismantling. French policy and the regulations applicable to BNIs aim to ensure that the licensee adopts a strategy of immediate dismantling: decommissioning is initiated as soon as the facility is shut down, without a waiting period, although the decommissioning operations can take a long time. ASN supports the inclusion of this principle in the legislation and it has been incorporated by the Government into the green growth energy transition bill. This bill also renovates the decommissioning procedure by making a clearer distinction between final shutdown of the facility and its decommissioning.

In 2014, ASN drew up draft guidelines for remediation of soils and structures in nuclear facilities. They will be consulted by the stakeholders, for publication in 2015.

FACILITIES

The final shutdown and decommissioning authorisation decree for the Ulysse reactor operated by CEA in Saclay was published on 18th August 2014 and makes provision for a five-year decommissioning period.



To examine the decommissioning authorisation application for the Phenix reactor, the Advisory Committee of Experts for Laboratories and Plants met on 12th November 2014 and considered the plant's decommissioning procedures to be acceptable, in particular the sodium processing option. ASN will issue a position statement in 2015. The ASN resolution of 8th January 2015 also sets additional prescriptions specifying the requirements applicable to the "hardened safety core" of the Phenix reactor and the management of emergency situations.

In a resolution of 9th January 2015, the old Siloé research reactor, mainly used for technological irradiation of structural materials and nuclear fuels, was delicensed.

ASN returned its conclusions on the stress tests submitted by EDF in order to take account of the lessons learned from the Fukushima Daiichi accident for the BNIs being decommissioned (Chinon A1, A2 and A3, Saint-Laurent-des-Eaux A1 and A2, Bugey 1, Chooz A, Superphénix, Brennilis) and the Fuel Evacuation Facility (Apec) in Creys-Malville. The ASN Commission also called EDF to a hearing on its decommissioning strategy for the old gas-cooled reactors (UNGG)

with a view to issuing a position statement in 2015. ASN will also issue a position statement on the decommissioning authorisation application for the Irradiated Material Facility (Ami) in Chinon.

The legacy waste recovery and packaging project (RCD) currently under way in the HAO silo and the organised disposal of hulls (SOC) represent the first hold point in decommissioning of the spent fuel reprocessing plant operated by Areva NC at La Hague. ASN authorised Areva NC to build the recovery and packaging unit in a resolution dated 10th June 2014. ASN issued a resolution on 2nd December 2014 stipulating its requirements concerning the content of the complete decommissioning application files for the old plants at La Hague, to be submitted by Areva NC in 2015, and set additional prescriptions concerning the safety of the decommissioning operations.

2015 will be marked by a large number of decommissioning authorisation application files for major facilities, such as Eurodif, the old plants at La Hague, the CEA centre at Fontenay-aux-Roses and so on. This illustrates the growth in the decommissioning work being done on old nuclear facilities.

16 RADIOACTIVE WASTE AND CONTAMINATED SITES AND SOILS



The management of radioactive waste is governed by the 28th June 2006 Programme act on the sustainable management of radioactive materials and waste, today codified in the Environment Code. This act sets a clear framework for management of all radioactive waste, in particular by requiring the adoption of a National Plan for Radioactive Materials and Waste Management (PNGMDR) revised every three years.

The purpose of the PNGMDR is to inventory the existing radioactive materials and waste management methods, to identify the foreseeable needs in terms of storage or disposal facilities and to clarify the necessary capacity for these facilities and the storage durations. Concerning radioactive waste for which there is as yet no final management solution, the PNGMDR defines the objectives.

SIGNIFICANT EVENTS, ASSESSMENTS 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 an agency for management of radioactive waste independent

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 updating of the PNGMDR, which should take place by the end of 2015, will be an opportunity to review progress and set new short and medium term objectives.

With regard to the regulations concerning the management of radioactive waste

ASN will contribute to the transposition of Council directive 2011/70/Euratom of 19th July 2011 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste. This transposition will in particular allow the definition of a procedure carried out by the administrative authority to requalify materials as radioactive waste, with reinforced administrative and penal sanctions in this field.

In 2015, ASN will finalise the resolutions concerning the study of waste management, the inventory of waste produced in the BNIs and the packaging of radioactive waste. It will draw up draft resolutions

concerning radioactive waste disposal facilities and radioactive waste storage facilities as well as a draft guideline on the application of the resolution concerning waste studies.

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 TENORM waste.

Concerning 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 sufficiently far in advance the construction of new facilities or renovation work on older facilities. In 2015, ASN will continue to closely monitor the legacy waste or spent fuel recovery and packaging operations, focusing on those with the most significant safety implications, for example in the Areva facility at La Hague.

In this respect, ASN will in 2015 be assessing EDF's waste management strategy and in 2016 will be receiving that of Areva.

Concerning reversible deep geological disposal (Cigéo project)

The year was marked by the conclusions of and the follow-up to the public debate held in 2013.

With regard to the Cigéo project for disposal of high and intermediate level, long-lived waste, ASN notes that a key step in the development of the project was reached in 2014, when Andra launched the preliminary design phase and published the conclusions of the public debate held on this project. Following the public debate, Andra decided to continue its studies so that in late 2017 it could submit a creation authorisation application for a deep geological radioactive waste disposal facility. Andra is also proposing new procedures for the development of its project.

Prior to routine operation of its facility, Andra is aiming for a phase which it refers to as the “pilot industrial phase”. ASN had underlined the importance of a gradual “ramp-up” phase for the installation before routine operation. It also specified that Andra should conduct in-situ tests on a representative scale. ASN thus considers that, in principle, this “pilot industrial phase” is able to meet these requirements. However, Andra shall be required to clarify the objectives.

The reversibility of deep geological disposal is a requirement contained in the Environment Code. It should be specified in a future act. In 2015, Andra will be submitting a file to ASN presenting the main technical options to ensure the recoverability of the emplaced waste packages.

ASN considers that the notion of reversibility must not only guarantee recoverability, in other words the possibility of recovering the waste packages already emplaced for a given period of time, but also that the facility is adaptable, so that during the construction and the operation of the disposal facility, it

is possible to modify the previously adopted provisions. So that these safety issues are incorporated as of the design studies, ASN considers that it is essential for the technical requirements linked to reversibility to be defined prior to submission of the creation authorisation application for such a disposal facility, in compliance with the 2006 act.

2015 will be marked by the submission of several major files by Andra: a safety options file, a recoverability technical options file, a preliminary version of the waste acceptance specifications and a project development plan. This file will be the first overall safety file for the facility since 2009.

Finally, in 2015, ASN will publish its initial policy on the reversibility of a deep geological disposal facility, more specifically with regard to the need to take account of the possibility of adapting the disposal facility to a potential change in the inventory of waste emplaced.

Concerning the management of the former uranium mining sites and polluted sites and soils

With regard to the former uranium mining sites, ASN will in 2015 attempt to address the concerns of the Regional Directorate of the Environment, Planning and Housing (DREAL) regarding the Areva Mines action plan for the management of mining waste rock. It will focus more specifically on the management of potentially sensitive situations, 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 on the management of former mining sites, in collaboration with the Ministry for the Environment.

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.

IRRS MISSION: ASN PEER-REVIEWED

F

rom 17th to 28th November 2014, ASN hosted an IRRS (Integrated Regulatory Review Service) peer review mission organised under IAEA supervision and concerning all activities regulated and monitored by ASN. The mission was chaired by Mark Satorius, Chief Operations Officer of the US Nuclear Regulatory Commission and by Ann McGarry, Director of the Office of Radiological Protection at the Irish Environmental Protection Agency. It examined the strengths and weaknesses of the French nuclear safety and radiation protection oversight system by comparison with IAEA standards.

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. This practice is now incorporated into the European nuclear safety directive, which requires a peer review mission every ten years. The aim is to assess the national regulatory infrastructures against the IAEA safety standards and to provide a framework for discussion between safety regulators concerning nuclear safety and radiation protection technical and policy questions.

ASN, together with IRSN and the relevant departments of the Ministry for Ecology, Sustainable Development and Energy, had been preparing for this mission for a year.

During the course of the mission, twenty-nine experts from the nuclear safety and radiation protection regulators of Australia, Belgium, Canada, Cuba, Czech Republic, Finland, Germany, Hungary, India, Ireland, Japan, Morocco, Norway, Pakistan, South Korea, Spain, Switzerland, United Kingdom, United States and IAEA, met teams from ASN and from the other Government departments concerned. Mr Satorius and Mrs McGarry also had a meeting with Mr Le Déaut, Chairman

of the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST).

The conclusions of the mission were presented to ASN on 28th November 2014 and were the subject of a press release from IAEA. This extremely detailed mission confirmed the robustness and rigour of the regulation and monitoring carried out in France by ASN.

The positive points or best practices underlined included the operation of ASN as an independent regulatory body, the effective regulatory structure benefiting from the support of IRSN and the Advisory Committees of Experts, the strong commitment in France to safety and the robust and effective organisational structure, giving great importance to the impartiality of the commissioners, advisory committees and the personnel as a whole, the extensive involvement of the stakeholders in the regulatory process and the transparency of the decision-making process, wide-ranging communication and, finally, the coordination between the oversight organisations involved in emergency planning and the effective interaction with the licensees in this field.

Attention was however drawn to several points:

- the need to assess the exhaustiveness of the regulatory framework for monitoring exposure in the medical field and the coordination between the organisations involved;
- the reinforcement of the system used by ASN to assess and modify its regulatory framework;
- in ASN's integrated management system, the need to specify all the processes ASN needs in order to perform its role.

The conclusions of the mission also show that 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.

The IAEA final report was transmitted to France in the first quarter of 2015 and posted on the ASN website.

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 and the ASN Director-general, Jean-Christophe Niel, have thus led IRRS missions in Finland and Switzerland respectively.

GREEN GROWTH ENERGY TRANSITION BILL

In 2014, the Government presented a green growth energy transition bill, part VI of which is entitled “Reinforcing nuclear safety and information of the citizens”. The bill was adopted at its first reading by the National Assembly on 14th October 2014 and it should be finally adopted at the beginning of 2015.

This text requires that the share of nuclear energy in the national production of electricity be reduced but it will nonetheless remain considerable: 50% in 2025. The French nuclear fleet will continue to be one of the world’s largest and its safety will have to be reinforced, with reference to the requirements applicable to the new reactors and by learning the lessons from the Fukushima Daiichi accident.

Without in any way pre-judging the final vote on the bill, ASN is pleased to see that this bill introduces a number of advances in the field of nuclear safety and radiation protection oversight and that it reinforces information of the citizens on these subjects.

It in particular notes the following positive points.

ENHANCED TRANSPARENCY AND INFORMATION OF THE CITIZENS

Each year, the local information committees (CLI) will be holding at least one meeting open to the public and the CLIs of BNIs situated in *départements* on the borders will include representatives of the foreign States concerned. Moreover, the CLIs may ask to visit the facility, in order to understand its normal operation and any significant events rated on the INES scale which may have occurred in it.

Without having to ask for it, those living in the vicinity of a BNI will, at the expense of the licensee, receive regular information about safety measures and the steps to be taken in the event of an accident. These population information operations will be regularly presented to the CLI.

Given the stakes associated with the continued operation of the nuclear reactors beyond forty years, the measures proposed by the licensee

during the reactor periodic safety reviews performed after thirty-five years of operation, will be the subject of a public inquiry.

Finally, the public’s right to information about radiological risks will be extended to all the risks and drawbacks of the nuclear facilities.

EVOLUTION OF THE BNI AUTHORISATION SYSTEM

Depending on the stakes involved and their scale, BNI modifications shall be the subject of:

- either a modification of the creation (or decommissioning) authorisation decree, after a public inquiry;
- or an ASN authorisation, which may involve participation by the public;
- or notification of ASN by the licensee.

This graduated system will thus allow processing appropriate to the risks and drawbacks of the facility and its modifications.

EVOLUTION OF THE BNI SHUTDOWN AND DECOMMISSIONING SYSTEM

The bill gives priority to BNI decommissioning as soon as possible after shutdown and incorporates the principle of immediate dismantling into the Environment Code. It renovates the decommissioning procedure, by making a clearer distinction than previously between the following:

- final shutdown of the facility, which is the responsibility of the licensee and must be notified to ASN;
- decommissioning of the facility, the procedures of which must be approved by the State on the basis of a file proposed by the licensee.

Final shutdown of a facility may also be declared automatically if it has not been in operation for several years.

REINFORCEMENT OF THE ASN MEANS OF INSPECTION AND POWERS OF SANCTION

The bill also provides for authorisations to legislate by means of ordinance in order to reinforce ASN's means of oversight and powers of sanction.

ASN should in particular be able:

- to impose measures to ensure the security of radioactive sources against malicious acts and verify correct application of these measures;
- to impose administrative fines and daily administrative penalties, impound items, take samples or require the deposit of funds, as well as conduct negotiated transactions. These actions will be taken by a sanctions committee, created within ASN, in order to maintain the principle of separation between the investigative and sentencing functions;
- to extend the inspections carried out by its inspectors to activities important for safety performed outside BNIs by the licensee, its suppliers, contractors, or subcontractors;
- in the BNIs, to check certain regulations linked to industrial risks (chemical risks, non-radioactive waste, explosive atmosphere) and have third party assessments carried out at the expense of the party concerned;

- to ensure that research is tailored to the needs of nuclear safety and radiation protection.

CLARIFICATION OF THE ORGANISATION OF THE OVERSIGHT OF NUCLEAR SAFETY AND RADIATION PROTECTION

ASN is in charge of the regulation and oversight of nuclear safety and radiation protection.

The bill incorporates into the Environment Code the existence and the duties of the French Institute for Radiation Protection and Nuclear Safety (IRSN). It recalls that ASN benefits from the technical support of IRSN and that these assessment activities are supported by research.

It also 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 an automatic and fully-fledged member of the Board of the institute.

The bill also mentions the principle of the publication of IRSN opinions.

REINFORCED MONITORING OF FORMER NUCLEAR SITES

The bill requires that the person acquiring land on which a BNI was operated, then decommissioned and delicensed, shall receive information

about the past activities carried out on the site.

Sites polluted by radioactive substances and which present environmental risks could be subject to active institutional controls designed to protect the population.

CONCLUSION

While the examination of the green growth energy transition bill continues in Parliament, ASN considers that the provisions of the current draft lead to an improvement in the oversight of nuclear safety and radiation protection, so that it is more effective and more closely tailored to the stakes involved. It also notes with satisfaction that transparency and public information have been reinforced. ASN will be consulted by the Government about the regulatory texts implementing the future act.



GREEN GROWTH ENERGY TRANSITION BILL

In the related chapters, these boxes present the changes brought about by the act in the fields concerned.



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