# CONTROLES DOSSIERS



ASN report abstracts on the state of Nuclear **Safety and Radiation Protection in France in 2009** 



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## **EDITORIAL**



Marie-Pierre COMETS, Marc SANSON, André-Claude LACOSTE, Michel BOURGUIGNON and Jean-Rémi GOUZE, ASN's Commission members

Paris, March 2nd, 2010

n behalf of the State, the Nuclear Safety
Authority (ASN) regulates nuclear safety and
radiation protection in France, to protect workers, patients, the public and the environment
from the risks involved in nuclear activities and to contribute to informing the citizens.

It is an independent administrative authority, run by a Commission of five commissioners, which was created by the Act on Transparency and Security in the Nuclear Field (TSN Act) on 13 June 2006.

As for the past three years now, the ASN Commission presents the annual report on the state of nuclear safety and radiation protection in France for 2009.

Like the previous years, 2009 was relatively satisfactory in the field of nuclear installations. It was however marked by two level 2 criticality incidents, one in the Marcoule MELOX plant and the other in the Plutonium Technology Facility (ATPu) in Cadarache. This second incident was widely reported. The Commission wishes to point out that this was a serious matter and, in the same way as all the activities it regulates, ASN

dealt with it stringently and transparently, calling in the expertise of IRSN. ASN reminded CEA of the importance of a rigorous approach to the operation of its installations.

Another concern for ASN, which was confirmed in 2009, relates to the condition of the steam generators in the nuclear power plants, with EDF revealing further unexpected deterioration of them. ASN makes sure that their level of safety remains satisfactory and that plans are made for their replacement sufficiently well in advance.

In the field of small-scale nuclear activities, ASN notes progress in 2009 in the radiotherapy sector, by comparison with previous years, although the situation varies from one radiotherapy centre to another. This situation led to the suspension of operations in several radiotherapy centres until such time as safe treatment conditions are provided, and in particular until such time as there are enough radiological physicists and operators. Another subject of concern is interventional radiology, in particular for certain neurological and cardiology procedures, because the doses delivered may be high.

ASN observed promising work on the justification of gamma radiography by COFREND and various stakeholders, including the *Institut de soudure*. This work is helping to find

alternative techniques to gamma radiography inspection using iridium 192, which can have serious consequences in the event of an accident.

For 2010, the Commission considers that the key subjects for ASN are the following. These priorities reflect the strategic thinking defined in the multi-year strategic plan and which, for the period 2010-2012, concern in particular how it reports on its actions, the integrated view of nuclear safety and radiation protection, and international affairs.

#### Reporting and accountability

For ASN, independence does not mean isolation. It informs the public, develops its relations with all the stakeholders, particularly the Local Information Committees (CLI), reports on its actions to Parliament and cooperates with its foreign counterparts.

As an illustration, in 2009, ASN strengthened its ties with the local press and locally elected representatives. Jointly with the Swiss federal nuclear safety inspectorate, it organised a public seminar on the seismic risk in nuclear installations and published its positions subsequent to the opinions submitted by the advisory committees, particularly with respect to the EPR instrumentation and control (I&C) system.

In 2009, ASN took part in a number of hearings organised by Commissions of the National Assembly and the Senate and by the French High Committee for Transparency and Information on Nuclear Security (HCTISN) concerning the ATPu, reprocessed uranium and the EPR. In addition to presenting this 2009 report to the OPECST and participation in the hearings, the ASN Commission aims to develop its exchanges with members of Parliament on subjects of importance to society that fall within the scope of ASN.

ASN presented France's report to the review meeting on the Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management, which took place in Vienna in May 2009. In 2009, it also received the international peer review mission from the Integrated Regulatory Review Service (IRRS), organised by IAEA. The experts noted that ASN had implemented the vast majority of the recommendations made following their first mission in 2006. The corresponding report, as well as that drawn up for the Joint Convention, is available on the ASN website (www.asn.fr). ASN will be continuing in this direction by distributing these reports more widely in France and by taking part in IRRS missions in other countries.

In 2010, ASN will be increasing the transparency of its decision-making process, and at the same time as

publishing its decisions, it will also make public the corresponding IRSN opinions on the key subjects it entrusts to it and on which it relies when reaching its decisions. Since 2002, ASN has published the follow-up letters for the inspections it conducts in nuclear installations and, since 2008, those concerning its inspections of radiotherapy departments. Its aim is to publish all follow-up letters to its inspections in the industrial, research and medical fields. ASN will also ensure that the licensees meet their transparency obligations as stipulated in the TSN Act.

## Developing an integrated view of nuclear safety and radiation protection

ASN has developed an integrated view of nuclear safety and radiation protection which takes account not only of the technical and material aspects, but also organisational and human factors, security and environmental aspects. ASN is continuing significant work on overhauling the technical regulations applicable to nuclear installations.

The TSN Act requires a safety review of nuclear installations every ten years. The first 900 MWe reactors therefore began their third ten-yearly inspection outages in 2009. ASN will issue a decision on the ability of each reactor to continue operating following this third safety review. EDF also notified ASN of its desire to extend the operating life of its reactors significantly beyond 40 years. In the forthcoming discussions, ASN will be particularly attentive to ensuring that the goals of the safety review studies are aligned with the EPR safety objectives.

The Government has announced the construction of a second EPR at Penly, in association with GDF-Suez. While specifying that the arrival of a new licensee in France could help improve the level of safety of the nuclear reactors in France by bringing in new working methods, ASN has already stressed the importance of defining the governance of the project. It is ready to provide assistance for this process, to which it will be particularly attentive.

The new 2010-2012 edition of the French National Radioactive Materials and Waste Management Plan (PNGMDR) has been completed. The ASN Commission stresses the importance for nuclear safety and radiation protection that the various management and disposal solutions for all radioactive waste be implemented as rapidly as possible. This applies in particular to the disposal projects for low level long-lived (LL-LL) waste and high-level, long-lived (HL-LL) waste.

In terms of radiation protection, particularly in the medical field, ASN has since 2008 been requesting interim criteria for operation of radiotherapy centres, without waiting for sufficient radiological physicist and dosimetrist staffing

levels to be reached. These criteria were published on 29 July 2009. ASN considers that between 5 and 10 years will be needed before sufficient staff are in place and it will remain vigilant with respect to their training. In 2010, it will also be checking implementation of the now mandatory quality assurance applicable to radiotherapy centres, in particular the logging and analysis of undesirable events. The international conference organised by ASN on radiation protection of patients in the radiotherapy field also highlighted the importance of the issue of complications and side-effects in radiotherapy, which concern about 5% of patients irrespective of any accidents. ASN will monitor the progress of the corresponding studies.

Another subject on which ASN will be focusing in 2010 is the increase in doses that result from the growing use of medical imaging techniques for diagnostic and therapeutic purposes (scanner and interventional radiology).

The vocation of the French National Network of Environmental Radioactivity Monitoring (RNMRE) is widespread distribution of high-quality measurements. This quality is obtained through a process of ASN approval of the laboratories carrying out these measurements. ASN is responsible for determining the orientations of this network and IRSN is in charge of its management. Its new website, www.mesure-radioactivite.fr, came on-line at the beginning of 2010, providing all the environmental radioactivity measurements as well as a number of explanatory notes to help inform the public about the doses they receive as a result of nuclear activities. The ASN Commission attaches considerable importance to the development of this site.

#### Expanding international relations

In the absence of European legislation on nuclear safety, the Council of the European Union (EU) adopted a directive on 25 June 2009 on the safety of nuclear installations, to which. ASN made a significant contribution. This text is of great importance for the creation of a legally binding community framework on nuclear safety. The directive, which in particular obliges all EU Member States to set up a legislative framework for nuclear safety and an independent safety regulator, also makes provision for a peer review system based on the IRRS missions, and contains requirements concerning public information, training and

competence. In 2010, ASN will be monitoring the transposition of this directive, a process which should be completed in July 2011.

As it did for the siting of nuclear reactors in the new nuclear countries, the ASN Commission adopted a public stance on the production of radionuclides for medical purposes. The operating life of the reactors producing the vast majority of the world's output, including the Osiris reactor in Saclay, has now exceeded 40 years. ASN considers that the risk of scarcity of these radionuclides should in no case lead to short-cuts being taken with regard to the safety of the reactors producing them, and that European and international level discussions and debate are required. The new status of the ASN enables it to adopt a strong public stance on key issues.

ASN published a joint declaration with the British (HSE) and Finnish (STUK) regulatory authorities concerning I&C on the EPR reactor. These joint actions will be continuing. A combined analysis with HSE, STUK and the American safety regulator (NRC) of the quality of component manufacturing for the Finnish EPR will in particular be carried out. The Commission considers that the transparency of the review process and international collaboration by safety regulators on these important subjects are beneficial for the overall safety of the project. ASN will be continuing these actions with a view to harmonising nuclear safety worldwide and with the goal of achieving recognition as an international benchmark for good practice.

ASN is the authority in charge of regulating the nuclear safety and radiation protection of civil nuclear activities in France. The competence and motivation of its personnel enable it to carry out its role in full and perform its duties with rigour, efficiency and independence. It also relies on the professionalism and expertise of IRSN. It will be continuing to carry out these duties in compliance with the four values it has adopted as its watchwords: independence, competence, rigour and transparency, to ensure that nuclear safety and radiation protection progress both in France and around the world.



## THE **YEAR** 2009

Paris, March 2nd, 2010

hat are the salient points of ASN operations in

Three years after the TSN Act was passed, 2009 was a year of consolidation for ASN.

2009 saw the drafting of the ASN multi-year strategic plan (PSP) for the period 2010-2012 "Affirm the role and responsibilities of ASN", following an exemplary participative process. The preparation of the plan involved seminars in

all ASN entities and a wide-ranging debate at the ASN 2009 Convention, which brought together the 440 ASN staff on 5 May 2009.

For ASN, 2009 was also a year of major projects, to which all the entities made a strong commitment.

As far as regulations are concerned, ASN continued its efforts to clarify the regulations governing basic nuclear installations (BNI), in particular the drafting of the BNI order and its related decisions, in order to meet the end of 2010 deadline. At the same time, ASN devoted itself to developing pressure vessel regulations, with the aim of involving all stakeholders. In this respect, it is worth mentioning that the modification of the 1943 Act by Act 2009/526 of 12 May 2009 clarified ASN's regulatory role. In collaboration with the Ministry in charge

of ecology, ASN also drafted the new French National Radioactive Materials and Waste Management Plan (PNGMDR) required by the Waste Act of 2006.

In the regulatory field, ASN extensively reviewed the preparatory process for its annual program of inspections, in order to better identify national priorities while leaving greater initiative to the regional divisions. In 2009, ASN carried out more than 2100 inspections of BNIs, small-scale nuclear activities and radioactive material transport operations.

In the field of transparency and public information,

ASN considers that it is responsible for ensuring correct implementation of the transparency requirements of the TSN Act, whether with regard to the parties being regulated, or civil society as a whole. In 2009, ASN reinforced its own actions concerning the general public, the media, and its professional and institutional audiences: launch of the ASN Newsletter, overhaul of the www.asn.fr website, improvements to the Contrôle review, organisation of professional conferences and symposia, iodine tablet distribution to populations living near nuclear power plants, and so on. ASN organised the international conference on the safety of radiotherapy treatments in Versailles in December 2009, and prepared the launch of the www.mesure-radioactivite.fr website for the French National Network of Environmental Radioactivity Monitoring (RNMRE). In 2009, ASN also organised national seminars, in particular concerning radiation protection, with the main nuclear licensees and small-scale nuclear operators (nuclear medicine, industrial radiography, etc.).

Jean-Christophe NIEL ASN Director-General

As an independent administrative authority, ASN was also invited to attend several Parliamentary hearings. ASN is highly in favour of these hearings, which provide it with an opportunity to report on its actions.

On the international stage, ASN continued in 2009 to make a significant commitment to international relations, with the aim of helping to improve safety and radiation protection worldwide and the goal of achieving recognition as "an international benchmark" for good practice.

Europe is the priority area for international action by ASN and it makes an active contribution to the work of WENRA (Western European Nuclear Regulators' Association) in the field of nuclear safety and of HERCA (Heads of

European Radiation Control Authorities) in the field of radiation protection, with a view to reinforcing European cooperation. The creation of an EU regulatory framework took a significant step forward with the adoption of the directive on the safety of nuclear installations in June 2009.

In 2009, ASN also continued to work on the MDEP (Multinational Design Evaluation Program) project launched with the NRC.

ASN had to deal with a number of internal difficulties involved in setting up certain major projects, such as improving its emergency response arrangements. ASN also considers that it will have to develop its management selfsufficiency if it is to achieve a level of independence more in keeping with its status and indeed closer to that of some of its foreign counterparts.

Another significant event of 2009 was the fact that ASN found itself faced by a number of "unforeseen circumstances".

In the exercise of its duties, ASN has to constantly adapt in the face of the unexpected. Alongside the more "routine" unforeseen circumstances, such as dealing with incidents and unscheduled requests from licensees or users of ionising radiations, the following noteworthy events occurred in 2009:

- "serious" matters that must be treated as such (refusal to approve EDF laboratories, problem with EPR I&C, level 2 incident in the ATPu) were given extensive media coverage. Apart from the immediate management required, these situations have significant consequences in terms of mobilisation of ASN staff;
- relatively frequent activation of the crisis centre (5 times in 2009) for which ASN will need to analyse the operating experience feedback, in particular with regard to the trigger criteria for these situations.

#### ... but also by more long-term duties concerning:

 implementation of the TSN Act and its decrees for BNI regulation: application of Article 26 of the TSN Act, penalties, BNI creation, application of Public Health Code (CSP) texts, the content of the Waste Act;  transparency: implementation of Articles 19 and 21 of the TSN Act, development of relations with the HCTISN, initiatives towards the CLI and professionals, etc.

In the course of these activities, ASN is required to interact with many stakeholders. ASN's performance and effectiveness depends on the quality of its day-to-day relations with them. ASN is particularly attentive to this aspect. Independence without isolation.

ASN would be unable to work the way it does without the competence, responsiveness and ready availability of its staff. The same applies to the IRSN and the members of the advisory committees which, together with ASN, contribute to the development of the high level of nuclear safety and radiation protection in our country.



## HIGHLIGHTS OF 2009

#### BY MAJOR TOPIC AND BY REGULATED FIELD AND ACTIVITY

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#### **ACTIVITIES REGULATED BY ASN**

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This introduction to the ASN Report on the state of nuclear safety and radiation protection in France in 2009 presents a summary of ASN actions and its assessment of the activities it regulates.

These thirty or so pages present an overview of the highlights of 2009 developed in greater detail in the report. This summary follows the same structure as the body of the report. The reader will thus be able to refer to the complete chapter concerned.

The format of this summary differs slightly between the first chapters (1 to 8), which are more descriptive of ASN's role and duties, and the later chapters (9 to 16) which present its actions in the various sectors regulated. Each chapter begins with a reminder of the duty or activity concerned, continues by highlighting the year's significant events and ends with the outlook for the coming year. For those chapters concerning the activities regulated, the abstracts also include ASN's assessment of nuclear safety and radiation protection in the main areas considered.

#### NUCLEAR ACTIVITIES: IONISING RADIA-TIONS AND HEALTH AND ENVIRONMENTAL RISKS

The common goal of nuclear safety and radiation protection is to protect people and property against the hazards, detrimental effects and inconveniences of all types arising from the operation of nuclear and radiological installations, the transport, use and transformation of radioactive or fissile materials, and the exposure to naturally occurring radioactive materials.

The effects of ionising radiations on living beings can be "deterministic" (health effects certain to appear when the radiation dose received exceeds a certain threshold), or "probabilistic" (probability of appearance of cancers in an individual but with no certainty). The steps taken to afford protection against ionising radiations aim to avoid deterministic effects while minimising the probability of radiation-induced cancers.

The measures taken in the fields of nuclear safety and radiation protection to prevent accidents and limit inconveniences has led to the risks concerned being reduced but not eliminated. A large degree of uncertainty and many unknowns still persist however, especially with regard to hypersensitivity to ionising radiations, the effects of small doses, hereditary effects or the assessment of effects on non-human species (currently the subject of work by the International Commission on Radiological Protection (ICRP). As the available data changes, the regulations are regularly adapted and ASN is closely monitoring the work in progress.

#### EXPOSURE TO IONISING RADIATIONS IN FRANCE

The entire French population is potentially exposed to ionising radiations, but not to the same extent (in particular depending on where people live and the number of radiological examinations they undergo), whether this is a result of naturally occurring radioactive material, or of human activities.

IRSN evaluates the average exposure of an individual in France at 3.3 millisieverts per year. The sources of this exposure are as follows:

- for about 1 mSv/year, naturally occurring radioactive material (NORM) except radon (in particular see the 2009 publication by ASN, the Ministry for Health and IRSN of a first national appraisal of the radiological quality of public mains water);
- for about 1.4 mSv/year, widely varying levels of radon (the activity measured in 2% of homes is eight times higher than the median measurement nationwide);
- for about 0.8 mSv/year, medical treatments, although there
  is a clear upward trend owing to the increased use of computed tomography and interventional radiology practices;
  one of ASN's priorities for the coming years will be to verify
  application of the justification and optimisation principles
  in medical imaging;
- for less than 0.1 mSv/year, other sources of artificial exposure: airborne nuclear tests in the past, Chernobyl accident, discharges from nuclear installations.

The nationwide automated monitoring networks managed by IRSN offer real-time monitoring of environmental radioactivity and highlight any abnormal variation.

Some workers are subject to particular exposure. With regard to workers in nuclear activities, the annual dose remained lower than 1 mSv (annual effective dose rate for the public) for more than 95% of the population monitored; the number of workers monitored for whom the annual dose exceeded 20 mSv (regulation limit for nuclear workers) is regularly dropping, as is the collective dose. For workers in sectors enhancing exposure to NORM, the doses received remain on the whole less than 1 mSv/year. In a number of identified industrial sectors this value is however liable to be exceeded.

Finally, aircrews are the subject of particular monitoring owing to their exposure to cosmic radiation at high altitude. The doses received can be up to 10 mSv/year for certain airmail delivery personnel.

In addition to its regulatory and inspection work, ASN closely monitors developments in research and knowledge in the fields of health and ionising radiations and international

radiation protection policy. In 2010, ASN will conduct an assessment of the currently ongoing research programs that concern it and will examine the conclusions of the expert appraisals it commissioned into the occurrence of child leukaemia in the vicinity of large BNIs and the environmental impact of tritium discharges.

## PRINCIPLES AND STAKEHOLDERS IN THE REGULATION OF NUCLEAR SAFETY, RADIATION PROTECTION AND ENVIRONMENTAL PROTECTION

Nuclear activities must be carried out in compliance with the eight fundamental principles contained in the Environment Charter, in the Environment Code and in the two major legislative texts that constitute the basis for regulating these activities: the 13 June 2006 Act on Transparency and Security in the Nuclear Field (TSN Act) and the Public Health Code (CSP)

These eight principles are the principle of prevention (anticipating any environmental damage by means of rules and actions 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 mitigation measures), the precautionary principle (the lack of certainty afforded by current scientific and technical knowledge should not delay the adoption of proportionate preventive measures), the public participation principle (the populations must take part in public decisions), the principle of justification (a nuclear activity can only be carried out if the resulting benefits outweigh the corresponding risk of exposure), the principle of optimisation (exposure to ionising radiations must be kept as low as reasonably practicable), the principle of limitation (the regulations set individual exposure limits for ionising radiations that result from a nuclear activity, except activities carried out for medical reasons or biomedical research purposes) and the principle of the nuclear licensee's responsibility for the safety of its installation.

## The stakeholders in the regulation of nuclear activities

In France, the regulation of nuclear safety and radiation protection is primarily the responsibility of three stakeholders: Parliament, the Government and ASN. The TSN Act and the CSP define the respective duties of the Government and ASN.

In addition to special occasions such as voting laws into force, **Parliament** regularly follows the nuclear safety and radiation protection regulation activities, in particular through its

specialised commissions which hold hearings, or the French 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 report on the state of nuclear safety and radiation protection in France, every year.

On the advice of ASN, the **Government** defines the general regulations concerning nuclear safety and radiation protection. Also on the advice of ASN, it issues key individual decisions concerning BNIs (creation or decommissioning decree, closure in the event of an unacceptable risk, etc.). It is responsible for civil protection in the event of an emergency.

In the current governmental organisation, the ministers responsible for nuclear safety are the Minister for Ecology, Energy, Sustainable Development and the Sea, with responsibility for Green Technologies and Climate Negotiations, and the Minister for the Economy, Industry and Employment. The Minister for Health and Sport is in charge of radiation protection except for radiation protection of workers, which is the responsibility of the Minister for Labour, Labour Relations, the Family and Solidarity.

In the *départements*<sup>1</sup>, the *préfets*<sup>2</sup> – as the representatives of the State – are the guarantors of public order and also play a major role in the event of an emergency, being responsible for the application of preventive measures to protect the population. The *préfet* also intervenes during the various procedures concerning the nuclear installation in his département, by coordinating local debates and submitting his opinion to the ministers or to ASN as applicable.

ASN is an independent administrative authority (AAI) created by the TSN Act. It is tasked with regulating nuclear safety and radiation protection and contributes to informing the citizens about these subjects. It submits draft regulatory texts to the Government and is consulted on the texts prepared by the ministers. It clarifies the rules and regulations by means of regulatory decisions submitted to the competent ministers for approval. It issues certain individual authorisations and submits proposals for others to the Government. The monitoring and regulation of nuclear activities are carried out by ASN personnel and by organisations approved by ASN for this purpose. ASN contributes to France's European and international actions and alerts and informs the authorities of third-party States in the event of a radiological emergency, receiving alerts and information from them in turn. Finally, it assists with the management of radiological emergency situations.

For technical matters, ASN calls on the expertise of the French Institute for Radiation Protection and Nuclear Safety (IRSN) and the Advisory Committees of experts (GPE) that it set up.

<sup>1.</sup> Administrative region headed by a préfet.

<sup>2.</sup> In a département, representative of the State appointed by the President.



ASN hearing before the Economy, Sustainable Development and Spatial Planning Commission, concerning the ASN review of the EPR reactor I&C system – November 2009

ASN is run by a Commission of five full-time commissioners who cannot be removed from office and who are appointed for a 6-year non-renewable mandate by the President of the Republic, the President of the Senate and the President of the National Assembly. ASN comprises its headquarters and eleven regional divisions spread around the country.

On 31 December 2009, the total ASN workforce stood at 443 staff. The ASN budget reached 48.3 million euros in 2009, excluding the services it receives from certain ministries for the operation of the headquarters or regional divisions. IRSN also receives a subsidy for the technical support it provides to ASN. In 2009, this amounted to 78.1 million euros.

When taken together, these resources enable ASN to perform the majority of its tasks. However, these appropriations are currently split among four budget programs within which they are not always clearly identified. ASN hopes to see a simpler system set up, giving greater visibility and more flexibility to the financing of the regulation of nuclear safety and radiation protection.

With the aim of continuous improvement, ASN hosted an international audit mission in 2009 ("IRRS" audit organised by the IAEA) which considered that it had provided a satisfactory response to 90% of the recommendations and suggestions put forward by the first audit in 2006.

Following wide-ranging internal consultations, ASN at the end of 2009 adopted its "Multi-year strategic plan" (PSP) for the period 2010-2012.

#### CONSULTATIVE BODIES

The organisation of security and transparency in the nuclear field also involves consultative bodies, in particular the French High Committee for Transparency and Information on Nuclear Security (HCTISN), a forum for information, discussion and debate on the risks linked to nuclear activities and the impact of these activities on human health, the environment and nuclear safety. There is also the French High Public Health Council (HCSP), a consultative scientific and technical body, reporting to the Minister for Health, which helps with the definition of the multi-year public health objectives, evaluates the extent to which national public health objectives are met and contributes to their monitoring on an annual basis.

#### **3 REGULATIONS**

The legal requirements specific to radiation protection are based on international standards and recommendations produced by various organisations, in particular the International Commission on Radiological Protection (ICRP), a non-governmental organisation which publishes

recommendations on protection against ionising radiations, the International Atomic Energy Agency (IAEA), which regularly publishes and revises standards in the fields of nuclear safety and radiation protection and the International Organisation for Standardization (ISO), which publishes international technical standards.

At a European level, under the terms of the EURATOM treaty, various directives set the basic rules applicable to radiation protection and, more recently, to safety. These directives are binding on all Member States.

Work is under way to incorporate the ICRP recommendations published at the end of 2007 into EU directives and the IAEA's radiation protection safety standards. In 2010, ASN will announce its stance with regard to this work when preparing the French position to be adopted for the purposes of international discussions.

At a national level, the legal and regulatory requirements applicable to nuclear activities have been extensively overhauled in recent years. The legislative armoury is now relatively well-stocked and publication of the implementing texts is well-advanced, although not yet complete. The main texts appear in the Public Health Code (CSP) and the TSN Act. Other texts are more specialised, such as the Labour Code, which deals with radiation protection of workers, or the 28 June 2006 Planning Act on the sustainable management of radioactive materials and wastes (known as the "Waste Act"). Finally, various texts apply to certain nuclear activities, but without being specific to them.

The activities regulated by ASN fall into various categories, presented below with the regulations that apply to them:

Basic Nuclear Installations (BNI): These are the 125 largest nuclear installations located on about 40 sites, comprising installations in the nuclear electricity generating sector (nuclear power plants, main installations in the "fuel cycle"), the main radioactive materials storage and disposal facilities, some research installations and the large accelerators and irradiators.

The legal regime applicable to the BNIs is defined by part VI of the TSN Act and its implementing decrees. This regime is said to be "integrated" because it aims to cover the prevention or control of all the risks and detrimental effects, whether or not radioactive, that a BNI is liable to create for man and the environment. It in particular stipulates that a BNI can only be created or decommissioned once authorised by a decree issued on the advice of ASN and that ASN authorises commissioning of the installation and sets the requirements for its design and operation in terms of protection of the population and the environment.

Following the adoption of the TSN Act, ASN began work on overhauling the general technical regulations in 2008, jointly with the Ministry responsible for energy (MEEDDM). This should lead to the publication of a ministerial order and twenty or so regulatory decisions from ASN. 2010 will in

particular be devoted to consultations with all the stakeholders, with the aim of publishing texts before the end of the year to ensure that the "reference levels" adopted by the WENRA association of European safety regulators are transposed into national law.

Transport of radioactive materials: The safe transport of radioactive materials is based on the principle of "defence in depth" involving the package, consisting of the packaging and its content, which must be able to withstand the foreseeable transport conditions, the means of transport and its reliability, and finally the means of dealing with an incident or accident. The responsibility for implementing these lines of defence lies with the consignor.

The regulations governing the transport of radioactive materials comprise a significant international component; they are based on IAEA recommendations incorporated into the international agreements covering the various modes of transport of dangerous goods. At a European level, the regulations are grouped under a single directive of 24 September 2008 transposed into French law by an order of 29 May 2009.

In accordance with these legal and regulatory requirements, ASN is above all responsible for approving package models for transport of the most dangerous shipments. Working groups will be set up in 2010 for the future revision of the radioactive materials transport regulations (publication scheduled for 2012/2013).

**Small-scale nuclear activities:** This category comprises the numerous fields using ionising radiations, including medicine (radiology, radiotherapy, nuclear medicine), human biology, research, industry, and certain veterinary or forensic applications, as well as the conservation of foodstuffs.

The Public Health Code (CSP) 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. The authorisations are issued by ASN and the notifications are to be made to the ASN's regional divisions.

ASN is continuing to publish the technical decisions made necessary by the CSP and the Labour Code updated at the end of 2007. A large number of technical decisions should be taken in 2010, which should also see the end of the two-year process to examine the implementation of regulation of "source security" for the prevention of malicious acts.

Radioactive waste: As with all industrial activities, nuclear activities produce waste, some of which is radioactive. The three fundamental principles underpinning stringent management of radioactive waste are the responsibility of the waste producer, traceability of the waste and public information. If it is to be fully effective, a management system based on these principles must rule out the setting of any general radioactivity threshold ("release threshold"), below which the disposal

of waste from nuclear installations would be completely uncontrolled.

The technical management arrangements required must be adapted to the risk presented by the radioactive waste. This risk can be assessed primarily through two parameters: the activity level, which contributes to the toxicity of the waste, and the lifetime as defined by the half-life, that is the time after which the activity level is halved.

Finally, how the radioactive waste is to be managed must be defined before any new activity can be created or any existing activity modified, in order to optimise the waste management solutions and confirm that disposal routes are in place for the various categories of waste liable to be produced, from the front end (waste production and packaging) to the back end (storage, transport, disposal).

Contaminated sites: Management of sites contaminated by residual radioactivity as a result either of a past nuclear activity or an activity which involved high concentrations of NORM, justifies specific radiation protection actions, particularly if rehabilitation is envisaged. On the basis of the current or future uses of the site, decontamination objectives must be drawn up and plans must be put in place for removal of the waste produced during clean-out of the premises and of the contaminated soil, from the site up to storage or disposal.

In the event of long-term exposure of individuals to ionising radiations, Article R. 1333-90 of the CSP gives the *préfet*, on the advice of ASN, the responsibility for taking various protective measures (definition of a perimeter, deployment of an exposure monitoring system, controlled access to or use of land and buildings, restriction on the sale of foodstuffs produced in the zone, collection of contaminated materials, and so on).

Activities producing TENORM: Some professional activities, which cannot be classified as "nuclear activities" may significantly enhance exposure to ionising radiations for workers and, to a lesser extent, for the nearby populations. This is particularly the case with activities using raw materials, construction materials or industrial residues containing NORM not used for their radioactive, fissile or fertile properties. Examples are the phosphate mining and phosphate fertiliser manufacturing industries, the dye manufacturing industries, in particular those using titanium oxide and the rare earths mining industry, including the extraction of monazite. The radiation protection actions required in this field are based on a precise identification of the activities, an estimation of the impact of the exposure for the persons concerned, the implementation of corrective measures to reduce this exposure, as necessary, and to ensure that it is monitored.

Surveillance of human exposure to radon in premises open to the public is targeted on the risk to the general population but also to workers. It is also a priority radiation protection action in geographical areas in which there is high potential exhalation of radon owing to the geographical characteristics of the terrain. A strategy to reduce this exposure is necessary, should the measurements taken exceed the action levels laid down in the regulations. Surveillance obligations have been established.

## REGULATION AND INSPECTION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATIONS

ASN regulation and inspection of nuclear activities consists in verifying that any party responsible for a nuclear activity assumes its responsibility in full and complies with the requirements of the regulations as they apply to nuclear safety and radiation protection. ASN attaches great importance to compliance with the principle of the responsibility of the licensee for safety and radiation protection and adapts the scale and scope of its regulation and inspection work to the stakes involved in terms of health and environmental safety. The performance of some inspections by organisations and laboratories providing the necessary guarantees as validated by means of ASN approval is part of regulation. This can when necessary be carried out with the assistance of IRSN.

ASN ensures compliance with the general rules and particular requirements concerning nuclear safety and radiation protection applicable to the licensees of BNIs, those in charge of building and operating pressure vessels (ESP) used in BNIs, those in charge of transporting radioactive materials, those in charge of activities comprising a risk of exposing individuals and workers to ionising radiations, those in charge of carrying out surveillance of exposure to ionising radiations, and the organisations and laboratories it approves.

The scope of regulation and inspection has been broadened to include organisational and human factors, taking account of individual and collective behaviour, as well as management, organisation and procedures. It includes regulation of the steps taken to protect the environment and, in the nuclear power plants, application of the Labour Code.

Inspection is ASN's main means of regulation. Using the principle of proportionality, ASN inspects activities at a frequency determined on the basis of the health and environmental stakes. The inspections are generally carried out by two inspectors, with the support of an IRSN representative specialising in the installation being inspected or in the topic of the inspection. They may be unscheduled or announced to the licensee several weeks in advance. They mainly take place on the site or during various activities (construction, transport operation) but can also concern the headquarters offices of the large nuclear licensees, the facilities or design offices of the subcontractors, the construction sites and the manufacturing plants for the various components important for safety.

The inspectors can on this occasion take radioactivity measurements or samples of discharges.

When the licensee's actions are in breach of the regulations or the legislation, or when it is important to take appropriate action to remedy the most important risks without delay, ASN may apply the sanctions stipulated by the Act, in a proportionate, objective and fair manner.

With regard to obligations and sanctions, ASN has a broad range of tools at its disposal, in particular observations made by the inspector to the licensee, an official letter to the licensee from ASN, formal notice from ASN to the licensee to ensure the conformity of its administrative situation or to meet certain stipulated conditions, within a specified period of time, and administrative sanctions issued after formal notice. In parallel with ASN's administrative actions, reports may be drafted by the inspector and sent by ASN to the public prosecutor's office with a view to criminal proceedings.

The monitoring of environmental radioactivity is mainly the duty of IRSN, which carries out monitoring nationwide, and of BNI licensees under the terms of their discharge licenses. ASN approves specialised laboratories to check the quality of their measurements. The results of these measurements are logged on the French National Network of Environmental Radioactivity Monitoring and accessible to the public on its website (www.mesure-radioactivite.fr).

#### HIGHLIGHTS OF 2009

In 2009, ASN carried out 2,112 inspections of BNIs, radioactive material transport activities, activities employing ionising radiations, organisations and laboratories it had approved and activities related to pressure vessels.

#### OUTLOOK

For 2010, ASN has scheduled 2,100 inspections of BNIs, radioactive material transport activities, activities employing ionising radiations, organisations and laboratories it has approved and activities related to pressure vessels. It is continuing with and indeed developing its application of the principle of proportionality in order to focus its inspections on activities where the stakes involved are high.

In the field of worker radiation protection, an inspection campaign will be carried out in 2010 jointly with the General Labour Directorate and the employees' national health insurance fund, to ensure that the regulatory changes that have taken place in recent years are being correctly implemented.

Following a first experience with the significant events notification guide for small-scale nuclear activities, ASN will be revising the notification guides for significant radiation protection events. Once this work is completed, ASN will have defined criteria for notification of significant events in all the fields under its responsibility.

The regulatory work in progress will lead in 2010 to the revision of the system applicable to organisations approved for radiation protection inspections. These changes aim to clarify ASN's requirements with regard to how they are organised and the nature of the inspections carried out.

With respect to monitoring of environmental radioactivity, ASN – along with all the stakeholders involved and in particular IRSN – will be defining changes to the nationwide monitoring strategy. These changes aim to take greater account of the expectations of society and develop a monitoring strategy that is proportionate to the stakes involved.

#### RADIOLOGICAL EMERGENCY SITUATIONS

A radiological emergency is the result of an incident or accident liable to lead to the dissemination of radioactive materials or a level of radioactivity such as to jeopardize public health.

Protection of the population is one of the key duties of the public authorities. Management of an emergency situation is based on a national organisation and emergency response plans, involving both the licensee and the authorities. Within this organisation, ASN assists the Government, informs the public about the state of safety of the installation which caused the emergency and informs international organisations and countries liable to be affected by the accident of how the situation is evolving.

This arrangement is regularly tested and evaluated and is also regularly revised to take account of operating experience feedback from exercises and actual situations that have occurred.

#### HIGHLIGHTS OF 2009

In 2009, with the creation of the new BNI regime resulting from the TSN Act, ASN continued with the drafting of an ASN decision defining the content of the licensees on-site emergency plans (PUI).

Stable iodine tablets offer protection of the thyroid in the event of an accident in a nuclear reactor with radioactive releases. At the request of the Ministry responsible for health, ASN produced a new "iodine policy" targeted at the most sensitive populations and harmonised with the policies of neighbouring countries. As a result of this work, ASN issued decision 2009-DC-0153 of 18 August 2009 lowering the trigger level for the administration of stable iodine. This decision was approved on 20 November 2009 by the Minister for Health.

In 2009, ASN ran the 4th iodine tablet distribution campaign for the populations living around EDF nuclear power plants, jointly with the Ministries for the Interior and Health and with the support of EDF, the national association of local information committees (ANCLI), the national order

of pharmacists, the retail pharmacy trade unions and the rural pharmacy association. About 400,000 homes and 2,000 establishments open to the public spread over 500 *communes*<sup>3</sup> were targeted by this campaign. Nationwide, nearly 50% of the individuals concerned collected their boxes of tablets from their pharmacy and more than 338,000 boxes were distributed in this way.

Boxes will be sent by post during the course of 2010 to those who failed to collect them in 2009.

ASN observes that there has been a rise in building projects around the nuclear sites. ASN's current policy regarding urban development around BNIs aims to guarantee the practical implementation of the measures stipulated in the off-site emergency plan (PPI) concerning sheltering and evacuation. In 2009, ASN worked together with the Ministry for the Environment, leading to the signing of a circular intended for the *préfets* asking them to exercise greater vigilance with respect to urban development in the vicinity of nuclear installations

Since 2005, ASN has been tasked by the Prime Minister with conducting an overall review of the management of the consequences of a nuclear accident. In 2009, the work of CODIRPA<sup>4</sup> continued with the following objectives: consolidation of initial policy elements; discussions with the stakeholders (State regional offices and civil society); broadening of the work to take account of other accident scenarios (plutonium scenario and accident abroad). Consultations with local and national stakeholders are currently ongoing in order to compare the proposals submitted with the actual situation in the field. An operational guide will provide the local authorities with information to help them prepare their local postemergency phase plans. An initial version of this guide should be submitted for local consultation in 2010. In 2009, the initial aspects of the post-accident strategy were tested during national nuclear or radiological emergency exercises. An international seminar will be held in early 2011 to share the work done by CODIRPA with French and foreign experts and organisations concerned.

The ASN emergency response centre was activated on five occasions in 2009 owing to the degraded climatic conditions threatening the Blayais nuclear power plant, a fire threatening the nuclear installations at Cadarache and loss of the heat sink at the Cruas and Fessenheim nuclear power plants.

In 2009, ASN continued its meetings with foreign organisations in charge of emergency situation management. ASN in particular met the NRC in the United States and was able to observe an emergency exercise in April 2009. On the basis of this experience, ASN submitted proposals for improvements to its own organisation, aimed at improving the decision-making and information exchange processes, in particular by deploying collaborative IT tools.



Website dedicated to the 2009 iodine tablet distribution campaign, www.distribution-iode.com

The SECNUC major emergency exercise organised by the French General Secretariat for National Defence (SGDN) was held on 21 October 2009. It tested the response of the national emergency organisation to a nuclear accident in a foreign country but with consequences in France. ASN in particular observed that the authorities could benefit from relying more on the existing organisation already in place for management of radiological emergency situations.

#### **OUTLOOK**

In the next few years, ASN will be looking to change its organisation and modernise its emergency response centre. In particular, during the course of 2010, ASN will be setting up a duty system to improve its responsiveness in the event of an emergency.

ASN is continuing to look at ways of reinforcing its policy concerning urban development around BNIs. The circular to the *préfets* on this subject was signed on 12 February 2010. One of ASN's particular duties is to inform local authorities of the risk created by nuclear installations with a PPI. For the longer term, it will be necessary to define the methodology for drawing up public protection restrictions designed to limit urban development and therefore the consequences of an accident in an installation.

In the post-accident field, drafting of an operational guide to the post-accident phase was started in 2009 and it will act as a reference for local authorities in the preparation of their emergency plans around each site containing a nuclear power

<sup>3.</sup> Smallest administrative subdivision administered by a mayor and a municipal council.

<sup>4.</sup> Management committee for management of the pot-accident phase of a nuclear accident or a radiological emergency.

plant. An international seminar on the subject is scheduled for early 2011.

Together with the administrations and public institutions concerned, ASN drafted the circular concerning exercises. The objectives were defined nationally in order to take account of operating experience feedback from the exercises regularly held. This practice will allow improved preparation and greater assimilation and involvement by the participants.

## PUBLIC INFORMATION AND TRANSPARENCY

ASN considers that it is responsible for the correct implementation of the transparency requirements of the TSN Act. It is strengthening its actions with regard to transparency through active communication with the general public, the media, the institutional public and professionals. It supports the work being done on transparency by the CLIs and the HCTISN. Finally, in its nuclear licensee regulation and inspection activities, ASN aims to attach greater importance to compliance with the transparency obligations contained in the TSN Act.

#### HIGHLIGHTS OF 2009

For its public information duty, ASN is looking to change its working methods and its information media in order to meet the expectations of the general and professional public, over and above the transparency requirements contained in the TSN Act. In 2009, ASN enhanced its actions with respect to the general public, the media and its professional and institutional audiences: launch of the ASN Newsletter, overhaul of the www.asn.fr website, changes to *Contrôle* review, professional conferences and symposia, iodine tablets distribution campaign, development of press and institutional relations.

ASN publishes the follow-up letters to the inspections carried out in the BNIs (more than 750 follow-up letters per year) and in radiotherapy centres (more than 150 follow-up letters per year) and in 2010 will be publishing all the other follow-up letters to the inspections of small-scale nuclear facilities. In total, ASN will thus make more than 1800 follow-up letters available on its www.asn.fr website every year. ASN will also be publishing on its site the opinions and recommendations from the Advisory Committees it has set up.

ASN applies its policy of "accountability" through its official presentation to Parliament of the annual ASN report on the state of nuclear safety and radiation protection in France. ASN informs and reports to the various opinion shapers and

national and regional stakeholders (elected officials, representatives of environmental protection associations), as well as industry and the administrations. At a local level, its public information role is carried out by the regional representatives and the heads of its eleven divisions.

#### LICENSEES AND THE RIGHT TO INFORMATION

The TSN Act imposes strict transparency requirements on all nuclear activities. The main licensees of nuclear activities implement proactive public information policies. They are also subject to legal obligations, both general and specific to the nuclear field. The TSN Act thus requires that each BNI licensee produce an annual report on its situation and the measures it takes with regard to nuclear safety and radiation protection (Article 21 of the TSN Act). This report must be published no later than 30 June of the following year. The first annual public information reports were published in 2007. As the applicable rules are frequently recent and their implementation can be problematical, ASN seeks to encourage exchanges between all stakeholders concerning the problems encountered and best practices. ASN therefore produced a draft writing guide for these reports, so that they can comply with the objectives of the Act. This draft was presented and discussed at the 21st CLI conference on 9 December 2009 before it is launched in the course of 2010.

In 2009, ASN analysed the 2008 reports from the licensees. Its analysis was on the whole positive: they were produced in good time, in compliance with the TSN Act concerning the themes covered, appropriate for the general public (improved graphics, clear text, instructive diagrams, glossaries), and accessible on-line, except for certain "small licensees". Despite the progress observed, the picture is nonetheless a contrasting one, with some licensees failing to take sufficient account of the recommendations made by ASN in its guide. The reports also strictly limit themselves to nothing more than the headings mentioned by the Act, comprise few if any strategic orientations, long-term objectives or critical analyses, and no qualitative or quantitative data on public information (number of queries, nature, time taken to answer, etc.). Finally, more details about transparency and the public's right to information would be appreciated. For the coming years, ASN therefore intends to continue working with the licensees, to share best practices and monitor progress.

#### CLIS, ANCLI, HCTISN

The TSN Act (Article 22) requires that a CLI be created for each BNI by the President of the *Conseil général*<sup>5</sup>. In 2008, renewal of the *Conseils généraux* and municipal councils delayed the CLI changes made necessary by the new legislative and regulatory framework (TSN Act and decree of 18 March 2008). This delay was to a large extent made up in



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2009. The final conformity work will take place in 2010. This in particular entailed adjustment of the composition of the CLIs according to the new rules, drafting of internal regulations and implementation of the new operating requirements. Four new CLIs were created in 2009. At the end of 2009, only three BNIs were still without a CLI. Subsequent to these changes, there will be about thirty-five CLIs covered by the TSN Act.

In 2009, ASN devoted about 600,000 euros to CLIs and their federation, ANCLI. It also submitted a proposal to the Government for implementation of the system provided for in the TSN Act, whereby the budget of the CLIs, given their association status, would be topped up with the proceeds of the BNI tax, however this system has not yet been put into place.

ASN considers that the correct operation of the CLIs contributes to safety through regular questioning of those in charge, and that it is a key factor in "ecological democracy". ASN thus makes sure that the CLIs receive information that is as complete as possible. With the approval of the licensees, it invites CLI representatives to take part in inspections. ASN considers that a diversified pool of expertise in the nuclear field is essential, so that whenever necessary, the CLIs can — when producing their opinions — call on assessments other than those produced on behalf of the licensee or ASN. It thus proposed that the HCTISN examine this issue.

In the last quarter of 2009, the CLI federation, ANCLI, adapted its articles of association, enabling it to assume in full the role of the CLI federation as stipulated in the decree of 12 March 2008. The CLI federation will now be called the National Association of Local Information Commissions and Committees (ANCCLI).

The HCTISN, set up by the TSN Act, held four meetings in 2009. It discussed BNI decommissioning strategy, the iodine tablets distribution campaign around nuclear power plants, the management of former uranium mining sites, the shortage of radiological physicists in radiotherapy centres and the management of radioactive waste, especially with regard to the notion of the reversibility of disposal sites. In the autumn of 2009, it was asked by the Minister for Energy Jean-Louis Borloo, and the OPECST, to review the question of information and transparency as they relate to the management of nuclear materials and wastes produced at all stages of the fuel cycle. Its reply will be finalised at the first session in 2010.

#### **OUTLOOK**

For 2010, ASN will continue to strengthen transparency and information jointly with the other players and stakeholders. It will propose holding national and international debates on general subjects concerning nuclear safety and radiation protection, but also on society's approach to risks in general. It will contribute to developing exchanges with the populations concerned by nuclear installation projects, by an activity using ionising radiations or by a radiological risk. It will organise local meetings/debates, in partnership with local organisations. In this respect, the environment will be one of the topics to be covered in 2010, in a number of ways: publications, press conference, professional symposium, debate with the public and the stakeholders. ASN intends to involve the public more widely in its decision-making process and to explain its decisions more fully. It will thus encourage public consultations via its website. Developing exchanges with institutions and the stakeholders will also be one of the focal points for 2010. ASN will expand its media activities, at both European and international levels, and will prepare a European conference on nuclear safety and radiation protec-

In 2010, ASN will also continue to promote implementation of the requirements of the TSN Act concerning the licensees obligation of transparency. It will in particular implement the reforms of the public consultation procedures contained in the future "Grenelle 2" Act, in particular the reform of public inquiries and, further to a proposal from ASN, the systematic requirement of a public consultation procedure for projects liable to lead to a significant rise in water intake or environmental discharges by a BNI. ASN will attempt to define practical measures to facilitate the application of the new requirements concerning access to the information in the possession of the licensees and the safety analysis report and hopes to see the completion in 2010 of the work undertaken by the HCTISN on reconciling the desire for transparency with the

need to protect secrecy when required by law. ASN will aim to ensure the completion of the project to extend to the transport field the right of access to information in the possession of those in charge of nuclear activities.

Finally, ASN will be continuing to support the work of the CLIs, will urge the CLIs to ensure full conformity with the TSN Act, will attempt to define rules of good practice with the ANCCLI and the licensees, to make it easier for the CLIs to carry out their duties, and will renew its proposals to the Government to give the CLIs the means they need to perform their duties.

# USINRC

Talk by the ASN Chairman at the plenary opening session of the Regulatory Information Conference on 10 March 2009 in Washington (USA)

#### INTERNATIONAL RELATIONS

The nuclear installations regulated by ASN represent one of the largest and most diverse groups in the world. This requires ASN to devote significant efforts to international relations with its foreign counterparts, with the aim of helping to improve safety and radiation protection around the world, and of achieving recognition as an "international benchmark for good practice".

#### HIGHLIGHTS OF 2009

The focus of ASN's international actions is Europe and in this way, it intends to help build a Europe that is a leader in the fields of nuclear safety, the safe management of waste and spent fuel, and radiation protection.

ASN makes an active contribution to the work of WENRA (Western European Nuclear Regulators' Association), an informal club created in 1999 at the initiative of the ASN Chairman of the time, and it now brings together the heads of all the safety regulators of the expanded European Union, plus Switzerland. In 2009, the association's meetings were opened up to the regulators of the ten European countries with no nuclear power reactors. Following the work initiated by WENRA shortly after its creation, the safety harmonisation of the reactors in operation in Europe should become effective in 2010. WENRA has also just published a report proposing harmonised safety objectives for new reactors across Europe.

In 2008, ENSREG (European Nuclear Safety Regulators' Group, previously known as the High Level Group (HLG)), was created as a forum for the heads of the European Union's safety regulators, at the request of the European Council meeting in March 2007. It began reviewing safety, waste and spent fuel management and transparency in the nuclear sector in Europe as a whole. This work found ready support from the French presidency of the European Union (second half of 2008), during which the initial debates on a nuclear safety directive were held. This directive, finally adopted on 25 June 2009, constitutes a binding EU framework for

nuclear safety and contributes to harmonising the safety requirements of the Member States.

In the field of radiation protection, the work done by HERCA (Heads of European Radiation Control Authorities) strengthened European cooperation. Considerable progress has been made by this committee and its working groups since it was set up in 2007.

Outside Europe, there are numerous examples of multilateral cooperation, in particular within IAEA and the Nuclear Energy Agency (NEA). At IAEA, ASN plays an active part in the work of the Commission on Safety Standards (CSS) which drafts international standards for the safety of nuclear installations, waste management, the transport of radioactive materials and radiation protection. Although not legally binding, these standards nonetheless constitute an international benchmark, including in Europe. The Chairman of ASN has chaired the CSS since 2005. ASN regularly takes part in the IRRS audit missions: it was itself the subject of one of these missions in 2006 and the follow-up mission in 2009. It frequently takes part in the teams of auditors for missions carried out on other safety regulators.

The American Nuclear Regulatory Commission (NRC) and ASN took the initiative of launching an international project, called the Multinational Design Evaluation Program (MDEP) for joint evaluation of the design of new reactors. This program, which has been expanded to take in numerous partners around the world, and for which the secretariat was entrusted to the OECD's NEA, allows the sharing of information on the safety assessments of the EPR and AP1000 reactors. The initiative aims eventually to ensure harmonisation of the safety objectives, codes and standards involved in the safety review of a new reactor.

ASN cooperates with many countries as part of bilateral agreements. The usually annual "steering committee" meetings identify subjects of cooperation and joint actions to be taken. ASN also promotes staff exchanges with its foreign

counterparts as a means of achieving improved mutual understanding and mutual benefit. This can take the form of occasional actions, such as cross-inspections and short-term missions to study a specific technical topic, or the secondment of an inspector to a foreign safety regulator for a longer period (one to three years). Moreover, the appointment by ASN of representatives from foreign safety regulators to the Advisory Committees is an aspect that should be underlined. This practice enables experts from other countries not only to be members of these Advisory Committees, but also sometimes to act as their chair or co-chair.

ASN is also contacted by certain countries looking for assistance. ASN first of all analyses the situation of the countries in question from the nuclear safety viewpoint. Following this analysis, should ASN conclude that safety cannot be guaranteed, it may express its reservations about the desirability of the envisaged cooperation. In cases where ASN does decide to begin cooperation, the aim is to enable the country concerned to achieve the independence and the safety and transparency culture essential to a national system of nuclear safety and radiation protection regulation that is both effective and credible. For example, in 2009, ASN helped the nuclear safety regulator of the United Arab Emirates to draft that country's nuclear legislation.

Finally, France is a contracting party to four international conventions, which aim to prevent accidents linked to the use of nuclear power and to mitigate their consequences should they occur. IAEA is the depositary and secretary for these conventions. The third review meeting for one of these conventions, the Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management, took place from 11 to 22 May 2009 at IAEA headquarters in Vienna. The contracting parties to this convention submitted their national reports in October 2008, describing how they meet their obligations under the Joint Convention. These reports were then the subject of questions, to which each contracting party was required to reply. A summary of this work was presented to the review meeting. With regard to France, several good practices were identified, such as the publication of the 28 June 2006 Act, transparency and the engagement alongside the local information committees and other stakeholders, as well as the steps taken to limit the production of radioactive waste. Generally speaking, progress has been observed in the establishment of national radioactive materials and waste management plans. Their actual implementation constitutes a challenge for the coming years. Many countries also presented projects of varying degrees of maturity for the creation of a national radioactive materials and waste management agency. In the light of its experience in this sector, France proposed organising technical meetings on these subjects. A first meeting of this type will be held in France by DGEC6, ANDRA (French National Agency for Radioactive Waste Management) and ASN in June 2010.

#### **OUTLOOK**

In 2010, in the field of international relations, ASN will seek to actively continue to help improve nuclear safety and radiation protection around the world. This goal will entail maintaining strong and permanent ASN involvement in European and international organisations. The adoption of the directive on the safety of nuclear installations in June 2009 also paved the way for the creation of a regulatory framework at EU level, extending beyond radiation protection alone

## REGIONAL OVERVIEW OF NUCLEAR SAFETY AND RADIATION PROTECTION

For the first time in its annual report, ASN intends to propose an additional approach to its national assessment of nuclear safety and radiation protection for each major sector of activity and each large licensee. ASN now presents the situation as observed locally by its divisions.

This assessment is presented in summary sheets and covers BNIs and small-scale nuclear activities (primarily medical and industrial). Finally, the ASN divisions highlight a number of local actions that best illustrate the work done by ASN in the regions.

This new chapter, which is based on a regional approach, pursues the same aim as the various ASN information media (www.asn.fr website or the quarterly *Contrôle* review): ensuring easier access to local information.

#### **MEDICAL USES OF IONISING RADIATIONS**

Whether for diagnosis or therapy, medicine utilises various sources of ionising radiations, produced either by electric generators, or by radionuclides.

In France, there are thus several thousand conventional and dental radiology devices, about a thousand computed tomography installations, more than 200 nuclear medicine units using unsealed sources for in vivo or in vitro diagnosis and for internal radiotherapy, and about 200 external radiotherapy centres, treating some 200,000 patients every year.

There is clear evidence of the medical benefits to be gained from using these techniques. However, the exposure of the health professionals, patients and the population to the associated radiations has to be justified and kept under control. This is why more than 180,000 people working with ionising radiations for medical purposes were the subject of dosimetric exposure monitoring. In total, according to the

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... In the coming years, ASN will make sure that medical radiophysics resources are increased, that the interim criteria published in July 2009 by the Minister for Health are complied with and that quality assurance is developed

data collected by IRSN in 2008, more than 98% of those monitored received an annual effective dose of less than 1mSv, whereas a dose in excess of the annual limit of 20mSv was recorded on eight occasions. These radiations are the second source of exposure of the population, after exposure to NORM.

#### RADIATION PROTECTION OF THE MEDICAL PROFESSIONS

In 2009, ASN published a report on the nuclear medicine inspections it carried out in 2008, and pointed out that the regulatory requirements concerning worker protection, an area in which the stakes are high, are inadequately applied. The inadequacies identified must however be put into perspective in the light of the particular risks. The results of dosimetric monitoring have in fact in recent years showed no overdose above the stipulated annual limit.

In radiology departments, ASN's targeted inspection campaigns show that the radiation protection regulations are on the whole followed in most cases but that certain radiology practices will need to take corrective measures to remedy the shortcomings observed.

In 2009, ASN was notified of 9 significant radiation protection events concerning individuals working in medical installations.

#### RADIATION PROTECTION OF PATIENTS

In the field of radiotherapy, the results of the 2008 inspections show an improvement over 2007, but there are still problems with procedure safety. Strengthening of the lines of defence (internal quality checks, formal definition of procedures, risks analysis, problems analysis, internal communication) is one area in which there is room for improvement. The results also show a contrasting picture of the radiotherapy centres between regions and even within a given region.

In the next three years, the ability of the centres to actually achieve a more rigorous organisation and stricter day to day traceability will be a determining factor. This will not be possible without staff training in quality assurance and risk management and without the direct involvement of the management of the practices concerned.

ASN found that there is still a shortage of staff (radiation oncologists, medical radiation physicists, medical radiation therapy technicians). Faced with this shortage, ASN was obli-

ged to temporarily suspend the accelerator operating licenses in radiotherapy centres in Blois, Gap, Roanne, Croix and Nevers.

In the coming years, ASN will make sure that medical radiophysics resources are increased, that the interim criteria published in July 2009 by the Minister for Health are complied with and that quality assurance is developed.

In general, ASN observes that the mandatory training of health professionals in radiation protection of patients is gradually being implemented, particularly in radiotherapy centres, where considerable efforts have been made.

In 2009, ASN was notified of 27 significant events concerning patients subjected to exposure for diagnostic purposes, 13 of which corresponded to nuclear medicine procedures. 5 events with no consequences concerned pregnant women, who at the time of the diagnostic examination were unaware of the fact that they were pregnant.

ASN was notified of 131 significant events concerning patients subjected to exposure for therapeutic purposes. 127 occurred during an external radiotherapy medical process (including 7 rated level 2 on the ASN-SFRO scale applicable to radiotherapy) and 4 during brachytherapy treatment. One was notified after the appearance of side-effects in 4 patients treated by interventional radiology.

This latter event led ASN to send a circular letter to the heads of vascular interventional neuroradiology departments and the director generals of regional and university hospitals, reminding them of the regulatory obligations concerning, in particular, application of the optimisation principle, staff training, the drafting of radiological protocols and the need to use the services of a medical radiation physicist for optimising radiological procedures. In 2010, jointly with professionals and the health agencies, ASN will draw up a draft program of actions to reduce exposure to ionising radiations from those interventional radiology procedures involving the highest exposure.

### IMPACT OF MEDICAL ACTIVITIES ON THE ENVIRONMENT AND THE POPULATION

Barring special cases, there is no specific monitoring of the impact of medical applications on the environment and the population, given its extremely diffuse nature. The information available on radiological monitoring of the environment shows that on the whole there is no evidence of any

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Talk by Mr Bourguignon, ASN Commissioner (right) during the meeting with the profession on the subject of radiotherapy safety in Marseilles – February 2009

significant level of exposure. The presence of radionuclides used in nuclear medicine may occasionally be detected in major rivers or in city sewage treatment plants. The associated doses are evaluated at a few microSieverts for the individuals most heavily exposed.

## International conference on the radiation protection of radiotherapy patients

From 2 to 4 December 2009, with the support of the WHO, IAEA and the European Commission, and with the participation of numerous organisations and professional and patient associations, ASN organised the first international conference on the radiation protection of radiotherapy patients, in Versailles. The debates between the 330 participants from 34 countries stressed the crucial role of radiotherapy in the treatment of cancers, the importance of mastering the new technologies, particularly through training and through an independent evaluation of initial deployment by professionals, the need to promote and develop quality assurance, operating experience feedback and the safety culture, and the necessary involvement of the patients and their associations in treatment safety. ASN will propose that these conclusions be incorporated into the national radiotherapy action plan set up by the Ministry for Health.

## NON-MEDICAL USES OF IONISING RADIATIONS

Industry, research and many other sectors use sources of ionising radiations in a wide variety of applications, from industrial irradiation, to non-destructive testing, to detecting lead in paint.

Given this diversity, the safety of workers, the public and the environment in particular entails management of the sources

and monitoring of their possession, utilisation and disposal, from manufacture to retirement.

#### HIGHLIGHTS OF 2009

Because of the equipment used and the intervention conditions, ASN sees industrial radiology as an activity with high stakes in terms of radiation protection and sees it as a priority.

ASN considers that the extent to which companies take account of the risk of worker exposure to ionising radiations varies widely and that there is still room for improvement, in particular through improved coordination between clients and contractors in preparing the work and in allowing effective preventive measures to be taken.

#### REGULATION OF ACTIVITIES

Industrial and research activities are subject to the requirements of the Public Health Code. They must offer radiation protection guarantees and take account of the justification, optimisation and limitation principles. They must be licensed by the authorities.

In 2009, the ASN Commission adopted several decisions tending to simplify and harmonise the licensing procedures, with implementation of a scale of risks.

ASN also adopted a number of approved decisions, concluding its work to implement a system of notification for the non-medical field, in particular with regard to certain veterinary radio-diagnostic devices. This should lead to a better balance between those activities requiring notification and those requiring authorisation, thus making the regulatory requirements better aligned with the radiation protection stakes involved.

With respect to justification, ASN produced a draft Government order in 2009, and two draft decisions, proposing and regulating gradual replacement of ion smoke detectors. While several years ago, these systems were justified on the basis of their benefits for human safety, other detection technologies (particularly optical) are now available and comply with fire detection regulations and standards.

## Conducting an inventory and supporting regulatory compliance

In 2009, ASN continued the search, started in 2007, for unauthorised suppliers of products in France. More than 10 companies were thus identified and were sent an information letter reminding them of the regulations applicable in France.

In 2009, ASN took steps to inventory the radioactive sources present in equipment in the national defence sector. This survey discovered a number of unauthorised suppliers, particularly in the aeronautical industry. All parties concerned have begun to take steps to comply with the regulations. In 2009, ASN continued with its educational measures to raise awareness of the regulations.

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Gamma radiography appliance and its transport case

In the gamma radiography sector, a committee was created to assess the health and safety impact of the steps taken by the profession and to ensure that they are kept up to date, in particular to take account of technical and regulatory developments. Work on the justification of gamma radiography was also undertaken. A guide was published by the industry, covering both optimisation and justification considerations.

ASN is continuing its work to explain the regulations applicable to electric devices emitting ionising radiations. In 2009, it organised numerous meetings with the suppliers of this equipment.

During meetings with the main licensees and through inspections, ASN regularly reminds such licensees of the main regulatory requirements applicable to BNIs and specifies the scope of the administrative simplification process in progress.

#### REGULATING SOURCES OF RADIATION

In the industrial sector, ASN is particularly attentive to the use of gamma radiography appliances. In 2009, as in 2008, this activity was identified as a priority in its inspection program. The main shortcomings identified concern the prior evaluation of doses and dose optimisation as well as the conditions in which gamma radiography operations are carried out on the worksites.

This year was also marked by the irradiation incident involving a worker during a gamma radiography inspection of a weld on the Flamanville site, an event that was rated level 2 on the INES scale.

ASN identified other inspection subjects with high stakes, in particular source suppliers and users of high-level sealed sources.

After a number of event notifications linked to the import of equipment contaminated with radioactive cobalt, ASN drew the attention of the Ministries concerned to the worrying rise in the number of these events, which can have potentially serious health and economic consequences. It proposed installing radioactivity detection systems in the country's ports and airports.

With regard to the regulation of ionising radiation applications in the non-medical sector, ASN is devoting efforts to ensuring that the operators take full account of the risks involved in the use of ionising radiations. This is all the more necessary given the diversity and number of those involved. In its regulatory actions, ASN must remain vigilant and determined with respect to any deviations which could lead to serious events for either workers or the public. Following the incidents linked to gamma radiography sources, it has initiated specific inspection actions targeted at high-level sources. ASN also considers that the public needs to be more precisely informed of its regulatory and inspection activities. ASN's publication of its inspection follow-up letters will therefore in 2010 be expanded to cover the non-medical sector.

## REGULATING PROTECTION OF RADIOACTIVE SOURCES AGAINST MALICIOUS ACTS

Work is now well-advanced on preparing the legislative and regulatory texts designed to give ASN the powers to regulate and inspect source safety. The safety objectives are yet to be defined and they could be clarified by orders and ASN decisions. Finally, human and material resources will need to be allocated to ASN, to enable it to carry out this new responsibility.

## TRANSPORT OF RADIOACTIVE MATERIALS

About 900,000 packages of radioactive materials are transported in France every year, although this represents a very small percentage of the dangerous goods traffic. Most of them (two-thirds) are packages intended for medical or industrial uses (lead analysers, gamma radiography appliances, etc.). These packages vary considerably. Their radioactivity spans more than 12 orders of magnitude, or from a few thousand becquerels (pharmaceutical packages) to millions of billions of becquerels (spent fuel), and their weight ranges from a few kilograms to about a hundred tons.

Road transport accounts for about 90% of radioactive material shipments, rail 3% and sea 4%. Air transport is widely used for small and urgent packages over long distances, for example short-lived radiopharmaceutical products. All of these transports can be international.

The sectors using these packages also vary widely. They obviously include the nuclear sector, but also the medical, conventional industrial and research sectors. These last three sectors account for more than 85% of the flow of radioactive material packages. The nuclear power generating industry entails the transport of a variety of radioactive materials. The largest transport operations involve about 300 shipments annually in the case of new fuel, 250 in the case of spent fuel, about thirty in the case of MOX fuels and about sixty in the case of plutonium oxide powder.

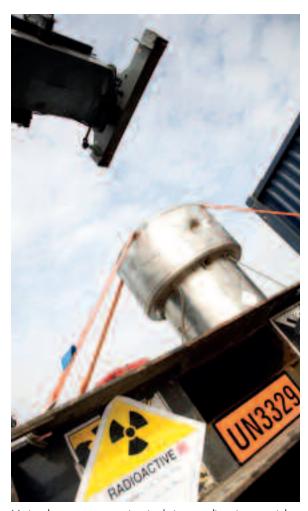
The main stakeholders involved in transport are the consignor and the transporter. The consignor is responsible for the safety of the package and confirms its liability in the shipment declaration issued when handing the package over to the transporter.

ASN is responsible for regulating the safe transport of radioactive and fissile materials for civil uses and for checking application of these regulations. Safety should not be confused with security or physical protection, which consists in preventing the loss, disappearance, theft or misappropriation of nuclear materials (of use in the production of weapons) and for which ASN is not responsible.

#### HIGHLIGHTS OF 2009

In 2009, ASN was notified of 83 events. 76 were rated level 0 and 7 were rated level 1 on the INES scale. These events can be of several types:

- package handling events;
- incidents or accidents during actual transport, in particular problems with tie-down;
- non-compliance with regulatory requirements, in particular pre-departure checks (problems concerning labelling, signalling, placarding, transport documents and contamination threshold).



National emergency exercise simulating a radioactive materials transport accident in Nantes – October 2007

In 2009, ASN issued 65 package model certificates, defining their manufacturing, operating and maintenance conditions.

In 2009, ASN carried out 96 inspections at various stakeholders involved in radioactive material transport operations, consistently with those performed by other authorities responsible in particular for inspecting the means of transport, conventional safety inspections in the transport sector or the protection of nuclear materials. The consignors and transporters are the subject of constant attention but the inspections also concern peripheral activities such as packaging manufacture and maintenance.

The observations made following the inspections show that the most frequently encountered problems concern quality assurance and documentation, division of responsibilities between the various parties, or compliance with the procedures stipulated in the approval certificates, the safety analysis files or, more generally, the regulatory texts. The importance of these discrepancies varies according to the nature of the transport.

These inspections show that progress has been made, especially in the drafting of radiation protection programs, which have been mandatory since 2001, but that this progress is still insufficient. In particular, for those packages which do not require approval by the competent authority, ASN considers that the situation is unsatisfactory and whether dealing with demonstrations of conformity with the regulations or checks prior to shipment, the inspections revealed a number of inadequacies. This situation is all the more worrying as these packages are the origin of most of the incidents that occurred in 2009.

Transport is by its very nature international. The regulations are therefore also essentially international. In this respect, ASN is closely involved in the various international exchanges associated with the drafting and implementation of these regulations, whether multilateral exchanges within IAEA or under the aegis of the European Commission, or bilateral exchanges with counterparts.

In 2009, during discussions at IAEA, ASN successfully argued its disagreement on the adoption of package surface contamination limits that differed according to the radionuclide involved. ASN was also involved in promoting the creation of the club of European authorities with competence for transport, along the lines of the WENRA association of nuclear safety regulators.

#### OUTLOOK

In 2010, ASN will be focusing on packages that do not require approval, particularly in the medical, conventional industry and research sectors, drawing on the experience of the inspections that it already carries out in these fields on the subject of radiation protection.

ASN will also continue to test its response to an accident during transport of a radioactive material. It considers that emergency exercises are of particular importance in this area, given that because an accident can happen anywhere, especially in *départements* in which there are no BNIs, the local players are likely to be inadequately prepared to deal with such an event.

Finally, ASN is also looking to improve regulation of dangerous goods transport within the nuclear sites themselves.

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#### **EDF NUCLEAR POWER PLANTS**

The design of the fifty-eight pressurised water reactors in the French nuclear power plants is appreciably the same. These plants are operated by a single licensee, EDF, which has significant engineering capability and an organisation enabling it to take advantage of this standardisation, but also to manage its drawbacks: given that the EDF nuclear power plants supply nearly 80% of electricity in France, it is important to prevent the occurrence of a serious, generic anomaly. ASN is particularly attentive to the measures taken by EDF in this respect. Since 2007, EDF has also been building an EPR type reactor on the Flamanville site, the design and construction of which is also regulated and inspected by ASN.

#### HIGHLIGHTS OF 2009

The periodic safety review for the third ten-yearly outages of the 900 MWe reactors.

The periodic safety reviews are one of the cornerstones of safety in France and require that the licensee must not only maintain the safety of its installation but must also improve it. The periodic safety review process comprises:

- a "conformity check" which involves an in-depth examination of the condition of the installation, in order to verify that it is fully compliant with all safety requirements applicable to it;
- a "safety review" of the installation designed to improve its level of safety, in particular by comparing the requirements applicable to the installation with those in force on more recent installations and taking account of national and international operating experience feedback.

After these two steps, the licensee sends ASN a report, on the basis of which ASN decides whether or not to allow continued operation of the installation.

The third ten-yearly outages for the 900 MWe reactors began in 2009 at Tricastin 1 and Fessenheim 1 and will end in about 2020 with the Chinon plant. The safety review associated with these ten-yearly outages in particular concerned the following topics: flooding and explosion of internal origin, fire, earthquake, resistance to extreme climatic conditions, protection of water intakes against oil slicks and situations liable to lead to simultaneous loss of the heat sink and the electrical power supply.

In July 2009, ASN adopted a public stance concerning the generic aspects of continued operation of the 900 MWe reactors. ASN has not identified any generic problem such as to compromise EDF's ability to ensure the safety of its 900 MWe reactors up to a service life of 40 years.

This ASN generic position will be subsequently supplemented by a specific position reactor by reactor following their third ten-yearly outages, primarily on the basis of the results of the checks carried out during the conformity check on

reach reactor during the third ten-yearly outage and on the assessment contained in the safety review report on each reactor.

## Inspection and maintenance work carried out by EDF on the steam generators

In recent years, the checks carried out on the steam generators during maintenance and refuelling outages or following isolated incidents, revealed a degree of deterioration. Some of this, which was both significant and unexpected, required that EDF take large-scale maintenance measures on a number of the power generating reactors in operation in France, with the inevitable consequences for reactor availability. ASN ensures that the level of safety of these steam generators remains satisfactory. ASN also asked EDF to conduct a complete review of its surveillance of the steam generator design process, which will in particular make it possible to guarantee that the replacement operations are planned sufficiently far in advance to prevent excessive degradation of the equipment

## Regulation of construction of the EPR reactor in Flamanville

Construction work on the EPR Flamanville 3 reactor began in September 2007, after the Government authorisation was issued on the basis of a favourable opinion from ASN. In this opinion, ASN considered that the design proposed was able to meet the ambitious safety objectives it had set for new reactors.

The next regulatory step is the "commissioning" licence, issued by ASN. In order to prepare for this step, ASN initiated a review in 2007 of certain topics requiring lengthy investigation, and of the detailed design of the most important systems, including the instrumentation and control (I&C) system, so as to be able to reach a decision on their ability to meet the safety requirements. After an in-depth review by IRSN and on the advice of the Advisory Committee for Reactors, ASN in October 2009 sent EDF a letter pointing out the complexity of the proposed design for the I&C system. ASN asked EDF to make changes and to provide additional safety justifications. This position is consistent with that of the Finnish and British regulators, with whom ASN published a joint declaration on 2 November 2009 concerning the safety of the EPR reactor's I&C system.

The EPR reactor safety review follows an iterative process, with industry proposing solutions and ASN adopting a stance on these proposals. ASN's positions can naturally lead to

design changes. A detailed technical dialogue of this nature is a means of promoting enhanced safety. The ASN position of October 2009 concerning I&C is just one step in this iterative process.

At the same time, ASN checks the construction of the reactor (detailed design studies, manufacturing in the plant, construction site), through documentary examinations and inspections proportionate to the safety, radiation protection and environmental protection issues. With the help of IRSN, ASN thus carried out 9 inspections in the engineering centres and 24 on the construction site. ASN also carried out or delegated to approved inspection organisations the performance of more than 1,600 inspections on this equipment on the premises of the manufacturer AREVA NP, its suppliers and their subcontractors. ASN also carried out its conventional safety inspection duties on the construction site.

With regard to civil engineering work on the construction site, whenever anomalies were observed, ASN checked that the way EDF dealt with them was satisfactory in terms of safety. ASN in particular asked EDF to improve the quality of the welds on the steel liner of the reactor building inner containment wall. These anomalies highlight the considerable pressure exerted by the construction schedule.

Concerning the manufacture of the nuclear pressure vessels, ASN evaluates or delegates evaluation by approved inspection organisations of their conformity with the regulatory requirements applicable to this equipment. This evaluation involves documentary examinations and inspections on the premises of the manufacturers, their suppliers and their subcontractors. Two significant anomalies discovered at the end of 2008 were dealt with in 2009:

- an error in the positioning of an opening drilled in a steam generator component. AREVA NP submitted a proposal to ASN for replacement of this component by another, which had already been manufactured, but whose characteristics were not identical. ASN checked that this proposal was acceptable;
- deviation from the procedures for production of castings at an Italian supplier of AREVA NP. ASN asked that additional mechanical tests be performed on certain components, while asking that certain others be scrapped. It also asked that surveillance of this supplier be increased.

ASN aims to give the above regulatory process an international dimension, by in particular maintaining close ties with the regulators of the countries in which construction of EPR type reactors is in progress (Finland) or planned. In 2009, ASN therefore intensified its cooperation with the British (HSE) and American (NRC) regulators, with the secondment

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General view of the future EPR Flamanville 3 reactor (Manche département) - January 2009

of British and American inspectors to ASN and French inspectors to HSE and NRC. ASN is also playing an active role in the Multinational Design Evaluation Program (MDEP) for new reactors. Four meetings to discuss the EPR reactor have been held as part of this program. Multinational cooperation within the MDEP led in 2009 to the HSE, STUK and ASN reaching consistent positions on the safety of the I&C system. A common stance could also be taken on other subjects, thereby guaranteeing the robustness of the safety reviews conducted.

#### ASSESSMENT BY ASN

ASN considers that 2009 was a relatively satisfactory year in terms of safety and radiation protection in the nuclear power plants.

With regard to routine operations, ASN feels that the efforts made by EDF in recent years to improve operational rigour need to be continued, even though progress was observed on certain sites in 2009.

ASN considers that EDF's preparedness for emergency situations is satisfactory. The national emergency response system was triggered 4 times this year and EDF correctly managed the situation in each case. Lessons must nonetheless be

learned from the operating experience feedback from these trigger situations.

The organisation put into place by EDF in the nuclear power plants to deal with operating experience feedback is on the whole satisfactory. However, ASN considers that EDF needs to improve the quality and depth of the analyses carried out. This point is illustrated by the fact that an incident occurred in 2009 in the Tricastin power plant that was identical to one that occurred the previous year in the same plant.

The equipment maintenance and replacement programs, the periodic safety review approach and the correction of the conformity anomalies identified all help to keep the equipment in the nuclear power plants in a generally satisfactory condition. ASN did however observe that EDF failed to anticipate certain problems far enough in advance, which today oblige it to carry out delicate and large-scale corrective maintenance on the steam generators in order to guarantee their safety. The lack of anticipation in the equipment maintenance and replacement programs also led, on certain steam generators, to extensive inspection and appraisal programs that are essential in being able to determine the condition of this equipment before returning it to service.

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With regard to the performance of maintenance, ASN notes that some operations were marred by quality defects, that EDF must make greater efforts to prevent. The quality of the risk analyses performed in order to prepare the maintenance operations and the extent to which they were assimilated by the participants need to be improved. EDF has to make progress in spare parts management, as spares are not always available and sometimes do not have all the required characteristics.

Most maintenance activities on the sites are entrusted to contractors selected by means of a qualification and evaluation system. ASN considers that this system is satisfactory in principle but that EDF needs to evaluate its contracting policy, because ASN has observed a deterioration in the site surveillance of the activities carried out by the contractors. For ASN, this surveillance needs to be rapidly improved and reinforced. Finally, as in previous years, ASN observed that the material resources are frequently inadequate or inappropriate and that the maintenance staff do not always have the time needed to work calmly.

With respect to radiation protection, and after falling for several years, the dosimetric results from the plants in service have remained at satisfactory levels, despite an increase in doses in 2009. ASN considers that vigilance must be maintained with regard to optimisation of doses during reactor outages and to management of contamination at source.

In the field of environmental protection, ASN considers that on the whole, the EDF situation in 2009 regressed, especially concerning non-radioactive discharges. A significantly higher number of deviations was observed than in the previous years. ASN considers that EDF will therefore need to take corrective measures.

On the 19 sites:

**Five sites stand out in this general assessment:** Golfech, in all aspects; Bugey, Gravelines and Penly in terms of nuclear safety, in particular operating rigour; Civaux, in terms of radiation protection.

Four sites are under-performing: Saint-Alban, in all aspects; Chinon and Flamanville in terms of nuclear safety, in particular operating rigour; Belleville, in terms of the environment.

#### OUTLOOK

With respect to the nuclear power plants, ASN's inspection work in 2010 will be guided in particular by the following aspects.

Inspection of the nuclear power plants in operation will remain a priority. ASN considers that maintaining the reactors in good condition will require that EDF continue with its maintenance efforts. The significant extension of the outage times of some reactors in 2009 reflects the scale of the maintenance operations necessary when equipment deterioration



Contrôle review issue dealing with the continued operation of nuclear power plants, July 2009 issue

is not anticipated far enough in advance. With regard to environmental protection, ASN is expecting action from EDF to allow a swift return to a more satisfactory situation. Finally, ASN will be looking in greater detail at the conditions for continued operation of the reactors currently in service beyond their forty year lifespan. This review will be carried out within an international framework.

Work will continue on developing technical regulations that are consistent with European best practices, with the aim of proposing to the Government a coherent set of regulatory texts (ministerial orders, ASN decisions) and related texts (ASN guides) inspired by the "reference levels" adopted in Europe by the WENRA association.

Inspection of the construction of the EPR Flamanville 3 reactor, involving sampling proportional to the safety issues involved, will continue. As the civil engineering and systems erection work peaks, ASN aims to focus its inspection work on conventional safety risks and EDF monitoring of the quality of the construction work. At the same time, ASN will continue to examine certain commissioning application preparatory work, in particular the accident design methods and the installation operating principles. It will aim to cooperate (whenever possible) with its foreign counterparts, to be able to reach harmonised positions. ASN will also begin a review of the conditions for the creation of an EPR reactor in Penly. Finally, for the longer term, ASN will intensify its discussions

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... ASN will be attentive to the results of the steam generator appraisal and inspection programs and to the response it expects from EDF to its letter of October 2009 concerning the EPR I&C  $_{\bullet\bullet}$ ...

with CEA, EDF and AREVA on the safety of the 4th generation reactors.

ASN will be attentive to the results of the steam generator appraisal and inspection programs and to the response it expects from EDF to its letter of October 2009 concerning the EPR I&C.

**NUCLEAR FUEL CYCLE INSTALLATIONS** 

Fuel fabrication and then fuel reprocessing once it has been used in the nuclear reactors make up the fuel cycle. The main plants in the cycle – COMURHEX, AREVA NC Pierrelatte, EURODIF, Georges Besse II, FBFC, Mélox, AREVA NC La Hague – are part of the AREVA group. These plants comprise installations with BNI status.

#### HIGHLIGHTS OF 2009

The periodic safety reviews of the BNIs at La Hague are the subject of intense work by ASN and its technical support organisation, IRSN. In 2008, ASN examined the periodic safety review of BNI 118 which comprises the effluent treatment station (STE3), the organic solvents mineralization facility (MDS-B) and the outfall at sea. The licensee has also started the safety review of BNIs 116 (UP3 plant) and 117 (UP2- 800 plant). When issuing the review guideline document, ASN specifies the main requirements resulting from the BNI decree of 2 November 2007. For the periodic safety reviews of the plants at La Hague, these requirements will in

particular concern the identification and complete description of the elements important for safety.

ASN is reviewing the decommissioning dossiers concerning the BNIs making up the UP2-400 plant which has been shut down since 1 January 2004. This particularly complex review led in 2009 to an initial final shutdown and decommissioning decree for the HAO facility (BNI 80).

In terms of incidents, the significant event of 2009 was that which occurred on 3 March 2009 in the Mélox facility and which was rated level 2 on the INES scale. During the course of an exceptional operation to take delivery of a sample of plutonium and uranium oxide from an entity outside the installation, a mass of fissile material was introduced into a workstation in excess of the applicable safety-criticality limit. This was caused by the application of an inappropriate and not officially documented procedure. It was not due to operator error. Furthermore, the fissile materials accounting software which is used to check compliance with the authorised limits, each time material enters or leaves, failed to generate an alarm because it does not include this type of operation.

#### ASSESSMENT

In 2009, the fuel cycle installations experienced a number of incidents reflecting weaknesses in the safety and radiation protection organisation of the AREVA group's installations. ASN hopes to see greater rigour in compliance with the notification criteria and the time taken to forward the reports of these events, as well as greater focus on the measures to be taken to prevent them happening again.



Aerial view of the La Hague site (Manche département)

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ASN considers that the operating results of the La Hague plants are on the whole satisfactory, in particular concerning personnel exposure. However, ASN does feel that efforts are still needed, especially on the occasion of the periodic safety reviews of the installations, when drafting general operating rules and defining the elements important for safety. Moreover, certain significant events revealed a lack of rigour in the operation of the plants.

With regard to the installations of the Tricastin site and although ASN sees in a positive light the changes which led to shutdown of the older installations and their replacement by plants with a higher level of safety, it is nonetheless concerned by the recent postponement of some projects felt to be essential, such as that concerning the site's effluent and waste treatment stations.

On the FBFC site in Romans-sur-Isère, ASN will in 2010 be closely monitoring confirmation of the progress already achieved in terms of safety. It in particular hopes to see good management of the waste storage areas. It will also be attentive to the steps taken further to the safety review of the facilities of the CERCA company.

#### OUTLOOK

In 2010, with regard to the nuclear fuel cycle installations operated by AREVA, ASN will be continuing the actions it initiated in 2009, in particular when reviewing the licensing applications and periodic safety reviews scheduled. Its actions will be defined by individual requirements incorporating the broad outlines of the regulatory texts currently being drafted.

ASN will also ensure that the shutdown of the Eurodif plants is prepared in accordance with the conditions specified in the TSN Act, particularly with regard to public communication.

Concerning the MELOX plant in Marcoule, ASN will remain attentive to the organisation and the resources deployed to increase the production capacity of this industrial tool and to monitor the changes to the materials employed. Dosimetry management and the ability to prevent risks linked to human factors will therefore remain inspection priorities. Shortcomings in the management of the criticality risk, especially with regard to the functioning of the nuclear materials mass monitoring software, were revealed by the incidents in 2008 and 2009. ASN will therefore be vigilant with respect to the handling of this risk, in particular during the periodic safety review of the installation scheduled for 2010-2011.

ASN will in particular ensure that the licensee complies with the deadlines for return of foreign waste to its country of origin

With regard to the recovery of legacy waste from the La Hague site, ASN is concerned by the U-turns in AREVA NC strategy, which are significantly delaying the recovery and

removal of the waste from the 130 and HAO silos. Here also, ASN will ensure that there is no slippage in the time-frame.

Finally, ASN notes the satisfactory transition at La Hague from a Special and Permanent Information Committee (CSPI) to a local information committee (CLI) in compliance with the requirements of the TSN Act, and in 2010 it will be encouraging the licensee to communicate about the major safety milestones for its installations, especially the periodic safety reviews which have started and the internal authorisations system, for which ASN should complete its review in 2010.

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## NUCLEAR RESEARCH AND OTHER NUCLEAR INSTALLATIONS

Nuclear research installations and installations not directly linked to the nuclear power generating industry include all the basic nuclear installations of the civil part of the French Atomic Energy Commission (CEA), the BNIs of other research organisations and several other BNIs which are not power reactors and which are not a part of the nuclear fuel cycle.

#### HIGHLIGHTS OF 2009

#### Safety management at CEA

In its 2008 annual report, ASN mentioned that it wanted CEA to strengthen the inspection role of its general and nuclear inspectorate and give it greater independence to enable it to express its assessment of the safety of CEA installations at the highest level. ASN notes with satisfaction the guarantees it received from CEA on this point in 2009, while continuing to deplore the fact that the hierarchical position of the general and nuclear inspector has not changed and does not correspond to the announced roles and level of independence.

#### CEA internal authorisations

CEA was the first licensee to implement a system of internal authorisations in 2002. This system, now governed by decree 2007-1557 of 2 November 2007, will be the subject of an ASN decision at the beginning of 2010. ASN considers that the system set up at CEA in 2002 is exemplary.

#### CEA management of civil engineering projects

ASN is particularly attentive to the construction of new installations or the renovation of existing installations by CEA. ASN thus carried out an in-depth review, jointly with the Defence Nuclear Safety Authority (ASND), on projects in progress at Cadarache. As a result of this review, ASN confirmed the mobilisation of CEA and the responsible attitude of its staff. Nonetheless, the exhaustiveness and effectiveness of the internal checks carried out by CEA, on both prime contractor and subcontractors, needs to be further improved.



The CEA PHENIX reactor in Marcoule (Gard département)

The PHÉNIX reactor, which was commissioned in 1973, was finally shut down on 6 March 2009. The rest of 2009 was devoted to performance of "end of life" tests. These tests are designed to provide additional data on sodium-cooled fast neutron reactor technology, with a view to the development of "generation IV" power generating reactor technology. The reactor decommissioning licence application should be sent to ASN in 2010.

## The installations of the European Organisation for Nuclear Research (CERN)

The safety of the LHC and SPS installations is governed by a convention between the French Government and CERN. A convention on radiation protection also exists between the Swiss Government and CERN. In order to clarify this situation, ASN and the Swiss Federal Office of Public Health

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... It is important that CEA devote financial and human resources to the correct performance of these "major commitments".

It wants to see this approach become a virtuous one, which implies its rigorous implementation. This is why, in 2009, ASN asked CEA to continue with this approach, which should lead to improved project management

prepared in 2009 a single tripartite convention jointly with CERN, to deal with nuclear safety and radiation protection in CERN's installations.

## The radiopharmaceuticals production installation operated by CIS bio International

CIS bio International is a key player on the French market for radiopharmaceutical products used for diagnostic and therapeutic purposes. Most of these radionuclides are produced in BNI 29 in Saclay. ASN considers that the safety management system at CIS bio International needs to be improved and that the resources devoted to nuclear safety and radiation protection in BNI 29 are inadequate. It therefore issued decision 2009-DC-145 on 16 July 2009, requiring CIS bio International to remedy this situation.

#### ASSESSMENT

In 2007, ASN noted with satisfaction CEA's presentation of a tool allowing supervision at the highest level of decisions concerning both the upgrading of older installations and new projects, thus guaranteeing greater transparency and offering ASN greater visibility of processes liable to delay complex projects with high nuclear safety and radiation protection stakes. This concerned about twenty major commitments focusing priorities on areas with the highest risk. In 2008, budgetary considerations forced CEA to request the postponement of certain items. ASN considers that the "major commitments" approach, which includes an official six-monthly review by CEA, and which ring-fences a small number of projects with high stakes, is designed precisely to prevent such postponements for any reasons other than unforeseen technical difficulties duly documented. It is important that CEA devote financial and human resources to the correct performance of these "major commitments". It wants to see this approach become a virtuous one, which implies its rigorous implementation. This is why, in 2009, ASN asked CEA to continue with this approach, which should lead to improved project management.

#### OUTLOOK

In 2010, ASN will continue to pay particularly close attention to CEA's management of civil engineering operations on the ongoing installation construction sites and on worksites where existing installations are being renovated. With regard to the criticality risk, ASN notes that CEA has undertaken the removal of unused sources, in particular neutron sources, and begun verification of the conformity of its installations with their safety requirements. In 2009, CEA in particular brought to light discrepancies in the management of fissile materials, which led to the notification of significant events. In 2010, ASN will be paying particular attention to the continuation of this process and the corrective measures proposed by CEA.

At the request of ASN, ten years after the last review on this topic, CEA submitted a report on the management of safety and radiation protection at CEA. This report will be

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## ... CEA will also be required to analyse the problems observed in its management of the ATPu incident notified on 6 October 2009, so that the necessary lessons can be learned

submitted in 2010 for review by the "Laboratories and plants" and "Reactors" Advisory Committees. This review will in particular look at skills management, the role of the various players at CEA and, in particular, the powers and independence of the general and nuclear inspectorate, and the management of safety and radiation protection in the projects. Aspects linked to safety management by subcontractors will be looked at especially closely, as ASN attaches great importance to:

- clarification of the interfaces between CEA and its subcontractors;
- management and monitoring by CEA of its subcontractors;
- reinforcing the safety culture of subcontractors.

CEA will also be required to analyse the problems observed in its management of the ATPu incident notified on 6 October 2009, so that the necessary lessons can be learned.

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... ASN submitted its installations decommissioning policy to HCTISN in 2009, on the basis of a memorandum which was released for public consultation in 2008

THE SAFE FINAL SHUTDOWN AND DECOMMISSIONING OF BASIC NUCLEAR INSTALLATIONS

#### Drafting of regulatory policy and requirements

Decommissioning, a phase which covers all activities carried out after shutdown of a nuclear installation and until the final state is reached, at present concerns about thirty nuclear installations. This phase comprises both radiological and conventional risks, in some cases similar to those present during the operation of the installation, while for others they are more specific. This is a crucial subject, for which ASN has gradually defined the regulatory requirements and policy.

ASN submitted its installations decommissioning policy to HCTISN in 2009, on the basis of a memorandum which was released for public consultation in 2008.

The revision of the policy for complete clean-out of structures was the subject of particular stakeholder consultation during the summer of 2009.

With regard to the regulatory picture, ASN sent the nuclear licensees a guide in 2009 specifying the regulations

applicable to decommissioning operations, as a result of the changes introduced by the TSN Act and its implementing decrees, and taking account of the work done by WENRA.

With regard to the financing of decommissioning, ASN examined the changes made to licensee strategy. Although significant efforts on the part of the licensees must be mentioned, certain elements are still incomplete with regard to the financing of legacy waste management, the precision of the scenarios proposed and the conformity with the final target states, some of which do not correspond to ASN policy in this area.

## The situation of nuclear installations being decommissioned in 2009

EDF reactor decommissioning operations in 2009 were on the whole satisfactory.

A new decommissioning licence application dossier was submitted for the Brennilis plant. In June 2009, it was deemed to be acceptable and it was thus possible to submit it for public inquiry at the end of the year.

Owing to the possible delay in the creation of a disposal centre for graphite waste, ASN asked EDF to look at a management strategy for this waste, with the possible construction of interim storage facilities.

With regard to decommissioning of CEA installations, ASN considers that it is on the whole proceeding satisfactorily. The year was mainly marked by the incident in the ATPu, during which the quantities of plutonium placed in the glove boxes during operation of the installation had been underestimated. Owing to the shortcomings observed in the management of



The HAO facility at La Hague during decommissioning in 2007 (Manche *département*)

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... Even if nuclear installation decommissioning activities have today developed as far as the industrial stage, ASN considers that there is still room for improvement

this incident by CEA, it will need to learn all the relevant lessons, particularly with regard to safety management.

The delicensing of the Harmonie reactor in Cadarache, announced in June 2009, illustrates the feasibility of complete decommissioning.

Concerning the decommissioning of AREVA installations, the year was marked by the publication of the final shutdown and decommissioning decree for the HAO facility at La Hague.

#### OUTLOOK

Over and above the individual decommissioning of each installation, ASN ensures that the licensees overall strategies are consistent with the constraints inherent in safety and radiation protection.

In the licensee strategies, ASN gives particularly close attention to the availability of waste disposal routes, management of flows and capacity, the consideration given to uncertainties and unforeseen technical problems, organisational arrangements, etc.

Even if nuclear installation decommissioning activities have today developed as far as the industrial stage, ASN considers that there is still room for improvement, especially in terms of the consistency of licensee decommissioning strategies, estimating the cost of the decommissioning operations, consideration of human and organisational factors and the application of all the rules introduced by the TSN Act with regard to transparency and involvement of the public in the decommissioning projects.

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#### RADIOACTIVE WATE AND POLLUTED SITES

The management of radioactive waste is regulated by the 28 June 2006 Act on the sustainable management of radioactive materials and waste. This Act specifies a roadmap for management of all radioactive waste, in particular by requiring the adoption every 3 years of a National Radioactive Materials and Waste Management Plan (PNGMDR). The aim of the PNGMDR is to inventory existing management methods for radioactive materials and waste, to identify fore-seeable needs for storage and disposal facilities and to clarify the capacity needed for these installations, along with the storage time-frame. Concerning radioactive waste for which there is as yet no final management solution, the PNGMDR defines the objectives.

#### HIGHLIGHTS OF 2009

## The National Radioactive Materials and Waste Management Plan (PNGMDR)

In 2009, the multipartite working group responsible for drafting the PNGMDR, coordinated by ASN and the Ministry responsible for Energy (MEEDDM), prepared the 2nd version of the PNGMDR (2010-2012). This edition was supplemented by a part dealing with the question of reusable materials and the overall coherence of the nuclear fuel cycle. This plan will be sent to Parliament at the beginning of 2010 and will be analysed by the French Office for the Evaluation of Scientific and Technological Choices (OPECST). The stipulations of the PNGMDR will be contained in a decree prepared by the MEEDDM and ASN.

#### Waste management in BNIs

At the end of September 2009, ASN gave a favourable opinion on the draft authorisation decree for creation of the ICEDA storage facility to be operated by EDF. The role of this installation will be to process and store radioactive waste from BNIs currently being operated by EDF, from the decommissioning of first generation reactors and from the decommissioning of the Creys-Malville plant.

#### Uranium mining waste

In 2009, there was considerable activity surrounding the management of former uranium mining sites. First of all, ASN reviewed the study submitted by AREVA into the long-term impact on health and the environment of the disposal facilities for the mining residues from the former uranium ore mining and processing installations. ASN considers that this study is a key milestone in verifying the safety of the uranium ore mining residue disposal sites. The multipartite expert group for the Limousin region's uranium mining sites also continued its work and at the beginning of 2010 should be submitting its report to the MEEDDM and to ASN. Finally, in



View of the spent fuel storage E pool in the Areva NC plant at La Hague (Manche *département*)

order to improve management of the former mining sites, the MEEDDM and ASN issued a circular on 22 July 2009 with a view to continuing and improving the regulation and inspection of these sites.

#### Long-term management of low level long-lived waste

In June 2008, ANDRA sent out an information file concerning the search for a site capable of housing a low level long-lived radioactive waste disposal centre to a number of *communes* which were in principle located in areas with potentially favourable geology. The candidate *communes* had until the end of October 2008 to make themselves known.

In June 2009, ANDRA announced the Government's decision to conduct in-depth investigations in two communes in the Aube *département* and thus check the feasibility of siting a disposal facility there. However, the municipal councils of the two above-mentioned *communes* decided to withdraw from the project during the summer of 2009. This disposal facility project required by the 28 June 2006 Act and considered by ASN to be essential, is therefore at present stalled.

#### Disposal in deep geological formations

The 28 June 2006 Act specifies a calendar prior to the 2025 commissioning – subject to licensing – of a reversible disposal facility in a deep geological formation. ANDRA therefore proposed to the Ministers responsible for energy, research and the environment an area of interest of 30 square kilometres for the detailed reconnaissance survey, with a view to siting the underground installations of the future disposal centre (ZIRA). ASN sent the Government a favourable opinion at the beginning of 2010 concerning the choice of the ZIRA.

At the end of 2009, ANDRA also sent ASN a file presenting an update of the safety and reversibility options for the disposal site.

#### Assessment and outlook

ASN considers that the 28 June 2006 Act and the PNGMDR provide a clear, coherent and complete framework for management of radioactive waste in France. It also considers that the procedures for discussing and debating the subject of radioactive waste, particularly with respect to the PNGMDR, are satisfactory.

In 2009, ASN continued its actions to ensure that radioactive waste is managed safely, from the moment of production onwards. ASN thus checks how it is managed within the nuclear installations and periodically evaluates the management strategies adopted by the licensees. ASN took a stance in 2006 on the possible recovery of legacy waste from the AREVA NC plant at La Hague. It would appear that, even if AREVA NC has sufficient means to implement its recovery

strategy, the safety of several storage facilities such as the HAO silos is unsatisfactory. ASN will remain attentive to verifying that the strategy changes announced by the licensee in 2009 do not compromise the announced time-frame for removal of the waste from storage.

In order to improve the safety of its waste and spent fuel treatment and storage installations, CEA had envisaged the creation of new installations plus the renovation of certain others. ASN observes that CEA is experiencing difficulties with meeting its overall commitments, especially in terms of the time-frame.

A new summary report on CEA's waste strategy will be transmitted in mid-2010. ASN will be attentive to ensuring that CEA presents a coherent and well-structured strategy for managing all existing and future waste, identifying the waste treatment, packaging, transport and storage needs and the expected resources (human and material) that will be required to meet these needs. ASN will also ensure that CEA complies with the storage removal schedules.

With regard to EDF, ASN will in 2010 review the document transmitted by EDF at the end of 2008 concerning the coherence of the nuclear fuel cycle.

With respect to the long-term management of radioactive waste, ASN is concerned by the problems being encountered in identifying a disposal facility for low level long-lived waste. ASN also considers that ANDRA is conducting thorough and responsible studies into the deep geological formation reversible disposal site project.

Since 2002, ASN has been involved in regulating and inspecting sites polluted by radioactive materials. In this field, ASN has intensified its actions and this will continue in 2010 in collaboration with the administrations concerned and the other stakeholders (ANDRA, IRSN, local authorities, associations, etc.). ASN stresses once again that in its view the solution whereby the contamination is kept in place on the site cannot be considered the reference solution for the management of sites polluted by radioactive materials and that this option can only be seen as an interim or standby solution for situations in which complete clean-out cannot be envisaged owing to the volume of waste to be excavated.

Finally, ASN will remain closely involved in international work, by maintaining an active role in the WENRA and NEA working groups and seeing through to completion the work which it had revived in 2009, within the European Pilot Group (group of European safety regulators and international bodies), on what is required from the safety demonstration of a deep geological disposal site and the acceptance criteria for radioactive waste.

### CONTR**Ô**LE.

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