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or the French Nuclear Safety Authority (ASN), the year 2006 was marked by two important nuclear laws being passed, one of which brought about a major change in its status. The year was a relatively satisfactory one with regard to nuclear safety, although the picture was more contrasted concerning radiation protection: in this area, more particularly in the medical field, the overall impression of good progress is offset by the declaration of a number of radiotherapy accidents. Given the benefits expected from radiotherapy treatment by the patient suffering from cancer, the conditions in which this activity is carried out are a subject of major concern for ASN, in the light of the serious risks linked to patient overexposure.

With regard to nuclear installations, the operating results achieved by EDF's nuclear power plants is relatively satisfactory in terms of radiation protection, environmental protection and equipment condition. However, despite operational stringency, the efforts made by EDF have not yet borne the expected fruit. ASN considers that CEA has made progress in safety, but that its strategy in these areas must be comprehensive and transparent. ASN is satisfied with the operation of the nuclear installations of the AREVA group, while noting that progress is expected with regard to the whole area of waste management and dismantling of old installations. Finally, the ASN issues a positive opinion of ANDRA's management of the radioactive waste disposal facilities and its research work concerning the Bure site.

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In the medical field, ASN feels that the importance of radiation protection management in the medical risks equation is moving in the right direction, particularly owing to greater involvement by learned societies and professional organisations and associations. However, overexposure of **RADIOTHERAPY** patients in hospitals in Epinal and Lyon show that serious efforts still need to be made in the medical field, more particularly with regard to ORGANISATIONAL AND HUMAN FAC-TORS. At the same time, ASN can see significant progress in incident declaration in this sector. This progress is without doubt the result of a combination of new legislative requirements concerning patient rights and ASN's inspections and awareness-raising campaigns.

In the industrial field except the nuclear industry, characterised by a large number of extremely diverse applications and users, ASN considers that efforts to ensure operational stringency and radiation protection training and awareness-raising must be continued.

2006 was naturally marked by the passing of LAW 2006-686 of 13 June concerning NUCLEAR TRANS-PARENCY AND SAFETY, known as the "TSN LAW". This law achieves major progress on three key points.

Firstly, it improves transparency concerning nuclear safety and radiation protection by setting up a right for the public to access information on these matters that is in the possession of the nuclear licensees and those in charge of transporting radioactive materials. It then overhauls the legislative foundations of the safety of nuclear installations and radioactive material transports. Finally, it consolidates the legitimacy of **ASN** by giving it the status of an **INDEPENDENT** ADMINISTRATIVE AUTHORITY. For ASN this change in status is a major one, but is also the continuation of work begun several years ago to organise coherent and integrated supervision of nuclear safety and radiation protection in France.

At a legislative level, the other important event is the multiyear sectorial estimates law 2006-739 of

Redaction note: The words in black letter, bold and green refer to information sheets that can be read after this foreword.

28 June concerning SUSTAINABLE MANAGEMENT OF RADIOACTIVE MATERIALS AND WASTE. This law, to which ASN contributed by submitting a recommendation to the Government on 1 February and by preparing a radioactive materials and waste management plan, is a key step in the policy of radioactive waste management in France. It is based on fifteen years of research started by the 31 December 1991 law, known as the "Bataille" law, and closely monitored by the Parliamentary office for the assessment of scientific and technological options (OPECST). It confirms the fact that disposal in deep geological formations is the reference solution for high-level, long-lived waste in France. It also provides a true roadmap for management of all radioactive waste, regardless of its nature and origin.

It is also worth noting that considerable progress was made in the process of HARMONISING NA-TIONAL APPROACHES TO NUCLEAR SAFETY in 2006. The Western European Nuclear Regulators Association (WENRA) finalised its reports on a common approach and formally approved that applicable to power reactors. These reports, to which the ASN made a significant contribution, were made public and presented to Brussels on 9 February 2006. On the basis of these documents, defining reference levels for nuclear safety, each country will by 2010 be required to revise its technical regulations and practices and harmonise them. With this in mind, the ASN has already begun work to incorporate these levels into the French regulations.

The context in which ASN is working is marked by the emergence of projects to build new nuclear installations, such as the **EPR REACTOR** on the Flamanville site, the George Besse II ultracentrifuge enrichment plant on the Tricastin site, or the ITER *(International Thermonuclear Experimental Reactor)* facility on the Cadarache site. ASN's role is to ensure that for any new project, the licensee endeavours to attain a very high level of nuclear safety and has the corresponding necessary technical and financial capabilities.

With regard to provision of **INFORMATION TO THE PUBLIC**, ASN considers that the year 2006 was a very fruitful one, in particular in terms of its relations with the media. Its new status and the requirements of the TSN law concerning public access to the information in the possession of the licensees, further enhanced ASN's role in this area and suggests that there will be new prospects and issues in 2007.

It should also be pointed out that in order to obtain an objective outside view of its activities, ASN asked the International Atomic Energy Agency (IAEA) to organise a **PEER REVIEW** by the **IRRS** *(Integrated Regulatory Review Service)*. The report on the review, which ran from 5 to 17 November, is available on ASN's website www.asn.fr. The overall impression is a positive one, reflecting satisfactory general working on the part of ASN, underpinned by a sound and solid base.

Regulation of nuclear installations and radioactive material transports

Operating results from the EDF nuclear reactors are relatively satisfactory, in particular with regard to radiation protection and protection of the environment. However, the conditions of work by subcontractors and EDF's surveillance of subcontractors' activities need to be further improved. Moreover, operational stringency has not yet reached satisfactory levels, despite improvement work carried out over the past two years by EDF. In 2007, ASN will be looking particularly closely at these various subjects.

The condition of plant equipment is for its part satisfactory. The work done during the periodic safety reviews means that safety is constantly improved. This year, the second ten-yearly inspections of the 900 megawatt reactors continued and will be completed in 2010. ASN also declared itself in favour of continuing operation of the 1300 megawatt reactors following their second periodic safety review. The second ten-yearly inspections for all these reactors, which began in 2005, will continue until 2014.

The internal authorisations process set up by EDF in 2005, in particular for reactor restart af-

ter outages without significant maintenance, was checked by ASN, and it was considered that this process was functioning correctly.

Finally, on 9 May, EDF sent the ministers responsible for nuclear safety the application for authorisation to create an EPR model reactor on the Flamanville site. EDF considers this reactor to be a "first-off" new generation reactor. ASN judged the safety options for this reactor to be in compliance with the regulatory requirements and technical instructions notified in 2004 for this generation of pressurised water reactors. In early 2007, the Government will make a final decision on whether or not to issue the authorisation decree to allow construction to commence.

ASN considers that progress in safety has been achieved by CEA, although in a somewhat unbalanced way, with emphasis placed on research tools to the detriment of the support installations, including effluent and waste treatment facilities. ASN considers that CEA must rapidly adopt a safety and radiation protection policy and strategy that is comprehensible and transparent to the safety authority, accompanied by a control tool enabling it to meet its commitments and thus fully assume its responsibility as a nuclear licensee.

In the field of research, the creation of an international organisation responsible for operating the ITER installation to be built on the Cadarache site must be noted. ASN has no particular nuclear safety concerns but, in particular by preparing a convention clarifying the international agreements, will ensure that the licensee is able to assume its full responsibilities and act in conformity with French regulations concerning basic nuclear installations, without taking undue advantage of diplomatic immunity.

With regard to the nuclear fuel cycle, the efforts devoted each year to inspection of the CO-GEMA La Hague plants confirm ASN's opinion of the stringency and responsibility shown by the licensee. However, on this site, the collection of waste from past practices and dismantling of the former UP2-400 plant are subjects on which ASN is waiting for firm commitments from CO-GEMA. ASN also considers that integrating all the French fuel cycle operators into the AREVA group would lead to greater consistency in the operation of the various installations. However, incidents such as that rated level 2 on the INES scale, which happened on 6 November in the ATPu facility at Cadarache, acts as a reminder that vigilance is still needed in day to day operations. Furthermore, against a background of increasingly difficult economic constraints, ASN ensures that the technical solutions adopted by industry have no detrimental consequences for nuclear safety and radiation protection.

ASN's opinion of the ANDRA is a positive one, both with regard to the research carried out at Bure into the deep geological disposal of highlevel, long-lived radioactive waste, and to operation of the waste repositories in the Manche region, at Soulaines-Dhuys and Morvilliers. Efforts will have to be continued in order to meet the proactive targets set by the law of 28 June 2006.

Finally, with respect to the safe transport of radioactive substances, 2006 saw no particularly significant events. At the request of the ASN, EDF took corrective measures to put an end to the regulatory contamination limit overshoots that had been observed in 2005. The IRRS review carried out in November also enabled the auditors to examine ASN's follow-up to the TranSAS (*Transport Safety Appraisal Service*) audit mission organised by the IAEA in 2004. It would seem that ASN has implemented all the recommendations and suggestions formulated on this occasion and also took account of good practices identified during the TranSAS audits carried out in other countries.

The 13 June 2006 law on nuclear transparency and safety, and its implementing decrees will once published - carry out an in-depth overhaul of the regulations applicable to BNIs. These new decrees will repeal the 1963 BNI decree and the 1995 decree on liquid and gaseous effluent discharges from BNIs.

Supervision of small-scale nuclear activities and radiation protection regulations

In the medical field, ASN still observes that the way radiation protection is dealt with is inconsistent. Improvements are visible, owing on the one hand to the more intense regulation by ASN, and on the other owing to rising awareness of the issues of radiation protection by the medical profession, thanks to increased involvement by learned societies and professional organisations in awareness-raising and training with a view to implementing good practices. Unfortunately the radiotherapy accidents declared over the past two years show that serious efforts still need to be made, particularly with respect to managing organisational and human factors, in order to improve the level of radiation protection. Owing to the serious medical consequences in the event of an accident, radiotherapy will remain ASN's main priority for regulation and awareness-raising. In this area, ASN is a key driving force, together with the Ministry for Health and its health agencies, in setting up an action plan for the safety of radiotherapy patients. ASN is also pursuing a policy designed to achieve greater transparency surrounding medical incidents, while preserving medical secrecy in all aspects concerning the patients.

In the industrial field, characterised by a large number of ionising radiation applications and users, ASN considers that, as in previous years, the efforts made in radiation protection training and awareness-raising need to be continued. ASN will carry on giving particularly close attention to the radiography sector, which is the activity entailing the highest risks.

While producing regulations and examining administrative procedures, ASN continues its efforts to set up a system of inspections on medical and industrial nuclear activities. In order to improve transparency and experience feedback in these fields, ASN will also in 2007 be setting up an experimental system for declaration of significant events. This system, inspired by the incident declaration procedure in use for many years in nuclear installations and for transportation of radioactive materials, aims to improve experience feedback in small-scale nuclear activities.

The ambitious work carried out to update the radiation protection legislation and regulations, started by ASN in 2002, was practically completed in 2006, with publication of the final decrees implementing the Public Health Code and the Labour Code. At the same time, ASN undertook to update the regulatory part of these two codes to ensure transposition of directive Euratom 2003/122 concerning supervision of high-level sources, integrate the new prerogatives given to ASN by the TSN law and effect clarifications and simplifications based on the experience acquired over four years of small-scale nuclear activity supervision. These modifications should be published in the first quarter of 2007.

Finally, in order to be in a position to influence the work constituting the basis for the radiation protection regulations, and therefore to anticipate future changes, ASN actively participates in the basic radiation protection standards revision process initiated by IAEA and the European Commission, which is already preparing the new European directive designed to update the Euratom 96/29 directive. These revisions take account of the future recommendations of the ICRP (International Commission on Radiological Protection) expected during the course of 2007. In this context and in that there is no scientific justification, ASN told the ICRP that it was not in favour of laving down any new recommendations extensively modifying the current system, at a time when France and most of the other States have just updated their regulations.

Radioactive waste management

The year 2006 was marked by the introduction of the multiyear sectorial estimates law 2006-739 of 28 June concerning the sustainable management of radioactive materials and waste. This law, announced by law 91-1381 of 30 December 1991 concerning research into radioactive waste management and known as the "Bataille" law, was preceded in 2005 by a remarkable report from the members of parliament Claude Birraux and Christian Bataille, made public by the OPECST, followed by a public debate organised under the supervision of the national public debates commission. Preparation of the law was also in part based on the recommendations from the national assessment commission set up further to the "Bataille" law and on the position adopted by ASN. This position, which concerned both management of high-level, long-lived radioactive waste and the management of all other waste and materials, was fully incorporated into the 28 June law.

This multivear sectorial estimates law plots a roadmap for the management of radioactive waste in France. With respect to high-level, longlived radioactive waste, it specifies that the three avenues of research stipulated by the "Bataille" law are complementary but indicates that reversible disposal in deep geological formations is the reference solution. The law states that a new law will be passed no later than 2015 to define the reversibility conditions. With regard to the other types of waste, the law sets deadlines for the study of solutions, for example concerning the graphite produced by dismantling of the first generation of nuclear power plants, or for industrial radioactive sources. The law adopts the principle of preparing and updating a national radioactive materials and waste management plan (PNG-MDR) on which ASN has been working for more than three years. Furthermore, the law explains the principle of banning the disposal of foreign radioactive waste in France. The law also enhances the role of the ANDRA, in particular by assigning it a public service duty to take charge of waste in the event of defaulting by the party responsible. Finally, the law very precisely defines the future obligations of nuclear licensees in terms of setting up provisions for funding management of radioactive waste and dismantling.

Radiological emergencies

With regard to preparedness for radiological emergencies, the year was devoted to intense work by the post-accident management committee set up by ASN in 2005. This committee's aim is to have at its disposal in 2007 the basis of a doctrine on the subject. Hitherto, the public authorities had concentrated their efforts on preparing for management of the emergency phase. It is therefore important to clarify the provisions for resolving complex problems such as managing the health of the populations, the economic consequences and rehabilitation of contaminated areas. ASN hopes to organise a seminar by the end of 2007 to present the work of the post-accident management committee.

2007 will also be devoted to incorporating ASN's new status into the national emergency organisation. The changes will however be limited because the TSN law stipulates that, as in the past, the role of ASN is to assist the government in the event of a nuclear accident and forward all useful recommendations to the public authorities.

Provision of information of the public

Informing the public is one of ASN's key duties, which has been confirmed by each institutional reform to the supervision of civilian nuclear activities in France and broadened to take in all areas of competence covered by ASN, in line with its changing role.

ASN's public information activities continued apace in 2006. The increased audience for its www.asn.fr website confirms its position as ASN's number one means of communication and its overhaul at the beginning of October should further improve information accessibility and clarity. Relations with the press in 2006 were regular and occasionally extremely intense.

The IRRS international audit in November confirmed the very high level achieved by ASN with regard to public information and stated that its actions in this field constituted "good practice" and an international benchmark.

In 2007, ASN will continue its efforts to see that the public receive information that is objective, clear and of good quality. ASN will endeavour to ensure that the various provisions of the TSN law are implemented: right of access by the citizens to the information in the possession of the BNI licensees and those responsible for transporting radioactive materials, a new status and guaranteed long-term financing for the CLIs, creation of a High Committee for transparency and information on nuclear safety.

For its part, ASN will continue and will extend its public information policy; in order to raise its own profile, strengthen its credibility and legitimacy and enable the citizens to forge their own opinion of nuclear safety.

The results of ASN opinion and recognition survey obtained at the end of 2006 show a rise in the general public's familiarity with ASN in relation to 2005: 21% (as against 16% in 2005) of those questioned replied that they recognised the name of the ASN and were certain that an organisation in charge of regulating nuclear matters in France existed. These results are encouraging and need to be confirmed.

ASN's technical support organisation

In order to carry out its nuclear safety and radiation protection supervision duties, ASN calls on the services of expert appraisal organisations, with pride of place given to IRSN. The quality and pertinence of IRSN's work are the pre-conditions for effective supervision by ASN. The TSN law states that ASN is required every year to submit its recommendation concerning the share of the state subsidy to IRSN that corresponds to the Institute's support work for ASN, thus enabling the authority to back-up IRSN's budget requests.

ASN and IRSN also work together in improving the transparency of the technical examination process which enables ASN to reach its decisions, in order to improve information of the public. The aim of this work is to define the procedures whereby IRSN can make public the opinions it sends to ASN.

With regard to public information, it is worth mentioning the opening of the <u>www.mesure-radioactivite.fr</u> website, jointly produced by ASN and IRSN. Its objective is to inform any citizen who so wishes about the state of radioactivity in the environment in France.

Finally, one should underline IRSN's internationally recognised know-how in responding to an irradiation or contamination accident. This year, IRSN intervened rapidly and appropriately to radiography accidents in Dakar and Abidjan and to the radiotherapy accident in Epinal.

IRSN also contributed to developing new therapeutic procedures (autografting of mesenchymatous stem cells and use of cytokines) to treat irradiation lesions. They were successfully applied in treating two irradiation victims, one from Chile and one from Belgium

ASN as an independent administrative authority

The law gives the Nuclear Safety Authority (ASN) the status of an independent administrative authority with responsibility, on behalf of the State, for supervising nuclear safety and radiation protection.

ASN is run by a board of five commissioners appointed for six years, three by the President of the Republic and one by the President of each of the two houses of parliament. These commissioners can only be revoked in exceptional circumstances and are bound by a duty of impartiality. ASN is accountable to Parliament, to whom it submits its annual report.

By decree or order, the Government defines the general regulations applicable to nuclear activities. It makes a limited number of major individual decisions concerning the key nuclear installations, in particular the authorisation and dismantling decrees. It is responsible for civil protection in the event of an emergency.

ASN is responsible for supervising nuclear activities, both in the large nuclear installations (Basic Nuclear Installations – BNI) and the "small-scale" nuclear installations (industrial facilities, research laboratories and medical installations using ionising radiation). ASN must be consulted on the nuclear safety related regulatory decrees and orders issued by the Government and may issue decisions to clarify them. It takes individual decisions concerning nuclear activities (for example a basic nuclear installation authorisation decree, authorisation to use a radioactive material transport packaging, authorisation to use a radioactive source, etc.) and may impose individual requirements on the licensees. It is responsible for inspections and may pronounce sanctions, up to and including suspension of operation of an installation. It organises a permanent watch on radiation protection (surveillance of the environment, of worker exposure, etc.) and assists the Government in the event of an emergency.

ASN is responsible for contributing to informing the public about nuclear safety and radiation protection.

The board of five commissioners, who held their first meeting on 13 November, is already actively involved in the very busy schedule it set for itself. Its first task was to draw up the ASN's internal regulations. The board also issued opinions to the Government concerning individual decisions such as the creation of the EPR type reactor and the Georges Besse II enrichment plant, and concerning the decrees modifying the Labour and Public Health Codes.

2007 will be a year of intense work for ASN, in order to implement the provisions of the TSN law, including by drafting the numerous implementing texts, and the recommendations made on the occasion of the IRRS review carried out in November and, for the nuclear safety, the WENRA reference levels.

Against this background, ASN's ambition continues to be the provision of efficient, impartial, legitimate and credible nuclear supervision, that is recognised by the citizens and perceived internationally as a benchmark for good practice.

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