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CHAPTER

CHAPTER REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

The regulation of nuclear activities is one of the fundamental roles of the Nuclear Safety Authority (ASN), involving checking that all users of ionising radiation fully assume their responsibilities and comply with the regulations concerning radiation protection and nuclear safety, with a view to protecting workers, patients, the public and the environment from nuclear-related risks.

Under the terms of article 4 of law 2006-686 of 13 June 2006 concerning nuclear transparency and safety, ASN is responsible for supervising compliance with the general rules and special requirements for nuclear safety and radiation protection applicable to:

-the basic nuclear installations (BNIs) defined in article 28 of the law;

-the construction and use of pressure vessels specifically designed for these installations;

-transports of radioactive materials (TMR);

- the activities mentioned in article L. 1333-1 of the Public Health Code and the persons mentioned in article L. 1333-10 of the same code, these activities being known as small-scale nuclear activities.

ASN also regulates radiation protection in premises where exposure of persons to natural radiation can be enhanced owing to the underlying geological context (radon in premises open to the public) or the characteristics of the materials used in industrial processes (non-nuclear industries).

In the case of BNIs, regulation by ASN extends to nuclear safety and protection of the environment. Given the specific technical constraints that exist in electricity generating plants comprising one or more BNIs, labour inspectorate duties are carried out by ASN personnel.

Regulation by ASN is part of a multi-level approach and is carried out with the support of the Institute for Radiation Protection and Nuclear Safety (IRSN):

-before the licensee performs an activity requiring licensing, through a review and exhaustive analysis of files, documents and information provided by the licensee to back up its actions. This review aims to ensure that the information supplied is credible and complete with respect to the interests protected by law;

-subsequently, through visits and inspections on all or part of an installation. This regulation uses the principle of spot checks and analysis of the justifications provided by the licensee concerning the performance of its activities and the analysis of any deviations and incidents it has observed.

ASN goal of guaranteeing efficient, impartial, legitimate and credible regulation is expressed through its respect for the values of competence, independence, rigour and transparency. In order to buttress the credibility and quality of its actions, ASN strives to aim for continuous improvement of its supervisory practices by drawing on the experience gained from more than thirty years of nuclear safety inspections, from observation of small-scale nuclear activity practices for 4 years, and from observation of the inspection methods employed by the main foreign safety authorities. In this way, ASN:

-like the main foreign safety authorities, defined a system of qualification for its inspectors, based on a recognition of their technical competence. This system is today regulated by a decree and was identified as a good practice in the audit report from the IRRS (Integrated Regulatory Review Service);

-adopted certain foreign experiences identified through exchanges of inspectors between safety authorities, either for a particular inspection, or for longer periods up to and including a 3-year assignment. Aware of the benefits to be gained from conducting broader-based inspections, involving larger numbers of people for a longer time, ASN adopted the in-depth inspection model described in this chapter. On the other hand, it did not opt for the system of inspectors resident on the nuclear sites: ASN considers that its inspectors must be in a structure that is large enough to allow experience to be shared and must take part in inspections of different licensees and installations. This should also help rule out any risk of collusion with the licensee;

-encourages an open-minded attitude on the part of its inspectors to other supervisory practices. ASN promotes professional careers encompassing other supervisory authorities (classified installations, SEVESO installations, French Health Products Safety Agency (AFSSAPS) and proposes organising joint inspections with them (labour inspectorate, inspectorate for installations classified on environmental protection grounds (ICPE) of activities covered by ASN. In order to identify other methods for risk management by the licensees, the ASN inspectors may also take part in inspections on specialised subjects in installations which do not fall within their field of expertise. A nuclear safety inspector was called in by the ICPE inspectorate to deal with the subject of fire during the inspection of a paint manufacturing plant in the *Nord département¹* and a hydrocarbons depot in *Côte-d'Or*.

Although traditionally focused on verification of the technical conformity of installations and activities with regulations or standards, inspection today incorporates a wider dimension covering human and organisational factors. It includes a review of individual and collective behaviour, management, organisation and procedures, on the basis of a variety of indicators: significant events, inspections, relations with the stakeholders (personnel, licensees, contractors, trade unions, occupational physicians, inspectorates, etc.). This regulation does not relieve the user of ionising radiation of the need to organise its own in-house supervision of its activities.

ASN aims to ensure that the principle of responsibility of the licensee for safety and radiation protection is respected. It includes the concept of proportionality when determining its actions, so that the scope and extent of the inspection is commensurate with the health and environmental safety stakes. In this respect, it relies on current scientific and technical knowledge to assess the issues involved in the operations or activities concerned.

This chapter presents the procedures involved in the regulation conducted by ASN, on the one hand of BNI licensees and transporters of radioactive materials, and on the other of users of ionising radiation. It also presents the procedures for monitoring exposure to natural radiation.

1 REGULATION OF BASIC NUCLEAR INSTALLATIONS AND RADIOACTIVE MATERIAL TRANSPORTS

In its Safety Fundamentals for nuclear installations (Safety Series 110) the International Atomic Energy Agency (IAEA) laid out the following principles:

- responsibility for safety must lie with the licensee organisation;

- the regulatory body must be effectively independent of the organisation in charge of promoting or using nuclear energy. It must have responsibility for licensing, inspection, and formal notices, and must have the authority, expertise and resources necessary for performance of the responsibilities entrusted to it. No other responsibility shall compromise or conflict with its responsibility for safety.

In France, the regulatory body meeting these criteria is ASN.

1. département: French administrative region.

1 | 1

Scope of regulation

1 1 1

Nuclear safety

BNI safety concerns all technical and organisational measures taken at all stages in the life of nuclear installations (design, creation, commissioning, operation, decommissioning, dismantling) to guarantee normal operation, prevent or mitigate the effects of accidents in order to protect the workers, the population and the environment against the effects of ionising radiation. It also comprises technical measures to optimise management of waste and radioactive discharges.

Transport of radioactive materials (TMR1) safety is based on three main factors:

-first and foremost, on the engineered toughness of the packages;

-on transport reliability and certain specially equipped vehicles;

-on an efficient emergency response in the event of an accident.

In its supervisory duties, ASN is required to look at the equipment and hardware in the installations, the persons in charge of operating it, the working methods and the organisation, from the start of the design process up to dismantling. It reviews the steps taken concerning safety or the monitoring and limitation of the doses received by the persons working in the installations, and the waste management, effluent discharge control and environmental protection procedures.

1 | 1 | 2

Pressure vessels

A large number of nuclear plant systems contain or carry pressurised fluids and are consequently subject to pressure vessel regulations (see chapter 3, point 2|2|1).

The law of 13 June 2006 states that ASN is in charge of supervising compliance with the general rules and special requirements concerning nuclear safety and radiation protection applicable to the construction and utilisation of BNI pressure vessels. Responsibility for supervising application of the regulations lies with ASN for nuclear pressure vessels containing radioactive materials inside BNIs, and the Directorate for Regional Action, Quality and Industrial Safety (DARQSI) at the Ministry for Industry, for other pressure vessels.

Of the BNI pressure vessels subject to ASN regulation, the main primary and secondary systems of EDF's pressurised water reactors are particularly important systems. Since under normal conditions they operate at high temperature and pressure, their in-service behaviour is one of the keys to nuclear power plant safety.

ASN regulation of these systems is consequently very specific. It is based:

-for the design and construction part, on the order of 12 December 2005 concerning nuclear pressure vessels;

-for the operational part, on the order of 10 November 1999 concerning surveillance of the operation of the main primary system and main secondary systems of pressurised water reactors (PWR).

^{1.} Transport includes all operations and conditions associated with the movement of radioactive materials, such as packaging design, manufacture, maintenance and repair, and the preparation, shipment, loading, routing, including interim storage in transit, unloading and reception at the final destination of the radioactive material loads and packages. Radioactive substances include radioactive materials and radioactive waste.

Pressure vessel operation is supervised. This regulation in particular applies to the in-service surveillance programmes, non-destructive testing, maintenance work, disposition of nonconformities affecting the systems and periodic post-maintenance testing of the systems. The principal PWR files currently being dealt with are discussed below in chapter 12.

1 1 3

Working conditions in BNIs

Supervising application of all requirements relative to labour regulations (in particular working contracts, working hours, personnel representation, health and safety, arbitration and conciliation, in particular in the event of collective labour disputes, advice and information to the employers, employees and personnel representatives concerning their rights and obligations) is the responsibility of the staff of the labour inspectorate.

In nuclear power plants generating electricity, regulation of nuclear safety, radiation protection and labour inspection share a number of common concerns, particularly with regard to the organisation of worksites or the conditions surrounding the use of subcontractors. The legislator therefore gave labour inspector powers to engineers and technicians specially designated to this role by ASN from among the personnel under its authority (article L. 611-4-1 of the Labour Code). They were designated by decision DEP-DEU-0054-2007 of 19 January 2007.

In the other BNIs, exchanges with other labour inspectors can also be a valuable source of information on the employment relations situation, in a nuclear safety and radiation protection context more attentive to the importance of individuals and organisations.

1 | 2

BNIs and radioactive material transport regulation procedures

The operator is required to provide ASN with all data it needs to carry out its inspection functions. The volume and quality of this data should enable the technical demonstrations presented by the licensee to be analysed and the inspections to be targeted. It should also allow identification and monitoring of the key events marking BNI operation or a TMR. The actions specific to inspection of TMR are described in detail in chapter 11.

When ASN supervisory actions reveal failures to comply with safety requirements, penalties can be imposed on the licensees concerned, in some cases, after service of formal notices. Penalties in such cases may consist in prohibiting restart of a nuclear installation or suspending operation until the requisite corrective measures have been taken (see point 1|4).

1 2 1

Technical review of licensee files

Review of the justification documents produced by the licensees and the technical meetings held with the BNI licensees, manufacturers of equipment used in the installations or manufacturers of transport packagings, are one of the forms of inspection carried out by ASN.

At the design and construction stage, ASN checks the safety cases describing and justifying basic design data, equipment design calculations, utilisation and test procedures, and quality organisation provisions made by the prime contractor and its suppliers. ASN also checks the manufacture of pressurised water reactor main primary system (CPP) and main secondary system (CSP) equipment. In

CHAPTER 4 REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

accordance with the same principles, it supervises the packages intended for the transport of radioactive materials.

Once the nuclear installation has started operating, all safety-related modifications made by the licensee are subject to ASN approval. In addition to meetings necessitated by developments in plant equipment or operating procedures, ASN requires periodic safety reviews from the licensees, providing opportunities to reinforce safety requirements according to both technological and policy developments and operating feedback.

Review of this data may lead ASN to accept or on the contrary reject the licensee's proposals, to ask for additional information or studies or to ask for work to bring the relevant items into conformity. ASN requirements take the form of a license or a decision (see point 1|2|4).



The ASN inspectors check a nuclear licensee's registers and operating documents

a) Appraisal of the data supplied

The purpose of much of the data submitted by the licensee is to demonstrate that the objectives set by the general technical regulations or those set by the licensee itself are respected. ASN is required to check the completeness of the data and the quality of the demonstration.

Whenever it deems necessary, ASN seeks the advice of technical support organisations, primarily IRSN. Safety assessment requires both the collaboration of many specialists and effective co-ordination structures to highlight the essential safety issues. The IRSN assessment relies on research and development programmes and studies focused on risk prevention and improving our knowledge of accidents. It is also based on in-depth technical exchanges with the licensee teams responsible for designing and operating the plants.

For major issues, ASN requests the opinion of the competent Advisory Committee of Experts, to which IRSN will present its analyses. For other matters, safety analyses give rise to IRSN opinions

transmitted directly to ASN. ASN procedures for requesting the opinion of a technical support organisation and, where required, of an Advisory Committee, are described in chapter 2.

b) The main fields concerned

• Nuclear power plant scheduled outages

Nuclear power plants are periodically shut down for refuelling and for maintenance of their main components.

Given the importance for safety of the maintenance work done during the outage and the safety hazards involved in certain outage situations, ASN requires detailed information from the licensee. This information mainly concerns the work programme involved (see chapter 12) and any anomalies observed during the outage. During the "site" inspections, the inspectors will carry out spot checks on the conditions in which the various worksites in progress are conducted, whether for repair or for modification of the installations, and the conditions in which equipment is monitored in-service, or periodic equipment testing is carried out.

Approval of the outage programme is the responsibility of ASN.

· Other data submitted by the licensees

The licensee submits routine activity reports and summary reports on water intake, liquid and gaseous discharge and the waste produced.

Similarly, there is a considerable volume of data on specific topics, such as, for example, the plant's seismic behaviour, fire protection, PWR fuel management strategies, relations with subcontractors, etc.

1 2 2

Internal authorisations

ASN looks to ensure that its regulation of nuclear safety and radiation protection is as effective as possible.

Expanding the scope of regulation exercised by ASN in recent years is not without risks: ASN could make all nuclear activities dependent on it issuing an authorisation, without any overall coordination, which could impair ASN efficiency as a whole. Furthermore, this regulation activity has a degree of influence on the level of responsibility of those persons carrying out nuclear activities. The inspector is sometimes incorrectly seen as being the ultimate line of defence, through his attentive reading of the safety files.

For these two reasons - performance of its actions (proportional to the stakes) and licensee accountability - ASN is developing an approach in which certain decisions are devolved to the licensee. For those which do not compromise the safety assumptions adopted for operation or dismantling of the installations, the licensees may - on the basis of an opinion from an internal commission independent of them - directly take decisions which had traditionally been the preserve of ASN.

These internal authorisations must be planned. The agenda is transmitted to ASN sufficiently in advance for ASN to check that the envisaged decisions do indeed correspond to internal authorisations. Once taken, they are declared to ASN, which may then decide to inspect correct implementation. By means of dedicated inspections, ASN also ensures the quality of the internal opinions given and assesses the independence of the commission. For decisions which can compromise the safety assumptions or the safety demonstration, the licensees must ask ASN for authorisation to implement them.

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This approach enables ASN to concentrate its efforts on those changes which could have the greatest impact on the safety of the installations, while making the licensee more accountable for its choices. It also gives greater value to the inspection, as an authorisation request, assessed in principle by ASN, becomes an internal decision checked subsequently by ASN.

1 2 3

Using feedback

A system of nonconformity or significant incident declaration by BNI licensees was set up in accordance with the requirements of the order of 10 August 1984 concerning the design, construction and operation of basic nuclear installations (see chapter 3), further to the Three Mile Island accident. This is a safety concept taken directly from application of the second line of defence in depth and resulting from the provisions of the international conventions ratified by France (article 9v of the Joint Convention on the Safety of Spent fuel Management and the Safety of Radioactive Waste of 5 September 1997; article 19vi of the Nuclear Safety convention of 20 September 1994). This requires that the licensee implements a reliable system for detecting possible anomalies, such as equipment failures or errors in application of operating rules. This system should allow early detection of any excursion from the normal operating range and constant improvement is required in BNI and radioactive material transport safety.

The purpose of analysing the events detected in an installation or during a transport operation is: -by taking account of appropriate corrective measures, to ensure that an event which has already occurred will not happen again;

-by analysing the potential consequences of events constituting early-warning signs of more serious incidents, to prevent an aggravated situation from occurring;

-to promote good safety improvement practices.

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DE LA SURETE NUCLEAIRE ET DE LA RADIOPROTECTION	
GUIDE	
relatif aux modalités de déclaration et à la codification des critères relatifs	aux
événements significatifs impliquant la sûreté, la radioprotection ou l'environ applicable aux installations nucléaires de base et au transport de matièr	nement
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MEMORYNAU DE LA KANTER UT DE MARTIN	
MINISTURE DE L'ECOLOGIE ET DU DEVELOPMENT DU RABLE	

Analysis of the anomalies and implementation of the corrective measures brought to light as being necessary by this analysis constitute a basic tool in the defence in depth approach, referred to as feedback. To give an idea of what this entails, the nuclear licensees detect and analyse 100 to 300 anomalies a year for each EDF reactor and about 50 a year for a research laboratory.

Classification of these events must ensure that the more important ones are given priority treatment. For this purpose and for all the BNIs, ASN has defined a category of unforeseen events known as "significant events". These are events that are sufficiently important in terms of safety to justify rapid notification of ASN, followed by a subsequent and more complete report. This report contains the conclusions drawn by the licensee from analysis of the events and the measures it is taking to improve safety. This information is extremely valuable for ASN and its technical support organisation, IRSN, in particular

Significant events declaration guide

for installation periodic safety reviews. About ten or so significant events are declared every year for an EDF reactor.

ASN ensures that the licensee has carried out a pertinent analysis of the event and taken appropriate steps to remedy the situation, prevent it happening again and ensure that experience feedback is sent out to the nuclear licensees.

On the basis of twenty years' experience, ASN felt that it would be useful to transpose this concept from the safety field to radiation protection and protection of the environment. ASN therefore updated the principles defined in the 1980s for safety, and extended them to radiation protection. The 21 October 2005 guide, that can be consulted on ASN website, www.asn.gouv.fr, now gives all the provisions applicable to the licensees and transporters concerning how to declare safety events affecting BNI safety, radioactive material transports, radiation protection or environmental protection.

This declaration system is a means of providing data for the experience feedback database. These significant event declarations should not be confused with radiological emergencies, for which a different organisation is put in place (see chapter 8) or with a system designed to penalise errors by the licensee or by an individual (see point 1|4).

ASN wanted to extend this concept beyond the transporters and BNI licensees. It produced a guide defining the declaration of significant radiation protection events for all small-scale nuclear activities. This guide was submitted to the main stakeholders concerned (licensees, learned societies) and ASN will be implementing it on an experimental basis in 2007.

1 2 4

ASN decisions

ASN decisions correspond to positions which it considers to be of particular importance and which are intended to be made public. Their purpose is to close a subject or at least a stage in the subject in question. They are the result of a technical review of the available information and expert assessments. It is not sufficient that these decisions be technically relevant, they must also be understood by those ASN has to convince: elected officials, media, associations, nuclear safety authorities in other countries, etc.

In 2006, two decisions were signed by the Director General for Nuclear Safety and Radiation Protection:

-decision DEP/SD5/0049/2006 concerning application of the decree of 10 November 1999 to spare parts for the PWR main primary system and main secondary systems. It stipulates the conditions to be met by these parts before they can be installed on reactor systems. It also specifies the requirements to be met by EDF when carrying out maintenance work or modifications on these parts, before they can be installed on reactor systems.

-decision DGSNR/SD3/0731/2006 of 22 September 2006 concerning the delicensing of basic nuclear installation n° 121, following its complete dismantling. This installation, operated by CEA in its *Cadarache* nuclear research centre (*Bouches-du-Rhône*), was designed to carry out irradiation work. It was removed from the BNI list.

ASN technical decisions described in chapter 3 and specified by the law of 13 June 2006 will replace these decisions, which had no real regulatory foundation.

1 2 5

Inspection

a) Principles and objectives

Compliance with the safety reference framework by the nuclear licensees is supervised by spot inspections in order to check effective implementation of the requirements concerning safety, radiation protection and the related fields supervised by the ASN (management of waste, effluent discharge, prevention of non-nuclear risks).

ASN inspection consists in checking that the licensee complies with the requirements applicable to it. Without it being systematic nor exhaustive, its purpose is to detect specific anomalies together with any symptoms suggesting a gradual decline in installation safety.



ASN inspector during an inspection in Pierrelatte involving an exercice triggering the emergency plan

These inspections give rise to factual records, made available to the licensee, concerning:

-anomalies in the installation or points requiring further justification in the opinion of the inspectors;

-deviations between the situation observed during the inspection and the regulatory texts or documents produced by the licensee pursuant to the regulations.

ASN draws up an annual programme of scheduled inspections. This programme is not communicated to BNI licensees. It is drawn up using a methodical approach enabling the technical areas inspected at fixed intervals to be supplemented by topical subjects on which ASN wishes to obtain a more comprehensive picture. It aims to ensure adequate distribution of ASN resources proportional to the issues and stakes involved in the various installations.

The inspections are either announced to the licensee a few weeks beforehand or may be unannounced. They take place primarily on the nuclear sites or during transport of radioactive materials. They may also concern the head office departments (or design and engineering departments) at the major nuclear licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

Inspections are usually performed by two inspectors, one of whom directs the operations, with the assistance of an IRSN representative specialised in the plant to be inspected or the technical topic of the inspection. ASN uses various types of inspections:

-standard inspections;

-reinforced inspections, on topics involving particular technical difficulties and normally directed by senior inspectors (see chapter 2 point 2|1|3);

-in-depth inspections, scheduled over several days and requiring a full team of inspectors. Their purpose is to enable examination in greater detail;

-inspections comprising sampling and measuring operations, aimed at spot checking discharge levels independently of licensee measurements;

-reactive inspections, carried out further to a particularly significant event;

-worksite inspections, ensuring a significant ASN presence on the sites on the occasion of PWR unit outages or particular work, especially in the dismantling phase.

Among the inspections carried out in 2006, ASN conducted a particular type of in-depth inspection from 30 January to 3 February, because it concerned several licensees on a nuclear site. The aim was to check the organisation and resources deployed by the nuclear licensees on the Tricastin site - COGEMA, EDF (BCOT), EDF (nuclear power plant), EURODIF, COMURHEX and SOCATRI - in the event of an incident or accident affecting several installations on the site. This inspection was decided on by ASN further to inadequacies observed in the coordination between licensees during national emergency exercises held in 2004 and 2005. It mobilised 20 ASN inspectors and staff and 10 experts from IRSN. It simulated two accidents requiring activation of the licensees' on-site emergency plans, which was an inspection innovation:

-simulation of a release of hydrofluoric acid (HF) and uranyl fluoride (UO_2F_2) following emptying of a container of uranium hexafluoride (UF_6) at EURODIF. The purpose was to observe the coordination between the various licensees in the event of an accident developing rapidly in the space of about ten minutes on the Tricastin nuclear site;

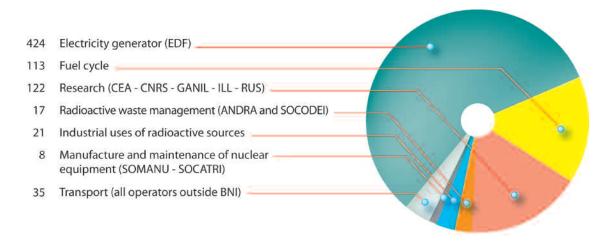
-simulation of a night-time fire in the nuclear power plant. This unannounced exercise mobilised the plant's teams, its duty personnel and the Drôme fire and emergency services which had not been informed of the exercise beforehand.

Apart from the observations made during this inspection, ASN learned the benefits of inspecting the operational nature of the on-site emergency plan, as a useful complement to the national emergency exercises and the documentary check on the PUI.

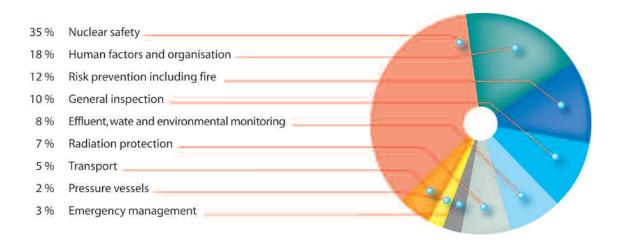
b) Action taken in 2006

In 2006, 740 inspections were conducted, 198 of which were unannounced. The breakdown according to the various installation categories is described in the following graphs.

Breakdown of 2006 inspections per type of operator



Breakdown of BNI inspections in 2006, per topic



1 3

ASN organisation for BNI regulation

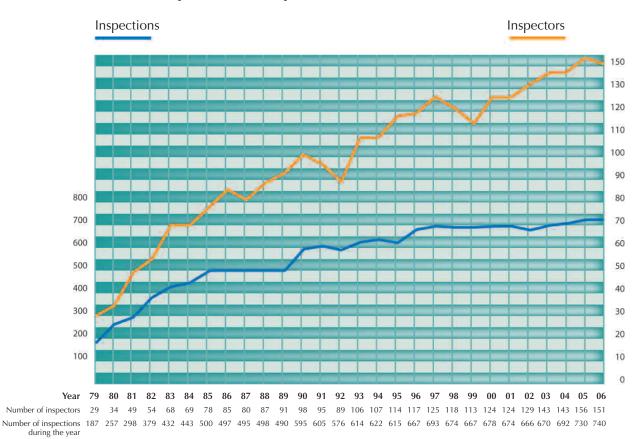
All of the nuclear safety regulation duties are distributed within ASN between head office and the regional divisions. These regional divisions are entrusted with "on the spot" regulation. They are in permanent contact with the nuclear licensees, take charge of most of the inspections carried out on the nuclear sites and provide step by step regulation of the various stages in PWR maintenance and refuelling outages, after which authorisation for restart will depend on ASN. They are also tasked with reviewing certain authorisation or waiver requests. ASN head office coordinates and oversees the regional divisions in these areas, deals with matters of national importance, and defines and implements national nuclear safety policy.

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BNI inspection

The nuclear safety inspectors (previously known as BNI inspectors) are ASN engineers designated by decision of ASN. They carry out their inspection duties under the authority of ASN Director General. They are sworn-in and bound by professional secrecy.

On 31 December 2006, the number of active nuclear safety inspectors stood at 151, including 80 in the regional divisions and 71 at head office.



Trends in numbers of inspectors and inspections

Note:

This table does not take account of the surveillance inspections carried out by the ASN on behalf of the Defence High Official of the Ministry for Industry and which concern protection against malicious acts. Action taken further to these inspections is the responsibility of the Defence High Official.

1 3 2

Regulation of pressure vessels

The law of 13 June 2006 requires ASN to select agents from among its staff, responsible for supervising compliance with the regulations concerning pressure vessels designed for use in BNIs. A decree should clarify the procedures for designating these agents.

ASN nuclear pressure vessel division (DEP) is responsible for monitoring application of nuclear pressure vessel regulations, including for PWR main primary and secondary systems.

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This division is directly responsible for supervising the design and manufacturing of the main primary and secondary systems (CPP and CSP) (see chapter 12 point 3|1). Regulation of the design and manufacture of the other nuclear pressure vessels is the job of organisations approved and monitored by ASN.

Regulation of the operation of nuclear pressure vessels is the responsibility of ASN regional divisions, with the support of the DEP.

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Investigation of significant events

The regional divisions are responsible for immediate analysis of significant events in order to check that urgent corrective steps have been taken and, if necessary, prepare for the necessary information to the public. ASN coordinates the actions of the regional divisions in this field and every year provides training for the engineers concerned.

Examination of a significant event covers compliance with the rules in force concerning detection and declaration of significant events, the immediate technical steps taken by the licensee to keep the installation in or bring it to a safe condition and finally, the pertinence of the significant event reports provided by the licensee.

ASN and its technical support body, IRSN, carry out a subsequent examination of the operating feedback from the events. The data supplied by the regional divisions and analysis of significant event reports, together with periodic records sent in by the licensees, form the basis of ASN operating feedback structures. This operating feedback is notably put to practical use during the periodic safety reviews of plants and by means of requests for improvements to the condition of plants and to the organisational provisions made by the licensee.

1 | 4

Penalties

In the absence of any legislative framework and in order to make its actions more transparent, ASN on 17 July 2000 set up an official system of formal notices. The purpose of these notices sent to the licensees was to ask them in the strongest possible terms to comply with the regulatory requirements or those set by ASN, within a reasonable time-frame. There was no real penalty for any failure to abide by these formal notices, their main strength lying in the publicity surrounding them and ASN credibility as perceived by the licensees.

In 2006, ASN served formal notice on the licensee of the TU5 workshop in the COGEMA Pierrelatte establishment. This required that within 3 months following validation of its action plan by ASN, the necessary steps be taken to ensure that no nuclear material containing more than 1% uranium 235 be present in the installation.

The law of 13 June 2006 set up an infringements system based on:

-a scale of administrative penalties defined in articles 41 to 44 of the law:

formal notice to regularise the administrative situation or meet certain conditions placed on the licensee of an installation or on the person responsible for transport, within a specified time-frame;
suspension of installation operation or of performance of the unauthorised operation;

• in the event of failure to comply with a formal notice, deposit with a public accountant of a sum covering the cost of the work to be done,

•after said deposit, performance of the work at the expense of the person served with formal notice.

The licensee is asked to submit its observations concerning these penalties.

-penal sanctions ranging from $75,000 \in$ to three years imprisonment and a fine of $150,000 \in$ depending on the nature of the violation. They are defined in articles 48 to 51 of the law and can apply to corporate bodies.

2 REGULATION OF SMALL-SCALE NUCLEAR ACTIVITIES

2 | 1

Scope of regulation

The international fundamental standards for protection against ionising radiation and the safety of radioactive sources issued by the IAEA define the general functions of the regulatory authority (see box).

The international fundamental standards

They include:

"-the examination of requests for authorisation to carry out practices entailing or potentially entailing exposure;

-authorisation of these practices and their corresponding sources in certain conditions;

-performance of periodic inspections designed to check that the conditions are met and, as necessary, the application of measures designed to ensure compliance with the regulations and standards.

Mechanisms must therefore be available for declaring, recording and issuing licences for the sources involved in these practices as well making provision, in certain conditions, for exclusion or indeed exemption of sources and practices from the scope of application of the regulations. Steps must also be taken to ensure regulation, radiological monitoring, examination, verification and inspection of sources and ensure that adequate plans are in place to deal with radiological accidents and provide the necessary emergency response (see chapter 8, point 1).

The regulatory authority may need to provide additional information on how to comply with certain regulations applicable to various practices, for example by publishing regulatory guides.

A climate of openness and cooperation must be encouraged between the inspectors and the individuals or corporate bodies subject to the regulations, in particular so that they facilitate inspector access to both premises and information.

The regulatory authority is also responsible for requiring that all parties concerned establish a safety culture consisting in:

-an individual and collective commitment to safety on the part of the workers, managers and regulatory bodies;

-accountability on the part of each and every individual with regard to protection and safety, in particular at management level;

-measures designed to encourage a systematically questioning attitude, the desire to learn and a refusal to take existing safety results for granted.

The regulatory organisation and the individuals or bodies subject to regulation must take due account of general experience and the most recent innovations in the fields of radiological protection and source safety."

CHAPTER REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

In France, ASN performs the role of regulatory authority, through its duty of drafting and monitoring technical regulations in the field of radiation protection. Article 4 of the law of 13 June 2006 indicates that ASN supervises compliance with the general rules and special requirements in the field of radiation protection applicable to the activities mentioned in article L. 1333-1 of the Public Health Code and the persons mentioned in article L. 1333-10 of the same code. The authority organises a permanent radiation protection watch nationwide. From among its staff, it designates the radiation protection inspectors. It issues the required approval to the organisations taking part in the radiation protection inspections and regulation.

The scope of ASN radiation protection regulation covers the use of ionising radiation in all activities. This duty is carried out jointly with other inspection organisations such as the labour inspectorate, the inspectorate for classified installations and the AFSSAPS inspectorate.

2|2

Regulation procedures for activities using ionising radiation

The user of ionising radiation is responsible for radiation protection within the context of its activities. ASN ensures that it meets its obligations and assumes its responsibilities. In this respect, and as required by the IAEA fundamental safety standard mentioned above, ASN regulation takes the form of review of files, pre-commissioning visits, inspections and finally discussions with professional organisations (trade unions, professional orders, learned societies, etc.). This action directly concerns either the users of ionising radiation, or organisations approved to carry out technical inspections on these users.

These actions can be summarised as shown in the following table:

	Review/authorisation	Inspection	Openness and cooperation
Users of ionising radiation	Files produced in accor- dance with the authorisa- tion procedures laid down in the Public Health Code (articles R. 1333-1 to R. 1333-54) specified in chapter 2. Review of the file and visit prior to commissioning. Leads to registration of the declaration or to issue of an authorisation.	Radiation protection inspection (article L. 1333-17).	Jointly with the professio- nal organisations, drafting of a guide of good prac- tices for users of ionising radiation.
Organisations approved for radiation protection inspections under article R. 1333-43 of the Public Health Code	Approval application file in accordance with the provisions of article R. 1333-44 of the Public Health Code. Review of the file and audit of the organisation. Leads to issue of approval.	Second level inspection through: – audit, – in-depth inspection at head office and in the branches of the organisa- tions, – unannounced inspec- tion in the field.	Jointly with the professio- nal organisations, drafting of guides of good prac- tices for performance of radiation protection ins- pections.

Methods of ASN regulation of the various radiation protection players

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Internal supervision of radiation protection by the users of ionising radiation

The purpose of the internal radiation protection checks is to regularly evaluate the radiological safety of installations that use ionising radiation sources, to check its level with respect to current regulations, and if necessary to reinforce it. These internal radiation protection checks are carried out under the responsibility of the establishments using the ionising radiation. Internal radiation protection checks may be carried out by the person with competence for radiation protection (PCR), designated and empowered by the head of the establishment, by inspection organisations approved by ASN or by IRSN. These internal checks do not take the place of the inspections carried out directly by ASN.

The following table specifies the various licensees likely to be involved on the basis of the requirements of the Public Health and Labour Codes and decree 2001-1154 of 5 December 2001 concerning the obligation of maintenance and quality control for medical appliances as stipulated in article L. 5212-1 of the Public Health Code.

Type of internal checks	Public Health Code (art. R. 1333-7 and R. 1333-43) Organisation and technical arrangements ensuring compliance with radiation protection rules	Labour Code (art. R. 231-84 and R. 231-86) Sources and appliances, protection and alarm systems and ambient environment measuring instruments	
Inspection on reception in the establishment (1)		Appliances, protection and alarm systems and measuring instru- ments: IRSN or OA or PCR.	
Inspection before first use	OA ⁽²⁾		
After modification	OA ⁽²⁾		
After overshoot of public or worker exposure limits		IRSN and OA	
Periodic	OA ⁽²⁾	Appliances ⁽³⁾ : organisation approved by AFSSAPS. Protection and alarm systems and measuring instruments: IRSN or OA. Inspection frequency: yearly.	
Cessation of activity		OA or IRSN or PCR for issue of a certificate of radiological clean- ness if unsealed sources are used.	
Ambient inspection in supervised area		OA or PCR. Inspection frequency: from one month to one year.	

Internal check operators

(1) This is an inspection of the performance of the protection systems.

(2) The installation inspection concerns the premises and all means employed for radiation protection.

(3) In the case of medical appliances such as radiology or radiotherapy equipment, the above-mentioned decree of 5 December 2001 set internal and external quality control checks for the appliances. Compliance with them is checked by organisations approved by the AFSSAPS.

OA: organisation approved by ASN under the terms of article R. 1333-43 of the Public Health Code.

PCR Personne Compétente en Radioprotection (person with competence for radiation protection).

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ASN review of the procedures laid down by the Public Health Code

It is up to ASN to review applications for the use of ionising radiation for medicine, dentistry, human biology and biomedical research, as well as for any other nuclear activity. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy inadequacies detected during these inspections.

Apart from the internal checks carried out under the responsibility of the establishments themselves, ASN conducts its own checks. In this respect it directly carries out checks during the procedures for issue (pre-commissioning inspections) or renewal (periodic inspections) of the authorisations to possess and use radiation sources granted on the basis of article R. 1333-24 of the Public Health Code. The authorisation notifications can only be issued if the requests submitted by ASN have been taken into account. These checks are in particular designed to compare the data contained in the files with the actual physical reality (sources inventory, check on the conditions of production, distribution and utilisation of the sources and the appliances containing them). They also enable ASN to ask the establishments to improve their in-house provisions for source management and radiation protection.

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Growth in radiation protection regulation by ASN

Following the reform of radiation protection regulation which took place in France in 2002, ASN adapted its management organisation to develop radiation protection regulation of small-scale nuclear

facilities. Law 2004-806 of 9 August 2004 concerning public health policy, introduced new requirements into the Public Health Code (articles L. 1333-17 to L. 1333 19, L. 1337-1-1.),), creating the radiation protection inspectorate. Pursuant to these provisions, ASN prepared decree 2006-694 of 13 June 2006 setting the procedures for designating, approving and swearing-in the radiation protection inspectors and modifying the Public Health Code (regulatory provisions). The first 62 radiation protection inspectors were designated by the order of 13 September 2006.

The radiation protection inspectors are ASN staff designated once they have acquired the necessary skills through their professional experience and appropriate training. They carry out their inspection work under the authority of ASN Director General. The inspectors take an oath and are bound to professional secrecy.

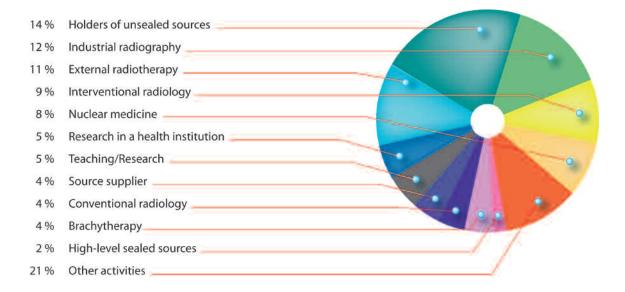
On 31 December 2006, the number of active radiation protection inspectors stood at 60, including 41 in the regional divisions and 19 at head office.



Dose rate check on a gammagraphy worksite during a radiation protection inspection

Pending designation of the radiation protection inspectors, ASN focused on identifying inspection priorities, defining its intervention procedures and those of the approved organisations, and deploying the necessary manpower. Various missions have been carried out along these lines since 2002 (reconnaissance mission, Vroussos mission, DRIRE/DRASS/DDASS working group). Since 2005, ASN has been preparing a program of visits to check users of ionising radiation. This programme was continued and intensified in 2006, taking the form of visits, until such time as the inspectors were appointed, followed then by inspections. 568 visits or inspections were carried out, 244 of which were in the medical field and 324 in the industrial and research fields. The breakdown according to the various categories of activity is described in the following graph.

Breakdown according to the various categories of small-scale nuclear activity of visits and inspections carried out in 2006



Of the topics dealt with, the following were priorities in 2006:

-interventional radiology: 50 visits or inspections;

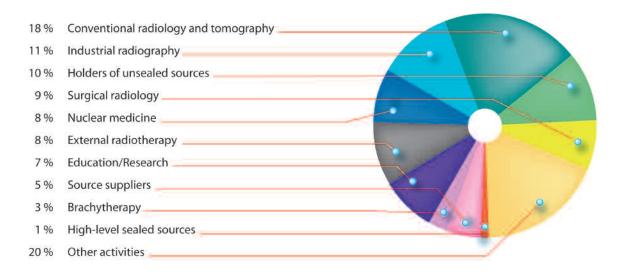
-radiotherapy: 61 visits or inspections;

-research departments in health care institutions: 29 visits or inspections.

During the course of 2007, checks will continue and will be enhanced by about 750 inspections scheduled as part of the initial programme and distributed according to the priorities defined by ASN, taking account of the health issues involved in the various nuclear activity categories.

ASN will continue with its regulation of ionising radiation uses involving the highest radiological risks. In addition to the action already initiated in supervising radiation protection in nuclear medicine and radiotherapy, a programme started in 2006 and focusing on interventional radiology installations, will be continued in 2007. In the industrial fields, action concerning industrial radiography activities will be maintained.

2007 inspection programme previsional: breakdown per type of activity



ASN has organised its supervisory activities so that its actions are proportional to the radiological issues and the ionising radiation risk and are consistent with the actions of the other inspectorates. Given the number of installations and nuclear activities concerned (more than 50,000), ASN aims to continue its work to identify those activities entailing real radiation protection issues and will define action priorities. In the light of the events described in chapter 9, radiotherapy constitutes a priority target in 2007 for inspections by ASN.

To ensure greater efficiency, this action will be organised on the following basis:

-systematic inspection of nuclear activities with high radiological risks, at a predetermined frequency;

-inspections covering a limited number of users for the other nuclear activities;

-systematic internal checks on the entire fleet by approved organisations.

Thus, for those nuclear activities involving lower-level issues, regulation will primarily be based on technical inspections conducted by the approved organisations. The programme of ASN inspections will concern a limited part of the fleet (principle of spot-checks), particularly targeted on the basis of the results of the inspections performed by the approved organisations or information collected through other channels (experience feedback from visits in previous years, incident frequency, major modifications to installations, transmission of dosimetry data, etc.).

Based on these data or recent topical information, national priorities will be defined annually, together with the General Labour Directorate (DGT) at the Ministry for Labour and the Inspectorate General for Social Affairs (IGAS). These priorities will enable action to be targeted on specific nuclear topics or activities, covering a number of installations or activities that is large enough to be representative of this sector (for example: gammagraph work sites, computed tomography, etc.).

Reactive inspections could also be held further to incidents. In 2006, a number of visits were performed in this way, jointly with the inspectorate for classified installations and/or the labour inspectorate.

2 2 4

Regulation procedures by organisations approved by ASN

The inspections performed by the approved organisations under application of articles R. 1333-43 of the Public Health Code and R. 231-84 and R. 231-86 of the Labour Code, are used in particular to check the technical conformity of electrical devices emitting ionising radiation and radioactive sources, the radiological environment of the workstations, source, waste and effluent management procedures, and the effectiveness of the organisation and technical arrangements in place under application of radiation protection regulations. These approvals are issued by ASN. The order of 20 March 2006 set the list of 49 organisations approved to carry out radiation protection technical inspections in basic nuclear installations and/or in small-scale nuclear facilities.

ASN ensures that these organisations conduct their activities in conditions of quality commensurate with their technical, organisational and ethical obligations. This second level regulation comprises: -review and monitoring of the approval file;

-approval follow-up or renewal audits;

- in-depth checks to ensure that the organisation's management arrangements are satisfactory;

- unscheduled inspections to ensure that the organisation's staff in the field work in satisfactory conditions.

In order to ensure that the work done by these organisations is consistent and diligent, in a competitive context, but also to obtain access to the results of these inspections, which are a valuable source of concise information (in particular, the main deviations observed), ASN aims to define the following, after discussion with the technical inspector professional bodies:

-the procedures for obtaining data on the actions of the organisations and the state of the fleet inspected;

-the tools used by the organisations to carry out their duties of regulation and information to the administration.

This work was started in 2005 and continued during the course of 2006.

In 2006, 31 organisations were audited or extensively inspected under the initial approval or approval renewal procedures.

2 2 5

Openness and discussion

Regulation will be supplemented by awareness programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations who will be implementing this approach by issuing good practice and professional information guides. Initiatives of this type are mentioned in point 1/5 of chapter 9.

Awareness also involves joint action with other administrations and organisations who carry out supervisory duties on the same installations, but with different prerogatives, such as the Labour Inspectorate, inspection of medical appliances by the AFSSAPS or health inspection as entrusted to the technical divisions of the Ministry for Health. Close collaboration with the High Health Authority (HAS) is to be envisaged, with respect to incorporating the conformity of installations and medical practices using ionising radiation into the framework of the assessment and accreditation procedures under its responsibility.

Finally, ASN envisages joint actions targeted at the administrations and organisations with central responsibility (Directorate for Hospitalisation and Health Care Organisation) (DHOS) and decentralised responsibility (regional hospitalisation agencies) for health care institutions.

Jointly with the DGT ASN thus initiated discussions into coordination of labour inspections and radiation protection inspections. Local and national information exchanges, joint inspections and crosstraining programmes are also being envisaged.

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Penalties

As in the field of nuclear safety, infringement of the provisions of the "ionising radiation" chapter of the Public Health Code leads to administrative and penal sanctions.

Administrative decision-making powers lie with ASN and can entail:

-revocation of license (after formal notice);

-interim suspension of an activity (whether licensed or notified) if urgent measures are required to safeguard human health.

The formal notices prior to revocation of a license (on the basis of article L. 1333-5 of the Public Health Code) concern application of all the requirements of the "ionising radiation" chapter of the legislative part of the same code (articles L. 1333-1 to L. 1333-20), regulatory provisions and the stipulations of the license. Temporary or final revocation of the license by ASN must be fully explained in a decision within one month following serving of formal notice.

Formal notices associated with penal sanctions (based on article L. 1337-6 of the Public Health Code) are served by ASN. They concern the provisions of articles L. 1333-2, L. 1333-8 (exposure monitoring measures, protection and information to individuals), L. 1333-10 (surveillance of enhanced natural exposure and exposure in places open to the public) and L. 1333-20 (decrees implementing certain legislative requirements).

Infringements are written up in reports by the radiation protection inspectors and transmitted to the Public Prosecutor's Office, which decides on what subsequent action is to be taken. The sections of the Public Health Code providing for penal sanctions are detailed in articles L. 1337-5 to L. 1337-9 and may lead to a fine of from 3,750 euros to one year in prison and a fine of 15,000 euros. These penalties may also apply to corporate bodies.

3 MONITORING OF EXPOSURE TO NATURALLY OCCURRING RADIOACTIVE MATERIALS (NORM)

3 1

Monitoring of exposure to radon

Since August 2004, the activity concentration of radon in places open to the public has to be measured, in accordance with the order of 22 July 2004, by organisations approved by ASN. The measurement campaigns must take place between 15 September of year N and 30 April of the following year.

For the 2006-2007 measurements campaign, the number of approved organisations it as follows:

	Approval until 15 September 2007	Approval until 15 September 2008	Approval until 15 September 2009
Level 1 (screening)	37	21	22
Level 2 (screening)	5	3	0

Based on the information transmitted by the approved organisations, initial results can be presented for the 3149 establishments that underwent screening during the 2005-2006 campaign:

- in 2,726 establishments, or about 86%, a radon activity level of less than 400 Bq/m³ was measured;

- in 334 establishments, or about 11%, a radon activity level of between 400 and 1000 Bq/m³ was measured;

- in 89 establishments, or about 3%, a radon activity level in excess of 1000 Bq/m³ was measured.

The DDASS in the 31 priority *départements* (see chapter 3), together with ASN (circular of 20 December 2004 concerning management of the radon risk in premises open to the public) are responsible for monitoring establishments in which radon concentrations higher than 400 Bq/m3 were measured. The steps taken to reduce exposure in these establishments will be evaluated by ASN in 2007, in collaboration with the DDASS.

3 | 2

Monitoring to exposure to NORM in non-nuclear industries

In 2005, the list of professional activities (industries, spas and drinking water treatment plants) requiring regulation of human exposure to Naturally Occurring Radioactive Materials (NORM) was published, owing to the fact that the materials used contain natural radionuclides and are likely to generate doses that are significant from the radiation protection standpoint.

Regulation of implementation of these new measures is not yet operational, but should be broken down as follows:

- the labour inspectors and radiation protection inspectors are competent to monitor the steps taken by the head of the establishment to assess the exposure of its workers and reduce it if necessary;

-the inspectors for classified installations and the radiation protection inspectors are competent to monitor the steps taken by the licensee to reduce public exposure, if necessary, whenever these industrial activities are subject to authorisation under the terms of the regulations applicable to installations classified on environmental protection grounds.

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Monitoring of natural radioactivity in drinking water

Monitoring the natural radioactivity in drinking water is now an integral part of the health monitoring activities of the DDASS. ASN is responsible for overall coordination, jointly with the Directorate General for Health. The new regulation programmes were implemented (see point 1|5 of chapter 3 and point 2|4 of chapter 5) in 2004. The data are fed into the SISE-EAU base managed by the Ministry for Health.

ASN is preparing a circular clarifying what to do when the reference levels concerning the radiological quality of this water are exceeded.

4 OUTLOOK

ASN regulation of nuclear activities is designed to check that all users of ionising radiation fully assume their responsibilities. ASN ensures that its actions are guided by the notion of proportionality, so that its level of inspection is commensurate with the health and environmental protection issues. Regulation involves review and investigation of the files and data supplied by the licensee to justify its actions, along with surveillance of installations, activities and the environment, follow-up of incidents (significant events) and inspections. As and when necessary, infringements can be penalised. In the case of an activity involving too many parties for direct regulation by ASN, this can be carried out via approved organisations and may be accompanied by an awareness-raising programme including work to promote the production of guides.

Awareness-raising

ASN vision of a world protected against risks for which the citizens as a whole take collective responsibility, implies the involvement of each and every one. ASN aims to ensure the spread of the radiation protection and safety culture so that everyone becomes a participant in his or her own supervision. There are two key steps in this goal, education in the safety culture and implementation of tools enabling each individual or organisation to identify their own faults and more generally assess the progress made in achieving the safety culture.

ASN will continue to encourage the production of national or international guides by professionals to promote conformity with regulatory requirements. Aware as it now is of the importance of human factors in the origin of the incidents that have occurred in France, ASN considers that thought needs to be given to the place devoted to safety culture in the training given to students as part of the nuclear safety curriculum and in medical and industrial activities using ionising radiation. It will initiate discussions with the main stakeholders in the sector in 2007.

Analysis of significant events

The detection and analysis of anomalies by the licensees is a fundamental tool contributing to the safety of nuclear installations. It is also a way of assessing the progress of the safety culture, as it expresses the ability of individuals and organisations to point out their own failings. ASN is satisfied with how the nuclear licensees have adopted this principle. It has reservations however concerning the nuclear licensees' subcontractors, where the penalty culture frequently takes precedence over the safety culture. Based on the experience acquired in the field of BNIs and radioactive material transports with regard to declaration of significant events, ASN will on 1 March 2007 be implementing an experimental system of significant event declarations for small-scale nuclear activities. At the end of the year it will analyse the results and draw conclusions before adapting this system and putting it into general use. The system is designed to protect workers, patients and the public by learning the lessons from past technical and organisational malfunctions.

Inspection

To ensure that the licensee abides by the requirements binding upon it, ASN carries out on-site inspections and, if necessary, conducts visits during the license review process. Every year, ASN draws up a schedule of inspections, the purpose of which is to detect any isolated deviations or anomalies and to ensure that the licensee or the user of ionising radiation meets its responsibilities. The inspections are carried out by specifically designated ASN staff. In 2006, ASN 217 inspectors conducted 740 inspections of BNIs and radioactive material transports (non-BNIs) and 568 radiation protection inspections. An assessment of the level of safety resulting from ASN regulation is presented in the chapters devoted to the various nuclear stakeholders. Quite apart from its assessment of each type of licensee, ASN considers that the inspection itself contributes to advancing nuclear safety and radiation protection. In 2007, ASN intends to take legislative measures providing it with the powers to designate its inspectors and put the finishing touches to the discussions conducted with the

Directorate General for Labour (DGT) for implementing the process of exchanges with the Labour Inspectorate.

Surveillance of BNI discharges

To ensure that the licensees fully assume their responsibility to monitor their discharges, ASN carries out unannounced inspections with sampling and sends the samples representative of the effluent discharged for analysis by an organisation it has designated. In 2006, ASN had IRSN carry out 17 sampling inspections. These inspections identified deviations or drift for which ASN demanded explanations from the licensees. ASN considers that this type of check helps instil confidence in the results of the regulation effluent measurements taken by the licensees. Under application of the polluter-pays principle, ASN aims in 2007 to have the financial burden borne by the licensees.

Regulation of approved organisations

ASN supervises the organisations it approves for nuclear pressure vessels, measurement of environmental and drinking water radioactivity, regulation of exposure to radon in premises open to the public and technical radiation protection checks.

ASN now has sole responsibility for approval and in 2007 aims to harmonise its review and inspection practices, in particular by basing its reference system on standards and making widespread use of the practice of audits and spot-checks.

Penalties

ASN inspections and checks are all official and all lead to a formal outcome issued by it. Depending on the gravity of the nonconformity, this outcome may be either a verbal observation on the part of the inspector, a letter which may include requests, a decision for partial or total revocation of a license, or an administrative or penal sanction defined by the nuclear transparency and safety law. In this way the ASN is following the recommendations of the IRRS mission report and in 2007 aims to formalise the procedure for scaled application of these penalties.

CHAPTER 4 REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION