REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATIONS

CHAPTER 4

1 VERIFYING THAT THE LICENSEE ASSUMES ITS RESPONSIBILITIES

1 | 1 Verifying compliance with regulations: a fundamental responsibility

Regulation of nuclear activities is ASN's fundamental responsibility. This regulation consists in verifying that any party responsible for a nuclear activity assumes full responsibility for it and complies with the requirements of the regulations with regard to nuclear safety and radiation protection. It helps assess the performance of a licensee and enables the stakes associated with a nuclear activity to be estimated.

1 | 2 Building regulatory responsibilities on principles

ASN aims to ensure that the principle of responsibility of the licensee for safety and radiation protection is respected.

ASN includes the concept of proportionality when determining its actions, so that the scope and extent of its regulation is commensurate with the health and environmental safety stakes involved.

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

– before the licensee performs an activity requiring licensing, through a review and analysis of files, documents and information provided by the licensee to back up its actions. This regulation aims to ensure that the information supplied is both relevant and sufficient;

– during operation, by means of visits, inspections on all or part of the facility, checks on documents, field checks during work involving high stakes, such as scheduled nuclear reactor outages, and the analysis of significant events. This regulation comprises sampling and the analysis of justifications provided by the licensee with regard to the performance of its activities.

To consolidate the effectiveness and quality of its actions, ASN is adopting an approach involving continuous improvement of its regulatory practices. It analyses operating experience feedback from more than thirty years of nuclear safety inspections, from observation of practices in the small-scale nuclear sector over the past six years, and from observation of the inspection methods used by the main foreign regulatory authorities.

1 | 3 Regulating nuclear activities: a vast area

Pursuant to Article 4 of the TSN Act, ASN regulates compliance with the general rules and particular requirements of nuclear safety and radiation protection, applicable to:
– licensees of basic nuclear installations (BNIs);
– those in charge of the construction and operation of pressure equipment in BNIs;
– those in charge of radioactive material transport (RMT);
– those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiations;
– those in charge of implementing ionising radiation exposure monitoring measures;
– the organisations and laboratories it approves, to enable them to take part in nuclear safety and radiation protection checks and monitoring.

In this chapter, these entities are called the "licensees".

Although historically based on verifying the technical conformity of facilities and activities with regulations or standards, regulation today also covers a broader field incorporating human and organisational factors. It takes account of individual and collective behaviour and attitudes, management, organisation and procedures, relying on a variety of sources: significant events, inspections, relations with the stakeholders (personnel, licensees, contractors, trade unions, occupational physicians, inspection services, approved organisations, and so on).

1 | 3 | 1 Regulating nuclear safety

Nuclear safety covers all technical and organisational measures taken at all stages in the life of nuclear facilities (design, authorisation, commissioning, operation, final shutdown, decommissioning) to guarantee normal operation, prevent or mitigate the effects of accidents in order to protect workers, the population and the environment against the effects of ionising radiations. It is also common practice to include in this range of measures the technical steps taken to optimise the management of radioactive waste and effluents.

IAEA defined the following principles in its safety fundamentals for nuclear facilities (Safety Series No. 110):
– 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, pursuant to the TSN Act, ASN is the regulatory body meeting these criteria.

a) Regulating basic nuclear installations

The safety of BNIs is guaranteed by a series of strong, leaktight barriers, for which the safety analysis must demonstrate the resistance in normal and accident conditions. There are generally three barriers. For power reactors, these are the fuel cladding, the primary system boundary, the reactor building containment and a secondary containment where applicable.

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

b) Regulating the transport of radioactive materials

Transport comprises all operations and conditions associated with radioactive material movements, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including transit storage, unloading and reception at the final destination of radioactive material consignments and packages (see chapter 11).

The safety of RMT is guaranteed by three main factors:
– primarily, the robustness of package design and the quality of package construction;
– the reliability of transport and of certain special vehicle equipment;
– an efficient emergency response in the event of an accident.

ASN is responsible for regulations pertaining to the safe transport of radioactive and fissile materials for civil use and for verifying their implementation. Its powers in this field were confirmed by the TSN Act.

In terms of regulations and practices, good coordination with the other regulatory transport authorities is sought, particularly those responsible for inspecting means of transport, conventional safety inspection in the transport sector and protection of nuclear materials.

c) Regulating pressure equipment

Numerous systems in nuclear facilities contain or carry pressurised fluids. They are therefore subject to pressure equipment regulations (see chapter 3, point 2|2|1).

Article 4 of the TSN Act states that ASN "monitors compliance with the general rules and special prescriptions as regards nuclear safety and radiation protection to which are subject […] the manufacture and use of pressurised equipment specially designed for these installations". ASN checks implementation of the regulations for pressure equipment used in a BNI. Furthermore, so that the BNI licensees only have to deal with a single point of contact, Article 50 of Act 2009-526 of 12 May 2009 entrusts ASN with the enforcement of regulations for all pressure equipment in a facility comprising a BNI.

Of the BNI pressure equipment regulated by ASN, the main primary and secondary systems of EDF's pressurised water reactors (PWRs) are particularly important. 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 (see chapter 12, point 1|1|3). ASN thus pays particularly close attention to the regulation of these systems.

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

1|3|2 Regulating activities entailing a risk of exposure to ionising radiations

The "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" issued by IAEA define the general functions of the regulatory body.

In France, ASN performs this responsibility of regulatory body by drafting and monitoring technical regulations in the field of radiation protection (see chapter 3, point 1).

The scope of ASN radiation protection regulation covers the use of ionising radiations in all activities. This duty is exercised jointly with other inspectorates, such as the conventional safety inspectorate, the inspectorate for installations classified on environmental protection grounds, the departments of the ministry responsible for health and the French Health Product Safety Agency (AFSSAPS).

As required by the IAEA basic safety standard, ASN regulation takes the form of review of dossiers, 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 radiations, or

organisations approved to carry out technical inspections on these users.

These actions are summarised in table 1.

1 | 3 | 3 Regulating the enforcement of Labour law in nuclear power plants

In nuclear power plants, the regulation of nuclear safety, radiation protection and the conventional safety inspection aspects very often covers common topics, such as worksite organisation or the conditions in which subcontractors are called in. The legislator therefore assigned conventional safety inspector duties to engineers or technicians specifically designated for this purpose by the ASN Chairman from among ASN staff (Article R. 8111-11 of the Labour Code). They operate under the authority of the minister responsible for labour.

There is nothing new in having the conventional safety inspection duties in nuclear power plants carried out by a technical inspectorate separate from the ordinary labour inspectorate. This responsibility previously lay with the officers designated by the DRIRE directors, who can today still intervene in facilities or works which are regulated by the ministry responsible for energy, such as dams or electricity transmission lines.

There are three main conventional safety inspection duties: inspection, information and advice. They concern working conditions and worker protection. Their legitimacy is underpinned not only by international standards (particularly ILO convention No. 81) but also by national texts regulating the inspection departments.

The six main issues identified by ASN in 2007 and related to the conventional safety inspection responsibility in NPPs are:
1. exercise closer regulation of contractor working conditions and of EDF's surveillance of the activities subcontracted;
2. deal with the growing problems of construction/dismantling;
3. take full account of organisational and human factors;
4. encourage EDF to include the goal of security in addition to safety and radiation protection;
5. ensure effective and uniform application nationwide of the Labour Code and collective agreements;
6. ensure the credibility of ASN's expanded conventional safety inspection responsibility.

ASN implemented changes to its organisation in order to clarify:
– the organisation, among the divisions, of conventional safety inspection duties in NPPs;
– relations with the other Government departments concerned, mainly the departments of the ministry responsible for labour;
– relations with the regional health insurance funds (CRAM) for technical appraisal, recommendations, inquiries into health and safety conditions, etc.;
– relations with the Occupational Risk Prevention Organisation for the Building and Civil Engineering Industries (OPPBTP) to promote the prevention of

Table 1: methods of ASN regulation of the various radiation protection players

	Review/authorisation	Inspection	Openness and cooperation
Users of ionising radiations	Files produced in accordance with the procedures laid down in the Public Health Code (Articles R. 1333-1 to R. 1333-54). Review of the file and visit prior to commissioning. Leads to registration of the notification or to issue of an authorisation.	Radiation protection inspectorate (Article L. 1333-17 of the Public Health Code).	Jointly with the professional organisations, drafting of a guide of good practices for users of ionising radiations.
Radiation protection inspection bodies	Application file for approval to perform the inspections specified in Article R. 1333-95 of the Public Health Code and Articles R. 4452-12 to R. 4452-17 of the Labour Code. Review of the file and audit of the organisation. Leads to issue of approval. (30 organisations approved as at 31.12.2009).	Second-level inspection through: – audits, – in-depth inspections at head office and in the branches of the organisations, – unannounced field inspections.	Jointly with the professional organisations, drafting of guides of good practices for performance of radiation protection inspections.

industrial accidents and occupational diseases, as well as to improve working conditions of building and civil engineering contractors, in particular for construction and dismantling activities;
– relations with the General Directorate for Energy and Climate for statutory and social issues concerning companies and organisations involved in providing the public gas and electricity service.

In 2009, ASN devoted particular efforts to setting up centralised support for the conventional safety inspectors in the divisions, by recruiting an experienced civil servant from the Ministry for Labour, given responsibility for overseeing and coordinating ASN's conventional safety inspection duties.

2 REGULATING IN A WAY THAT IS PROPORTIONATE TO THE STAKES INVOLVED IN THE ACTIVITIES

ASN organises its regulatory work in a way that is proportionate to the stakes involved in the activities. The licensee remains the key player in the regulation of its activities. The performance of certain inspections by organisations and laboratories offering the necessary guarantees as validated by ASN approval, contributes to this action.

2|1 Defining the stakes

In order to consider both the health and environment issues and licensee nuclear safety and radiation protection performance, and in the light of the large number of activities it regulates, ASN periodically identifies those activities and topics with high stakes so that it can regulate them directly.

In order to identify these activities and topics, ASN relies on current scientific and technical knowledge and uses the information collected by both itself and IRSN: results of inspections, frequency and nature of incidents, major modifications made to facilities, review of files, feedback of data concerning the dose received by workers, information resulting from checks by approved organisations. It can revise its priorities further to significant events occurring in France or elsewhere in the world.

High-stakes activities in 2009 are presented in table 2.

2|2 Deploying the principle of licensee responsibility

ASN considers that operations taking place in BNIs with high stakes in terms of nuclear safety and radiation protection must obtain prior authorisation from it. Conversely, it believes that operations for which the nuclear safety and radiation protection stakes are limited must remain the responsibility of the licensee.

In any case, the licensee is fully responsible for its activities and any inspection or monitoring carried out by ASN does not relieve it of its duty to organise its own inspection and monitoring.

2|2|1 Operations subject to a licensee internal authorisations procedure

For intermediate operations, with nuclear safety and radiation protection stakes that are significant but that do not compromise the safety scenarios used in BNI operation or decommissioning, ASN allows the licensee to assume direct responsibility for them provided that it sets up a system of enhanced, systematic internal checks, offering sufficient guarantees of quality, independence and transparency. The decision on whether or not to carry out the operations must be the subject of a formal authorisation issued by the licensee's duly qualified staff. This organisation is known as the "internal authorisations system" and is presented to the BNI's local information committee (CLI).

This internal authorisations system is regulated by the decree of 2 November 2007 and by ASN decision 2008-DC-106 of 11 July 2008, which clarifies ASN's requirements.

ASN verifies correct application of the internal checks arrangements by various means: inspections, review of the periodic reports forwarded by the licensees, cross-checking of the dossiers, etc. It can at all times either terminate or temporarily suspend an "internal authorisations system" if it considers it to be unsatisfactorily implemented, in which case the corresponding operations must be referred to ASN for prior authorisation.

Table 2: significant activities in 2009

Field	High-stakes topics or activities
BNIs including: – Nuclear power plants – Research reactors – Laboratories and plants – Installations undergoing decommissioning	– Reactor outages – Organisational and human factors – Operation of the installation – Condition of barriers – Condition of systems – Prevention and management of risks, emergency situations – Radiation protection – Environment and transport
Small-scale nuclear activities	– Industrial radiography activities – External radiotherapy – Interventional medical radiology – Brachytherapy – Suppliers of ionising radiation sources – Nuclear medicine units performing therapeutic and/or in vivo diagnostic procedures – Holders of unsealed source licences – Industrial or research irradiation facilities or particle accelerators – Thin layer thickness measurement – Gammadensimetry – Use of neutron sources – Implementation of high activity sealed sources
Radioactive material transport	– Compliance with quality assurance requirements for radioactive material transport – Safety adviser duties

2|2|2 Internal monitoring of radiation protection by the users of ionising radiations

The aim of internal monitoring of radiation protection is to ensure regular assessment of the radiological safety of the facilities using sources of ionising radiations. This monitoring is performed under the responsibility of the licensees. It may be carried out by the person with competence for radiation protection (PCR), appointed and mandated by the employer, or be entrusted to IRSN or to organisations approved by ASN. It does not replace either the periodic checks required by the regulations, or the inspections conducted by ASN. It for example concerns the performance of the protection systems, monitoring of the ambient atmosphere in regulated areas, checks on medical appliances before they enter service or after modification, and so on.

2|2|3 Packages not requiring approval

The package models with the highest safety stakes require approval from ASN. This includes those intended for the transport of high activity level radioactive materials, or those in which the contents entail a criticality risk (see chapter 11). However, for the other types of packages, in particular those for which destruction can lead to exposure of up to 50 mSv in 30 minutes at a distance of 1 metre, the consignor is responsible for demonstrating that the package model used does indeed meet the safety requirements set by the regulations and that it is appropriate for the contents to be transported. ASN regularly conducts inspections to check the measures adopted by the consignors of these packages, referred to as "packages not requiring approval".

2|3 Increasing ASN regulation resources by approving organisations and laboratories

Paragraph 2 of Article 4 of the TSN Act states that "ASN issues the required approvals to the bodies participating in the controls and in the watch over nuclear safety or radiation protection". Depending on the health or safety stakes involved in a nuclear activity or facility category, ASN may rely on the results of checks carried out by independent organisations and laboratories it has approved and which it monitors via second level checks.

ASN thus approves organisations for carrying out the technical inspections required by the regulations in the

fields within its scope of competence. The organisations approved in this way carry out:
– radiation protection checks;
– measurement of radon activity concentration in premises open to the public;
– evaluations of nuclear pressure equipment conformity and inspection of operational equipment.

The checks carried out by these organisations contribute to ASN's overview of all nuclear activities.

In order to approve those organisations which apply, ASN ensures that they perform the inspections in accordance with their technical, organisational and ethical obligations and in compliance with the rules of professional good practice. Compliance with these provisions should enable the required level of quality to be obtained and maintained.

ASN ensures that maximum benefit is gained from the approval issued, in particular through regular exchanges with the organisations it has approved and the mandatory transmission of an annual report, in order to:
– exploit operating experience feedback;
– improve the approval process;
– improve intervention conditions.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. It thus approves laboratories:
– for monitoring of environmental radioactivity (see point 4);
– for worker dosimetry (see chapter 1).

The list of approvals issued by ASN is kept up to date on its website ("bulletin officiel de l'ASN/agréments d'organismes" section, available in French only).

In 2009, ASN issued:
– 30 new or renewed approvals for organisations responsible for radiation protection inspections;
– 29 approvals for level 1 radon activity concentration measurements;
– 7 approvals for worker dosimetry (4 for internal monitoring of workers and 3 for external monitoring of workers).
– 398 approvals for measurement of environmental radioactivity.

ASN sends the General Directorate for Health an opinion on the approval of the laboratories analysing radioactivity in water intended for human consumption.

It sends the ministers responsible for nuclear safety and/or transport an opinion on approval of the organisations responsible for:
– training the drivers of vehicles transporting radioactive materials (class 7 dangerous goods);
– organising safety adviser examinations for transport of dangerous goods by road, rail or navigable waterway;
– certifying the conformity of packagings designed to contain 0.1 kg or more of uranium hexafluoride (initial and periodic checks);
– issuing type approval for tank-containers and mobile tanker units intended for transport of class 7 dangerous goods by road;
– initial and periodic checks on tankers intended for the transport of dangerous goods.

3 DEPLOYING THE MOST EFFICIENT REGULATION AND INSPECTION MEANS

The licensee is required to provide ASN with the information it needs to perform its regulatory responsibility. 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 milestones in the operation of a nuclear activity. The actions specific to inspection of radioactive material transport are described in detail in chapter 11.

3|1 Assessing the supporting documents submitted by the licensee

The purpose of the documents submitted by the licensee is to demonstrate compliance with the objectives set by the general technical regulations, as well as those that it has set for itself. ASN is required to check the completeness of the data and the quality of the demonstration.

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's requirements are expressed in the form of a decision.

3|1|1 Analysing the information supplied by BNI licensees

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of inspection carried out by ASN.

Whenever it deems necessary, ASN seeks the advice of technical support organisations, primarily IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety, radiation protection and protection of the environment.

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. 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.

At the design and construction stage, ASN checks the safety analysis reports describing and justifying basic design data, equipment design calculations, utilisation rules and test procedures, and quality organisation provisions made by the prime contractor and its suppliers. ASN also checks the construction and manufacture of structures and equipment, in particular those of PWR main primary systems (MPS) and main secondary systems (MSS). In accordance with the same principles, it checks the packages intended for the transport of radioactive materials.

Once the nuclear facility has been commissioned, following ASN authorisation, all changes made by the licensee and such as to affect security, public health and safety, or protection of nature and the environment, are notified to ASN. In addition to these submissions, made necessary by changes to the facilities or how they operate, the licensee must, pursuant to the TSN Act, carry out periodic safety reviews in order to update the evaluation of the facility in the light of changing techniques and regulations and on the basis of operating experience feedback. The conclusions of these reviews are submitted to ASN, which can issue new provisions in order to tighten the safety requirements.

Other data submitted by BNI licensees

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

Similarly, there is a considerable volume of data on specific topics, such as, for example, fire protection, PWR fuel management strategies, relations with subcontractors, and so on.

Nuclear power plant scheduled outages

The nuclear power plants operated in France are periodically shut down in order to:
– replace the spent fuel;
– carry out checks and maintenance on the parts of the facility which are not accessible during operation.

These shutdowns are referred to as "reactor outages". ASN approves the outage programme submitted by EDF and decides on whether or not the facilities can subsequently be restarted. From preparation of the outage to implementation of the post-outage steps, ASN oversees the safety measures adopted by the licensee.

In the light of the importance for safety of the work carried out during the outage, 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. The ASN regional divisions regulate the outage process, step by step. During the "worksite" inspections, the inspectors will carry out spot checks on the conditions in which the work in progress on the various sites is conducted, whether for repair or for modification of the facilities, in-service monitoring of equipment, or periodic equipment testing.

3|1|2 Reviewing the procedures laid down by the Public Health Code

It is up to ASN to review applications for the use of ionising radiations 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.

In addition to the internal inspections carried out under the responsibility of the establishments and the periodic

checks required by the regulations, ASN carries out its own verifications. In this respect it directly carries out checks during the procedures for issue (pre-commissioning inspections) or renewal (periodic inspections) of the authorisations to possess and use radiation sources granted on the basis of Article R. 1333-23 of the Public Health Code. The authorisation notifications can only be issued if the requests submitted by ASN following the checks have been taken into account. These checks are in particular designed to compare the data contained in the files with the actual physical reality (sources inventory, check on the conditions of production, distribution and utilisation of the sources and the devices containing them). They also enable ASN to ask the establishments to improve their in-house provisions for source management and radiation protection.

3 | 2 Inspecting facilities and activities

3 | 2 | 1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:

1. the inspection aims to detect any deviations indicative of a possible deterioration in facility safety or the protection of individuals and any non-compliance with the legislative and regulatory requirements the licensee is bound to apply;
2. the inspection is proportionate to the level of risk presented by the facility or activity;
3. the inspection is neither systematic nor exhaustive, is based on sampling and focuses on subjects for which the stakes are highest.

3 | 2 | 2 Inspection resources

To ensure greater efficiency, ASN's action is organised on the following basis:

– inspections, according to a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
– inspections on a representative sample of licensees in other nuclear activities;
– systematic technical inspections of all facilities by approved organisations.

ASN focuses its inspection resources on activities and topics for which the stakes are particularly high. For the other activities, ASN relies in particular on the organisations it has approved. However, to avoid ignoring activities of lesser significance, it does devote a part of its inspection programme to them through targeted action. In 2009, ASN continued with its programme of inspection of medical radiology practices and lead paint inspection companies. This type of action maintains an ASN presence among those in charge, evaluates application of the regulations in a particular sector and helps raise awareness within the profession.

The inspections may be unannounced or notified to the licensee a few weeks before the visit. They take place mainly on the site or during the course of the relevant activities (work, transport operation). They may also concern the head office departments (or design and engineering departments) at the major nuclear licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

The ASN inspector in the turbine hall during the ten-yearly outage inspection of the Tricastin NPP (Drôme *département*) – 26 May 2009

ASN inspector carrying out checks during an inspection in the Henri Mondor hospital in Créteil (Val-de-Marne *département*) – August 2008

The inspections are generally carried out by two inspectors, with the support of an IRSN representative specialising in the facility visited or the topic of the inspection. ASN uses various types of inspections:
– standard inspections;
– in-depth inspections, which take place over several days and mobilise about ten or so inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors (see chapter 2);
– inspections with sampling and measurements. These are designed to check discharges by means of samples that are independent of those taken by the licensee;
– reactive inspections, carried out further to a particularly significant event;
– worksite inspections, ensuring a significant ASN presence on the sites on the occasion of reactor outages or particular work, especially in the decommissioning phase.

These inspections give rise to factual records, made available to the licensee. They concern:
– anomalies in the facility or aspects warranting additional justifications;
– deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations.

To achieve its goals:

a) ASN employs inspectors chosen for their professional experience and for their legal and technical expertise.

The inspectors carry out their inspection duties under the authority of the ASN Director General. They are sworn-in and bound by professional secrecy. They are appointed once they have acquired the necessary competence through their professional experience, tutoring and appropriate training. To ensure constant progress, ASN:
– in the same way as the main foreign nuclear regulatory bodies, has defined a system for qualification of its inspectors. This is based on recognition of their technical expertise;
– adopted a number of foreign practices identified through inspector exchanges between nuclear regulatory bodies. These exchanges are organised either for a particular inspection or for a longer period, via a secondment of up to 3 years. For example, once it had confirmed the potential benefits, ASN adopted the in-depth inspections model described in point 3|2|2. However, it did not opt for the system involving a resident inspector on a nuclear site: ASN considers that its inspectors must work within a structure large enough to allow cross-pollination of experience and that they must take part in checks on different licensees and facilities in order to acquire a broader view of this field of activity. This also avoids a confusion of responsibilities;
– encourages an open-minded attitude on the part of its inspectors to other regulatory practices. ASN encourages its departments to take on inspectors from other regulatory bodies (ICPE inspectorate, AFSSAPS, technical services of the Ministry for Health, etc.). It also proposes organising joint inspections with these bodies concerning the activities falling within its scope of expertise. In order to identify other methods for risk management by the licensees, the ASN inspectors may also observe inspections on specialised subjects in facilities which do not fall within their field of expertise.
– aims to ensure the uniformity of its practices. It encourages participation by its staff in inspections on different subjects, in different regions and sectors.

The ASN Chairman appoints the inspectors as defined by decree 2007-831 of 11 May 2007 which determines the procedures for the appointment and qualification of nuclear safety inspectors (formerly known as BNI

inspectors) and the staff responsible for checking pressure equipment specifically designed for BNIs and by Articles R. 1333-100 to R. 1333-108 of the Public Health Code (radiation protection inspectors).

Table 3 presents the inspector staffing levels on 31 December 2009. Some officers are inspectors in several categories.

In 2009, ASN carried out 2128 inspections on BNIs, radioactive material transport, activities using ionising radiations, organisations and laboratories it has approved and activities involving pressure equipment.

b) To guarantee an adequate distribution of the inspection resources, proportionate to the nuclear safety, radiation protection and environmental protection impact of the various facilities and activities, ASN each year drafts an inspections forecast schedule. It identifies the facilities, activities and subjects targeted. This is not known beforehand to those in charge of nuclear activities.

c) ASN trains its inspectors and provides them with inspection guides and decision-making aids concerning any follow-up to deviations observed.

d) ASN performs qualitative and quantitative supervision of the inspection programme and the actions taken subsequent to the inspections. Reports are issued on compliance with the forecast schedule of inspections and enable the activities checked to be evaluated in terms of both the licensee and the sector or particular topic concerned.

e) ASN informs the public by placing the nuclear safety and radiotherapy centre inspection follow-up letters on its website, as well as through its publications. This subject is developed in greater detail in chapter 6.

f) ASN is setting up a system for constant improvement of its inspection process, which can be based on internal and external audits.

3|2|3 Inspection of basic nuclear installations and pressure equipment in 2009

In 2009, 814 inspections were carried out, including 219 unannounced BNI inspections. The breakdown according to the various facility categories is described in the following graphs.

In 2009, ASN also delegated 1600 inspections to approved organisations to assess the conformity of nuclear pressure equipment.

3|2|4 Inspection of radioactive material transport in 2009

The 94 inspections on transport activities in 2009 can be broken down according to topic as shown in graph 4.

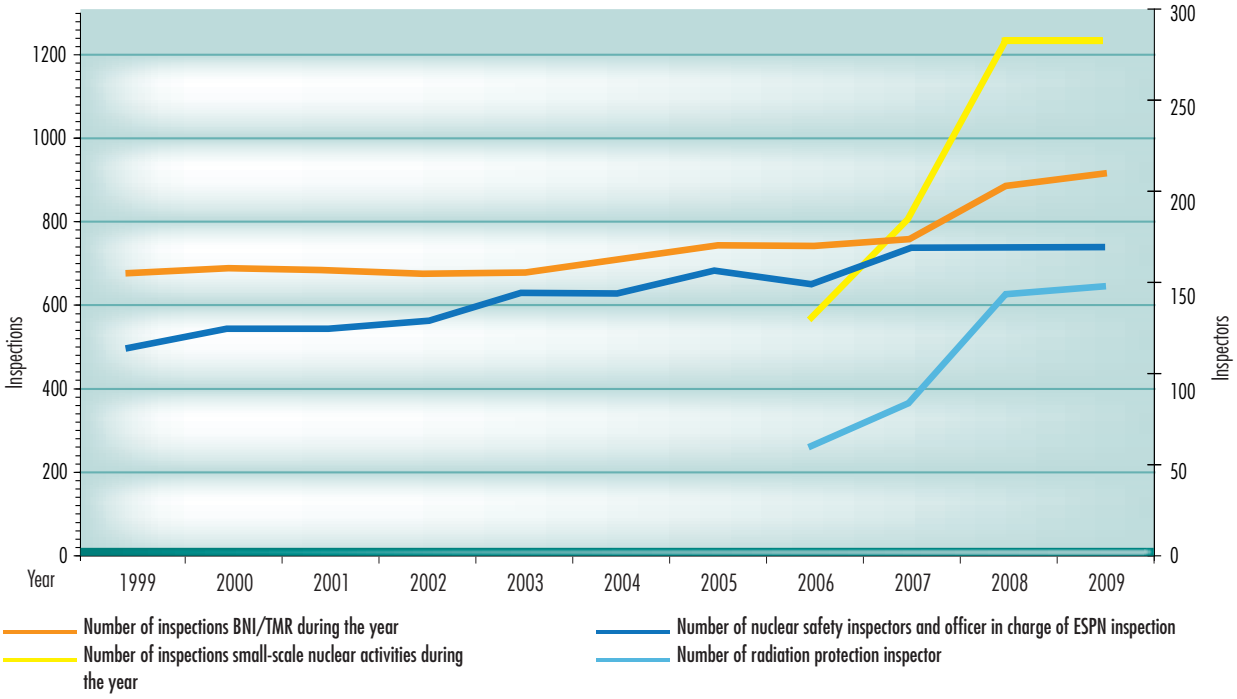
3|2|5 Inspection of small-scale nuclear activities in 2009

ASN organises its regulation so that it is proportionate to the radiological issues involved in the use of ionising radiations, and consistent with the actions of the other inspection services. On the 50,000 or so nuclear facilities and activities in the sector, ASN carried out 1,081 inspections in 2009, including 617 in the medical sector, 438 in industry or research and 26 on landfills, mines and spoil heaps, polluted sites or companies not exercising a nuclear activity but exposing their staff to ionising radiations. The breakdown according to the various categories of activity is described in graph 5.

Table 3: breakdown of inspectors per type of inspection (as at 31.12.2009)

Type of inspector	Departments	Divisions	Total
Nuclear safety inspector (BNI) and nuclear pressure equipment inspection officer	74	96	**170**
Nuclear safety inspector (transport)	10	41	**51**
Radiation protection inspector	36	111	**147**
Conventional safety inspector	1	13	**14**
Number of inspectors (all fields included)	95	150	**245**

Graph 1: trends in the number of ASN inspectors and inspections

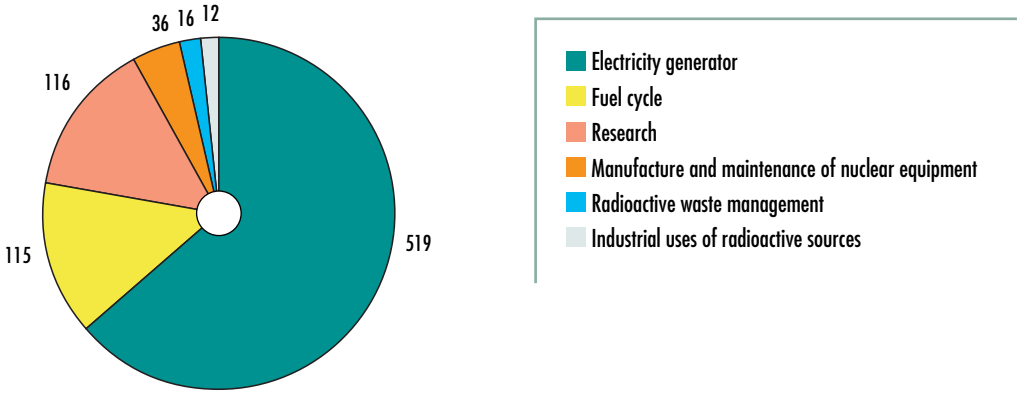


3 | 2 | 6 Inspection of ASN approved organisations and laboratories in 2009

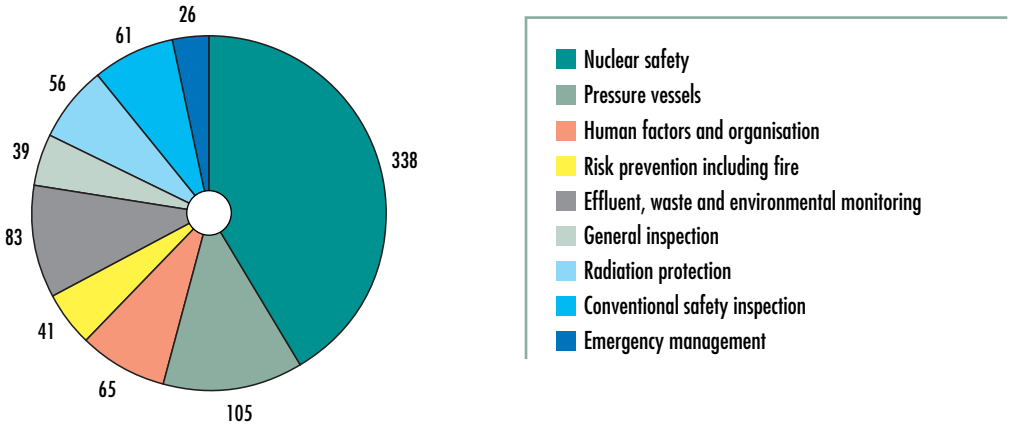
ASN carries out a second level of inspection on approved organisations and laboratories. In addition to reviewing the application file and issuing the approval, this comprises surveillance such as the following:
– approval follow-up or renewal audits;
– checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
– supervisory checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2009, ASN carried out 139 inspections of approved organisations and laboratories, broken down as follows:
– organisations carrying out radiation protection technical checks: 98 including 67 unannounced supervisory checks;
– organisations evaluating nuclear pressure equipment conformity and inspecting operational equipment: 21 inspections;

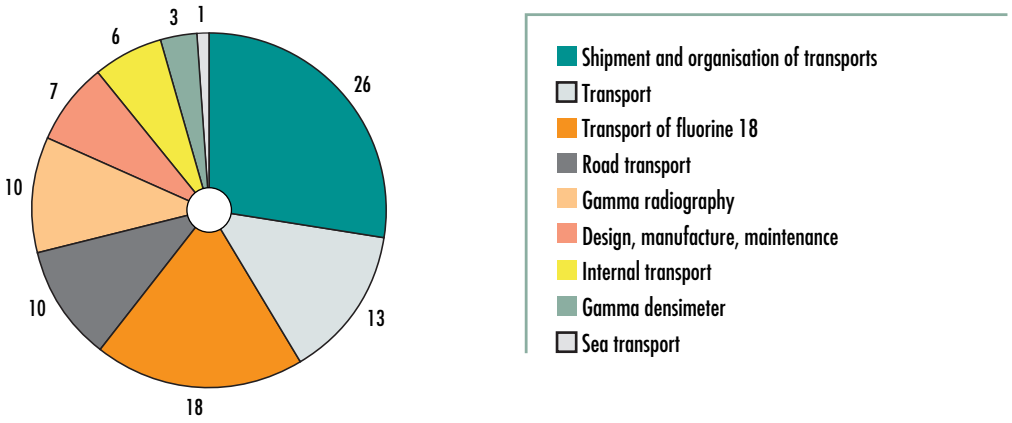
Graph 2: breakdown of BNI inspections in 2009 per type of licensee



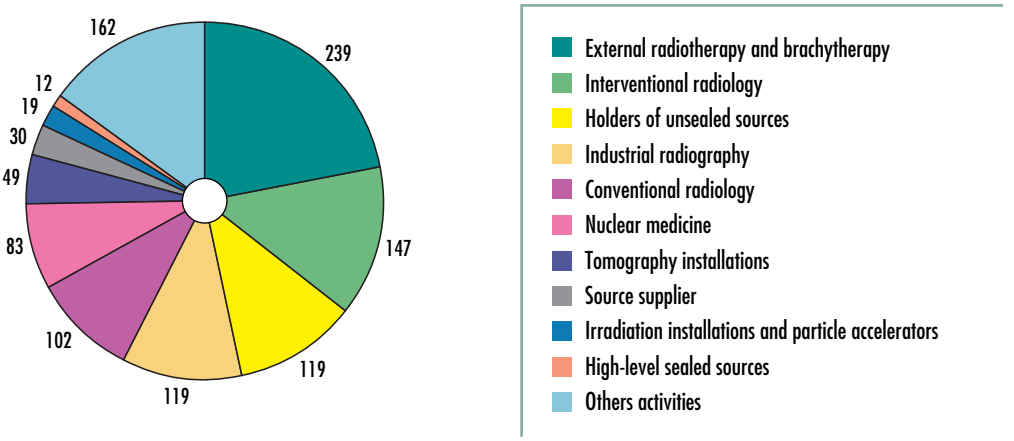
Graph 3: breakdown of BNI inspections in 2009 per topic



Graph 4: breakdown of radioactive material transport inspections in 2009 per topic



Graph 5: breakdown, per activity category, of visits or inspections carried out in 2009 in the small-scale nuclear facilities



– organisations measuring radon activity concentration: 11 inspections;
– laboratories approved for environmental radioactivity measurements: 9 inspections.

3|2|7 Monitoring of exposure to radon and natural ionising radiations in 2009

ASN also monitors radiation protection in premises where exposure of individuals to natural ionising radiations 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).

a) Monitoring 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 radon monitoring bodies approved by ASN. The measurement campaigns must take place between 15 September of year N and 30 April of the following year.

For the 2009-2010 measurement campaign, the number of approved bodies is summarised in table 4.

b) Monitoring exposure to natural ionising radiations in non-nuclear industries

The order of 25 May 2005 published the list of professional activities (industries, spas and drinking water treatment plants) requiring monitoring of human exposure to natural ionising radiations, 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.

Verifications of implementation of these new requirements over the period 2007-2008 confirmed that certain industries were more particularly concerned by the issue of enhanced natural ionising radiations. These include facilities for zircon production and for processing of titanium ore and rare earths, to which the worker radiation protection regulations apply in accordance with Articles R.4457-13 and R.4457-14 of the Labour Code.

The inspection and evaluation actions taken in collaboration with the conventional safety inspectorate and the ICPE inspectorate were carried out over the period 2008-2009. These actions completed the results obtained and improved understanding of the issues in these industrial sectors, as well as in spas and groundwater extraction facilities.

c) Monitoring natural radioactivity in water intended for human consumption

Since 1 January 2005 (order of 12 May 2004), monitoring of natural radioactivity in water intended for human consumption is an integral part of the health monitoring carried out by the Departmental Health and Social Action Directorates (DDASS). It takes account of the recommendations issued by ASN (DGS circular of 13 June 2008) and the results concerning the radiological quality of this water are jointly analysed by the Ministry for Health and ASN. A summary of these results is presented in chapter 1.

3|3 Regulating the impact of nuclear activities on the environment

3|3|1 Regulating basic nuclear installation discharges

a) Monitoring of discharges

The monitoring of discharges from an installation is essentially the responsibility of the licensee. The provisions regulating discharges stipulate the minimum checks that the licensee is required to carry out. These checks in particular concern effluents (monitoring of discharge activity level, characterisation of certain types of effluents prior to discharge, etc.). They also contain provisions for monitoring in the environment (checks at mid-discharge, sampling of air, milk, grass, etc.). Finally, related parameters must also be measured whenever necessary (in particular meteorology).

The results of the regulatory measurements must be stored in registers which, in the case of BNIs, are forwarded on a monthly basis to ASN, which checks them.

BNI licensees are also required regularly to transmit a number of discharge samples to an independent laboratory

Table 4: number of organisations approved to measure radon activity concentration in premises open to the public

	Approval until 15 September 2010	Approval until 15 September 2011	Approval until 15 September 2012
Level 1 (screening)	27	20	13
Level 2 (additional investigations)	3	4	0

for analysis. The results of these "cross-checks" are communicated to ASN. The cross-check programme, specified by ASN, is designed to bolster the conviction that the results obtained by the licensees are in fact accurate.

Finally, ASN uses a system of unannounced inspections to ensure that the licensees abide by the regulations. During the course of these inspections, inspectors – assisted when necessary by technicians from a specialised, independent laboratory – check compliance with the regulation requirements, take samples from the effluents or the environment, and have them analysed by this laboratory. Since 2000, ASN has carried out 10 to 30 inspections - with sampling - every year (16 in 2009).

b) Accounting of basic nuclear installation discharges

The lowering of the activity level of the radioactive effluents discharged by BNIs, the changes made to the categories of radionuclides regulated in the discharge licence orders and the need to be able to calculate the dosimetric impact of the discharges on the population, led ASN to change the radioactive discharge accounting rules in 2002.

Accounting principles:
- for each category of radionuclides regulated, the activity levels discharged are based on a specific analysis of the radionuclides rather than on total measurements;
- compulsory detection limits are defined for each type of measurement;
- for each BNI and for each type of effluent, a "reference" spectrum is defined, in other words a list of radionuclides whose activity must be systematically considered, whether or not higher than the decision threshold. These evolving reference spectra are based on operating experience feedback from the analyses carried out. When the activity is lower than the decision threshold, then the latter value is used;
- other radionuclides, which are occasionally present, are considered if their activity concentration is higher than the decision threshold.

These rules are already applied in all NPPs and in most laboratories and plants (CENTRACO, AREVA and ANDRA establishments at La Hague, FBFC in Romans-Sur-Isère, CEA centres in Cadarache, Saclay, etc.). They will be applied to the other sites as their discharge licence orders are renewed. As other countries use different accounting methods, it is hard to compare the results published by the various national nuclear regulators.

With regard to the measurements

– The decision threshold (SD) is the value above which the measurement technique guarantees that a radionuclide is present.

– The detection limit (LD) is the value above which the measurement technique gives a reliable result.

In practice LD ≈ 2 x SD

Reference spectra used for NPPs

As an example, the following reference spectra are used for NPPs:

– Liquid
- *– ^{3}H,*
- *– ^{14}C,*
- *– Iodines: ^{131}I,*
- *– Other fission and activation materials: ^{54}Mn, ^{58}Co, ^{60}Co, ^{110m}Ag, ^{123m}Te, ^{124}Sb, ^{125}Sb, ^{134}Cs, ^{137}Cs.*

– Gaseous:
- *– ^{3}H,*
- *– ^{14}C,*
- *– Rare gases:*
  - *ventilation (permanent discharges): ^{133}Xe, ^{135}Xe*
  - *"RS" tank drainage: ^{85}Kr, ^{131m}Xe, ^{133}Xe*
  - *decompression of reactor buildings: ^{41}Ar, ^{133}Xe, ^{135}Xe.*
- *– Iodines: ^{131}I, ^{133}I,*
- *– Other fission and activation materials: ^{58}Co, ^{60}Co, ^{134}Cs, ^{137}Cs.*

Quality of measurement is a precondition if the results obtained and published are to be conclusive. In the field of effluents measurement, in view of the shortcomings in the available body of standards, ASN supported the creation of a working group by the nuclear equipment standardisation office (BNEN). This programme will eventually produce a set of high-quality methods that are standardised and therefore comparable.

3|3|2 Assessing the radiological impact of nuclear activities

Under the optimisation principle, the licensee is required to reduce the radiological impact of its facility to values as low as reasonably achievable based on economic and social factors.

The licensee is required to assess the dosimetric impact of its activity. Depending on the case, this obligation arises from Article L. 1333-8 of the Public Health Code, or from the regulations concerning BNI discharges. The result must be compared with the annual dose limit for the public (1 mSv/year) defined in Article R.1333-8 of the Public Health Code.

In practice, only traces of artificial radioactivity are detectable in the vicinity of nuclear facilities. As soon as one moves away from a facility, the activity levels fall below the sensitivity threshold of the measuring instruments and cannot therefore be used for dose estimates. It then becomes necessary to use models of radioactivity transfer to man, fed by facility discharge measurement data. These models are specific to each licensee. ASN aims for optimum harmonisation of the methods used and in 2009 initiated an examination of this subject with IRSN.

Nonetheless, programmes to monitor the radioactivity present in the environment (water, air, earth, milk, grass, agricultural produce, etc.) are imposed on the licensees in order to check compliance with the scenarios postulated in the impact assessment. The laboratories carrying out these measurements must be approved by ASN (see 4|3).

An estimation of the doses from BNIs is presented in table 5.

The doses from BNIs for a given year are determined on the basis of the actual discharges from each installation for the year in question. This assessment takes account of the discharges through the identified outlets (stack, discharge pipe to river or seawater). It also includes diffuse emissions and sources of radiological exposure to the ionising radiations present in the installations. These elements are the “source term”.

The estimate is made in relation to one or more identified reference groups. These are homogeneous groups of individuals receiving the highest average dose from among the population exposed to a given installation according to realistic scenarios. This population category (adults, infants, children) differs from one site to another and from one year to another, as does the group’s distance from the site.

Finally, the estimate is made according to modelling parameters specific to each site, such as meteorological data (locally observed wind rose).

All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

For each of the nuclear sites presented, the radiological impact remains far below 1% of the limit for the public of 1 mSv per year. ASN is therefore of the opinion that in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

3|4 Learning the lessons from significant events

3|4|1 Anomaly detection and analysis

a) History

The international conventions ratified by France (Article 9v of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management of 5 September 1997; Article 19vi of the Convention on Nuclear Safety of 20 September 1994) require that BNI licensees implement a reliable system for detecting any anomalies that may occur, such as equipment failures or errors in the application of operating rules. This system should allow early detection of any abnormal operation and is a factor in defence in depth. These anomalies must be notified to ASN.

Based on twenty years of experience, ASN felt that it would be useful to transpose this approach to radiation protection and protection of the environment. ASN thus drafted two guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:

– the 21 October 2005 guide contains the requirements applicable to BNI licensees and to carriers. It concerns significant events affecting BNI safety, RMT safety, radiation protection and protection of the environment;
– the ASN/DEU/03 guide of 15 June 2007 is intended for those in charge of nuclear activities as defined in L. 1333-1 of the Public Health Code and the heads of the facilities in which ionising radiations are used

Table 5: radiological impact of BNIs since 2003 calculated by the licensees on the basis of the actual discharges from the installations and for the most exposed reference groups (data provided by the nuclear licensees)

Licensee/Site	Most exposed reference group (population/distance from site in km)[a]	Estimation of received doses, in mSv					
		2003	2004	2005	2006	2007	2008
AREVA/La Hague	Digulleville (Child/2.6) Fisherman, Goury (Adult (2008: child)/7.5)	1.10^{-2} 7.10^{-3}	1.10^{-2} 6.10^{-3}	1.10^{-2} 6.10^{-3}	1.10^{-2} 6.10^{-3}	1.10^{-2} 6.10^{-3}	8.10^{-3} 5.10^{-3}
GANIL/Caen	IUT (Adult/0.6)	2.10^{-3}	3.10^{-3}	2.10^{-3}	3.10^{-3}	$< 6.10^{-3}$	$< 9.10^{-3}$ [b]
EDF/Penly	Saint-Martin Plage (Adult/1.05)	4.10^{-3}	1.10^{-3}	9.10^{-4}	5.10^{-4}	6.10^{-4}	3.10^{-3}
EDF/Cattenom	Garche nord (Adult/2.15)	2.10^{-3}	2.10^{-3}	2.10^{-3}	3.10^{-3}	3.10^{-3}	3.10^{-3}
EDF/Paluel	Le Tôt (Adult/1.45)	2.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}	2.10^{-3}
CEA/Cadarache	Saint-Paul-Lez-Durance (Adult/2)	8.10^{-3}	8.10^{-3}	8.10^{-3}	3.10^{-4}	2.10^{-3}	2.10^{-3}
EDF/Chooz	Les Pirettes (gymnase) (Adult/0.75)	*	*	*	*	*	2.10^{-3}
EDF/Dampierre	La Maison Neuve (Adult/0.9)	*	*	*	*	*	8.10^{-4}
EDF/Civaux	Ervaux sud (Adult/0.7)	*	*	*	*	*	8.10^{-4}
EDF/Golfech	Pascalet (Adult/0.85)	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	5.10^{-4}	8.10^{-4}
ANDRA/Manche	Hameau de La Fosse (Adult/2.5) Pêcheur Goury (Adult/8)	9.10^{-4} 6.10^{-8}	9.10^{-4} 7.10^{-8}	8.10^{-4} 7.10^{-7}	8.10^{-4} 8.10^{-8}	7.10^{-4} 9.10^{-8}	7.10^{-4} 5.10^{-8}
EDF/Flamanville	La Berquerie (Adult/0.8)	3.10^{-3}	3.10^{-3}	5.10^{-3}	5.10^{-3}	1.10^{-3}	7.10^{-4}
EDF/Nogent-sur-Seine	Port Saint-Nicolas (Adult/2.25)	5.10^{-4}	6.10^{-4}	7.10^{-4}	8.10^{-4}	9.10^{-4}	7.10^{-4}
CEA / Saclay	Fishermen, Christ de Saclay (Adult/1) Farmers, Christ de Saclay (Adult/1)	4.10^{-3} 1.10^{-3}	4.10^{-3} 7.10^{-4}	4.10^{-3} 5.10^{-4}	5.10^{-3} 5.10^{-4}	9.10^{-4} 4.10^{-4}	7.10^{-4} 4.10^{-4}
EDF/Belleville-sur-Loire	Neuvy-sur-Loire (Adult/1.3)	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	6.10^{-4}
AREVA/FBFC	Ferme Riffard (Adult/0.2)	*	*	*	*	*	6.10^{-4}
EDF/Blayais	Le Bastion (Adult/1.1)	3.10^{-4}	3.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}
AREVA/Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Prés Guérinés (Adult (2005: child)/ 3; 3.1 ; 2.16 ; 1.3 ; 1.5)	2.10^{-3}	2.10^{-3}	2.10^{-3}	1.10^{-3}	1.10^{-3}	5.10^{-4}
	Clos de Bonnot (Adult/2.2; 2.3 ; 1.3 ; 0.6; 0.8)	*	*	*	*	*	7.10^{-4}
EDF/Bugey	Saint-Étienne-d'Hières sud (Adult/0.45)	*	*	*	*	*	5.10^{-4}
CEA/Marcoule (Atalante, Centraco, Phénix, Mélox, Cis-Bio)	Codolet (Adult/2)	4.10^{-4}	4.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}	4.10^{-4}
EDF/Chinon	Le Neman (Adult/1.25)	2.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	4.10^{-4}
EDF/Cruas-Meysse	Ferme de Grimaud (Adult/1.25)	6.10^{-5}	2.10^{-4}	2.10^{-4}	2.10^{-4}	8.10^{-5}	4.10^{-4}
EDF/Tricastin	Clos du Bonneau (Adult/1.25)	2.10^{-5}	7.10^{-5}	7.10^{-5}	6.10^{-5}	7.10^{-5}	4.10^{-4}
EDF/St-Laurent-des-Eaux	Port au Vin (Adult/0.7)	2.10^{-4}	7.10^{-5}	7.10^{-5}	9.10^{-5}	2.10^{-4}	4.10^{-4}
EDF/Gravelines	Petit-Fort-Philippe (Adult/1.45)	5.10^{-5}	2.10^{-4}	2.10^{-4}	3.10^{-4}	3.10^{-4}	3.10^{-4}
EDF/St-Alban	Les Crès (Adult/1.45)	9.10^{-5}	9.10^{-5}	2.10^{-4}	2.10^{-4}	7.10^{-5}	3.10^{-4}
EDF/Fessenheim	Cité EDF (Adult/1.2)	*	*	*	*	*	8.10^{-5}
EDF/Creys-Malville	Ferme de Chancillon (Adult/0.85)	*	*	*	*	1.10^{-5}	2.10^{-5}
CEA/Fontenay-aux-Roses	Fontenay-aux-Roses (Child/1.5)	2.10^{-5}	2.10^{-5}	2.10^{-5}	2.10^{-5}	9.10^{-6}	1.10^{-5}
ANDRA/CSA	Pont du CD24 (Child/2.1)	8.10^{-5}	8.10^{-6}	6.10^{-6}	5.10^{-6}	3.10^{-6}	2.10^{-6}
CEA/Grenoble[c]	Fontaine (gaseous discharges); Saint-Egrève (liquid discharges) [(Baby (2003, 2004, 2008: adult)/1 (Fontaine); 1.4 (Saint-Egrève)]	2.10^{-5}	7.10^{-6}	7.10^{-7}	2.10^{-6}	7.10^{-7}	1.10^{-6}
	Saint-Egrève [(Baby (2004, 2007: adult)/ 1.4 (liquid); 3.9 (gaseous)]	2.10^{-6}	3.10^{-6}	4.10^{-7}	8.10^{-7}	3.10^{-7}	6.10^{-7}

a: For installations operated by EDF, only "Adult" figures are calculated.
b: This figure is grossly over-estimated, according to the licensee.
c: Because the outfall for the liquid discharges is geographically distant from the stack, two impact calculations are performed. One reflects the aggregate of maximum impact of gaseous discharges plus maximum impact of liquid discharges. The other corresponds to an actual reference group.
*Information not supplied by the licensees.
Source: annual reports from the licensees concerned when this is required by the discharge licenses.

(medical, industrial and research activities using ionising radiations). It has been experimentally implemented since 1 June 2007, in order to familiarise the professionals with this approach and take account of any problems they could encounter, while enabling them to meet their legal obligations straight away.

These guides can be consulted on the ASN website, www.asn.fr.

b) What is a significant event?

Detection of events (deviations, anomalies, incidents, etc.) by those in charge of the activities using ionising radiations, and implementation of corrective measures highlighted after analysis, play a fundamental role in accident prevention. 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.

Rating the anomalies should enable priority to be given to addressing the most important ones. ASN has defined a category of anomalies called "significant events". These are events that are sufficiently important in terms of safety or radiation protection to justify rapid notification of ASN, followed by a subsequent and more complete analysis. Significant events must be notified to it, as specified in the TSN Act (Article 54), the Public Health Code (Articles L. 1333-3 and R. 1333-109 to R. 1333-111) and the Labour Code (Article R. 4455 7). The criteria for notification to the public authorities of events considered to be "significant" take account of the following:

– the actual or potential consequences for workers, the public, patients or the environment, of events that could occur and affect nuclear safety or radiation protection;
– the main technical, human or organisational causes that led to the occurrence of such an event.

This notification process is part of the continuous safety improvement approach. It requires the active participation of all licensees (users of ionising radiations, carriers, etc.) in the detection and analysis of deviations. It enables the authorities:

– to ensure that the individual in charge of the activity has carried out a relevant analysis of the event and taken appropriate measures to remedy the situation and prevent it happening again;
– to analyse the event in the light of the experience available to other parties in charge of similar activities.

The purpose of this system is not to identify or penalise any individual person or party (see point 4).

3|4|2 Implementation of the approach

a) Event notification

As required by the TSN Act, in the event of an incident or accident, whether or not nuclear, with a real or potential risk of significant consequences for the safety of the facility or transport or, as a result of significant exposure to ionising radiations, liable to constitute a risk to individuals, property or the environment, the BNI licensee or individual in charge of a radioactive material transport must immediately notify ASN and the State's representative in the département* in which the incident or accident occurred and, as applicable, the State's maritime representative.

As specified in the Public Health Code, the individual required to notify the significant event is the individual in charge of the nuclear activity.

According to the provisions of the Labour Code, the party declaring a significant event affecting a worker is the employer. When the head of a facility carrying out a nuclear activity calls in an external contractor or non-salaried worker, the significant events affecting salaried or non-salaried workers are notified in accordance with the prevention plans and the agreements concluded pursuant to Article R. 4451-8 of the Labour Code.

b) ASN analysis of the notification

Within two months of the notification, it is followed by a report indicating the conclusions the licensee has drawn from analysis of the events and the steps it intends to take to improve safety or radiation protection. This information is extremely valuable for ASN and its technical support organisation, IRSN, in particular for the periodic safety reviews conducted on BNIs.

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

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

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

ASN and its technical support organisation, 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's operating experience feedback. This operating experience feedback can lead to requests for improvement of the condition of the facilities and the organisation adopted by the licensee, as well as for changes to the regulations.

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

3 | 4 | 3 Public information

Independently of this process, the public must be informed of those events with consequences that so warrant (see chapter 6).

3 | 4 | 4 Statistical summary of events in 2009

Graphs 6 to 11 describe in detail the significant events notified to ASN in 2009, differentiating between the various notification criteria for each domain:
– nuclear safety, radiation protection and environment for BNIs;
– non-BNI radiation protection.

The statistics for significant events involving the transport of radioactive materials are given in chapter 11.

Apart from the technical analysis specific to each criterion, it can be seen that half of the events notified are due to non-compliance with requirements or rules.

3 | 5 Raising awareness

Compliance with the regulations can also be obtained through education. Regulation is thus 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 implement this approach by issuing good practice and professional information guides. These initiatives are described in greater detail in chapter 9.

Raising awareness also involves joint action with other administrations and organisations who carry out regulatory duties on the same facilities, but with different prerogatives, such as the conventional safety inspection, inspection of medical appliances by AFSSAPS or health inspection as entrusted to the technical divisions of the Ministry for Health.

This approach is illustrated by the joint creation by ASN and the French Society for Radiation Oncology (SFRO) of a common scale for rating radiation protection events affecting patients undergoing radiotherapy treatment.

Finally, jointly with the General Directorate for Labour (DGT), ASN initiated coordination of the conventional safety inspectorate and the radiation protection inspectorate. This will include information exchanges, both local and national, joint inspections and cross-training courses.

3 | 6 Conducting a technical inquiry in the event of an incident or accident concerning a nuclear activity

By entrusting ASN, an independent administrative authority, with the regulation of nuclear safety and radiation protection and public information in these fields, the TSN Act (5° of Article 4) gave it the powers to call a technical inquiry in the event of an incident or accident concerning a nuclear activity. This inquiry consists in collecting and analysing all useful information, without prejudice to the judicial inquiry, in order to determine the circumstances and the identified or possible causes of the event, drawing up recommendations if necessary. The inquiry is conducted by an inquiry team which, in addition to ASN staff, can comprise specifically designated outside individuals.

Table 6: rating of significant events on the INES scale in 2009

Level	Pressurised water reactor	Other facilities	Transport	Total
3 et +	0	0	0	0
2	1	2	0	3
1	95	28	7	130
0	699	166	76	941
Total	**795**	**196**	**83**	**1074**

This arrangement covers incidents and accidents associated with both BNIs and radioactive material transport as well as those which can occur during activities entailing a risk of human exposure to ionising radiations, in particular activities carried out for medical purposes.

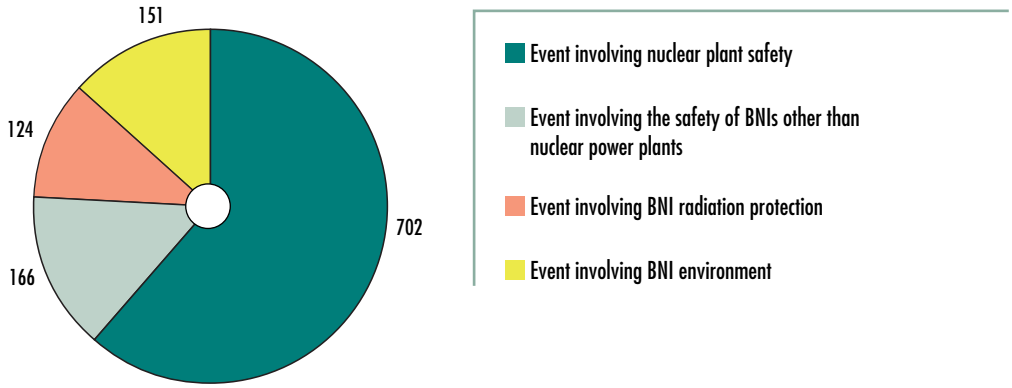
Insofar as ASN previously carried out investigations into incidents or accidents as part of its regulation and inspection duties, the main contribution of the TSN Act in this field is to give ASN the power to set up the board of inquiry, to determine its membership, to define the objectives and scope of the investigations and to access the necessary data in the event of a judicial inquiry.

However, unlike the investigation bureaux set up in other fields[1], whose sole purpose is to conduct inquiries, disseminate information gleaned from operating experience feedback and conduct research into accidents and their causes, ASN's main responsibility is inspection and regulation. This entails certain particularities in how the investigators and ASN work together.

This primarily concerns three aspects:
– for inquiries concerning a nuclear activity, it is necessary to differentiate between the inquiry duty, the aim of which is to determine the circumstances and causes of the event, and the ASN's regulation duty, the aim of which is to protect workers, patients, the public and the environment from risks related to nuclear activities. It is for this purpose that ASN will use the recommendations issued by the board of inquiry;
– the BEA officers whose duty is to take part in the inquiries, receive permanent commissions as technical investigators. As the responsibility of the ASN officers is primarily one of inspection, they are temporarily commissioned on a case by case basis;
– the investigators must offer guarantees of independence and impartiality. This requirement applies to ASN officers, who must not have taken part in the inspection of the activity which is the subject of the inquiry for which they are commissioned.

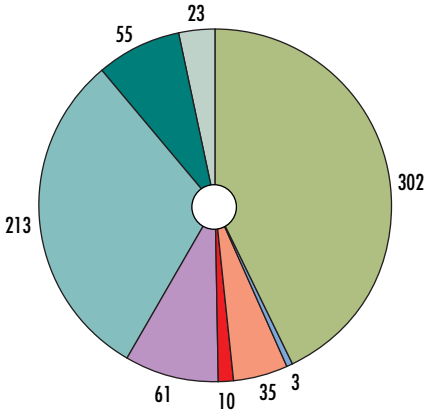
Decree 2007-1572 of 6 November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity specifies the procedure to be followed. It is based on the practices established for the other accident investigation bureaux and takes account of the specific characteristics of ASN, particularly its independence, its ability to impose requirements if necessary and the co-existence of its investigative and other duties.

Graph 6: breakdown per type of event for BNIs



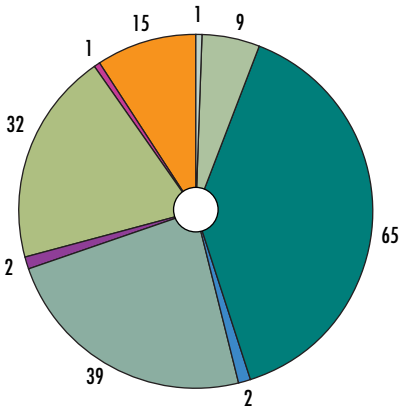
1. The French Marine Accident Investigation Bureau (BEA-mer), the French Land Transport Accident Investigation Bureau (BEA-TT), the French Aircraft Accident Investigation Bureau (BEA) and the French Defence Air Accident Investigation Bureau (BEAD-air).

Graph 7: safety related events for nuclear power plants



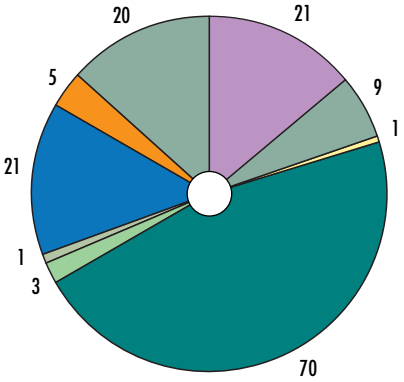
- Reactor trip
- Unscheduled activation of a protection or safeguard system
- Non-compliance or event which could lead to non-compliance with technical operating specifications (STE)
- Internal or external aggressions affecting the availability of critical equipment
- Shutdown through application of the STE or accident procedures
- Event or anomaly specific to the primary or secondary system
- Design, manufacturing or assembly fault
- Other significant event that could affect safety

Graph 8: safety related events for BNIs other than nuclear power plants



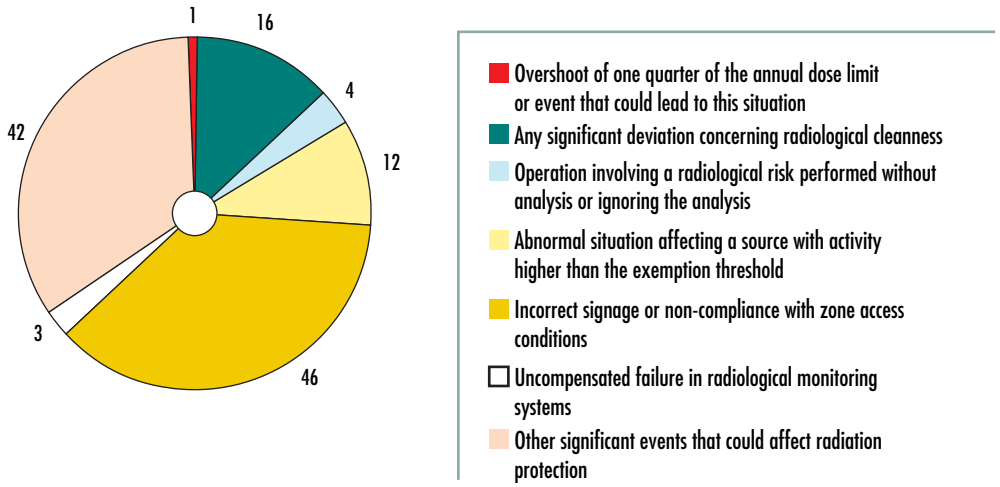
- Events resulting in injury or death due to equipment failure
- Unscheduled start-up of a protection or safeguard system
- Event leading to overshoot of safety limit(s)
- Internal or external hazard affecting the availability of important equipment
- Events affecting the containment of hazardous substances
- Event which caused or could have caused multiple failures
- Fault, damage or failure affecting a safety function
- Event affecting a safety function that could constitute accident warning signs
- Other significant event that could affect safety

Graph 9: significant environmental events in 2009

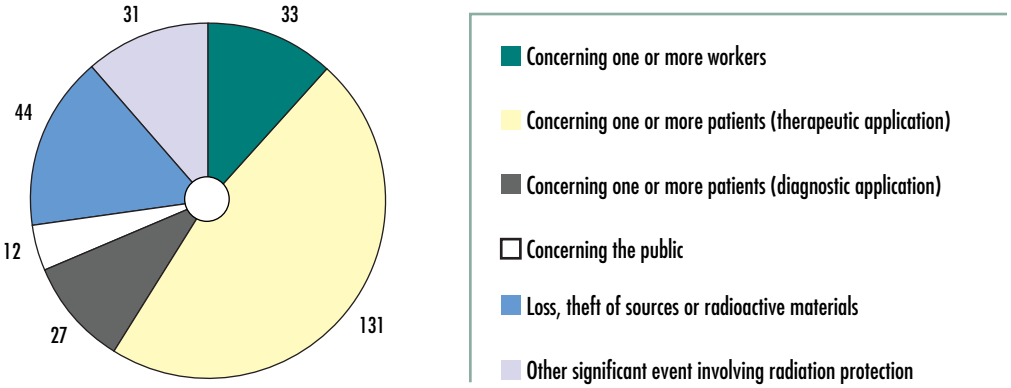


- Bypass of normal discharge routes with a significant radioactive impact
- Bypass of normal discharge routes with a significant chemical impact
- Confirmed overshoot of a discharge or concentration limit
- Non-compliance with an operational requirement, with potential significant impact
- Malevolent acts or attempted malevolent acts
- Non-compliance with the order of 31 December 1999
- Non-compliance with the site or installation waste study
- Discoveries of contaminated sites
- Other significant event that could affect the environment

Graph 10: events involving radiation protection in BNIs



Graph 11: events involving radiation protection (other than BNI and radioactive material transport)



4 MONITORING ENVIRONMENTAL RADIOACTIVITY

Within a European regulatory context, the monitoring of the environment is in particular based on:
– monitoring around the nuclear facilities by the licensees in accordance with the terms of their discharge licences;
– monitoring of environmental radioactivity by IRSN;
– the national network for environmental radioactivity measurement, the aim of which is to collate the environmental measurements taken nationwide as required by the regulations. The quality of these measurements is guaranteed by an approval procedure for the laboratories taking them.

4|1 European context

Article 35 of the Euratom Treaty requires the Member States to establish the facilities necessary to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the population and workers against the hazards of ionising radiations. All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

By virtue of the provisions of this same Article 35, the European Commission also has the right of access to these monitoring facilities, in order to check their operation and effectiveness. Following these checks, the European Commission issues an opinion on the resources put in place by the Member States for monitoring of:
– radioactive liquid and gaseous discharges into the environment;
– the levels of radioactivity in the land and aquatic environment around nuclear sites and nationwide.

It in particular gives its opinion on:
– the operation of the measuring instruments;
– the representativeness of the samples and the sampling methods;
– the relevance of the analytical methods:
– management and archival of results;
– reports and procedures;
– quality control of the measurements.

Since 1994, the Commission has carried out the following inspections:
– the La Hague reprocessing plant and ANDRA's Manche repository in 1996;
– Chooz nuclear power plant in 1999;
– Belleville-sur-Loire nuclear power plant in 1994 and 2003;
– the La Hague reprocessing plant in 2005.
– the Pierrelatte nuclear site in 2008.

This latter check took place in May 2008 on the Pierrelatte nuclear site. The international team in charge of the verification brought to light no significant deviation and underlined the quality of the monitoring system in place. It concluded that France was compliant with the provisions of Article 35 of the EURATOM Treaty. The conclusions of this verification are available on the European Commission's website (http://ec.europa.eu).

4|2 Environmental monitoring by the licensees

4|2|1 Purpose of environmental monitoring

Generally speaking, the regulations concerning environmental monitoring are linked to the authorisations or the individual stipulations regarding water intake and effluent discharge by the installations. When the BNI generates no effluent discharges, monitoring may nonetheless be required.

European Commission inspection on the EURODIF site in Pierrelatte (Drôme *département*) – May 2008

This is particularly the case of irradiation facilities, for which the environmental monitoring requirements were included in the facility creation authorisation decree.

Licensee responsibility includes monitoring the environment around nuclear sites in accordance with individual requirements (creation authorisation decree, discharge license or ASN decision) defining the steps to be taken and their frequency, regardless of any additional arrangements made by the licensees for their own monitoring.

This environmental monitoring:
– gives a picture of the condition of the environment through measurement of regulated parameters and substances, whether or not radioactive, in the various compartments of the environment (air, water, soil) as well as in the various biotopes and the food chain (milk, vegetables, etc.): a zero reference point is identified before the creation of the facility and environmental monitoring enables any changes to be tracked;
– verifies that there are no emissions of unauthorised substances;
– evaluates the impact of the facility on public health and on the environment, comparing it with the impact assessment;
– triggers an alert in the event of any problems on the facility, including by means of checks on groundwater.

Téléray monitoring network: device continuously measuring ambient gamma radioactivity in the air

4 | 2 | 2 Content of monitoring

Virtually all nuclear sites in France carry out systematic environmental monitoring. The nature of this monitoring is proportionate to the potential environmental risks or drawbacks of the facility, as presented in the authorisation file, particularly the impact assessment.

The regulatory monitoring of the BNI environment is tailored to each type of installation, depending on whether it is a power reactor, a plant or a laboratory. The nature of the environmental monitoring associated with liquid discharges, which must be stipulated in the authorisation order, is defined in Articles 14, 22 and 23 of the ministerial order of 26 November 1999.

To bring it into line with the progress achieved through the TSN Act, ASN has initiated an update of the general technical regulations applicable to BNIs.

In accordance with these regulations, the principle of radiological monitoring of the environment can be summarised as shown in table 7.

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has for example been the case on the Cadarache and Pierrelatte sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

The licensees thus carry out nearly 200,000 measurements in all compartments of the environment, every year.

4 | 3 Environmental monitoring nationwide

IRSN carries out environmental monitoring through a measurement and sampling network dedicated to:
– air monitoring (aerosols, rainwater, ambient gamma activity);
– monitoring of surface water (water courses) and groundwater (aquifers);
– monitoring of the human food chain (milk, cereals, food intake);
– terrestrial continental monitoring (reference stations located far from all industrial facilities).

It uses two approaches for this:
– continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:

Table 7: principle of environmental radiological monitoring

Environment monitored or type of inspection	Nuclear power plant	Laboratory or plant
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total β activity (βG). γ spectrometry if βG > 2 mBq/m^3. • 1 continuous sampling under the prevailing winds with weekly tritium measurement (^{3}H)	
Ambient γ radiation	• 4 detectors at 1 km with continuous measurement (ranging from 10 nGy/h to 10 Gy/h) and recording • 10 integrating dosimeters at the site limits (monthly recording) • 4 detectors at 5 km with continuous measurement (ranging from 10 nGy/h to 0.5 Gy/h)	• 4 detectors with continuous measurement and recording • 10 integrating dosimeters at the site limits (monthly recording)
Rain	• 1 station under the prevailing wind (monthly collector) with measurement of βG and ^{3}H on a monthly mixture	• 2 continuous sampling stations including one under the prevailing wind with weekly measurement of βG and ^{3}H
Liquid discharge receiving environment	• Sampling in the river upstream and at mid-discharge, for each discharge (riverside plant) or sampling after dilution in the cooling water and bi-monthly sampling at sea (coastal plant): Measurement of βG, of potassium (K) Continuous sampling of ^{3}H (daily average mixture) • Annual sampling in sediments, aquatic fauna and flora with measurement of βG, K and ^{3}H (γ spectrometry)	• At least weekly sampling of water in the receiving environment with measurement of the total α activity, βG, K and ^{3}H • Annual sampling in sediments, aquatic fauna and flora for γ spectrometry
Groundwater	• 5 sampling points (monthly check) with measurement of βG, K and ^{3}H	• 5 sampling points (monthly check) with measurement of βG, K and ^{3}H • Measurement of total α activity
Soil	• 1 annual sample of topsoil with γ spectrometry	
Plants	• 2 grass sampling points (monthly check) with measurement of βG, K and γ spectrometry. Measurement of carbon 14 (^{14}C) and total carbon (quarterly) • Annual campaign on the main agricultural produce, with measurement of βG, K, ^{14}C and total carbon, and γ spectrometry	• 4 grass sampling points (monthly check) • Annual campaign on the main agricultural produce, with measurement of βG, K, ^{14}C and total carbon, and γ spectrometry
Milk	• 2 sampling points (monthly check) with measurement of βG activity (except ^{40}K), K and annually ^{14}C	• 1 sampling point (monthly check) with measurement of βG activity and γ spectrometry (+ ^{3}H and ^{14}C periodically)

βG = total β

- the Téléray network (ambient gamma radioactivity of the air) which uses about 180 measurement detectors;
- the Sara network (radioactivity in atmospheric aerosols);
- the Hydrotéléray network (monitoring of the main water courses downstream of all nuclear facilities, before they cross national boundaries);
- the Téléhydro network (monitoring of waste water in the sewerage treatment plants in the main French cities);

– processing and measurement in a laboratory of samples taken from the various compartments of the environment, whether or not close to facilities liable to discharge radionuclides.

Every year, IRSN takes more than 25,000 samples in all compartments of the environment (excluding the remote-measurement networks).

4 | 4 Maintaining measurement quality

Articles R.1333-11 and R.1333-11-1 of the Public Health Code make provision for the creation of a national network of environmental radioactivity measurements and a procedure for having the radioactivity measurement laboratories approved by ASN.

This network is being deployed for two main reasons:

– to ensure the transparency of information on environmental radioactivity by making the results of this environmental monitoring and information about the radiological impact of nuclear activities in France available to the public;

– to continue a quality assurance policy for environmental radioactivity measurements by setting up a system of laboratory approvals granted by ASN decision, pursuant to Article 4-2° of the TSN Act.

The approvals cover all components of the environment, water, soils or sediments, all biological matrices (fauna, flora, milk), aerosols and atmospheric gases. The measurements concern the main artificial or natural, gamma, beta or alpha emitting radionuclides, as well as the ambient gamma dosimetry (see approval chart below in table 8).

In total, about fifty types of measurements are covered by approvals. There are just as many corresponding inter-laboratory comparison tests. These tests are organised by IRSN according to a 5-year cycle, which corresponds to the maximum approval validity period.

4 | 4 | 1 A new procedure for laboratory approval

ASN decision 2008-DC-0099 of 29 April 2008, confirmed by the order of 8 July 2008, specifies the organisation of the national network and sets new approval arrangements for the environmental radioactivity measurement laboratories. This ASN decision, which replaced the ministerial order of 27 June 2005, takes account of the changes to the Public Health Code, the ASN prerogatives defined by the TSN Act and the operating experience feedback acquired since 2003.

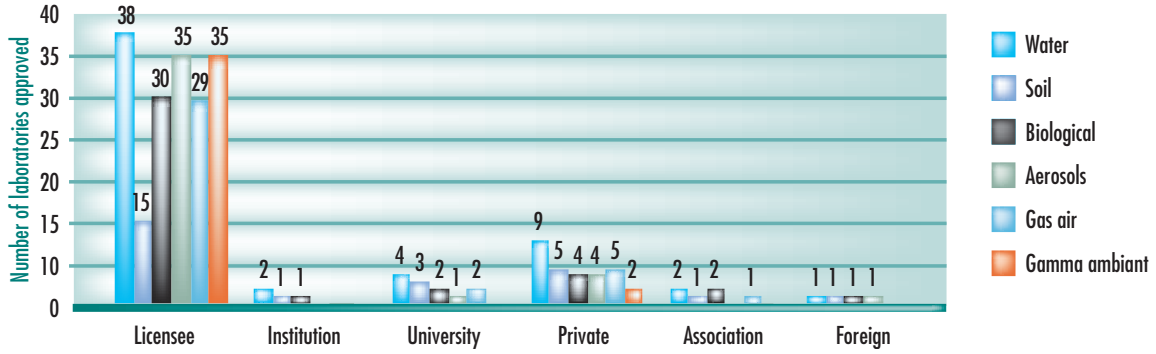
Table 8: approval chart for the scheduled five-year programme of inter-laboratory tests

		Type 1		Type 2		Type 3		Type 4		Type 5		Type 6	
Code	Radioactive measurements category	Water		Soil matrices		Biological matrices		Aerosols on filter		Gas air		Ambient environment	
.. -01	Emetteurs gamma E > 100 keV	1	1_01	1	2_01	1	3_01	2	4_01	1	5_01		-
.. -02	Emetteurs gamma E < 100 keV	1	1_02	1	2_02	1	3_02		4_02	1	5_02		-
.. - 03	Alpha global	1 2	1_03		-		-	2	4_03		-		-
.. -04	Bêta global	1 2	1_04		-		-	2	4_04		-		-
.. -05	H-3	1 2	1_05		2_05	2	3_05		-		Cf eau		-
.. -06	C-14	1	1_06		2_06	2	3_06		-	1	5_06		-
.. -07	Sr-90/Y-90	1	1_07	2	2_07	2	3_07	2	4_07		-		-
.. -08	Autres émetteurs bêta purs (Ni-63, Tc99,...)	2	1_08	2	2_08	1	3_08		-		-		-
.. -09	U isotopique	2	1_09	1	2_09	1	3_09	2	4_09		-		-
.. -10	Th isotopique		1_10	1	2_10	1	3_10		4_10		-		-
.. -11	Ra-226 + desc.	2	1_11	1	2_11	1	3_11		-		Rn 222: 5_11		-
.. -12	Ra-228 + desc.	2	1_12	1	2_12	1	2_12		-		Rn 220: 5_12		-
.. -13	Isotopes Pu, Am, (Cm, Np)	2	1_13	2	2_13	1	3_13	2	4_13		-		-
.. -14	Gaz halogénés		-		-		-		-	1	5_14		-
.. -15	Gaz rares		-		-		-		-	1	5_15		-
.. -16	Dosimétrie gamma		-		-		-		-		-	2	6_16
.. -17	Uranium pondéral	2	1_17	1	2_17	1	3_17	2	4_17		-		-

2009 2010 2011 2012 2013

*The figures 1 or 2 correspond to the 1st or 2nd half of the year in question.

Graph 12: breakdown of number of approved laboratories as at 1st January 2010



The approval procedure in particular includes:
- presentation of an application file by the laboratory concerned, after participation in an inter-laboratory test (ILT);
- review of it by ASN;
- review of the application files by a pluralistic approval commission which issues an opinion on anonymous files.

The laboratories are approved by ASN decision, published in its Official Bulletin.

This decision in particular requires that the licensees of BNIs must have the environmental radioactivity monitoring measurements required by regulations taken by approved laboratories.

Refusal to authorise EDF laboratories and subsequent approval in 2009

To ensure that nuclear regulation in France continues to improve, ASN made an approval procedure mandatory for laboratories measuring radioactivity in the environment, as of 1 January 2009. It therefore created a pluralistic approval commission (Government departments, associations, laboratory representatives, IRSN, qualified experts, etc.), responsible for issuing an opinion on the technical quality of the approval applications submitted by the measurement laboratories.

In the second half of 2008, ASN examined approval applications from EDF laboratories, which brought to light anomalies in the environmental radioactivity measurement methods.

After the approval commission issued its unfavourable opinion, ASN refused further applications on 16 December 2008 and suspended current EDF laboratory approvals. Under these decisions, EDF's in-house laboratories were refused approval to measure tritium and beta radioactivity in air and water, or had their approval suspended.

ASN asked EDF to undertake a programme of remedial measures with immediate effect, and these measures were operational as of 1 February 2009. The refusal and suspension of approval of EDF laboratories for environmental radioactivity measurements did not interrupt radioactivity monitoring around the NPPs. Until approvals were obtained, EDF subcontracted these environmental radioactivity measurements to approved outside laboratories, while continuing to take its own measurements. IRSN also monitors the environment throughout French territory, including around the nuclear sites.

The 12th meeting of the laboratory approval commission took place at ASN on 26 May 2009, to examine some 320 approval applications for environmental radioactivity measurements, submitted by 53 laboratories from nuclear licensees, universities, institutions, private companies and associations.

In the light of the remedial measures implemented by the EDF laboratories, ASN's on-site checks on their effective implementation, the participation of these laboratories in the new inter-comparison tests organised by IRSN and the favourable opinion of the approval commission, ASN once again approved the EDF laboratories and the suspension orders were lifted on 1 July 2009.

4 | 4 | 2 The approval commission

The approval commission is the body which, within the national network for environmental radioactivity measurements, is tasked with ensuring that the measurement laboratories have adequate organisational and technical competence to provide the network with quality measurement results. The commission is responsible for forwarding to ASN its proposed approval, refusal, revocation or suspension of approval. It decides on the basis of an application file submitted by the candidate laboratory and the results of the inter-laboratory tests organised by IRSN.

Article 21 of the above-mentioned ASN decision defines the membership of the approval commission, the procedures for appointment of the commission's members and how the commission works. ASN decision 2008-DC-0117 of 4 November 2008 renewed the mandates of the commission's members for a further 5 years.

4 | 4 | 3 Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in inter-laboratory tests (ILT) organised by IRSN. The ILT programme, which now operates on a five-yearly basis, is updated annually. It is reviewed by the approval commission and published on the national network's website (www.mesure-radioactivite.fr).

The ILT organised by IRSN can cover up to 70 laboratories in each test, including a few foreign laboratories.

To ensure that the laboratory approval conditions are fully transparent, precise assessment criteria are used by the approval commission. These criteria are published on the national network's website.

From 2003 to the end of 2009, IRSN organised 29 inter-comparison tests covering 41 approval types. Most of the approved laboratories specialise in water monitoring, with 56 laboratories holding up to 12 different approvals for monitoring of this medium. About forty laboratories are approved for measurement of biological matrices (food chain), atmospheric dust and ambient gamma dosimetry. About 25 laboratories deal with soils. Although most of the laboratories are competent to measure gamma emitters in all environmental matrices, only about ten of them are approved to measure carbon 14, transuranium elements or radionuclides of the natural chains of uranium and thorium in water, soil and biological matrices.

In 2009, ASN issued 398 approvals and extended a further hundred. As at 1 January 2010, the total number of approved laboratories stood at 60, totalling 718 currently valid approvals.

The detailed list of approved laboratories and their scope of technical competence is available on ASN's website.

5 IDENTIFYING AND PENALISING INFRINGEMENTS

5 | 1 Ensuring that licensee penalty decisions are fair and consistent

In certain situations in which the licensee fails to conform to the regulations or legislation, or when it is important that appropriate action be taken by it to remedy the most important risks immediately, ASN may impose the penalties provided for by law. The principles of ASN's actions in this respect are:

1. penalties that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the health and environmental consequences of the anomaly detected and also takes account of intrinsic factors relating to the behaviour of the party at fault and external factors relating to the context of the infringement;
2. administrative action initiated on proposals of the inspectors and decided on by ASN in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

When it detects an anomaly during its checks, ASN must ensure that its decisions concerning both enforcement (action obligation) and penalties are fair and consistent. ASN has a range of tools at its disposal, in particular:

– remarks made by the inspector to the licensee;
– the official letter from the ASN departments to the licensee;
– formal notice from ASN to the licensee to regularise its administrative situation or meet certain specified conditions, within a given time-frame;
– administrative penalties applied after formal notice.

In parallel with ASN's administrative action, reports can be drafted by the inspector and sent by ASN to the Public Prosecutor's Office.

To provide the inspectors with the tools they need to determine the importance of the anomalies observed and impose appropriate penalties, ASN has drawn up procedures and decision-making tools regarding the position to be adopted. These documents provide a structured framework enabling an impartial decision to be reached that is proportionate to the anomaly detected, coherent between all the inspectors and in conformity with ASN policy. They also constitute a learning aid for the less experienced inspectors.

The decision to issue demands is based on the observed risk for people or the environment and takes account of factors specific to the licensee (history, behaviour, repeated nature of the problem), contextual factors and the nature of the infringements observed (regulations, standards, "rules of good practice", etc.).

5 | 2 Tailoring the response to the stakes: a proportionate approach

5 | 2 | 1 For basic nuclear installations and radioactive material transport

When ASN's regulatory 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 plant or suspending operation until the requisite corrective measures have been taken.

If an infringement is observed, the TSN Act provides for a graduated series of administrative penalties following formal notice and defined in Articles 41 to 44 of the Act:

– deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
– have the work or prescribed measures carried out without consulting the licensee and at its expense of the licensee (any sums deposited beforehand can be used to pay for this work);
– suspension of operation of the installation or of performance of an operation until the licensee conforms.

If the licensee has any observations concerning these penalties it shall present them to the ASN Commission.

The Act also makes provision for interim measures to safeguard public health and safety or protect the environment. ASN can therefore:

– provisionally suspend operation of a BNI, immediately notifying the ministers responsible for nuclear safety, in the event of any serious and imminent risk;
– at all times require assessments and implementation of the necessary measures in the event of a threat to the above-mentioned interests.

Infringements are written up in reports by the nuclear safety inspectors and transmitted to the Public Prosecutor's Office, which decides on what subsequent action, if any, is to be taken. The TSN Act makes provision for penalties as detailed in Articles 48 to 51 of the Act, ranging from a fine of 7,500 euros to three years of imprisonment plus a fine of 150,000 euros, depending on the nature of the infringement. They may apply to corporate bodies, with the amount of the fine rising to up to 1,500,000 euros.

Decree 2007-1557 of 2 November 2007 concerning BNIs and the regulation of the transport of radioactive materials with respect to nuclear safety, also makes provision for class 5 infringements as detailed in its Article 56.

5|2|2 For small-scale nuclear activities, approved organisations and laboratories

The Public Health Code makes provision for administrative and criminal sanctions in the event of breach of the radiation protection requirements.

Administrative decision-making powers lie with ASN and can entail:
– revocation of licence (after formal notice);
– interim suspension of an activity (whether licensed or notified) if urgent measures are required to safeguard human health;
– revocation or suspension of any approvals it has issued.

The formal notice prior to revocation of a licence (based on Article L.1333-5 of the Public Health Code) concerns implementation of all the requirements of the "ionising radiations" chapter of the legislative part of the Public Health Code (Articles L.1333-1 to l.1333-20), regulatory requirements and the stipulations of the licence. Temporary or final revocation of the licence by ASN must be fully explained in a decision within one month following serving of formal notice.

The formal notices prior to criminal sanctions (based on Article L.1337-6 of the Public Health code) are served by ASN. They concern the provisions of Articles L.1333-2, L.1333-8 (monitoring of exposure, protection and information of individuals), L.1333-10 (monitoring of exposure to enhanced natural ionising radiations and of premises open to the public) and L.1333-20 (decrees implementing certain legislative provisions).

Infringements are written up in reports by the radiation protection inspectors and transmitted to the Public Prosecutor's Office, which decides on what subsequent action, if any, is to be taken. The Public Health Code makes provision for criminal sanctions as detailed in Articles L.1337-5 to L.1337-9 and range from a fine of 3,750 euros to one year of imprisonment and a fine of 15,000 euros.

2009 results concerning enforcement and penalties

ASN took administrative action (formal notice, suspension, etc.) against 11 licensees and managers of nuclear activities. Further to the infringements observed, it sent 19 reports to the Public Prosecutors, including 7 concerning conventional safety matters in the NPPs (see point 5|2|3).

5|2|3 For labour law

In the performance of their duties in the NPPs, the ASN's conventional safety inspectors have at their disposal all the inspection, decision-making and constraining resources of ordinary inspectors. Observation, formal notice, official report, injunction (to obtain immediate cessation of the risks) or even shutdown of the site, offer a range of enforcement and constraining measures for the conventional safety inspector that is broader than that available to a nuclear safety inspector or a radiation protection inspector.

The conventional safety inspector has special decision-making powers enabling him to check the employer's disciplinary capability, to protect the general interest from an economic standpoint and to act as arbitrator, if necessary by delegation from the DDTEFP. He is also tasked with examining approval applications by the occupational health departments, jointly with the occupational physicians.

The conventional safety inspector is in contact with many parties from different EDF entities. Management of these internal interfaces is an integral part of his duties. The conventional safety inspector is first of all in contact with the unit senior management, the risk prevention departments and the occupational health departments. It is in direct contact with the members of the health, safety and working conditions committees (CHSCT) and the trade union representatives. The members of the CHSCT are a vital means of transmitting information for the conventional safety inspector, in the light of their knowledge of the facility, the operating procedures, working conditions and accidents that occur in the facility. The members of the CHSCT are informed of the inspector's visits and of his observations during the inspections.

The inspector is notified of the ordinary meetings of the CHSCT (one every quarter) and the inter-company working conditions and safety committee (CIESCT) meetings held on the power plant sites, and can attend them. He takes part in extraordinary meetings held following an industrial accident, and in issuing an alert in the event of serious and imminent danger.

The mandatory posting of the contact details of the inspector with competence for each nuclear power plant leads to him being frequently contacted both by EDF personnel and by the personnel of the contractors working in the nuclear power plants. The main subjects concern performance of their employment contract (working times, rest periods, travel, leave, etc.), but also notification of degraded working conditions.

The labour inspector is in contact with the occupational health departments. He may be required to validate (or

invalidate) a decision by the occupational physician. Close relations with the occupational physician may enable him to gain a relatively clear picture of the "health" of the facility, in particular with regard to the organisational and human factors to be monitored.

Relations on the site can also concern EDF entities from outside the plant, which have their own staff consultation and medical supervision structures. The entities most concerned are the National Electricity Generating Equipment Centre (CNEPE) which is in charge of carrying out and supervising major non-nuclear works, the Nuclear Equipment Engineering Department (CIPN) for major operations on the nuclear island (in particular steam generator replacement), the Nuclear Environmental and Decommissioning Engineering Centre (CIDEN) for all work relating to the decommissioning of retired nuclear power plants, and which on some sites has a separate structure, the workforce of which will rise as the decommissioning phases progress.

The ASN conventional safety inspectorate sent out seven reports, concerning 5 sites, to the various Public Prosecutor's Offices concerned. These reports concern violations with respect to health and safety (4 cases, 3 of which caused industrial accidents) or working hours (3 cases).

5 | 3 Information about ASN's inspections

ASN attaches importance to coordinating Government departments and informs the other departments concerned of its inspection programme, the follow-up to its inspections, the penalties imposed on the licensees and any significant events.

To ensure that its inspection work is transparent, ASN informs the public (both general and specialised) by placing the following on its website:
– inspection follow-up letters concerning nuclear safety and radiotherapy departments;
– approval authorisations or rejections;
– incident notifications;
– the results of reactor outages;
– its publications on specific subjects (*Contrôle* magazine, etc.).

The conditions in which this information is made public must protect medical secrecy, industrial secrecy, national defence interests and individual freedoms. ASN makes every effort to avoid publishing any nominative information (patients, employers, employees, etc.).

6 OUTLOOK

In 2010, ASN scheduled 1,973 inspections on BNIs, radioactive material transport, activities using ionising radiations, organisations and laboratories it has approved and activities involving pressure equipment. In this field, it continued and developed its implementation of the proportionality principle, in order to enhance its regulation of activities involving high stakes.

In the field of worker radiation protection, an inspection campaign will be carried out in 2010, jointly with the DGT and the National Health Insurance Fund (CNAM) to ensure that the changes to the regulations in recent years are correctly taken into account.

Following the experiment with the significant events notification guide in the small-scale nuclear facilities sector, ASN will be revising the significant event notification guides for radiation protection. Once this work is complete, ASN will have defined the significant event notification criteria for all the activities it regulates.

The regulatory work in progress will in 2010 lead to a revision of the regime for organisations approved for radiation protection inspections. These changes aim to clarify ASN requirements concerning how they are organised and the nature of the inspections carried out.

With regard to monitoring of environmental radioactivity, ASN together with all stakeholders, especially IRSN, will define changes to the national monitoring strategy. These changes aim to take greater account of the expectations of society and develop a monitoring strategy that is proportionate to the issues and to the stakes.