# REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION



CHAPTER 4

In France, nuclear activity licensees hold prime responsibility for the safety of their activity. They cannot delegate this responsibility, and must ensure permanent surveillance of their installations. In view of the risks that ionising radiation present for persons and the environment, the State exercises its own independent control over the nuclear activities through ASN, which it has empowered for this task.

Control and regulation of nuclear activities is thus a fundamental responsibility of ASN. The aim is to verify that all licensees fully assume their responsibility and comply with the requirements of the regulations relative to radiation protection and safety to protect workers, patients, the public and the environment against the risks associated with nuclear activities.

Inspection is the key means of control available to ASN. Its purpose is to verify on the sites and the facilities of licensees and their suppliers, that the provisions relative to safety and radiation protection are applied, and to detect any deviations leading to a reduction in the safety of the installations or the protection of persons.

ASN has a broad vision of control and regulation, encompassing material, organisational and human aspects. It materialises its action by decisions, instructions, inspection follow-up documents and assessments of safety and radiation protection by sector of activity.

# 1 VERIFYING THAT THE LICENSEE ASSUMES ITS RESPONSIBILITIES

## 1|1 The principles underpinning the regulatory role

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

ASN applies the principle of proportionality when determining its actions, so that the scope, conditions and extent of its regulatory action is commensurate with the health and environmental safety implications 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). It applies to all phases in the life of the installation, including operation shutdown and decommissioning where applicable:
– before the licensee exercises an activity subject to authorisation, by reviewing and analysing the files, documents and information provided by the licensee to justify its project with regard to safety and radiation protection. This verification aims to ensure that the information supplied is both relevant and sufficient;
– during exercise of the activity, by site visits, inspections on all or part of the installation, verification of high-risk operations performed by the licensee, reviewing of operating reports and analysing significant events. This verification 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 uses the experience feedback from more than thirty years of nuclear activity inspections and the sharing of good practices with its foreign counterparts.

## 1|2 Regulating nuclear activities: a vast area

Pursuant to Article 4 of the Nuclear Security and Transparency (TSN) Act, ASN regulates compliance with the general rules and particular requirements of safety and radiation protection, applicable to:
– licensees of basic nuclear installations (BNIs);
– those in charge of the construction and operation of pressure equipment (PE) 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 radiation;
– those in charge of implementing ionising radiation exposure monitoring measures;
– the organisations and laboratories it approves, to enable them to participate in safety or radiation protection control 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

ASN inspection on the site of the EURODIF plant in Tricastin – March 2010

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|2|1 Regulating safety

Safety covers all technical and organisational measures taken at all stages in the life cycle of nuclear installations (design, creation, commissioning, operation, final shutdown, decommissioning) to prevent or mitigate the risks for safety, public health, the environment, and so on. This notion thus includes the measures taken to optimise waste and effluent management.

The International Atomic Energy Agency (IAEA) defined the following principles in its safety fundamentals for nuclear facilities (publication No. SF-1):
– responsibility for safety lies with the nuclear licensee, who is the originator of the risk;
– the regulatory body has the legal authority, the technical and management skills and the financial resources necessary to fulfil its responsibilities. It must be independent of the licensees and of any other organisations, so that stakeholders cannot exert undue pressure on it.

In France, pursuant to the TSN Act, ASN is the regulatory body meeting these criteria.

### *Regulating BNIs*

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 nuclear safety and 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.

### *Regulating pressure equipment*

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

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 verification of application of the 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 (NPP) 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 non-conformities affecting the systems and periodic post-maintenance testing of the systems. The principal PWR files currently being dealt with are presented in chapter 12.

### *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 radioactive material transport (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 drafting the regulations pertaining to the safe transport of radioactive and fissile materials for civil use and for verifying their implementation.

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.

## 1|2|2 Regulating activities entailing a risk of exposure to ionising radiation

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 fulfils this role of regulatory body by drafting and monitoring technical regulations in the field of radiation protection (see chapter 3, point 1).

The scope of ASN's regulatory role in radiation protection covers all the activities that use ionising radiation. This duty is exercised, where applicable, jointly with other State services such as the occupational health and safety, the inspectorate for installations classified on environmental protection grounds

(ICPE), the departments of the ministry responsible for health and the French Health Product Safety Agency (AFSSAPS).

ASN's regulatory action takes the form of reviews of files, pre-commissioning visits, inspections, and discussions with professional organisations (trade unions, professional orders, learned societies, etc.). This action directly concerns either the users of ionising radiation sources, or organisations approved to carry out technical inspections on these users.

These actions are summarised in table 1.

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

| | Review/authorisation | Inspection | Openness and cooperation |
|---|---|---|---|
| **Users of ionising radiation sources** | Files produced in accordance with the procedures laid down in the Public Health Code (articles R. 1333-1 to R. 1333-54).<br><br>Review of the file and visit prior to commissioning.<br><br>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 radiation. |
| **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.<br><br>Review of the file and audit of the organisation.<br><br>Leads to issue of approval. (48 organisations approved as at 31/12/2010). | Second-level inspection through:<br>– audits,<br>– in-depth inspections at head office and in the branches of the organisations,<br>– unannounced field inspections. | Jointly with the professional organisations, drafting of guides of good practices for performance of radiation protection inspections. |

## 1|2|3 Regulating the enforcement of labour law in NPPs

In NPPs, the regulation of safety, radiation protection and the occupational health and safety aspects very often covers common topics, such as worksite organisation or the conditions in which subcontractors are called in. The legislator therefore assigned labour 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 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 convention No. 81 of the International Labour Organisation (ILO), 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 subcontracted activities;
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. highlight ASN's expanded labour 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 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 labour inspectors in the divisions, by recruiting an experienced civil servant from the Ministry for Labour, given responsibility for overseeing and coordinating ASN's labour inspection duties.

# 2 REGULATION THAT IS PROPORTIONATE TO THE ISSUES INVOLVED IN THE ACTIVITIES

ASN organises its regulatory work in a way that is proportionate to the issues 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 issues

In order to consider both the health and environmental issues and licensee safety and radiation protection performance, and the large number of activities it regulates, ASN periodically identifies those activities and topics with significant implications 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 doses received by workers, information resulting from checks by approved organisations. It can revise its priorities further to significant events that have occurred in France or elsewhere in the world.

Strong-implication activities in 2010 are presented in table 2.

## 2|2 Setting down the principle of licensee prime responsibility

ASN considers that operations taking place in BNIs that represent the greatest implications in terms of safety and radiation protection must obtain prior authorisation from it (see chapter 3). Those for which the safety and radioprotection implications are limited must remain under the responsibility and control of the licensee.

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

For intermediate operations, with safety and radiation protection implications 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 called "internal authorisations system". It is presented to the competent local information committee (CLI).

**Table 2: significant activities in 2010**

| Field | Strong-implication topics or activities |
|---|---|
| BNIs including:<br>– NPPs<br>– Research reactors<br>– Laboratories and plants<br>– Installations undergoing decommissioning | – Reactor outages<br>– Organisational and human factors<br>– Operation of the installation<br>– Condition of barriers<br>– Condition of systems<br>– Prevention and management of risks, emergency situations<br>– Radiation protection<br>– Environment and waste |
| Small-scale nuclear activities | – Industrial radiography activities<br>– External radiotherapy<br>– Interventional medical radiology<br>– Brachytherapy<br>– Suppliers of ionising radiation sources<br>– Nuclear medicine units performing therapeutic and/or in vivo diagnostic procedures<br>– Holders of unsealed source licences<br>– Industrial or research irradiation facilities or particle accelerators<br>– Thin layer thickness measurement<br>– Gammadensimetry<br>– Use of neutron sources<br>– Implementation of high activity sealed sources |
| Radioactive material transport | Compliance with quality assurance requirements for radioactive material transport<br>– Packages not requiring approval<br>– Internal transport |

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.

### 2|2|2 Internal monitoring of radiation protection by the users of ionising radiation sources

The aim of internal monitoring of radiation protection is to ensure regular assessment of the radiological safety of the facilities using sources of ionising radiation. 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 implications 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 safety or radiation protection control and monitoring". Depending on the health or safety implications of 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 to perform 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 the applicant organisations, 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:
– turn operating experience feedback to good account;
– 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 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 (www.asn.fr "Bulletin officiel de l'ASN/agréments d'organismes" section, available in French only).

In 2010, ASN issued:
– 18 new or renewed approvals for organisations responsible for radiation protection inspections;
– 22 approvals for level 1 radon activity concentration measurements;
– 7 approvals for worker dosimetry (2 for internal monitoring of workers and 5 for external monitoring of workers).
– 208 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 hazardous materials);
– 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 hazardous materials by road;
– the initial and periodic checks of tankers for transport of class 7 hazardous materials by road.

# 3 DEPLOYING THE MOST EFFICIENT REGULATION AND INSPECTION MEANS

The licensee is required to provide ASN with the information it needs to fulfil 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 (RMT) are described in detail in chapter 11.

## 3|1 Assessing the supporting documents submitted by the licensee

The purpose of the documents supplied by the licensee is to demonstrate compliance with the objectives set by the general 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 as decisions.

### 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 control 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 and radiation protection.

ASN inspectors examine document conformity during the ten-year inspection of the Tricastin NPP – May 2010

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 discussions 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, IRSN examines the safety analyses and gives its opinion 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 - aided by its technical support organisation - examines 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 that could affect security, public health and safety, or protection of nature and the environment, are notified to ASN. In addition to these procedures, 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 (see chapter 12 point 2|2|3).

*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 fire protection, PWR fuel management strategies, relations with subcontractors, and so on.

### 3|1|2 Reviewing the applications provided for by the Public Health Code

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

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 any actions demanded by ASN further to the checks have been carried out. 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 Inspection of installations 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 with the greatest implications.

### 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 sample of installations representative of the other nuclear activities;
– systematic technical inspections of all facilities by approved organisations.

ASN focuses its inspection resources on activities and topics for which the implications are particularly strong. 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.

**ASN inspection of the medicine service of the North Saint-Denis Cardiology Centre – December 2010**

TO BE NOTED IN 2010

### National inspection campaign in application of radiation protection rules for workers

*This inspection campaign, which ran from 3 May to 30 September 2010, was organised jointly by the DGT (General Directorate for Labour), ASN, and the CNAM (French national health insurance fund) for salaried workers. Its main objectives were to review the situation regarding application of the radiation protection provisions of the Labour Code and to identify the main difficulties in applying this regulation.*

*2,333 inspections, of which 23% were unannounced, were carried out in the following sectors:*

*– Conventional radiology*
- *Medical sector*
- *Dental surgery*
- *Veterinary medicine*

*– Industry*
- *ICPE (installation classified on environmental protection grounds) classified on account of an industrial activity and possessing a sealed source (category 1715)*
- *Activity possessing a sealed source used as a measuring gauge*
- *Service provider subject to authorisation on account of the Public Health Code (mammography excluded)*

*– Baggage inspection*

*A national report drawn up from the analysis of all the results of this campaign will be released jointly by the DGT and ASN.*

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 licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

The inspections are generally carried out by two inspectors, with the support of an IRSN representative specialised 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 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;
– 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 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 and qualified once they have acquired the necessary competence through their professional experience, tutoring and appropriate training. To ensure constant progress, ASN:
– has defined a system of qualification for its inspectors, based on recognition of their technical competence, in the same way as the leading foreign safety authorities.
– adopted a number of foreign practices identified through inspector exchanges between regulatory bodies. These exchanges are organised either for a particular inspection or for a longer period, via a secondment of up to 3 years. Thus, after having observed its advantages, ASN has adopted the concept of in-depth inspections described earlier. However, it has not opted 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 the sharing of experience and that they must take part in inspections on different licensees and facilities in order to acquire a broader view of this field of activity. This also avoids 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, ARS (Regional Health Agencies), 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).

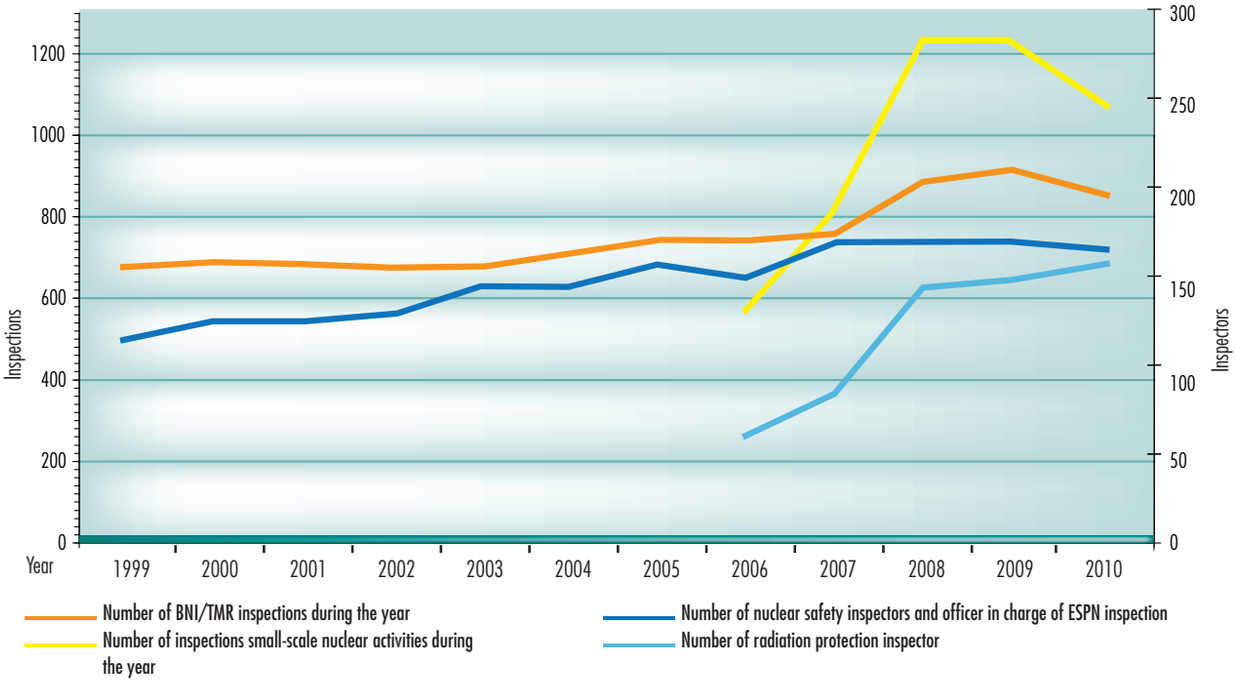
Table 3 presents the inspector staffing levels on 31 December 2010. Some inspectors are qualified in several inspection domains.

In 2010, ASN carried out 1,964 inspections on BNIs, radioactive material transport, activities using ionising radiation, organisations and laboratories it has approved and activities involving pressure equipment.

**Table 3: Number of inspectors per inspection domain (as at 31.12.2010)**

| Type of inspector | Departments | Divisions | Total |
|---|---|---|---|
| Nuclear safety inspector (BNI) | 75 | 85 | **160** |
| Pressure equipment (PE) inspector | 11 | 31 | **42** |
| Nuclear safety inspector (transport) | 9 | 35 | **44** |
| Radiation protection inspector | 45 | 108 | **153** |
| Labour inspector | 1 | 12 | **13** |
| Number of inspectors (all fields included) | 101 | 147 | **248** |

Graph 1: Trends for the number of ASN inspectors and inspections




b) To guarantee an adequate distribution of the inspection resources, proportionate to the safety and radiation protection implications 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 posting its inspection follow-up letters and publications on its website www.asn.fr (see chapter 6).

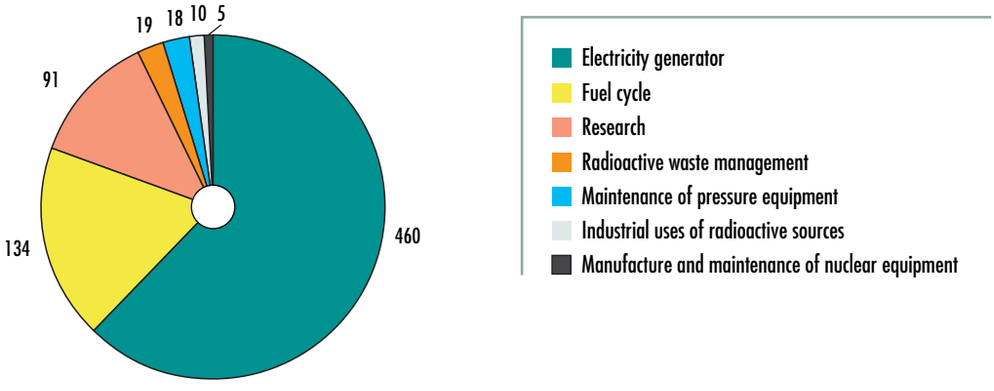
f) ASN is setting up a system for continuous improvement of its inspection process, which can be based on internal and external audits.

## 3|2|3 Inspection of BNIs and pressure equipment in 2010

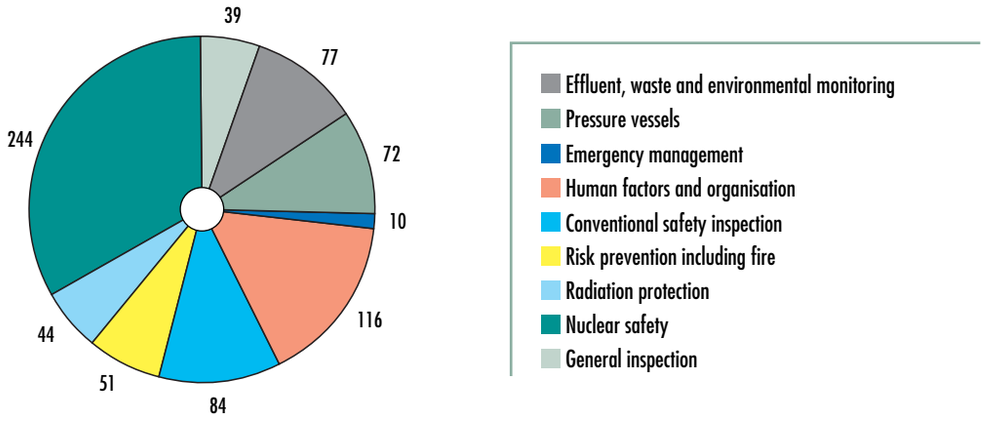
In 2010, 737 inspections were carried out, of which 181 (25%) were unannounced BNI inspections. The breakdown according to the various installation categories is described in the following graphs.

In 2010, ASN also delegated 884 inspections to approved organisations to assess the conformity of nuclear pressure equipment.

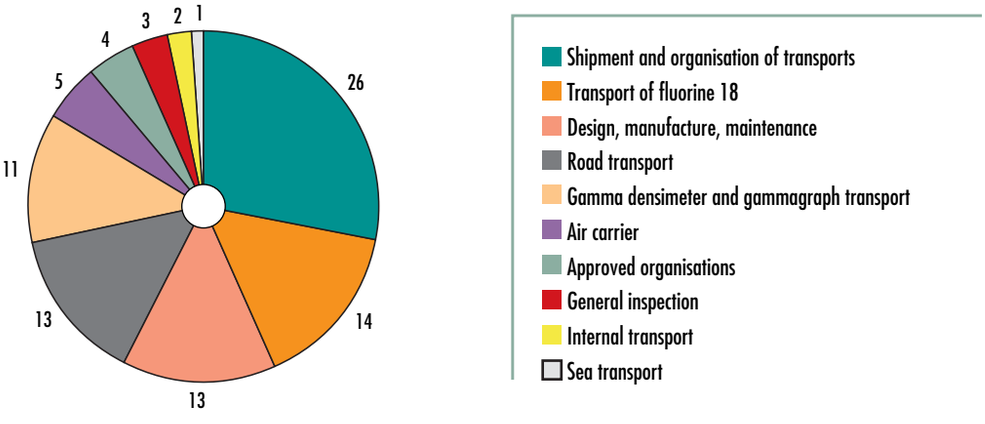
Graph 2: Breakdown of BNI inspections in 2010 by type of activity



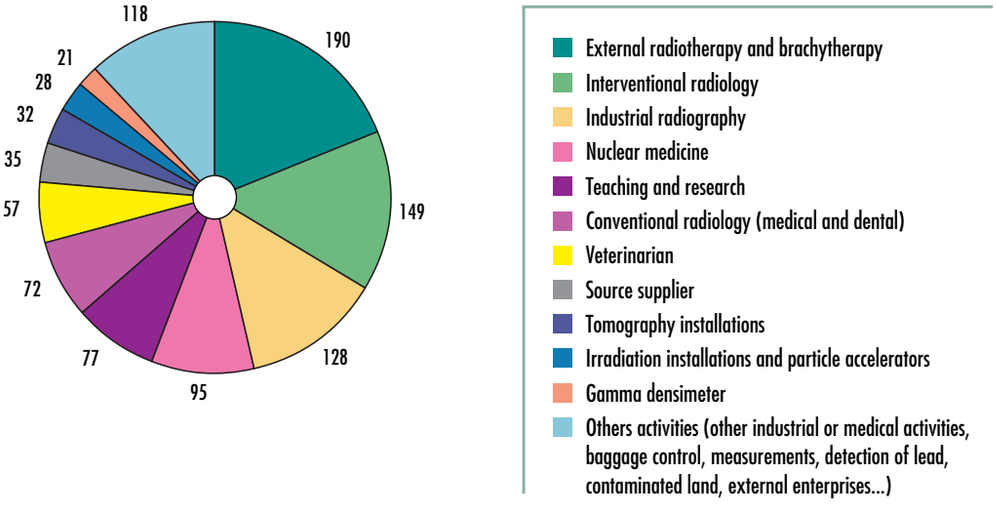
## Graph 3: Breakdown of BNI inspections in 2010 by topic




## Graph 4: Breakdown of radioactive material transport inspections in 2010 by topic




## Graph 5: Breakdown of inspections in the small-scale nuclear sector in 2010, by type of activity



## 3|2|4 Inspection of radioactive material transport in 2010

The 92 inspections on transport activities in 2010 can be broken down according to topic as shown in graph 4.

## 3|2|5 Inspection of small-scale nuclear activities in 2010

ASN organises its inspection actions so that they are proportionate to the radiological risks involved in the use of ionising radiation, 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 1,002 inspections in 2010, including 549 in the medical sector, 418 in industry or research and 35 on landfills, mines and spoil heaps, polluted sites or companies not exercising a nuclear activity but exposing their staff to ionising radiation. The breakdown according to the various activity categories is described in graph 5.

## 3|2|6 Inspection of ASN approved organisations and laboratories in 2010

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 2010, ASN carried out 133 inspections of approved organisations and laboratories, broken down as follows:
– organisations carrying out radiation protection technical checks: 103 including 66 unannounced supervisory checks;
– organisations evaluating nuclear pressure equipment conformity and inspecting operational equipment: 15 inspections;
– organisations measuring radon activity concentration: 5 inspections;
– laboratories approved for environmental radioactivity measurements: 10 inspections.

## 3|2|7 Checks on exposure to radon and Naturally Occurring Radioactive Materials (NORM) in 2010

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

### *a) Monitoring exposure to radon*

Article R.1333-15 of the Public Health Code and article R.4451-136 of the Labour Code provide for the radon activity concentration to be measured either by IRSN or by ASN-approved organisations. These measurements are to be taken between 15 September and 30 April of the following year.

For the 2010-2011 measurement campaign, the number of approved organisations is indicated in table 4.

### *b) Monitoring exposure to natural ionising radiation in non-nuclear industries*

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

Verification of application of these provisions over the 2007-2010 period confirmed that certain industries using enhanced natural ionising radiation came within the scope of application of the regulatory radiation protection provisions. 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.4451-143 and R.4451-144 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 2008-2010. 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 Regional Health Agencies. The checks take account of the recommendations issued by ASN (DGS circular of 13 June 2008) and the results concerning the radiological

**Table 4: Number of organisations approved for measuring radon levels**

| | Approval until 15 september 2011 | Approval until 15 september 2012 | Approval until 15 september 2015 |
|---|---|---|---|
| Level 1 or Level 1 option A | 18 | 15 | 8 |
| Level 1 option B | 6 | | |
| Level 2. | 5 | | 1 |

The Saint-Laurent-des-Eaux NPP viewed from the banks of the River Loire

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 BNI 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 during discharge, sampling of air, milk, grass, etc.). Lastly, the measuring of environmental - particularly meteorological - parameters is imposed when necessary.

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 for analysis. The results of these "cross-checks" are communicated to ASN. This programme of cross-checks defined by ASN is a way of ensuring that the accuracy of the laboratory measurements is maintained over time.

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 20 inspections - with sampling - every year (16 in 2010).

#### *b) Accounting rules for BNI 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;
– applicable decision thresholds 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 applied in all BNIs. The rules for chemical discharges are identical to those in force for ICPEs. All these rules will be put down in writing in the general regulations applicable to BNIs, which are currently being revised.

**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.*

UNDERSTAND

UNDERSTAND

### Reference spectra used for NPPs

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

*– Liquide:*
*– $^{3}H$,*
*– $^{14}C$,*
*– 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: $^{58}Co$, $^{60}Co$, $^{134}Cs$, $^{137}Cs$.*

As other countries use different accounting methods, it is hard to compare the results published by the various national nuclear regulators.

Quality of measurement is a precondition if the results obtained and published are to be conclusive. In the area of effluent 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.

It must be pointed out that in practice, only traces of artificial radioactivity are detectable in the vicinity of the nuclear facilities and that most measurements taken during routine surveillance are below the decision threshold or reflect the natural radioactivity. Consequently, these measurements cannot be used for estimating doses. It then becomes necessary to use models of radioactivity transfer to man, for which the input is the 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).

**Table 5: radiological impact of BNIs since 2004 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 licensees)**

| Licensee/Site | Most exposed reference group (population/distance from site in km)[a] | Estimation of received doses, in mSv | | | | | |
|---|---|---|---|---|---|---|---|
| | | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
| AREVA/La Hague | Digulleville (Child / 2.6)<br>Pêcheur Goury (adult (2008, 2009: child) / 7.5) | $1.10^{-2}$<br>$6.10^{-3}$ | $1.10^{-2}$<br>$6.10^{-3}$ | $1.10^{-2}$<br>$6.10^{-3}$ | $1.10^{-2}$<br>$6.10^{-3}$ | $8.10^{-3}$<br>$5.10^{-3}$ | $8.10^{-3}$<br>$4.10^{-3}$ |
| GANIL/Caen | IUT (adult / 0.6) | $3.10^{-3}$ | $2.10^{-3}$ | $3.10^{-3}$ | $< 6.10^{-3}$ | $< 9.10^{-3}$ [b] | $3.10^{-3}$ |
| EDF/Penly | Saint-Martin Plage, Vassonville (2009) (adult / 1.05) (2009: fisherman / 0.7) | $1.10^{-3}$ | $9.10^{-4}$ | $5.10^{-4}$ | $6.10^{-4}$ | $3.10^{-3}$ | $9.10^{-4}$ |
| EDF/Cattenom | Garche nord, Warpich (2009) (adult / 2.15) (2009: baby / 1.5) | $2.10^{-3}$ | $2.10^{-3}$ | $3.10^{-3}$ | $3.10^{-3}$ | $3.10^{-3}$ | $3.10^{-3}$ |
| CEA/Cadarache | Saint-Paul-Lez-Durance [adult / 2] | $8.10^{-3}$ | $8.10^{-3}$ | $3.10^{-4}$ | $2.10^{-3}$ | $2.10^{-3}$ | $2.10^{-3}$ |
| EDF/Chooz | Les Pirettes (gymnase) (adult (2009: baby) / 0.75) | * | * | * | * | $2.10^{-3}$ | $1.10^{-3}$ |

Table continued

| Licensee/Site | Most exposed reference group (population/distance from site in km)[a] | Estimation of received doses, in mSv | | | | | |
|---|---|---|---|---|---|---|---|
| | | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
| EDF/Dampierre | La Maison Neuve, Les Serres (2009) [adult / 0,9 (2009: adult / 0.7)] | * | * | * | * | $8.10^{-4}$ | $1.10^{-3}$ |
| EDF/Gravelines | Petit-Fort-Philippe, Esp. Cult. Decaestecker (2009) [adult (2009: fisherman) / 1.45 (2009: 1.1)] | $2.10^{-4}$ | $2.10^{-4}$ | $3.10^{-4}$ | $3.10^{-4}$ | $3.10^{-4}$ | $1.10^{-3}$ |
| EDF/Flamanville | La Berquerie, Hameau es Louis (2009) [adult / 0.8] [2009: fisherman / 0.8] | $3.10^{-3}$ | $5.10^{-3}$ | $5.10^{-3}$ | $1.10^{-3}$ | $7.10^{-4}$ | $9.10^{-4}$ |
| EDF/Golfech | Pascalet, Labaquière (2009) [adult / 0.85] [2009: adult : 1] | $2.10^{-4}$ | $2.10^{-4}$ | $2.10^{-4}$ | $5.10^{-4}$ | $8.10^{-4}$ | $8.10^{-4}$ |
| AREVA/FBFC | Ferme Riffard [adult / 0.2] | * | * | * | * | $6.10^{-4}$ | $8.10^{-4}$ |
| AREVA/Tricastin (AREVA NC, COMURHEX, EURODIF, SOCATRI, SET) | Les Prés Guérinés [adult (2005: child) / 3; 3.1; 2.16; 1.3; 1.5] | $2.10^{-3}$ | $2.10^{-3}$ | $1.10^{-3}$ | $1.10^{-3}$ | $5.10^{-4}$ | $5.10^{-4}$ |
| | Clos de Bonnot [adult / 2.2; 2.3; 1.3; 0.6; 0.8)] | * | * | * | * | $7.10^{-4}$ | $8.10^{-4}$ |
| EDF/Belleville-sur-Loire | Neuvy sur Loire [adult / 1.3] | $2.10^{-4}$ | $2.10^{-4}$ | $2.10^{-4}$ | $2.10^{-4}$ | $6.10^{-4}$ | $7.10^{-4}$ |
| EDF/Civaux | Ervaux sud [adult / 0.7] | * | * | * | * | $8.10^{-4}$ | $7.10^{-4}$ |
| EDF/Tricastin | Clos du Bonneau, Le Trop Long (2009) [adult / 1.25] [2009: baby / 1.25] | $7.10^{-5}$ | $7.10^{-5}$ | $6.10^{-5}$ | $7.10^{-5}$ | $4.10^{-4}$ | $7.10^{-4}$ |
| ANDRA/Manche | Hameau de La Fosse [adult / 2.5] | $9.10^{-4}$ | $8.10^{-4}$ | $8.10^{-4}$ | $7.10^{-4}$ | $7.10^{-4}$ | $6.10^{-4}$ |
| | Fisherman Goury [adult / 8] | $7.10^{-8}$ | $7.10^{-7}$ | $8.10^{-8}$ | $9.10^{-8}$ | $5.10^{-8}$ | $8.10^{-8}$ |
| EDF/Paluel | Le Tôt [adult (2009: fisherman) / 1.45] | $2.10^{-3}$ | $2.10^{-3}$ | $2.10^{-3}$ | $2.10^{-3}$ | $2.10^{-3}$ | $6.10^{-4}$ |
| EDF/Nogent-sur-Seine | Port Saint-Nicolas, Maison de l'éclusier (2009) [adult / 2.25] [2009: adult / 1] | $6.10^{-4}$ | $7.10^{-4}$ | $8.10^{-4}$ | $9.10^{-4}$ | $7.10^{-4}$ | $6.10^{-4}$ |
| EDF/Blayais | Le Bastion [adult (2009: fisherman) / 1.1] | $3.10^{-4}$ | $4.10^{-4}$ | $4.10^{-4}$ | $4.10^{-4}$ | $5.10^{-4}$ | $5.10^{-4}$ |
| EDF/Bugey | St Etienne d'Hières sud [adult / 0.45] | * | * | * | * | $5.10^{-4}$ | $5.10^{-4}$ |
| EDF/Cruas-Meysse | Ferme de Grimaud, Serres (2009) [adult / 1.25] [2009: baby / 1.1] | $2.10^{-4}$ | $2.10^{-4}$ | $2.10^{-4}$ | $8.10^{-5}$ | $4.10^{-4}$ | $5.10^{-4}$ |
| CEA/Saclay | Fisherman, Christ de Saclay [adult / 1]<br>Farmer, Christ de Saclay [adult / 1] | $4.10^{-3}$<br>$7.10^{-4}$ | $4.10^{-3}$<br>$5.10^{-4}$ | $5.10^{-3}$<br>$5.10^{-4}$ | $9.10^{-4}$<br>$4.10^{-4}$ | $7.10^{-4}$<br>$4.10^{-4}$ | $4.10^{-4}$<br>* |
| EDF/St-Alban | Les Crès [adult / 1.45] | $9.10^{-5}$ | $2.10^{-4}$ | $2.10^{-4}$ | $7.10^{-5}$ | $3.10^{-4}$ | $4.10^{-4}$ |
| CEA/Marcoule (ATALANTE, CENTRACO, PHÉNIX, MÉLOX, CIS-Bio) | Codolet [adult / 2] | $4.10^{-4}$ | $4.10^{-4}$ | $4.10^{-4}$ | $5.10^{-4}$ | $4.10^{-4}$ | $4.10^{-4}$ |
| EDF/Chinon | Le Neman [adult / 1.25] | $3.10^{-4}$ | $3.10^{-4}$ | $3.10^{-4}$ | $2.10^{-4}$ | $4.10^{-4}$ | $4.10^{-4}$ |
| EDF/St-Laurent-des-Eaux | Port au Vin [adult / 0.75] | $7.10^{-5}$ | $7.10^{-5}$ | $9.10^{-5}$ | $2.10^{-4}$ | $4.10^{-4}$ | $3.10^{-4}$ |
| ILL/Grenoble | Fontaine (gaseous discharges) and Saint-Egrève (liquid discharges) [Baby / 1 (Fontaine); 1.4 (Saint-Egrève)] | * | * | * | * | * | $1.10^{-4}$ |
| EDF/Fessenheim | Cité EDF (Koechlin) [adult / 1.2] | * | * | * | * | $8.10^{-5}$ | $8.10^{-5}$ |
| 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] | $2.10^{-5}$ | $2.10^{-5}$ | $2.10^{-5}$ | $9.10^{-6}$ | $1.10^{-5}$ | $5.10^{-6}$ |
| ANDRA/CSA | Pont du CD24 [child / 2.1] | $8.10^{-6}$ | $6.10^{-6}$ | $5.10^{-6}$ | $3.10^{-6}$ | $2.10^{-6}$ | $5.10^{-6}$ |
| CEA/Grenoble [c] | Fontaine (gaseous discharges) and Saint-Egrève (liquid discharges) [baby (2004, 2008: adult) / 1 (Fontaine); 1.4 (Saint-Egrève)] | $7.10^{-6}$ | $7.10^{-7}$ | $2.10^{-6}$ | $7.10^{-7}$ | $1.10^{-6}$ | $3.10^{-7}$ |
| | Saint-Egrève [baby (2004, 2007: adult) / 1.4 (liquid) ; 3.9 (gaseous)] | $3.10^{-6}$ | $4.10^{-7}$ | $8.10^{-7}$ | $3.10^{-7}$ | $6.10^{-7}$ | * |

a: For installations operated by EDF, only "adult" figures are calculated. It is now the dose of the reference group most exposed to every site that is mentioned.
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.

An estimation of the effective 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 radiation 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 - which was initially limited to nuclear safety - 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 nuclear safety of BNIs and RMTs, radiation protection and protection of the environment;
– guide No. 11 of 15 June 2007 (modified on 7 October 2009) 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 radiation are used (medical, industrial and research activities). It has been used 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 radiation, and implementation of corrective measures highlighted after analysis, play a fundamental role in accident prevention. To give an idea of what this entails, the licensees detect and analyse 100 to 300 anomalies a year for each EDF reactor and about 50 a year for a research facility.

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 Public Health Code (articles L. 1333-3 and R. 1333-109 to R. 1333-111) and the Labour Code (Article R. 4451-99). The criteria for notifying 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 radiation, 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.

This system is not to intended to identify or penalise any individual person or party.

### 3|4|2 Implementation of the approach

*a) Event notification*

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 liable to constitute a risk for people, property or the environment through significant exposure to ionising radiation, the person in charge of a nuclear

### The Tritium White Paper

*Further to questions as to what becomes of tritium in the environment and its impact on man, ASN created two pluralistic think-tanks in 2008, one examining the sources of tritium, the other examining its impact on health and the environment. The chairmen of the groups, Dr. Patrick Smeesters of the Belgian Federal Agency for Nuclear Control (FANC) and Mr. Roland Masse of the Academy of Technologies, have reached their conclusions and the recommendations of the two think-tanks were submitted to ASN in April 2010.*

*The work confirmed the low impact of tritium discharges in France, but also evidenced the need for further studies and research to underpin existing data and knowledge on the behaviour of tritium in the environment.*

*On the basis of the conclusions and recommendations of the think-tanks, ASN has proposed a plan of action on the standardisation of the measurement of tritium, the control of tritiated discharges, the improvement of environmental monitoring and the estimation of the impact of tritium. It has asked the research organisations to further research into the evaluation of the impact of tritium, its effects on the foetus and embryo, and the potential induction of hereditary effects. With regard to the radiological impact, ASN has asked the licensees to supplement their impact studies by a critical study, taking a tritium impact that is twice that considered previously.*

*The Tritium White Paper and the ASN plan of action are available on the website www.asn.fr http://livre-blanc-tritium.asn.fr.*

activity is obliged to notify ASN and the State representative in the *département*[1] without delay.

According to the provisions of the Labour Code, employers are obliged to declare significant events affecting their workers. 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.

The declaring party determines the urgency of the notification in the light of the actual or potential severity of the event and the speed of response necessary to prevent the situation from getting worse or to mitigate the consequences of the event. The notification time of two working days tolerated in the ASN notification guides (see point 3|4|1), is not applicable if the consequences of the event necessitate intervention by the public authorities.

#### *b) ASN analysis of the notification*

ASN analyses the initial notification to check the implementation of immediate corrective measures, decide whether to conduct an on-site inspection to analyse the event in depth, and to prepare for informing of the public if necessary.

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 analysed the event pertinently and has taken appropriate steps to remedy the situation and prevent it from recurring, and has circulated the operating experience feedback.

ASN's review focuses on compliance with the applicable rules for detecting and notifying significant events, the immediate technical measures taken by the licensee to maintain or bring the installation into safe condition, and the pertinence of the licensee's analysis.

ASN and IRSN subsequently examine the operating feedback from the events. The assessment by ASN, the significant event reports and the periodic results sent by the licensees constitute the organisational basis of operating experience feedback. This 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 Conducting a technical inquiry in the event of an incident or accident concerning a nuclear activity

ASN has the authority to carry out an immediate technical inquiry in the event of an incident or accident in a nuclear activity. This inquiry, carried out for events that justify it, 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, and 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.

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

1. *Département* : administrative region headed by a *préfet*.

human exposure to ionising radiation, in particular activities carried out for medical purposes.

The TSN Act gives ASN the power to set up a board of inquiry, to determine who sits on it, 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 bureaus set up in other fields[2], 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 the inspection of nuclear activities and the drafting of the regulations. 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 investigation bureaus and takes account of the specific characteristics of ASN, particularly its independence, its ability to impose requirements or penalties if necessary and the concurrence of its investigative and other duties.

### 3|4|4 Public information

Independently of this process, the public must be informed of those events whose importance so warrants (see chapter 6).

### 3|4|5 Statistical summary of events in 2010

In 2010, ASN was notified of:
– 1033 significant events for the BNIs, concerning nuclear safety, radiation protection and the environment, 886 of which were classified on the INES scale;
– 62 significant events concerning the transport of radioactive materials;
– 494 significant events concerning radiation protection in small-scale nuclear activities, 159 of which were classified on the INES scale.

This number, which is stable for the BNIs and transport, is regularly increasing in small-scale nuclear activities because the persons in charge of these activities have widely adopted the notification procedure.

The distribution of significant events classified on the INES scale is specified in table 6. The INES scale is not applicable to patients, which are classified on the ASN-SFRO scale of significant events affecting one or more radiotherapy patients, and is described in chapter 9.

Graphs 6 to 12 below describe in detail the significant events notified to ASN in 2010, differentiating between the various notification criteria for each domain.

## 3|5 Raising awareness

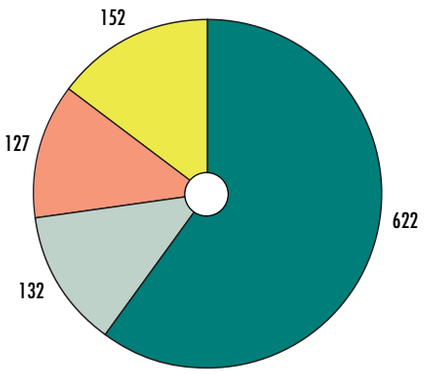
Compliance with the regulations can also be obtained through education. Regulation is thus supplemented by awareness programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations who implement this approach by issuing good practice and professional information guides (see chapter 9).

**Table 6: rating of significant events on the INES scale in 2010**

| Level | Pressurised water reactors | Other BNI nuclear activities | Transport | Small-scale nuclear activities | Total |
|---|---|---|---|---|---|
| **3 and +** | 0 | 0 | 0 | 0 | 0 |
| **2** | 1 | 1 | 0 | 1 | 3 |
| **1** | 74 | 20 | 9 | 37 | 140 |
| **0** | 642 | 148 | 53 | 121 | 964 |
| **Total** | **717** | **169** | **62** | **159** | **1107** |

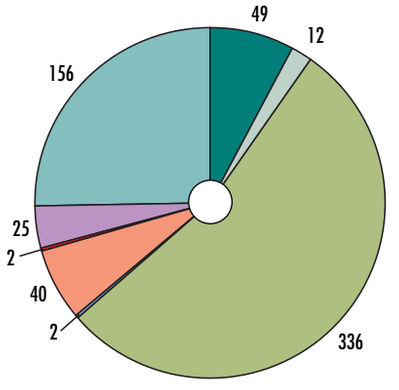
2. The French Maritime Events Investigation Bureau (BEAmer), the French Land Transport Accidents Investigation Bureau (BEA TT), the French Aircraft Accident Investigation Bureau (BEA), and their counterparts for events affecting military means of transport

## Graph 6: Breakdown of BNI events per type



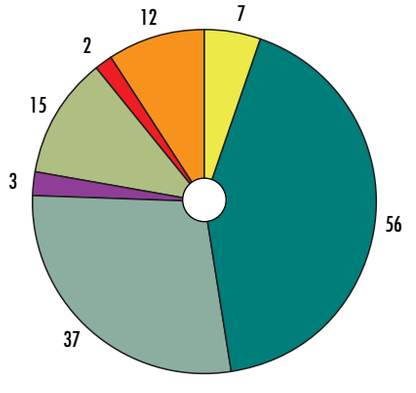

- Event involving nuclear plant safety
- Event involving the safety of BNIs other than nuclear power plants
- Event involving BNI radiation protection
- Event involving BNI environment

## Graph 7: Events involving safety in NPPs



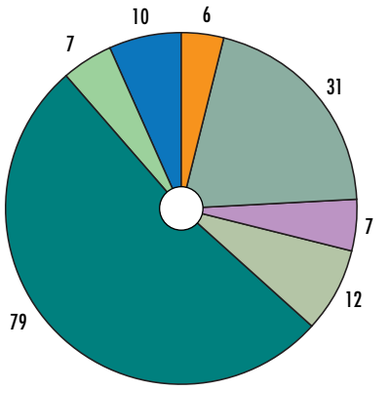

- Reactor trip
- Unscheduled activation of a protection or safeguard system
- Non-compliance or event which could lead to non-compliance with technical operating specifications (STE)
- Internal or external hazard affecting the availability of important equipment
- Shutdown through application of the 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: Events involving safety in BNIs other than NPPs



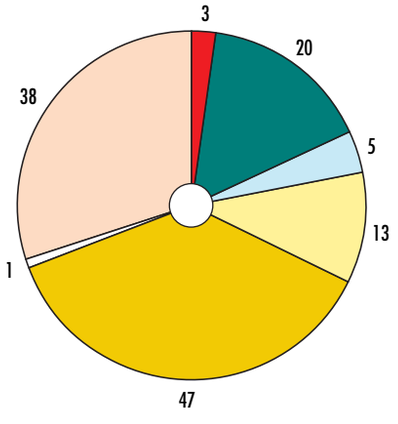

- Unscheduled start-up of a protection or safeguard system
- Event leading to overshoot of safety limit(s)
- Event compromising or potentially compromising the containment of dangerous materials
- Event which caused or could have caused multiple failures
- Fault, damage or failure affecting a safety function
- Event affecting a safety function that could constitute accident warning signs
- Other significant event that could affect safety

## Graph 9: Significant events concerning the environment in 2010



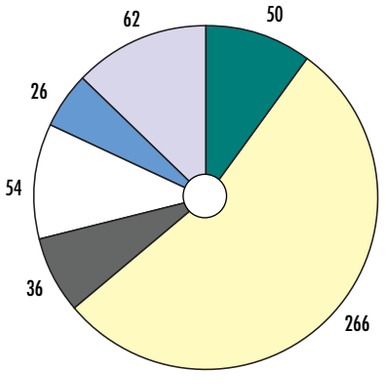

- Bypass of normal discharge routes with a significant radioactive impact
- Bypass of normal discharge routes with a significant chemical impact
- Confirmed overshoot of a discharge or concentration limit
- Non-compliance with an operational requirement, with potential significant impact
- Non-compliance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

## Graph 10: Events involving radiation protection in BNIs



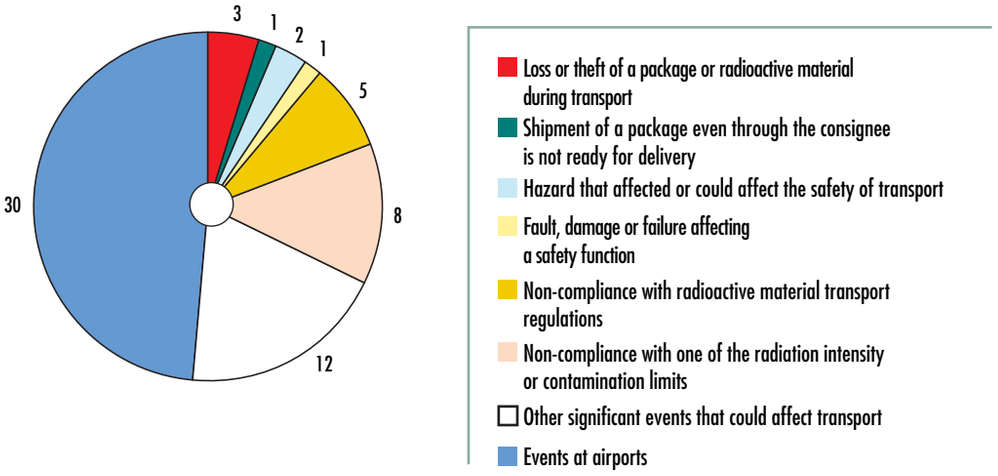

- Overshoot of one quarter of the annual dose limit or event that could lead to this situation
- Any significant deviation concerning radiological cleanness
- Operation involving a radiological risk performed without analysis or ignoring the analysis
- Abnormal situation affecting a source with activity higher than the exemption threshold
- Incorrect signage or non-compliance with zone access conditions
- Uncompensated failure in radiological monitoring systems
- Other significant events that could affect radiation protection

## Graph 11: Events involving radiation protection (excluding BNIs and RMT)




- Concerning one or more workers
- Concerning one or more patients (therapeutic application)
- Concerning one or more patients (diagnostic application)
- Concerning the public
- Loss, theft of sources or radioactive materials
- Other significant event involving radiation protection

## Graph 12: Events involving radioactive material transport




Raising awareness also involves joint action with other administrations and organisations that 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 includes information exchanges, both local and national, joint inspections and cross-training courses.

# 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 of environmental radioactivity measurement (www.mesure-radioactivite.fr – see chapter 6), the aim of which is to collate and make available to the public all the environmental measurements taken nationwide as required by the regulations. The quality of these measurements is guaranteed by subjecting the measuring laboratories to an approval procedure.

## 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 radiation. 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 to monitor:
– radioactive liquid and gaseous discharges into the environment;
– the levels of radioactivity in the land and aquatic environment around nuclear sites and nationwide.

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

Since 1994, the Commission has carried out the following inspections in France:
– the La Hague reprocessing plant and ANDRA's Manche repository in 1996;
– Chooz NPP in 1999;
– Belleville-sur-Loire NPP in 1994 and 2003;
– the La Hague reprocessing plant in 2005.
– the Pierrelatte nuclear site in 2008.
– the old uranium mines in the Limousin département in 2010.

This latter inspection took place in September 2010 on the AREVA site of Bessines and in neighbouring old uranium mines. The Commission's experts noted the good level of expertise in France, and more particularly underlined the quality of the information furnished to the public. They concluded that France was compliant with the provisions of article 35 of the EURATOM Treaty.

### 4|1|1 Purpose of environmental monitoring

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 radiological state 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;
– contributes to the evaluation of the radiological exposure of populations;
– enables an abnormal rise in radioactivity to be detected as

"Environmental monitoring" inspection by ASN at Cadarache – September 2010

Sampling station on a site of ANDRA

early as possible and to be alerted in the event of a malfunction of the installation, by inspection of the ground water tables among other things;
– provides a means of checking that licensees comply with the regulations;
– contributes to transparency and informing of the public by transmitting monitoring data to the national measurement network.

## 4|1|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 research facility. 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 regulatory provisions, the conditions of radiological monitoring of the environment around BNIs can be summarized 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 been the case on the Cadarache and Pierrelatte sites since 2006, for example.

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.

Each year, in addition to forwarding the monitoring results to ASN, as required by the regulations, the operators send some 120,000 measurements to the French National Network of Environmental Radioactivity Monitoring (see chapter 6).

## 4|2 Environmental monitoring nationwide

IRSN ensures the environmental monitoring of the French territory through a measurement and sampling network dedicated to:
– air monitoring (aerosols, rainwater, ambient gamma activity);
– monitoring of surface water (watercourses) 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:
  • the Téléray network (ambient gamma radioactivity of the air) which uses 164 measurement detectors;
  • the Sara network (radioactivity in atmospheric aerosols);
  • the Hydrotéléray network (monitoring of the main water courses downstream of all nuclear facilities and 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).

The radioactivity levels measured in France are stable and situated at very low levels, generally at the detection sensitivity threshold of the measuring instruments. The artificial radioactivity detected in the environment results essentially from fallout from the atmospheric tests of nuclear weapons carried out in the 1960's, and from the Chernobyl accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added very local contaminations resulting from past industrial incidents or activities, and which do not represent a health risk.

## 4|3 Guaranteeing 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.

Table 7: conditions of radiological monitoring of the environment around BNIs

| Environment monitored or type of inspection | Nuclear power plant | Research 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/m³.<br>• 1 continuous sampling under the prevailing winds with weekly tritium measurement ($^3H$) | |
| Ambient γ radiation | • 4 detectors at 1 km with continuous measurement (ranging from 10 nGy/h to 10 Gy/h) and recording<br>• 10 integrating dosimeters at the site limits (monthly recording)<br>• 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<br>• 10 integrating dosimeters at the site limits (monthly recording) |
| Rain | • 1 station under the prevailing wind (monthly collector) with measurement of βG and $^3H$ on a monthly mixture | • 2 continuous sampling stations including one under the prevailing wind with weekly measurement of βG and $^3H$ |
| Liquid discharge receiving environment | • Sampling in the river upstream and at mid-discharge, for each discharge (riverside plant)<br>or<br>sampling after dilution in the cooling water and bi-monthly sampling at sea (coastal plant):<br>Measurement of βG, of potassium (K)<br>Continuous sampling of $^3H$ (daily average mixture)<br>• Annual sampling in sediments, aquatic fauna and flora with measurement of βG, K and $^3H$ | • At least weekly sampling of water in the receiving environment with measurement of the total α activity, βG, K and $^3H$<br>• Annual sampling in sediments, aquatic fauna and flora for γ spectrometry |
| Groundwater | • 5 sampling points (monthly check) with measurement of βG, K and $^3H$ | • 5 sampling points (monthly check) with measurement of βG, K and $^3H$<br>• 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)<br>• 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) with measurement of βG, K and γ spectrometry<br>• Annual campaign on the main agricultural produce, with measurement of βG, K, $^{14}C$ and total carbon, and γ spectrometry |
| | • 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 (+ $^3H$ and $^{14}C$ periodically) |

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 and natural radionuclides, gamma, beta and alpha emitters, and the ambient gamma dosimetry.

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|3|1 Laboratory approval procedure

ASN decision 2008-DC-0099 of 29 April 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.

The approval procedure 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 - which are made anonymous - by a pluralistic approval commission which delivers an opinion on them.

The laboratories are approved by ASN decision published in its Official Bulletin on the website www.asn.fr.

This decision obliges BNI licensees to have approved laboratories take the environmental radioactivity monitoring measurements required by regulations.

## 4|3|2 The approval commission

The approval commission is the body which, for the national network of 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 giving 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 its results in the inter-laboratory tests (ILT) organised by IRSN.

The commission presided over by ASN comprises qualified persons and representatives of the State services, laboratories, standardising authorities and the IRSN. ASN decision 2008-DC-0117 of 4 November 2008 renewed the mandates of the commission's members for a further 5 years.

## 4|3|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.

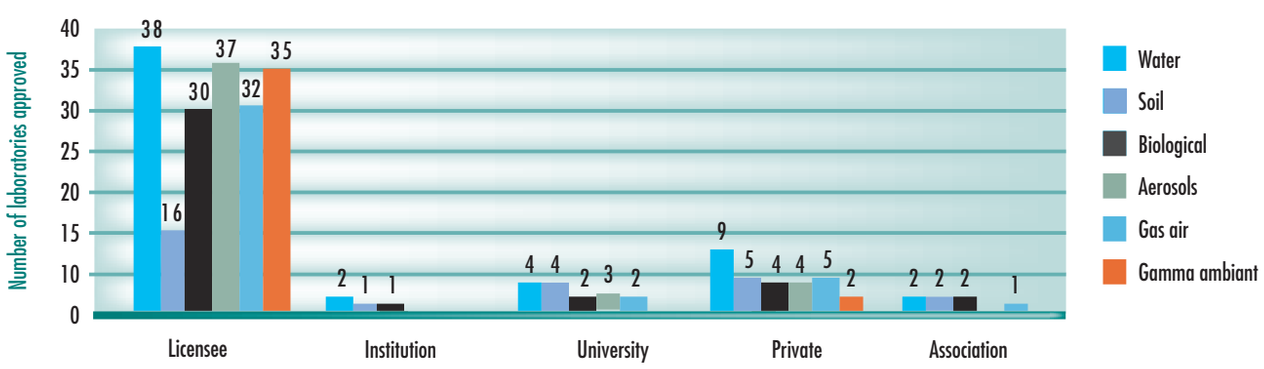
To ensure that the laboratory approval conditions are fully transparent, precise assessment criteria are used by the approval commission. These criteria are published on the national network's website.

From 2003 to the end of 2010, IRSN organised 34 ILT covering 43 approval types. Most of the approved laboratories specialise in water monitoring, with 55 laboratories holding up to 13 different approvals for monitoring of this medium. About forty laboratories are approved for measurement of biological matrices (food chain), atmospheric dust, air and ambient gamma dosimetry. About 30 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 2010, ASN issued 208 approvals and extended a further hundred. As at 31 December 2010, the total number of approved laboratories stood at 60, totalling 746 currently valid approvals.

The detailed list of approved laboratories and their scope of technical competence is available on *www.asn.fr*.

Graph 13: Breakdown of the number of approved laboratories as at 31/12/2010



# 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 serious 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 associated with 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.

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 to the Public Prosecutor's Office.

To provide the inspectors with the tools they need to assess the seriousness 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 Implementing a penalties policy

### 5|2|1 For the BNI and RMT licensees

When ASN's regulatory actions reveal failures to comply with safety requirements, penalties can be imposed on the licensees concerned, after serving formal notice if necessary. 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 has brought it into conformity.

If the licensee has any observations concerning the penalties it shall present them to the ASN Commission before they are applied.

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 persons responsible for small-scale nuclear activities, organisations and approved 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:
– temporary or definitive authorisation withdrawals (after receiving 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 radiation"


99

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 radiation 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.

### 5|2|3 Failure to comply with labour law

In the performance of their duties in the NPPs, the ASN's labour 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 labour 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 Regional Directorate for Enterprises, Competition, Consumption, Work and Employment (DIRECCTE). He is also tasked with examining approval applications by the occupational health departments, jointly with the occupational physicians.

The labour 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 NPP leads to him being frequently contacted both by EDF personnel and by the personnel of the contractors working in the NPPs. 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 NPPs, 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 four reports, concerning five sites, to the various Public Prosecutor's Offices concerned. These reports recorded infringements relative to health and safety (three cases having caused industrial accidents) or obstructing the conventional safety inspector in the fulfilment of tasks (one case).

### 5|2|4 2010 results concerning enforcement and penalties

ASN took administrative action (formal notice, suspension, etc.) against six licensees and managers of nuclear activities. Further to the observed infringements, it sent eighteen reports to the Public Prosecutors, four of which were on account of conventional safety inspection in NPPs (see point 5|2|3).

On 14 October 2010, the County Court of Carpentras gave its verdict on the event that occurred on the SOCATRI facility in the night of 7 to 8 July 2008, condemning the enterprise for failing to give immediate notification of the incident. ASN had drawn up an infringement report resulting from the findings of an inspection carried out on 10 July 2008, which it had sent to the Public Prosecutor of Carpentras. The Public Prosecutor's office appealed against the verdict of this court action.

## 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: www.asn.fr
– inspection follow-up letters for all the activities it inspects;
– approval authorisations or rejections;
– incident notifications;
– the results of reactor outages;
– its publications on specific subjects (*Contrôle* magazine, etc.).

## 6 OUTLOOK

In 2011, ASN scheduled 1920 inspections on BNIs, radioactive material transport, activities using ionising radiation, organisations and laboratories it has approved and activities involving pressure equipment. Continuing in line with 2010, ASN will give priority to the inspection of the strong-implication activities defined in point 2 | 1.

Other activities, such as services in BNIs, the supply of electrical generators of ionising radiation and computer tomography will also receive particular attention.

ASN is currently revising the conditions of notifying significant events, which will take into account the experimentation of the events notification guide in small-scale nuclear activities and the changes in regulations in the BNI sector. The notification criteria and conditions shall be detailed and harmonised between the different sectors.

ASN will continue to deploy its action plan relating to tritium. This action plan will be tracked over time by a monitoring committee, which will hold its first meeting in the first half of 2011.

With regard to the monitoring of environmental radioactivity, ASN will continue the work it has started with all the players in the national measurement network. This will notably include assessing the results after one year of existence of the website of the National Network of Environmental Radioactivity Monitoring and defining the changes in the monitoring strategy around nuclear sites and over the rest of the national territory.

Lastly, ASN is preparing to inspect a new domain, namely the safety of radioactive sources (see chapter 10).