

The supervision of nuclear activities by the ASN aims to check that all users of ionising radiation exercise in full their responsibilities and their obligations with regard to radiation protection. In the case of basic nuclear installations (BNIs), this supervision is extended to cover nuclear safety and environmental protection and applies to all stages of the life of the installations: design, creation, commissioning, operation, final shutdown, dismantling. This supervision also includes visits, inspections of all or part of an installation, and examination and analysis of files, documents and data supplied by the operator to justify its actions. Although traditionally more focused on verifying the technical conformity of installations and activities with regulations and standards, this supervision today encompasses a broader dimension taking in human and organisational factors that are harder to assess; it thus includes an examination of individual and collective behaviour, of management, organisation and procedures, based on a variety of indicators (such as events, inspections or relations with the stakeholders (personnel, operators, contractors, trade unions, occupational physicians, inspectorates, and so on)). This supervision by the ASN does not relieve the user of ionising radiation of the need to organise its own in-house supervision of its activities.

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

This chapter presents the procedures involved in the supervision conducted by the ASN, on the one hand of BNI operators and transporters of radioactive materials, and on the other of users of ionising radiation. It also presents the procedures for monitoring exposure to Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM).

1 SUPERVISION OF BNIS AND RADIOACTIVE MATERIAL TRANSPORTS

Although prime responsibility for safety lies with the operator, the regulatory body is responsible for authorization, inspection and formal notice. In France, under application of decree 2002-255 of 22 February 2002 which created the Directorate General for Nuclear Safety and Radiation Protection (DGSNR), the regulatory body is the ASN: this body is in particular tasked with preparing and implementing all measures concerning the safety of BNIs and transports of radioactive and fissile materials for civil purposes (TMR), in particular by checking application of technical regulations and organising BNI and TMR safety inspections. For the ASN, this responsibility covers safety, radiation protection and pressure vessels.

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Scope of supervision

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Supervision of nuclear safety

BNI safety, the principles of which are recalled in chapter 2, covers all technical and organisational measures taken at all stages in the design, construction, operation, shutdown and dismantling of nuclear installations in order to ensure normal operation, prevent accidents and limit their effects, in order to protect workers, the population and the environment against the effects of ionising radiation. It also comprises technical measures to optimise management of waste and radioactive discharges.

The safe transport of radioactive materials depends on three main factors:

- first and foremost, on the engineered toughness of the packages;
- on transport reliability and certain specially equipped vehicles;
- on an efficient emergency response in the event of an accident.

The ASN's supervisory activities cover all elements contributing to BNI and TMR safety. It is thus required to look at the equipment constituting the installations and the persons in charge of operating it, at the working and organisational methods from the initial design phases up to dismantling. It examines on the one hand the steps taken concerning safety or the monitoring and limitation of the doses received by the persons working in the installations, and on the other waste management, effluent control and environmental protection procedures.



In-depth inspection at Pierrelatte

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Pressure vessels

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

At central government level, responsibility for supervising application of the regulations lies with the ASN for nuclear pressure vessels containing radioactive products inside BNIs, and the Directorate for Regional Action, Quality and Industrial Safety (DARQSI) for other pressure vessels.

Of the BNI pressure vessels subject to ASN supervision, the main primary and secondary systems of EDF's 58 pressurised water reactors are particularly important systems. Since under normal conditions they operate at high temperature and pressure, their in-service behaviour is one of the keys to nuclear power plant safety.

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

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

- with regard to the design and construction phase, on the order of 26 February 1974 for the main primary system (CPP) and on basic safety rule II3.8 of 8 June 1990 for the main secondary systems (CSP);
- with regard to the operations phase, on the order of 10 November 1999 concerning supervision of the operation of the main primary system and the main secondary systems of pressurised water nuclear reactors, which gives the requirements for these two types of systems.

The ASN has prepared a new regulatory text, the order of 12 December 2005 concerning nuclear pressure vessels, which was published at the end of 2005. It will apply as of 2006 to the construction of nuclear pressure vessels, in particular reactor main primary and secondary systems (see chapter 3 point 2|2|1).

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

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BNI working conditions

In BNIs, as in any industrial firm, compliance with regulations concerning health and safety in the workplace is the responsibility of labour inspectors. In the case of EDF's nuclear power plants, supervision is carried out by DRIRE agents under the authority of the Directorate for Energy Demand and Energy Markets (DIDEME) at the Ministry for the Economy, Finance and Industry, by delegation of the Ministry for Labour. At the DRIREs, the agents carrying out this activity may also be BNI inspectors and could in the future be radiation protection inspectors.

Nuclear safety supervision, radiation protection and labour inspection actions have common concerns, notably the organisation of work sites and the conditions governing use of subcontractors. Whenever necessary, the ASN and the DIDEME therefore aim to co-ordinate their respective actions.

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

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BNI and radioactive material transport supervision procedures

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

When ASN supervisory actions reveal failures to comply with safety requirements, penalties can be imposed on the operators concerned, in some cases, after service of formal notices. Penalties in such cases may consist in prohibiting restart of a plant or suspending operation until the requisite corrective measures have been taken (point 1|2|3).

Finally, to ensure that supervision is as effective as possible, by checking that adequate resources are allocated to its duties, the ASN is developing an approach involving transfer to the operator of certain decisions for which it was hitherto responsible. This is the principle of "internal authorizations" (see point 1|2|5).

Technical investigation of the operator files

Examination of the justification documents produced by the operators and of the technical meetings organised on the site with the BNI operators or the manufacturers of equipment used in the installations is one of the forms of supervision conducted by the ASN.

At the design and construction stage, the ASN checks the safety analysis reports describing and justifying basic design data, equipment design calculations, utilisation and test procedures, and quality organisation provisions made by the prime contractor and its suppliers. The ASN also checks the manufacture of pressurised water reactor main primary system (CPP) and main secondary system (CSP) equipment. In accordance with the same principles, it supervises the packages intended for the transport of radioactive materials.

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

Examination of this data may lead the ASN to accept or on the contrary reject the operator's proposals, to ask for additional information or studies or to ask for work to bring the relevant items into conformity. The ASN expresses these requirements in the form of either an authorization, or a decision (see point 1|2|3).

a) Appraisal of the data supplied

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

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

ASN procedures for requesting the opinion of a technical support organisation and, where required, of an Advisory Committee, are described in chapter 2. For major issues, the ASN requests the opinion of the competent Advisory Committee, to which the IRSN will present its analyses. For other matters, safety analyses give rise to IRSN opinions transmitted directly to the ASN.

b) The main fields concerned

- Nuclear power plant scheduled outages

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

Given the importance for safety of the maintenance work done during the outage and the safety hazards involved in certain outage situations, the ASN requires detailed information from the operator. This information mainly concerns the work programme involved (see chapter 12) and any anomalies observed during the outage. During the "site" inspections, the inspectors will carry out spot checks on the conditions in which the various worksites in progress are conducted, whether for

repair or for modification of the installations, and the conditions in which equipment is monitored in-service, or periodic equipment testing is carried out.

Approval of outage programmes has been a DRIRE assignment since 1985. Restart of a reactor requires approval by the Director General for Nuclear Safety and Radiation Protection, on proposals from the competent DSNR.

- Other data submitted by the operators

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

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

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Using experience feedback

A system of nonconformity or significant incident declaration by BNI operators was set up in accordance with the requirements of the order of 10 August 1984 concerning the design, construction and operation of basic nuclear installations (see chapter 3). This safety concept is derived directly from application of the second level of defence in depth, as described in chapter 2, and resulting from the provisions of the international conventions ratified by France (article 9 of the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management, of 5 September 1997; article 19 of the Convention on Nuclear Safety of 20 September 1994). This requires implementation of a reliable system for detecting possible nonconformities or deviations, such as equipment failures or errors in application of operating rules. This system should allow early detection of any excursion from the normal operating range and constant improvement is required in BNI and radioactive material transport safety. It is therefore necessary to analyse the events detected in an installation or during a transport operation, in order:

- by taking account of appropriate corrective measures, to ensure that an event which has already occurred will not happen again;
- by analysing the potential consequences of events constituting early-warning signs of more serious incidents, to prevent an aggravated situation from occurring;
- to promote good safety improvement practices.

Analysis of the events detected in this way and implementation of modifications and corrective measures brought to light by this analysis, constitute what is known as experience feedback. It is a fundamental tool in the defence in depth approach. To give an idea, between 100 and 300 deviations are detected and analysed every year for each EDF reactor, and about fifty per year for a research laboratory.

Classification of these events must ensure that the more important ones are given priority treatment. For this purpose and for all the BNIs, the ASN has defined a category of unforeseen events known as "significant events". These are events that are sufficiently important in terms of safety to justify rapid notification, followed by a subsequent and more complete report. This report indicates the operators' conclusions concerning analysis of the events and the steps they are taking to improve safety. This information is extremely valuable for the ASN and its technical support organisation, the IRSN, in particular for the installations' periodic safety reviews. As an illustration, about ten significant events are declared for an EDF reactor every year.

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

Based on twenty years of experience, the ASN felt that it would be a good idea to transpose this safety concept to the fields of radiation protection and environmental protection and therefore updated the safety principles defined in the 1980s, extending them to radiation protection. A guide that can be consulted on the ASN's website, www.asn.gouv.fr, now gives all the provisions applicable to the operators and transporters concerning how to declare safety events affecting BNIs, radioactive material transports, radiation protection or environmental protection.

This declaration system is a means of providing data for the experience feedback data base. Significant events should not however be confused with radiological emergency situations, for which a different organisation is in place (see chapter 8).

The ASN wishes to expand this concept beyond the transporters and BNI operators. A similar approach is in progress for defining significant event declaration criteria concerning radiation protection in all local nuclear activities.

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ASN decisions and formal notices

a) General framework

Decisions which the ASN takes itself or proposes be taken by the ministers concerned result from a technical examination of available information and assessment data. It is not sufficient that these decisions be technically relevant, they must also be understood by those the ASN has to convince: elected officials, media, associations, nuclear safety authorities in other countries, etc.

Technical dialogue between the ASN and the operators is a key factor in preparation of the ASN's decisions: the arguments examined must be complete and exhaustive. When all the arguments have been exchanged, the regulatory decisions are imposed.

Ensuing actions include the following:

- granting or refusal of the requested authorization;
- requests for information or additional commitments on the part of the operator;
- requests that certain work or tests be performed;
- partial or complete, temporary or final shutdown of the installation;
- submission of a report to the State Prosecutor.

It must be emphasised that the ASN has the power to interrupt plant operation on safety grounds. This is not a frequent occurrence but the capacity to shut down an installation is a vital element in the effectiveness of the ASN. Every year, several PWR maintenance and refuelling outages are in fact extended owing to additional checks or justifications required by the ASN.

Compliance with ASN decisions and requests gives rise to supervisory action, notably in the form of site inspections.

b) Formalisation of ASN decisions and formal notices

With a view to enhancing the transparency of its actions, the ASN set up a formalised system for decisions and formal notices.

ASN decisions correspond to positions which it considers to be of particular importance and which are intended to be made public.

In 2005, four decisions were signed by the Director General for Nuclear Safety and Radiation Protection:

- decision DGSNR/SD3/ 0698/2005 of 18 November concerning decommissioning of basic nuclear installation no. 48 known as the SATURNE synchrotron, operated by the French Atomic Energy Commission on the Saclay site in Saint-Aubin (Essonne);
- decision DGSNR/SD2/ 298/2005 of 2 August, concerning the primary flow rate of the pressurised water reactors of the 900 MWe plant series: this sets the time-frame for transmission of the studies aimed at reviewing the relevance of the water flow limit value in the primary systems of nuclear reactors and the uncertainties linked to the measurement. In the meantime, and if the flow limit value is exceeded, EDF must ensure that the locating pins on the core lower plate are in good condition;
- decision DGSNR/SD2/ 124/2005 of 18 April 2005 stipulating a one month change in the time-frame for carrying out the conformity work on the lifting and handling cranes in the reactor building and on a number of their components, with respect to their seismic performance, for the 1300 MWe series of reactors. These conformity time-frames had been set by a decision of 22 April 2003;
- decision DGSNR/SD2/ 95/2005 of 1 March concerning prevention and monitoring requirements for insertion of reactor control clusters in pressurised water reactors. It authorises EDF to load fuel assemblies under RCCs for their last burnup cycle and puts an end to the obligation to conduct RCC drop time tests during the course of the cycle. The requirements concerning the RCC drop time tests at the end of the cycle and the particular fuel assembly deformation measurements are however maintained for all reactors in order to consolidate experience feedback.

The formal notices are injunctions addressed to operators, notably further to non-compliance with:

- the general technical regulations;
- requirements defined by order;
- a decision;
- a commitment made to the ASN.

Their purpose is to enjoin operators to comply with the requirements specified in the above documents within a realistic time frame set by the ASN. If the operators fail to comply, they become liable to sanctions, the nature of which is stipulated in the formal notice.

In 2005, no formal notice was issued.

Both decisions and formal notices are made public, notably via the ASN web site (www.asn.gouv.fr). When a particular site is concerned, the Local Information Committee (CLI) is informed.

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Inspection

a) Principles and objectives

Compliance with the safety reference system by the nuclear operators is monitored through regular supervision. This in particular takes the form of inspections on the nuclear sites, but also in the central or corporate departments (or design offices) of the main nuclear operators or their suppliers, in order to check actual application of the safety requirements.

An ASN inspection consists in checking that the operator complies satisfactorily with safety and radiation protection provision requirements. It is neither systematic nor exhaustive and its purpose is to detect specific deviations or nonconformities together with any symptoms suggesting a gradual decline in safety or radiation protection.

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

- nonconformities in regard to plant safety or radiation protection, or safety-related points requiring additional justification in the opinion of the inspectors;
- deviations between the situation observed during the inspection and the regulatory texts or the documents produced by the operator under application of the regulations, concerning both safety

and radiation protection and the related fields supervised by the ASN (waste management, effluent discharge, prevention of non-nuclear risks).

A programme of upcoming inspections is produced annually by the ASN. The topics dealt with take account of the inspections already performed, the extent to which the DRIREs and the ASN are familiar with the installations and the progress of the technical subjects under discussion between the ASN and the operators. It is prepared after consultation between the ASN, the DSNRs, and the IRSN, using a methodical approach defining priority national topics and suitable coverage of the different sites. This programme is not communicated to BNI operators.

The inspections are either announced to the operator a few weeks beforehand or may be unannounced.

They mostly take place on nuclear sites, but may also be carried out in operator engineering offices, the workshops and design departments of a subcontractor or on the construction sites or at factories and workshops where various safety-related components are manufactured. Even when the inspection is not performed on the nuclear site, it is the BNI operator who is ultimately responsible for the quality of the work performed by its subcontractor and for the efficiency of its own surveillance at the supplier's works.

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



Inspection in a BNI control room by ASN inspectors

b) Action taken in 2005

• Inspection practices

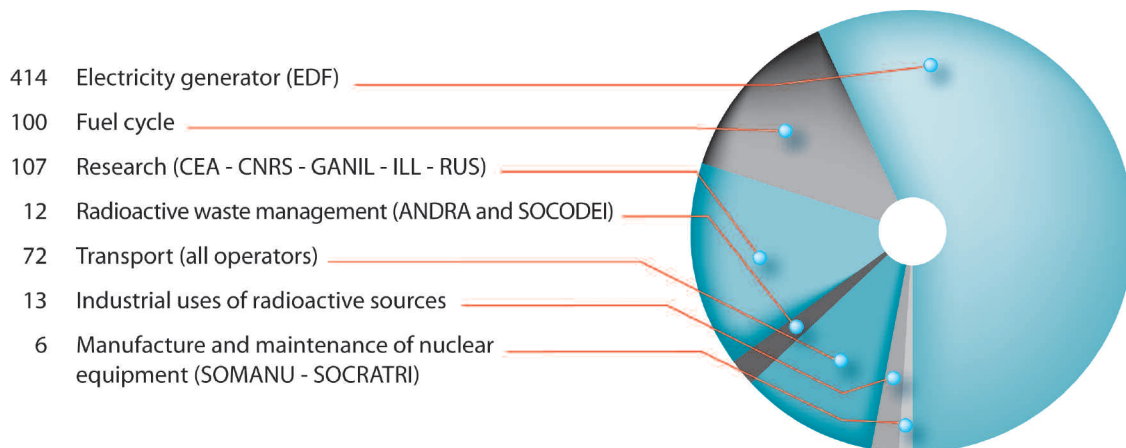
The ASN uses six types of inspections:

- standard inspections;
- reinforced inspections, on topics involving particular technical difficulties and normally directed by confirmed inspectors (see chapter 2 point 2|1|3);
- in-depth inspections, scheduled over several days and requiring a team of inspectors. Their purpose is to enable examination of previously identified issues in greater detail;
- inspections comprising sampling and measuring operations, aimed at spot checking discharge levels independently of operator measurements;
- reactive inspections, carried out further to a particularly significant event;
- worksite inspections, ensuring a significant ASN presence on the sites on the occasion of PWR unit outages or particular work, especially in the dismantling phase.

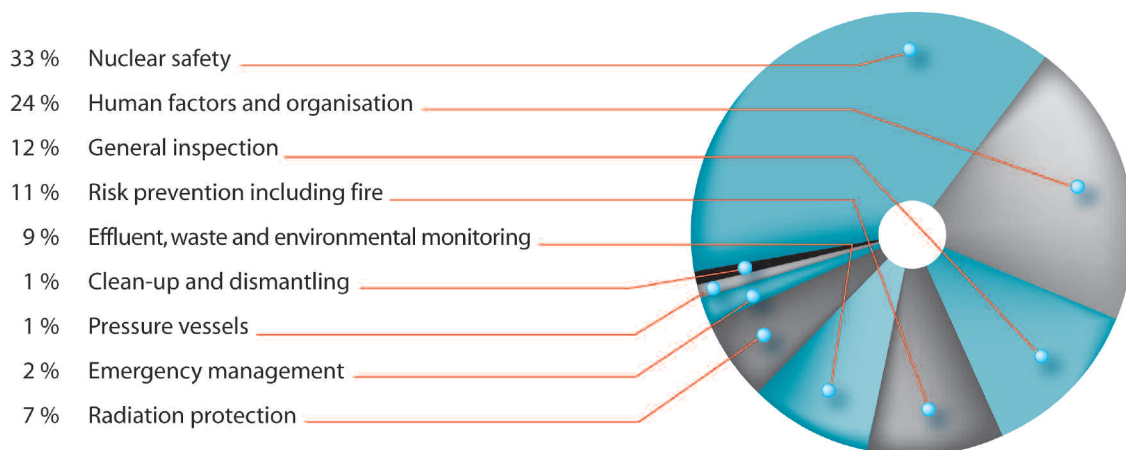
• Inspections in 2005:

In 2005, 724 inspections were conducted, 192 of which were unannounced. The breakdown according to the various installation categories is described in the following graphs.

Breakdown of 2005 inspections per type of operator



Breakdown of BNI inspections in 2005, per topic



The topics dealt with include the following, some of which were priority issues for 2005 and will be the subject of a summary analysis:

BNI:

- management of radioactive sources at the CEA 2 inspections
- steam generator maintenance 20 inspections
- contracted work (PWR) 23 inspections
- operational diligence 18 inspections
- radiation protection at industrial contractors 2 inspections

Transport:

- non-approved packages 9 inspections
- gammagraphs and gamma-densimeters 23 inspections

Internal authorizations

The ASN must focus its efforts on topics which contribute to guaranteeing supervision of nuclear safety and radiation protection that is as effective as possible.

Expansion of the scope of supervision by the ASN in recent years, in particular owing to inclusion of supervision of radiation protection in local nuclear activities, is not without risks: the ASN could make operation of all nuclear activities dependent on granting of authorizations that would be issued by itself, without consideration for the overall picture and which could be prejudicial to the overall effectiveness of the ASN. Furthermore, this supervision activity has a degree of influence on the level of responsibility of those persons carrying out nuclear activities. The inspector is sometimes incorrectly seen as being the ultimate line of defence, through his attentive reading of the safety files.

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

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

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

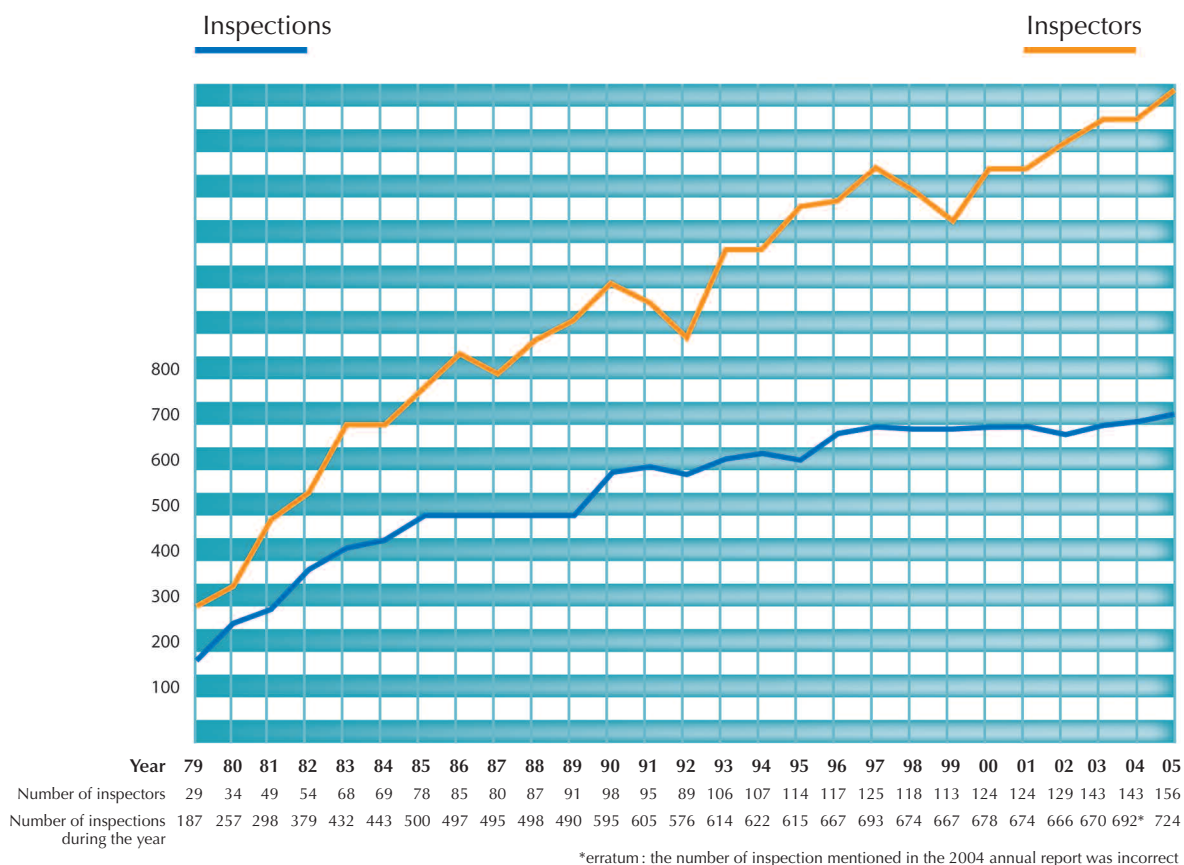
The ASN organisation for BNI supervision

All the tasks involved in supervising nuclear safety are split within the ASN between the DGSNR and the DSNRs. The DSNRs are entrusted with “on the spot” supervision. They are in permanent contact with the nuclear operators, take charge of most of the inspections carried out on the nuclear sites and provide step by step supervision of the various stages in PWR maintenance and refuelling outages, after which authorization for restart will depend on the ASN. The DSNRs are also tasked with examining certain authorization or waiver requests. The DGSNR is responsible for co-ordinating and steering the DSNRs in these areas, deals with all matters of national importance and defines and implements national nuclear safety policy.

BNI inspectorate

The BNI inspectors are ASN management level staff appointed from among the inspectors for installations classified on environmental protection grounds (ICPEs) by joint order of the ministers for the Environment and for Industry. Their supervisory functions are carried out under the authority of the Director General for Nuclear Safety and Radiation Protection. The inspectors are sworn in and bound by professional secrecy (see chapter 2 point 2|1|3).

Trends in numbers of inspectors and inspections



Note:

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

On 31 December 2005, the number of BNI inspectors on duty stood at 156, including 78 in the DRIREs and 78 at the DGSNR. For the past 3 years, this number has remained on the whole stable. The list of these inspectors is given in Appendix A.

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Supervision of pressure vessels

Within the ASN, a specific sub-directorate is in charge of monitoring application of regulations concerning the main primary system and the main secondary systems for pressurised water reactors as well as all pressure vessels in the nuclear field.

It directly supervises the construction (design and manufacture) of the main primary and secondary systems (CPP and CSP) (see chapter 12 point 3|1). In-service supervision of the main primary and secondary systems, as of all other pressure vessels, is the responsibility of the relevant DRIRE.

Examination of significant events

The DSNRs are responsible for immediately investigating significant events in all basic nuclear installations, to check that immediate corrective measures are implemented and, if necessary, to prepare the necessary information of the public. The ASN ensures co-ordination of DSNR action in this field and provides suitable training courses each year for the engineers concerned.

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

A subsequent examination of event experience feedback is conducted by the ASN and its technical support organisations, particularly the IRSN. The data supplied by the DSNRs and analysis of significant event reports, together with periodic records sent in by the operators, form the basis of the ASN operating feedback structures. This operating feedback is notably put to practical use during the periodic safety reviews of plants and by means of requests for improvements in the condition of plants and in the organisational provisions made by the operator.

2 “LOCAL” NUCLEAR SUPERVISION

Scope of supervision

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

In France, the ASN performs the role of regulatory authority, through its duty of drafting and monitoring technical regulations in the field of radiation protection. Decree 2002-255 of 22 February 2002 also states that the DGSNR is responsible for organising radiation protection inspections as provided for in the Public Health Code and its implementing texts, and for coordinating all inspections contributing to monitoring of radiation protection in the industrial, medical and research fields, including the monitoring of sources of ionising radiation used in these fields.

The scope of radiation protection supervision by the ASN thus extends to the use of ionising radiation in all nuclear activities defined in article L. 1333-1 of the Public Health Code. This duty is performed jointly with other inspection organisations such as the labour inspectorate, the inspectorate for classified installations and the French Health Products Safety Agency (AFSSAPS).

The basic international standards comprise:

- “ -the examination of requests for authorization to carry out practices entailing or potentially entailing exposure;
- authorization of these practices and their corresponding sources in certain conditions;
- performance of periodic inspections designed to check that the conditions are met and, as necessary, the application of measures designed to ensure compliance with the regulations and standards.

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

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

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

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

- an individual and collective commitment to safety on the part of the workers, managers and regulatory bodies;
- accountability on the part of each and every individual with regard to protection and safety, in particular at management level;
- measures designed to encourage a systematically questioning attitude, the desire to learn and a refusal to take existing safety results for granted.

The regulatory authority and the individuals and corporate bodies subject to the regulations must take due account of general experience and of the most recent innovations in the fields of radiological protection and source safety.”

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Supervision procedures for activities using ionising radiation

The user of ionising radiation has prime responsibility for radiation protection within the context of its activities. The ASN ensures that it meets its obligations and assumes its responsibilities. In this respect, and as required by the IAEA standard described above, the ASN's supervision of users of ionising radiation involves examination of data, visits prior to commissioning of installations, inspections and finally discussion, in a climate of openness and cooperation, with the professional organisations (trade unions, orders, learned societies, etc.). This action directly concerns either the users of ionising radiation, or organisations approved to carry out technical inspections on these users.

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

Methods of ASN supervision of the various radiation protection players

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

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Internal supervision of radiation protection by the users of ionising radiation

The purpose of the internal radiation protection checks is to regularly evaluate the radiological safety of installations that use ionising radiation sources, to check its level with respect to current regulations, and if necessary to reinforce it. Under application of the current regulations, internal radiation protection checks may be carried out as necessary by the person with competence for radiation protection (PCR), appointed and duly empowered by the head of the establishment, by approved supervisory bodies or by the IRSN. These internal checks do not replace the checks carried out directly by the ASN as part of its inspection activities at renewal or modification of an authorization, or in the event of loss or theft of a source.

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

Inspection operators for electrical generators and sealed or unsealed radioactive sources

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

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

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

(3) In the case of medical appliances, such as radiology or radiotherapy appliances, the above-mentioned decree of 5 December 2001 requires inspection of the internal and external quality of the appliances, performance of which is checked by organisations approved by the AFSSAPS.

OA: Organisation approved by the Director General for Nuclear Safety and Radiation Protection and the DRT, in accordance with article R. 1333-43 of the Public Health Code.

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

2 | 2 | 2

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

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

Apart from the internal inspections conducted under the responsibility of the establishments themselves, the ASN carries out its own checks as part of its role to supervise application of radiation protection regulations. In this respect it directly carries out checks during the procedures for issue (pre-commissioning inspections) or renewal (periodic inspections) of the authorizations to possess and use radiation sources granted on the basis of article R. 1333-24 of the Public Health Code. The authorization notifications can only be issued if the requests submitted by the ASN have been taken into

account. These checks are in particular designed to compare the data contained in the files with the actual physical reality (sources inventory, check on the conditions of production, distribution and utilisation of the sources and the appliances containing them). They also enable the ASN to ask the establishments to improve their in-house provisions for source management and radiation protection. In 2005, the ASN carried out 69 inspections of this type.

2 | 2 | 3

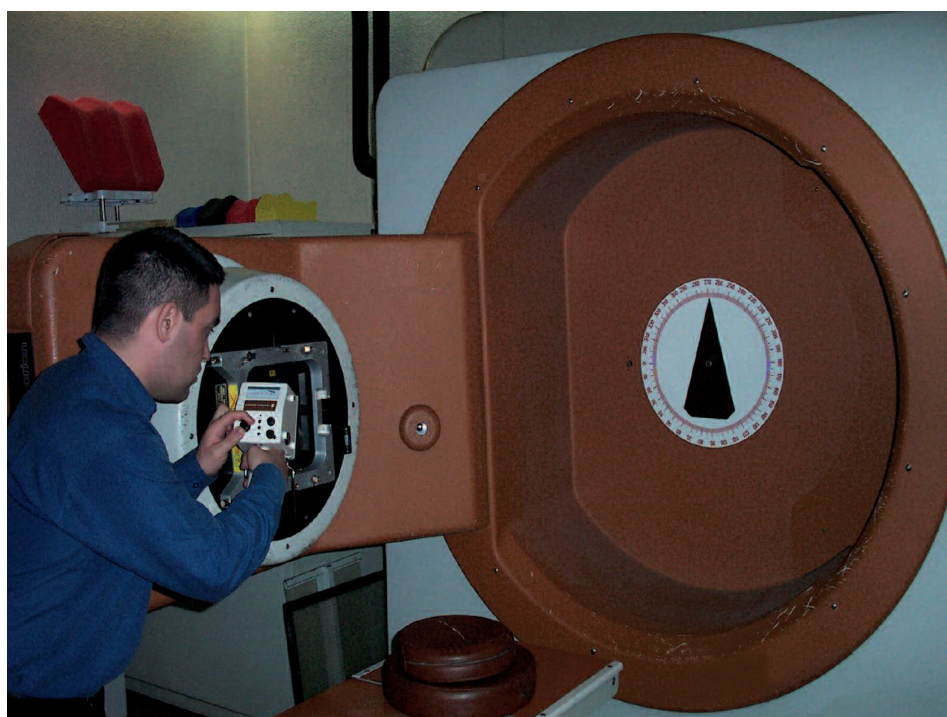
Growth in radiation protection supervision by the ASN

Following the reform of radiation protection supervision which took place in France in 2002, the ASN adapted its management organisation to develop radiation protection supervision in local nuclear fields. It thus focused on identifying supervision priorities, defining intervention procedures for itself and for the approved organisations, and deploying the necessary manpower. Various missions have been carried out along these lines since 2002 (reconnaissance mission, Vrousos mission, DRIRE/DRASS/DDASS working group). 557 visits were also made to ionising radiation users in 2005, with the following breakdown:

- medical field: 215 visits;
- industrial and research fields: 342 visits including 78 devoted to gammagraph operators.

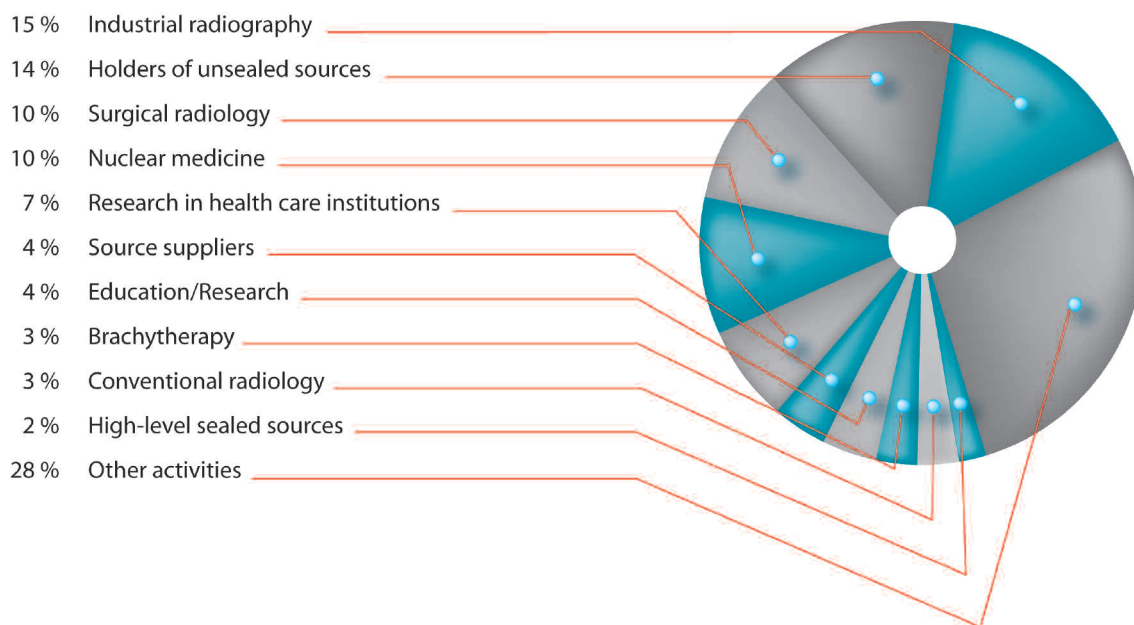
Law 2004-806 of 9 August 2004 concerning public health policy, introduced new requirements into the Public Health Code (articles L. 1333-17 to L. 1333-19, L. 1337-1-1.), creating the radiation protection inspectorate. Under application of these provisions, the ASN in 2005 prepared the decree defining the conditions for appointing and swearing-in the inspectors. Once it is published, the ASN will examine the appointment and clearance applications for the future radiation protection inspectors, so that the manpower required for performance of the supervision tasks can be made rapidly available.

During the course of 2006, inspections will continue and will be reinforced by performance of an initial programme of 521 visits (or inspections once the inspectors are appointed) broken down according to the priorities defined by the ASN on the basis of the health issues represented by the various categories of nuclear activities.



Checking a radiotherapy accelerator

2006 inspection programme schedule: breakdown per type of activity



The ASN will continue with its supervision of ionising radiation uses involving the highest exposure risks. In addition to the action already initiated in supervising radiation protection in nuclear medicine and radiotherapy, a programme will therefore be started in 2006 and targeted on surgical radiology installations. In the industrial fields, action concerning industrial radiography activities will be maintained.

At the same time, the ASN will define its supervisory management organisation on the basis of the principle that its actions must be proportional to the health issues linked to ionising radiation and consistent with the action of the other inspectorates. In the light of the number of installations and nuclear activities concerned (more than 50,000), the ASN will continue its work to identify those activities entailing real radiation protection issues and will define action priorities. To ensure greater efficiency, this action will be organised on the following basis:

- systematic inspections of nuclear activities with high or intermediate level health issues, at a frequency to be determined;
- inspections concerning a small number of users for the other nuclear activities;
- systematic internal checks on the entire fleet by approved organisations.

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

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

Reactive inspections could also be held further to incidents. In 2005, a number of visits were performed in this way, jointly with the inspectorate for classified installations and/or the labour inspectorate.

This organisation of supervision will gradually develop, in particular according to the pace at which the teams of radiation protection inspectors become available.

2 | 2 | 4

Supervision procedures by organisations approved by the ASN

The in-house inspections performed by the approved organisations under application of articles R. 1333-43 of the Public Health Code and R. 231-84 and R. 231-86 of the Labour Code, are used in particular to check the technical conformity of electrical devices emitting ionising radiation and radioactive sources, the radiological environment of the workstations, source, waste and effluent management procedures, and the organisation and technical arrangements in place under application of radiation protection regulations. These approvals are issued by the Director for Labour Relations and the Director General for Nuclear Safety and Radiation Protection. The orders of 17 March 2005 and 18 July 2005 specify the list of organisations approved for performance of technical radiation protection inspections in basic nuclear installations and/or in local nuclear facilities. About 40 organisations had been approved up to 31 December 2005.

The ASN ensures that these organisations conduct their activities in conditions of quality commensurate with their technical, organisational and ethical obligations. This second level supervision comprises:

- examination and monitoring of the approval file;
- approval follow-up or renewal audits;
- in-depth checks to ensure that the organisation's management arrangements are satisfactory;
- unscheduled inspections to ensure that the organisation's staff in the field work in satisfactory conditions.

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

- the procedures for obtaining data on the actions of the organisations and the state of the fleet inspected;
- the tools used by the organisations to carry out their duties of supervision and information of the administration.

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

Most of the approved organisations underwent auditing or in-depth visits during the last quarter of 2005, as part of the approval renewal procedures.

2 | 2 | 5

Openness and discussion

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

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

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

3 MONITORING OF EXPOSURE TO TENORM

3 | 1

Monitoring of exposure to radon

Since August 2004, the activity concentration of radon in premises open to the public has to be measured, in accordance with the order of 22 July 2004, by organisations approved by the Director General for Nuclear Safety and Radiation Protection. Measurement campaigns are run between 15 September of year *n* and 30 April of the following year. For the 2004-2005 campaign, 33 organisations were approved to carry out screening (level N1), 9 of which were approved for performance of the subsequent investigations (level N2) necessary for identifying radon transfer channels within a building.

At the request of the ASN (DGSNR circular of 20 December 2004 concerning management of the radon risk in premises open to the public), the DDASS in the 31 priority departments (see chapter 3) acted to inform the property owners of their new obligations to measure radon in teaching, health care and social institutions, spas and penitentiaries. This campaign was launched belatedly and the number of screening operations carried out remained low (a few tens) owing to the time needed to prepare the calls for bids locally.

A fresh campaign began in autumn 2005. For this campaign, 101 organisations were approved for N1 level screening, with 6 of them approved for additional N2 level investigations.

In terms of supervision, the ASN examined the approval applications submitted by the organisations and visited the head offices of several of them (5), with the support of the IRSN. This second level supervision is supplemented by a DDASS examination of the inspection reports produced by the approved organisations, whenever the activity levels measured exceed the supplementary action level of 400 Bq/m³. Owing to the small number of inspections conducted in 2004-2005, no results summary was produced.

3 | 2

Monitoring of exposure to NORM in non-nuclear industries

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

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

- the labour inspectors and radiation protection inspectors are competent to monitor the steps taken by the head of the establishment to assess the exposure of its workers and reduce it if necessary;
- the inspectors for classified installations and the radiation protection inspectors are competent to monitor the steps taken by the operator to reduce public exposure, if necessary, whenever these industrial activities are subject to authorization under the terms of the regulations applicable to installations classified on environmental protection grounds.

3 | 3

Monitoring of natural radioactivity in drinking water

Monitoring the natural radioactivity in drinking water is now an integral part of the health monitoring activities of the DDASS. The ASN is responsible for overall coordination, jointly with the Directorate General for Health. Implementation of the new monitoring programmes has been under way (see point 1|5 of chapter 3 and point 2|4 of chapter 5) since 2004.

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

4 OUTLOOK

2006 will be devoted to implementation of the decree setting the procedures for designating, qualifying and swearing-in the radiation protection inspectors mentioned in articles L. 1333-17, L. 1333-18 and L. 1337-1-1 of the Public Health Code, amending this code (regulatory provisions) and will see the appointment of the first radiation protection inspectors.

Jointly with the Directorate for Labour Relations (DRT), the ASN will begin to look at ways of organising its supervision of the activities of the organisations approved for radiation protection inspections. This work will concern four areas:

- using and managing approvals in conditions such as to avoid any distortion of the practices of these organisations;
- through field inspections conducted by the ASN, checking that the organisations carry out their duties in conditions of quality consistent with their technical and ethical obligations;
- organising feedback to the administration of information concerning the state of the “fleet” of ionising radiation users obtained during the inspections carried out by the organisations;
- encouraging the organisations to produce a professional guide of good practices for radiation protection technical inspections on sources and devices emitting ionising radiation, ambient environment technical checks, source, waste and effluent management checks.

Based on the experience it has acquired with regard to significant event declarations in the BNI and radioactive material transport fields, the ASN aims to develop a similar approach for local nuclear activities.