INDUSTRIAL AND RESEARCH ACTIVITIES

CHAPTER 10

For many years, industry and research have been using sources of ionising radiations in a wide variety of applications and locations. The issue for the radiation protection regulations currently in force is to check that, despite this great diversity, the safety of workers, the public and the environment is correctly assured. This safety in particular involves source management, supervision of the conditions in which sources are held, used and disposed of, from fabrication to the end of their lives. It also involves increasing the oversight of the main stakeholders, the source manufacturers and suppliers, and enhancing their accountability.

1 PRESENTATION OF INDUSTRIAL AND RESEARCH ACTIVITIES USING IONISING RADIATIONS

Industry and research employ sources of radiation, which are either radionuclides - primarily artificial - in sealed or unsealed sources, or electrical generators. The main applications in these sectors are presented below.

1 | 1 Sealed radioactive sources

The following are among the main uses of sealed radioactive sources.

1 | 1 | 1 Industrial irradiation

This is used for sterilising medical equipment, pharmaceutical or cosmetic products and for conservation of foodstuffs.

At low doses, irradiation inhibits germination (potatoes, onions, garlic, ginger), kills insects and parasites in cereals, leguminous plants, fresh and dried fruits, fish and meat, and slows down the physiological process of decomposition of fresh fruits and vegetables.

At medium doses, ionisation by irradiation prolongs the shelf-life of fresh fish and strawberries, eliminates deterioration agents and pathogenic micro-organisms in shellfish and meat (fresh or frozen), and technically improves foodstuffs, for example by increasing juice production from grapes or reducing the cooking time of dehydrated vegetables.

At high doses, ionisation offers industrial sterilisation of meat and seafood, of ready-to-eat foods, of hospital meals and decontamination of certain food additives and ingredients such as spices, gums, and enzyme preparations. These consumer product irradiation techniques may be authorised because once the products are treated, they show no signs of added artificial radioactivity. Industrial irradiators use cobalt 60 sources, the total activity of which can exceed 250,000 TBq. Some of these installations are classified as basic nuclear installations (BNIs).

1 | 1 | 2 Non-destructive testing

Of the non-destructive testing techniques, gamma radiography in particular uses radioactive sources. It is used to inspect homogeneity defects in metal, particularly in weld beads. This technique mainly uses iridium 192 and cobalt 60 sources, with activity not exceeding about twenty terabecquerels. Gamma radiography is usually performed using a mobile device which can be moved from one worksite to another and consists primarily of:

- a source applicator, used as a storage container when the source is not in use and for transport;
- an ejector tube and remote-control for moving the source between the projector and the object to be radiographed, while protecting the operator who can thus remain at a distance from the source; and
- a radioactive source inserted into a source-holder.

1 | 1 | 3 Checking of parameters

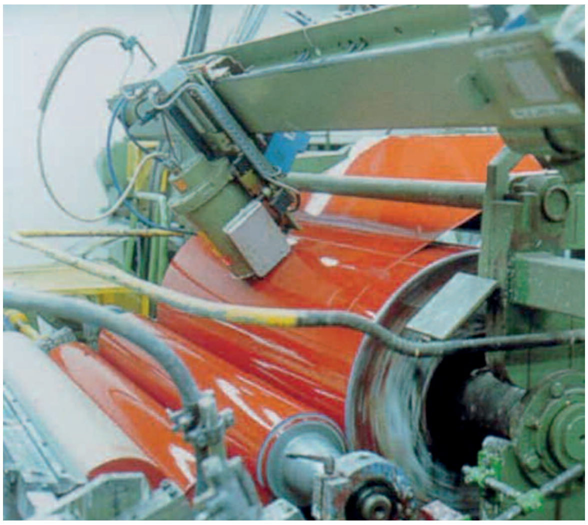
The operating principle of these appliances is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the information looked for.

Range 80 gamma radiography appliance

The radionuclides most frequently employed are krypton 85, caesium 137, americium 241, cobalt 60 and prometheum 147. The activity levels of the sources are between a few kilobecquerels and a few gigabecquerels.

These sources are used for the following purposes:

– atmospheric dust measurement; the air is permanently filtered through a tape running at a controlled speed, placed between source and detector. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most commonly used sources are carbon 14 (activity level:3.5 MBq) or prometheum 147 (activity level: 9 MBq). These measurements are particularly used for air quality monitoring by checking the dust content of discharges from plants;
– basis weight measurement: a beta radiation beam passes through the paper and is then received by a detector. The signal attenuation on this detector gives the paper density and thus the basis weight. The sources used are generally krypton 85, prometheum 147 and americium 241 with activity levels lower than 3 GBq;
– liquid level measurement: a beam of gamma radiation passes through the container filled with a liquid. It is received by a detector positioned opposite. The signal attenuation on this detector provides the level of filling of the container and automatic triggering of certain operations (stop/continue filling, alarm, etc.). The radionuclides used depend on the characteristics of the container and the content. As applicable, americium 241 (activity level: 1.7 GBq), caesium 137 - barium 137m (activity level: 37 MBq) are generally used;
– density measurement and weighing: the principle is the same as for the above two measurements. The sources used are generally americium 241 (activity level: 2 GBq), caesium 137-barium 137m (activity level: 100 MBq) or cobalt 60 (30 GBq);
– soil density and humidity measurement, or gammadensimetry, in particular in agriculture and public works.



Thermoradiometry – basis weight measurement by backscatter 1

These devices operate with a pair of americium-beryllium sources and a caesium 137 source;
– logging, which enables the geological properties of the sub-soil to be examined by inserting a measurement probe comprising a source of cobalt 60, caesium 137, americium 141-beryllium or californium 252.

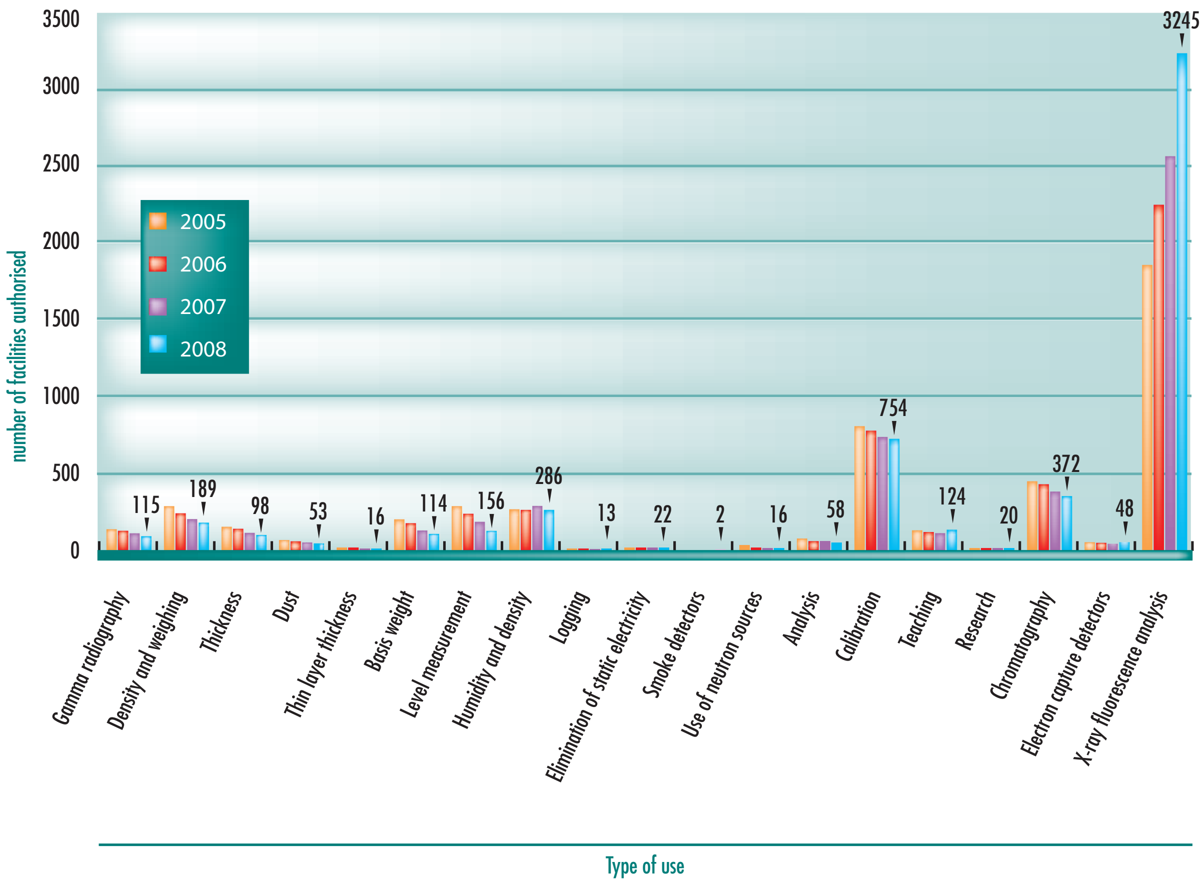
1 | 1 | 4 Other common applications

Sealed sources can also be used for:

– eliminating static electricity;
– calibrating measuring instruments (radiation metrology);
– practical teaching work concerning radioactivity phenomena;
– electron capture detectors using sources of nickel 63 or tritium in gaseous phase chromatographs. This technique can be used to detect and dose various elements. These often portable devices are used to dose pesticides or detect explosives, drugs or toxic products;

Portable X-ray fluorescence device to locate lead in paint – ARELCO

Diagram 1: use of sealed radioactive sources



– detection using X-ray fluorescence devices. This technique is particularly useful in detecting lead in paint (see point 2|4 of this chapter).

Diagram 1 specifies the number of facilities authorised to use sealed radioactive sources in the applications identified. It illustrates the diversity of these applications and how they evolved from 2005 to 2008.

It should be noted that a given facility may carry out several activities and therefore appears in diagram 1 and the following diagrams.

1|2 Unsealed radioactive sources

The main radionuclides used in the form of unsealed sources are phosphorus 32 or 33, carbon 14, sulphur 35, chromium 51, iodine 125 and tritium. They are used as tracers for calibration and teaching. Radioactive tracers incorporated into molecules is common practice in biological research. They are thus a powerful investigative tool in cellular and molecular biology. Unsealed sources are also used as tracers for measuring wear, searching for leaks, for friction research, for building hydrodynamic models and in hydrology.

The number of facilities authorised to use unsealed sources stands at 1,010.

Diagram 2 specifies the number of facilities authorised to use unsealed radioactive sources in the applications identified from 2005 to 2008.

1|3 Electrical generators of ionising radiations

Electrical generators of ionising radiations (generally X-rays) are mainly intended for use in industry for non-destructive structural analyses (tomography, diffractometry, etc.), checks on weld bead quality, or material fatigue inspections (mainly in the aerospace sector).

These devices, which use the principle of X-ray attenuation, are also employed as industrial gauges (tank filling measurements, etc.) or to inspect goods containers or

Diagram 2: use of unsealed radioactive sources

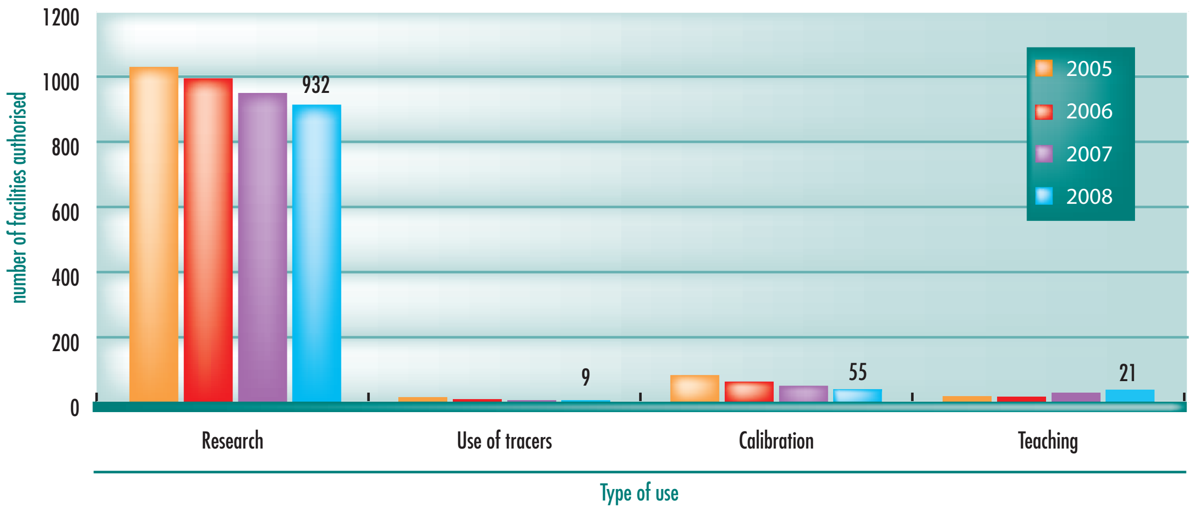
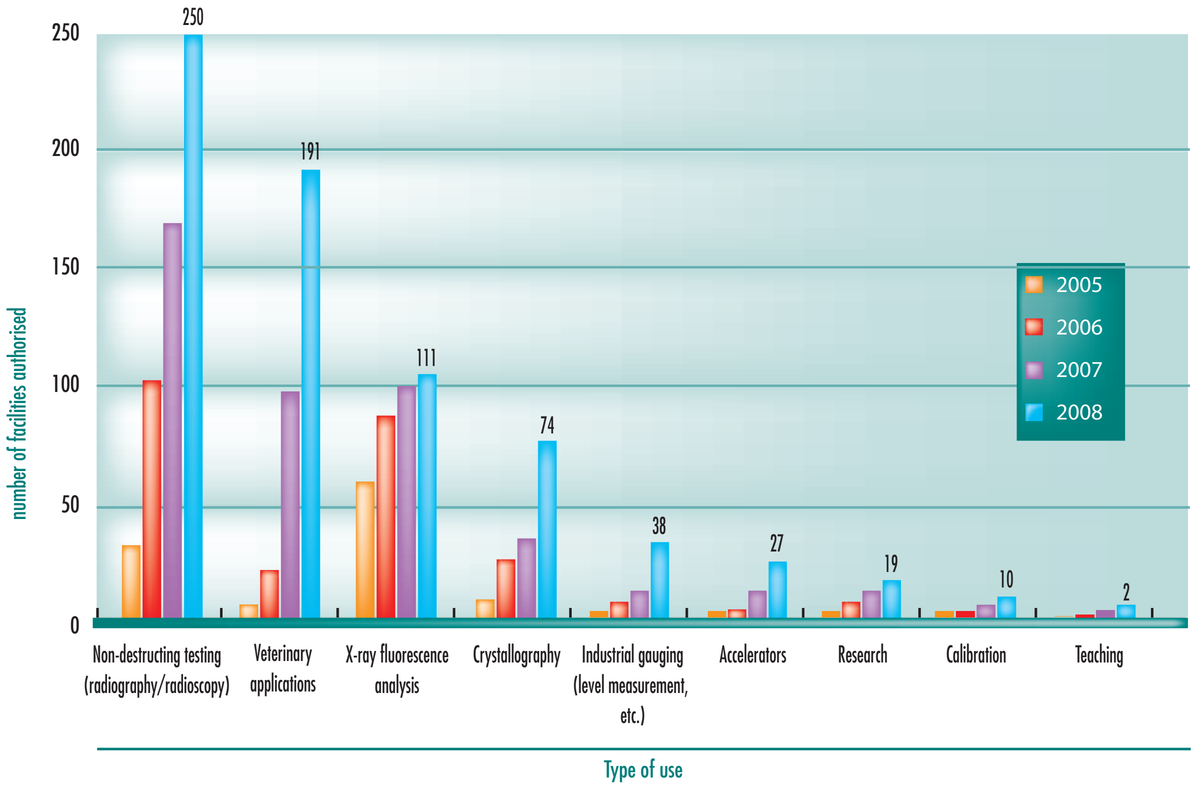


Diagram 3: use of electrical generators of ionising radiations



luggage. There are also more specific uses based on radiography for restoration of musical instruments or paintings, archaeological study of mummies or analysis of fossils.

Veterinarians also use these appliances for bone radiography and other common diagnosis procedures.

Unlike the electrical generators used in the medical field, there is no CE marking obligation, allowing free circulation of these appliances throughout the European Union.

Diagram 3 specifies the number of facilities authorised to use electrical generators of ionising radiations in the listed

Electrical X-ray inspection devices (explosives, baggage)

applications. It illustrates the diversity of these applications and their evolution from 2005 to 2008. This evolution is the result of regulatory changes introduced in 2002, which implemented a new system of licensing for use of these devices. The situation of the professionals concerned is currently being regularised in many sectors of activity, as shown in diagram 3, but there are still a large number of devices and users not covered by a licence (see point 3|1 of this chapter).

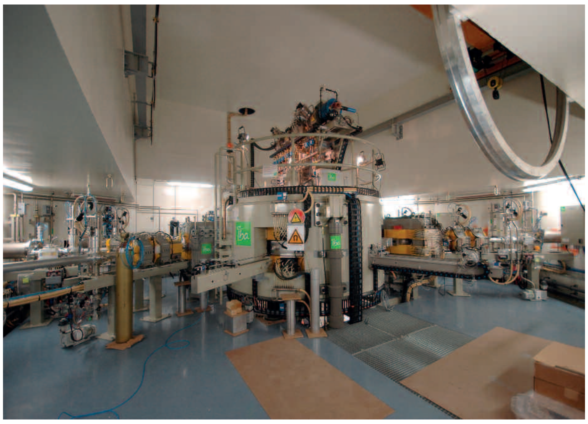
1|4 Particle accelerators

Finally, certain applications require the use of particle accelerators which produce photon or electron beams.

The inventory of particle accelerators in France, whether linear (linacs) or circular (cyclotrons and synchrotrons), comprises about 50 identified installations which can be used in a wide variety of fields, as presented in table 1.

Table 1: scope of use of particle accelerators

Industries	Processes	Products
Chemistry Petrochemistry	Cross-linking Depolymerisation Covalent bonding – Polymerisation	Polyethylene, polypropylene, copolymers, lubricants, alcohol
Coatings Adhesives	Vulcanisation Covalent bonding Polymerisation	Adhesive tapes, coated paper products, ply panels, heat shields, wood-plastic and glass-plastic composites
Electricity	Cross-linking Thermal memory Modification of semi-conductors	Constructions, instruments, telephone wires, power cables, insulating tape, shielded cable splices, Zener diodes, etc.
Foods	Disinfection - Pasteurisation Conservation - Sterilisation	Animal feedstuffs, grains, cereals, flour, vegetables, fruit, poultry, meat, fish, shellfish
Health Pharmacy	Sterilisation Modification of polymers	Disposable equipment, powders, drugs, membranes
Plastics Polymers	Cross-linking Manufacture of foam Thermal memory	Heat-shrink food wrapping, gymnastics apparatus, pipes and ducts, moulded packaging, flexible laminate packaging
Environment	Disinfection - Precipitation Organic detoxification Fermentation inhibition DeSOx/DeNOx	Sludges for spreading, emission of smoke, gas, solvents, water and various effluents, nutrients from sludges or waste
Paper pulp Textiles	Depolymerisation Covalent bonding	Polyethylene, polypropylene, copolymers, lubricants, alcohol
Rubber	Vulcanisation, strength enhancement Controlled vulcanisation	Adhesive tapes, coated paper products, ply panels, heat shields



IBA brand alpha, deuton and proton particle accelerator (cyclotron) installed in the Arronax research centre in the suburbs of Nantes

In the field of research, a number of synchrotron radiation production installations must be mentioned: the ESRF in Grenoble (European synchrotron radiation facility) and the SOLEIL synchrotron in Saint Aubin (91) operated by CEA.

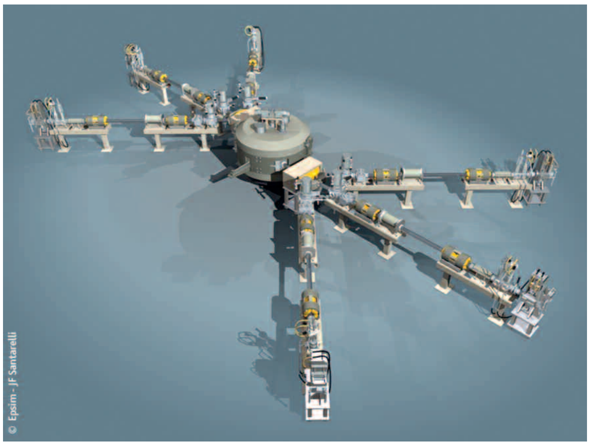
1 | 5 Worker dosimetry

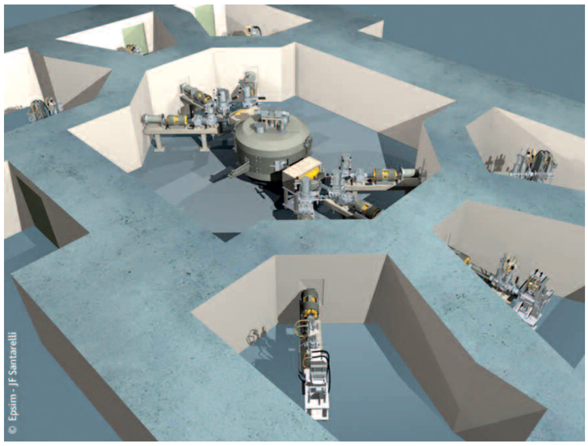
According to the latest data collated by IRSN concerning the results of external occupational exposures, more than 92,000 people working in the industrial, research and veterinary sectors are monitored for exposure.

In the veterinary sector in particular, the steps taken by the profession for exposure monitoring have lead to an almost 32% increase in the number of workers monitored since 2005.

Of the workers in the industrial, research and veterinary sectors, 95% of those monitored received an effective dose over the course of a year of less than 1 mSv.

The average dose received by the workers in these three activity sectors has varied little since 2006 and today stands at 260 µSv.





General view of the cyclotron installed in the Arronax research centre in the suburbs of Nantes with an without its biological shielding (computer generated images)

2 REGULATING INDUSTRIAL AND RESEARCH ACTIVITIES

The requirements of the Public Health Code specifically concerning industrial and research applications, as introduced by decree 2002-460 of 4 April 2002 and modified by decree 2007-1582 of 7 November 2007, are summarised below.

2 | 1 Licensing systems for ionising radiation sources used for industrial and research purposes

ASN is not the only authority regulating the manufacture, possession and use of radioactive sources. The requirements of the Public Health Code concerning sources of ionising radiations are contained in licences covered by the Mining Code, the system applicable to basic nuclear installations or to installations classified on environmental protection grounds.

The *préfet*[1] and the Delegate for Nuclear Safety and Radiation Protection for National Defence (DSND) therefore regulate these aspects for facilities subject to the requirements for installations classified on environmental grounds or the Mining Code, and defence-related installations respectively.

Table 2 presents the procedures which in 2008 govern the various industrial and research applications, including for veterinary purposes.

Diagram 4 gives a breakdown of the sealed radioactive sources held on French territory according to the authorities regulating this possession.

2 | 2 Licensing procedures

For each nuclear activity mentioned in table 2 and requiring a licence issued by ASN, the corresponding application must be submitted by the person in charge of the nuclear activity, jointly with the head of the facility or

Table 2: procedures applicable to industrial or research nuclear activities

Nature of the nuclear activity	Procedure and competent authority	Observations
Manufacture of radioactive sources or devices containing them	ASN licence(1), except if nuclear activity in licensed ICPE: authorisation by *préfet*	
Manufacture of products or devices containing radioactive sources		Exemption possible if criteria set in article R.1333-18 of the CSP are met(2)
Use of radioactive sources		
Irradiation of products, including food products		
Use of electrical generaators, including particle accelerators	ASN licence	Exemption possible if criteria set in article R.1333-18 of the CSP are met(2)
Import or export of radioactive sources or devices containing them		
Distribution of radioactive sources or devices containing them		Exemption possible if criteria set in article R.1333-18 are met(2)

(1) The provisions of the Public Health Code are incorporated into the licences issued under the Mining Code or the licensing system applicable to basic nuclear installations.

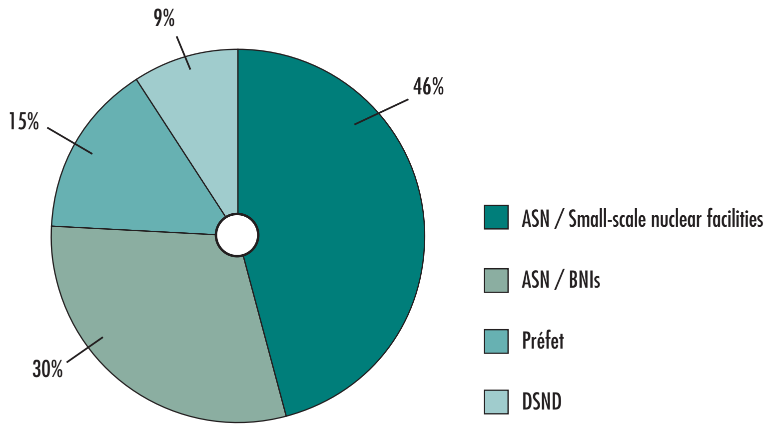
(2) The criteria for exemption from the licensing procedures apply:

– to radionuclides, if the total quantities involved or their concentration per unit of mass are below the thresholds set in the appendix to the Public Health Code (provided that the masses of materials involved do not exceed one ton);

– to electrical generators of ionising radiations, for which, in normal operation, at no point located at a distance of 0.1 m from their accessible surface, there is an equivalent dose rate higher than 1 µSv/h (to generators of a type certified as conforming to the standards for which the references are set by an ASN, approved by the ministers responsible for health, labour and industry, or in the case of equipment operating with a potential difference of 30 kV or less, in the same equivalent dose rate limit conditions.)

1. In a *département*, representative of the State appointed by the Président.

Diagram 4: distribution of sealed radioactive sources around the country according to the authority regulating their possession



his/her representative. This file is to be drawn up on the basis of a form available from the website www.asn.fr, in the "*formulaire*" (form) section and returned to ASN, accompanied by all other documents required. This website also contains explanatory notices to help applicants prepare their files.

The file should establish that radiation protection guarantees are in place and effective and that they were defined taking account of the principles of justification, optimisation and limitation specified in article L. 1333-1 of the Public Health Code. This file should therefore comprise elements concerning:

– the justification for the application;
– the conditions of possession and use of the sources;
– the presence of a person with competence in radiation protection;
– the characteristics and performance of appliances containing the sources held and used;
– radiation protection provisions;
– drafting of safety instructions; and
– the precautions taken against the risks of theft or fire.

In 2008, ASN continued with its actions to promote handling of licensing by its regional divisions. The task of reviewing the applications for possession and use of ionising radiations was therefore entrusted to ASN's regional divisions.

Responsibility for review of supplier licences was retained at the national level.

Revision of all the forms and notices was started in 2008, with the aims of simplification, ranking of risks and harmonisation. These new methods will be implemented in 2009 according to procedures to be issued in approved decisions by the ASN Commission.

2 | 3 Radionuclide source management rules

These rules, already presented in chapter 3, are of course also applicable to the fields of industry and research. It should be remembered that these rules concern:

– the obligation to obtain a licence prior to any transfer or acquisition of sources;

Scope of application of the special utilisation conditions (CPE) of the commonly used radiation sources

– *licensing of sealed sources: conditions applicable to the recovery and disposal of expired sources or sources which are no longer used (CPAs);*
– *extension of the authorisation to use sealed artificial radioactive sources beyond the ten-year period stipulated in the CPA (currently undergoing revision by an ASN decision);*
– *use of portable devices;*
– *use of smoke or combustion gas detectors (currently undergoing revision);*
– *use of sealed sources for calibration and testing (currently undergoing revision).*

– preliminary registration of all source movements with IRSN;
– the obligation on the licensee to keep detailed accounts of the sources in its possession and their movements;
– immediate notification to the préfet and ASN of any loss or theft of radioactive sources;
– return by the user to its suppliers - who are then obliged to take them – of sealed sources that have expired, are damaged or are no longer needed.

A number of conditions for use previously determined by the Interministerial Commission for Artificial Radioelements (CIREA) also apply. CIREA, which was responsible for issues concerning artificial radionuclides until 2002, had laid down special utilisation conditions (CPE) to inform the future licensee of the conditions for implementation of the regulations in its field of activity. Pending publication of a text of at least equivalent scope, the CPEs are still in force in accordance with decree 2002-460.

Those most frequently used have been or will be transcribed into orders or ASN decisions, while the others will remain special technical requirements referred to in the individual licences.

2 | 4 Revocation of unjustified or prohibited activities

The Public Health Code stipulates that "A nuclear activity or intervention may only be undertaken or carried out if justified by the advantages it procures, particularly in health, social, economic or scientific terms, with respect to the risks inherent in the exposure to ionising radiations to which the individuals are likely to be subjected". It also states that "No intentional addition of radionuclides in consumer goods and construction products is authorised" (articles R. 1333-2 and 3 of the Public Health Code).

In the case of sources used for industrial and research purposes, the justification decision is entrusted to ASN by Act 2006-686 of 13 June 2006 on nuclear transparency and security.

Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit would not seem to outweigh the risk. This prohibition is either generic (for example: ban on the intentional addition of radioactive materials in consumer goods), or the licence required with regard to radiation protection will not be renewed.

With regard to the ban on the intentional addition of radionuclides in consumer goods and construction products (articles R. 1333-2 and 3 of the Public Health Code), the sale of irradiated precious stones, of accessories such as key-rings, hunting equipment (sights), navigation equipment (compasses), or river fishing equipment (floats), equipped with sealed tritium sources, is prohibited.

For existing activities, justification will be reassessed if current know-how and technology so warrants. This is the case

Smoke detection

The aim is to signal an outbreak of fire as early as possible, by detecting the smoke produced. The devices used comprise two ionisation chambers, including one reference chamber being tight to the ambient gas, while the other lets combustion gases enter. The intensity of the current passing through the reference chamber is compared with that of the current passing through the measurement chamber. When the difference in intensity is higher than a preset threshold, an alarm is triggered. The gases contained in the reference chamber are ionised by emission of radiation from a sealed source. Although in the past several types of radionuclides were used (americium 241, plutonium 238, nickel 63, krypton 85), at present only americium is used, with an activity not exceeding 37 kBq (the most recent ones use a 10 kBq source).

However, if just a few years ago this situation could be justified owing to the human safety advantages of this technique, this is no longer the case given that new detection techniques using an optical technology have been developed and can comply with fire detection regulations and standards.

Pursuant to article L.1333-1 of the Public Health Code, this change requires that arrangements be made to retire smoke detectors containing radionuclides. To enable this to happen, a draft government order proposing gradual replacement was drawn up by ASN and proposed for consultation to various groups and bodies representing the various stakeholders involved in this retirement process (suppliers, installers, users) as well as to the ministries concerned, whether or not signatories of the text. It was also reviewed by the Advisory Committee for radiation protection in the industrial field. Following its comments, the professionals will again be consulted soon.

Lead detection in paint

Saturnism is a disease caused by lead poisoning. This poisoning usually results from ingestion or inhalation of dust from paint containing lead salts. This paint is to be found in older homes (built before 1 January 1949), as the use of paint as an additive was subsequently prohibited.

A legislative text concerning the fight against social exclusion requires action to prevent saturnism in children by including a check on the lead concentration of paint in the transaction for the sale of any residential real estate built before 1 January 1949 (validity of one year except if absence of lead: permanent validity) and when significant work is carried out on the coverings and coatings of communal parts of residential buildings built before 1 January 1949 (renewal for all work unless absence of lead: permanent validity). The order of 12 July 1999 concerning diagnosis of the risk of intoxication from the lead contained in paint, implementing article R. 32-2 of the Public Health Code (CSP), states that "the lead will preferably be measured using a portable X-ray fluorescence device". This non-destructive analysis method allows instantaneous detection of lead in a coating.

As the decree and supplementary orders concerning the fight against saturnism and published in the Official Gazette of 26 April 2006 (decree 2006-474 of 25 April and 4 orders of 25 April) laid down the use of detection appliances "capable of analysing the K line of the fluorescence response spectrum emitted by lead" (article 2 and appendix 2 of the order of 25 April 2006 concerning the determination of the risk of exposure to lead (CREP)), the licences for use of electrical X-ray generators for this application were not renewed as they are unable to comply with the objective set by the regulations.

The portable devices used today contain sources of cadmium 109 (half-life 464 days) or cobalt 57 (half-life of 270 days). The activity of these sources can range from 400 MBq to 1500 MBq.

with smoke detection systems (see box) and various other activities that are disappearing, in particular owing to technological changes: dew point determination, level measurement and density measurement, for which X-ray or ultrasound techniques are tending to replace those using radionuclides, or snow height measurement and cable car gondola positioning systems using a radioactive source fixed in the support cable splices.

On this subject of justification, ASN has initiated discussions with its European counterparts concerning the issues involved in implementing this principle arising from directive 96/29 of 13 May 1996. The particular aim is to minimise discrepancies with the other member countries, while preserving the way France applies the justification principle.

3 ASSESSING THE SITUATION AND EXPLAINING THE REGULATIONS

3 | 1 Assessing the situation

In 2008, ASN continued a process initiated in 2007, which was to search the country for any unauthorised suppliers distributing products in France. More than 20 companies were identified and received an information letter recalling the regulations applicable in France.

The inspections carried out at trade fairs discovered further suppliers, but also unauthorised possession or utilisation.

ASN also scans the Internet, looking for any advertising or offers of radioactive sources on commercial sites.

In 2008, ASN expanded the scope of its action beyond those simply possessing/using radioactive sources, to include electrical X-ray generators.

In this field, the regulatory requirements changed in 2002. One of the main developments was to do away with the system of notifications and implement a licensing procedure for use of these appliances. The situation of the professionals concerned is currently being regularised in many areas of activity, but there are still a large number of appliances and users without a licence.

Initial operating experience feedback shows that a large number of appliances have no certificate of conformity with the standards applicable in France, despite this having been mandatory for many years.

Furthermore, for this equipment category, there is no technical reference system recognised by all stakeholders.

ASN has begun discussions with the Ministry for Labour and the Central Laboratory of the electrical industries and strongly recommended that the Union technique de l'électricité (UTE) begin work on updating the above-mentioned standards. The UTE therefore initiated a revision of the NF-C 15-160 standards and the associated specific standards.

The changes made to the Public Health Code by decree 2007-1582 of 7 November 2007 now require authorisation for distribution of these appliances, in the same way as the system set up for the suppliers of radioactive sources. This new system will eventually enable ASN to gain a clearer picture of the situation and better regulate the appliances in use and available on the French market. These provisions will enter into force once the ASN decisions required by the decree have been approved.

These provisions also apply to accelerators of all types of particles and to electrical appliances emitting ionising radiations, including those emitting stray X-rays, except for electron microscopes.

Electrical generators of ionising radiations offer an alternative to the use of devices containing radioactive sources and are widely used, including in industrial radiography. The advantages of this technology are significant with regard to radiation protection, given the total absence of ionising radiations when the equipment is not in use.

Human screening – activity prohibited in France (simulation – demonstration equipment)

3 | 2 Explaining the regulations

In 2008, and in addition to its regulatory preparation work, ASN initiated or continued with several actions of a more general nature designed to improve awareness of the applicable regulations, rationalise the scope of certain licences concerning a given facility, or promote the drafting of guides of good practice by the professionals.

These actions enable ASN to recall the main applicable regulatory requirements, to specify what they expect and to stress practical aspects for facilitating the smooth running of the licensing process. They are also the opportunity for ASN to obtain direct feedback from the users concerning any constraints and difficulties they are experiencing.

Encouraging professionals to define guides of good practice concerning radiation protection in their daily activities is seen by ASN as a priority. In July 2005, it proposed to COFREND that an examination of the justification for gamma radiography be carried out, with production of a document detailing good practices to be observed, both by the customers and by the gamma radiography contractors. This action, which began in 2006, led in January 2008 to a national radiographic inspection safety day, organised by the SFRP. The results of the work done by nine thematic workshops were presented and are to be published.

At the same time, regional approaches aimed at producing good practice charters for industrial radiography were initiated. We can for example mention the signing of the Provence Alpes Côte d'Azur and Haute-Normandie charters and the launch of the process in the Nord Pas de Calais and Rhone-Alpes regions. Gamma radiography is an area in which the radiation protection stakes are high, as incorrect use of the appliances or loss of a gamma radiography equipment source are likely to have serious health consequences.

With regard to the efforts devoted to information, ASN's participation in a large number of events organised by the professional trade unions or organisations (order and union of veterinarians, GESI, GIMELEC, ports and airports, security firms, armed forces, fire brigade, etc.) should be highlighted.

4 REGULATION OF RADIATION SOURCES

4 | 1 Licenses issued by ASN

Suppliers

In 2008, ASN carried on with priority action initiated in 2003, concerning the suppliers of radionuclide sources or appliances containing them and used for industrial or research purposes. These companies have considerable responsibility for the safety of source movements, their traceability, the recovery and the disposal of used or unwanted sources. It is therefore important that their situation with regard to radiation protection rules be satisfactory and that their activities be duly covered by the licence specified in article R. 1333-17 of the Public Health Code.

In 2008, 47 licences were issued to suppliers and 6 licences were revoked. Several dozen files are also being investigated by ASN.

It should be underlined that since 2003, more than 220 authorisation or renewal files have been reviewed and 35 cancelled. The complete initial review of this type of file can take a relatively long time, owing to the combination of a number of negative factors (the problem of getting in touch with the right people, then of obtaining relevant information about the sources and devices, the complexity of the analyses linked to the radiation protection of appliances and radionuclide sources, the problems with obtaining precise guarantees for actual recovery of used or end of life sealed sources.

This initial preparatory work makes for easier subsequent review when the licences are renewed or if applications are made to modify them.

Diagram 5 presents the licences issued or revoked in 2008 and the trend in this area from 2005 to 2007.

Users

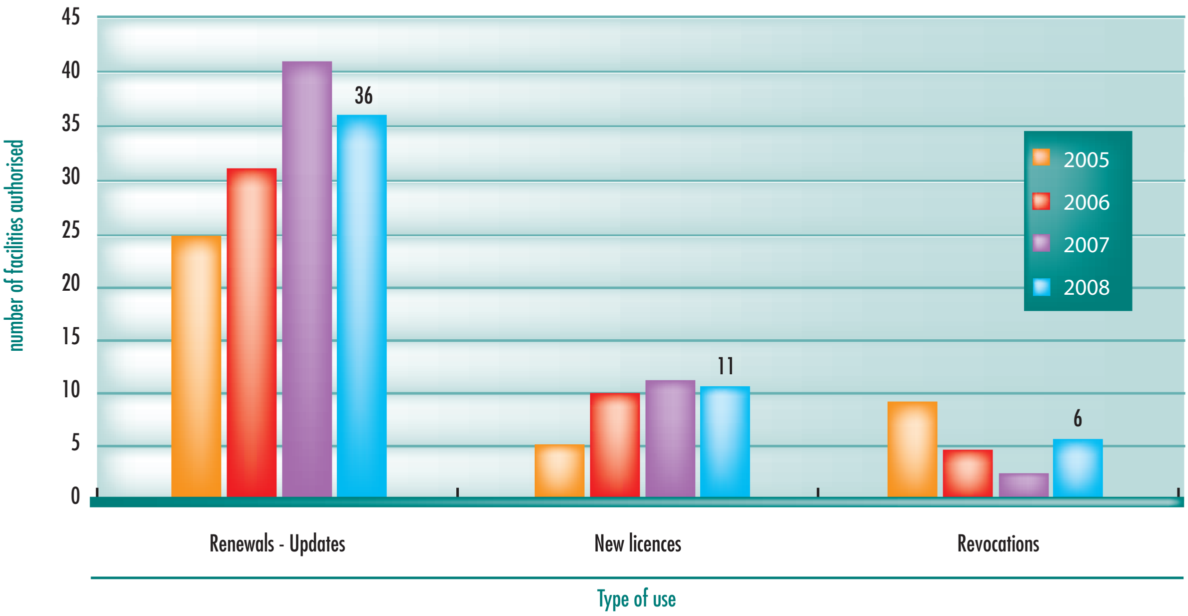
Review by ASN of more than 2000 application files for possession and use of radionuclides led to 739 new licences being notified and 181 licences being revoked. About 1,100 files dealing with an industrial or research activity are currently being reviewed by ASN. Diagram 6 presents the licences issued or revoked in 2008 and the trend in this area from 2004 to 2008.

Once the licence is obtained, the licensee may procure sources. To do this, it collects supply request forms from IRSN, enabling the institute to check that the orders are in accordance with the licences of both user and supplier, it being one of the institute's duties to update the inventory of ionising radiation sources. If the order is correct, the movement is then recorded by IRSN, which notifies the interested parties that delivery may take place. In the event of any difficulty, the matter is referred to ASN.

Electrical generators of ionising radiations

ASN is continuing to gradually examine applications for a licence to possess and use electrical generators. It should

Diagram 5: radioactive source "supplier" licences issued



be remembered that until the publication of decree 2002-460 modifying the Public Health Code, these installations simply required notification.

A number of problems were identified during this examination process (see point 3.1 of this chapter). X-ray generators are in particular defined as working equipment by the Labour Code and therefore have to comply with a number of design and installation standards.

In 2008, ASN granted 190 licences and 110 licence renewals for the use of electrical generators of X rays. 660 licences have been granted since the publication of decree 2002-460.

Sources of ionising radiations used in BNIs

Article R. 1333-17 of the Public Health Code states that the licence (authorisation decree) issued for a basic nuclear installation (BNI) is equivalent to a licence to possess and use ionising radiation sources as required by article L.1333-4. This simplifying arrangement only applies to sources necessary for the operation of the BNI and for activities linked to this operation. The other sources held or the other nuclear activities performed remain subject to licensing as specified in R.1333-17 of the Public Health Code.

The administrative simplification introduced by article R.1333-17 is intended to avoid the multiplication of the licences needed for the performance of a particular nuclear activity. The beneficiary is in no way exempted from the need to comply with the requirements of the Public Health Code, in particular those concerning the acquisition and transfer of sources.

The BNI licensees drew up a list of the sources in their possession, differentiating between those required for operation of the installations and the others. ASN asked them to incorporate management of the sources necessary for operation into the installations' safety requirements.

For its part, CEA regularised its situation with respect to the Public Health Code, by obtaining licences for its various establishments in place of the ordinary law exemptions which it had previously enjoyed. The regularisation work continued in 2008 with respect to electrical generators of ionising radiations and the registration of the sources in its possession.

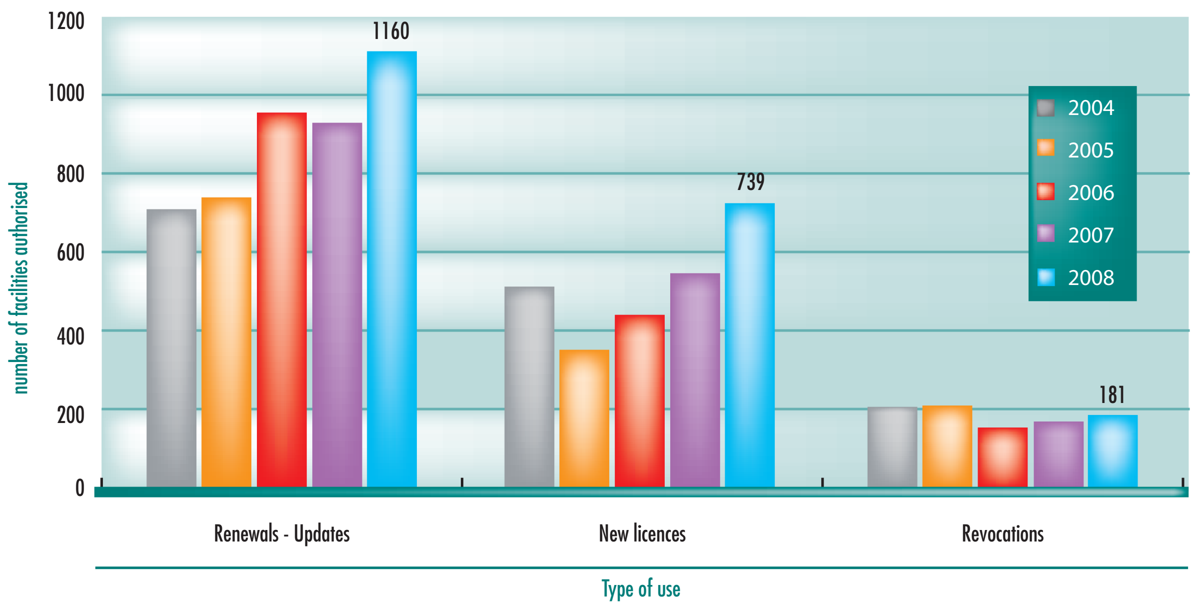
Jointly with ASN, the BNI licensees also drew up a guide intended for outside contractors working in BNIs, clarifying the rights and obligations of each party under the Public Health Code, with regard to the use of radioactive sources within the establishments.

4 | 2 Regulation by ASN

Regulation of radiation sources depends on the nature of the source and the stage of production and use reached. It is presented in chapter 4.

In the industrial field, ASN pays particularly close attention to the use of gamma radiography appliances and

Diagram 6: radioactive source “user” licences issued



ASN inspection in an establishment handling radioactive sources

ASN inspection on a gamma radiography site

accelerators. ASN has made inspection of establishments using gamma radiography appliances one of its priority inspection topics since 2004. In 2008, this topic was once again a priority, with particular attention focused on application of the "zoning" order of 15 May 2006 to industrial radiography activities. The main inadequacies identified concern prior evaluation and optimisation of doses, as well as the conditions for carrying out gamma radiography operations on the worksites.

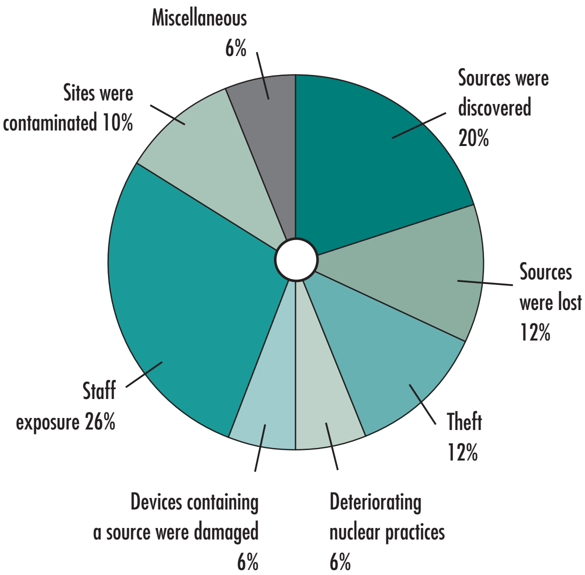
While setting up its industrial inspection programme, ASN identified other topics with high stakes, in particular source suppliers and users of high-level sealed sources.

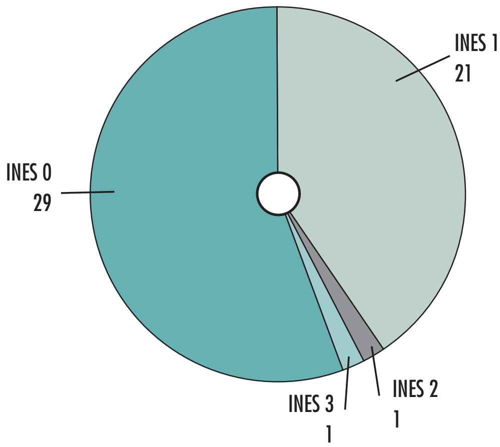
4 | 3 The main incidents and accidents in 2008

ASN also controls the handling of the incidents notified to it. These primarily concern loss or theft of radioactive sources or portable devices containing them (lead detection, etc.), inappropriate use or total or partial accidental destruction of a radionuclide source, in addition to accidental irradiation of individuals.

In 2008, about fifty incidents occurred in the industrial, research and veterinary field, some of which were in fact recurring:

Diagrams 7 and 8: typology and INES rating of incidents in 2008 (industrial, research, veterinary fields)





– 15 incidents leading to exposure of individuals (12 by irradiation, with 4 overdoses, and 1 by contamination)
– 11 sources were discovered;
– 6 sources were lost;
– 6 sources were stolen (mainly contained in devices for detecting lead in paint);
– 3 devices containing a source were damaged;
– 5 sites were contaminated;
– 3 deteriorating nuclear practices;
– 3 miscellaneous incidents.

Once of these incidents was rated level 3 on the INES scale (serious incident – see ONERA box), another was rated level 2 (see MAFELEC box), while 21 were rated level 1 (anomaly), and 29 level 0 (deviation).

Incident at ONERA in Toulouse (Haute-Garonne *département*[2])

On 12 March 2008, a worker in the Hirex Engineering company working in the ONERA plant in Toulouse was accidentally exposed to the radiation emitted by a high-level radioactive source of cobalt 60 inside a gamma radiography device. This worker stayed for several minutes in a bunker used to irradiate electronic components, while the radioactive source used for this operation was not in its safety position.

ASN was notified of the event on 13 March 2008 and immediately placed a ban on operation of this installation.

ASN and the conventional safety inspectorate, accompanied by IRSN experts, inspected the site on 17 March. The inspectors observed technical and organisational problems and numerous breaches of radiation protection regulations, which were the cause of the accident. Deficiencies in the safety systems which should normally have prevented access to the bunker in such circumstances were brought to light. Significant shortcomings in the training and supervision of the personnel in charge of irradiation operations meant that they were unable to immediately detect the fact that the source was not in the correct position.

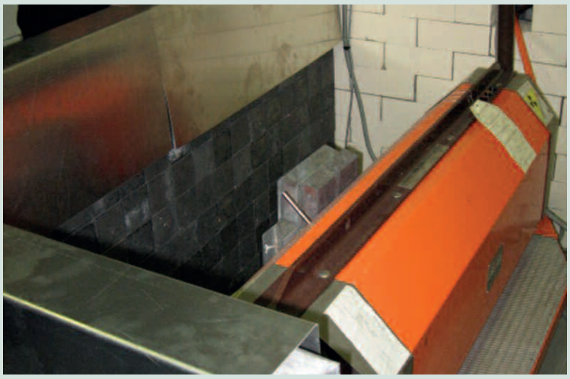
The irradiated worker was treated by his General Practitioner, with the assistance of IRSN physicians specialising in this type of event. The reconstruction of this accident and the results of the biological examinations carried out by IRSN evaluated the dose received by this individual at 120 millisieverts.

ASN rated this event level 3 on the INES radiological events scale (from 0 to 7).

ASN asked all those in possession of the same type of appliance in France (about ten) to check the effectiveness of the safety systems on their installation, using a specific procedure drawn up by the appliance supplier. The results of this check and a summary of the technical and organisational measures taken to prevent the risk of accidental irradiation will be produced for each of these installations.

At present, the ONERA installation has not yet been returned to service.

On 20 October 2008, ASN and the conventional safety inspectorate jointly sent the Toulouse Public Prosecutor's Office two reports concerning the many observed breaches of the Labour Code and the Public Health Code.



ONERA irradiation installation – March 2008

2. Administrative region headed by a *Préfet*.

Radiation protection incident at the MAFELEC company in Chimilin (Isère *département*)

On 7 October 2008, ASN was informed by the Isère préfecture[3] *of the presence of radiation emitted by metal parts used in the manufacture of lift buttons by the MAFELEC company on its Chimilin site.*

ASN carried out an inspection on the MAFELEC site on 8 October, together with its technical support organisation, IRSN, which took measurements to determine the exposure levels. This inspection also established the fact that packages of materials contaminated with cobalt 60 were delivered to the MAFELEC site from India, as of 21 August.

MAFELEC had already been warned on 3 and 7 October by the OTIS United States company that radioactivity was present in the products delivered. It was also warned on 17 September by the transport company that there was radioactivity in the packages being exported, as they passed through Roissy airport on their way to the United States.

MAFELEC receives raw materials from India consisting of the metal pushers used in lift pushbuttons. These raw materials are not machined in France, but simply assembled. It also receives finished buttons from India, which are simply checked. All of these items are lift pushbuttons, finished to varying degrees. The Otis company (France and abroad) is virtually MAFELEC's only customer for these products. All the products received from India as of this date and still present on the MAFELEC site on the day of inspection were withdrawn from sale.

ASN continued its investigations with the OTIS company and the transport companies. It carried out an inspection at Roissy airport on 10 October, in collaboration with the General Directorate for Civil Aviation, to determine the exact circumstances surrounding MAFELEC's shipment to the United States of a package of contaminated lift buttons. A second package of lift buttons from MAFELEC, contaminated with cobalt 60, was located in the cargo zone on the day of the inspection. The inspectors had it isolated in an area reserved for radioactive packages.

ASN's investigations revealed that of the 400 packages intended for the United States and systematically checked, no other anomaly was detected, other than the 2 packages previously mentioned, thereby confirming the hypothesis of isolated contamination of the metal products from India.

The OTIS company had been informed by MAFELEC and ASN and steps to identify and sort the contaminated parts were immediately initiated on the company's various industrial sites in France, in order to prevent any contaminated parts being distributed around the OTIS network. The defective batches were immediately recalled and eliminated. ASN also asked for any contaminated buttons that may already have been distributed or even installed to be identified and listed. The Otis company gave ASN a commitment to carry out all of these identification, recall and replacement operations by 31 December 2008.

This was done and involved checks on 1686 sites and devices and 92 service centres. 1% of the 30,000 buttons checked proved to be contaminated.

The doses absorbed by the MAFELEC company's workers were initially estimated by IRSN at between 1 and 3 mSv for about twenty workers, leading ASN to rate the incident level 2 on the INES "radiation protection" scale. Following information received from MAFELEC, the doses for these workers were reassessed and IRSN concluded that for all the workers, exposure was below the regulation annual limit for the public of 1 mSv.

The dosimetry evaluations for the workers of the other companies concerned, particularly OTIS, were carried out by private contractors. The doses received by the workers were all below the annual regulation limit for the public of 1 mSv.

According to the information obtained by the Indian Atomic Energy Regulatory Board (AERB), the only French customer identified by the Indian companies involved is MAFELEC. However, together with the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) and the General Directorate of Customs and Excise (DGDDI), a list of the companies liable to be using material from India was drawn up and checks were carried out by the DGCCRF as part of its routine duties.

Furthermore, based on the information provided by the Indian Atomic Energy Regulatory Board, the Indian companies involved in this incident have now acquired radioactivity detection equipment and an information and awareness campaign has been launched among all Indian companies working in this sector.

Finally, according to the information sent to ASN by its foreign counterparts, most of the European customers of the Indian companies identified have been inspected by their regulatory bodies. The parts delivered by this supplier showed no traces of contamination.

3. Office of the *préfet.*

4 | 4 Sealed source recovery and replacement requirements

The provisions of the Public Health Code (Articles L.1333-7 and R.1333-52 and 53) state that the supplier is obligated, without condition and whenever requested, to recover any sealed source it has distributed, in particular when this source has exceeded its service life or the user no longer needs it. It must also be able to present financial guarantees such as to cover the cost of recovering and disposing of end-of-life sources by another party or by the French National Agency for Radioactive Waste Management (ANDRA), in the event of the supplier itself defaulting.

This guarantee can take the form of a bank bond, an insurance policy, deposit of the total cost of recovery with ANDRA, which is returned if the source is recovered by the supplier, or registration with a mutual collateral institution, such as the Ressources association, created by the suppliers in 1996.

The collecting organisation must issue the user with a confirmation of recovery, certifying that the user is no longer responsible for use of the source. On the basis of this document, the source is removed from the user's inventory in the national source inventory managed by IRSN, but a trace of it is kept in the Institute's "archives" file.

When renewal applications are reviewed, in the event of closure of the company or during occasional periodic inspections ASN, with the assistance of IRSN, systematically checks the situation and the future of the sealed sources for each user.

French legislation requires the creation of a financial guarantee by the final supplier, that is the party distributing the source to a user. Other European countries have opted to require this financial guarantee from the user, while yet others only require it for high-level sources.

In order to draft the Government decree required by Article R.1333-54 concerning the procedures for calculating and implementing the financial guarantee, the current system should be revised in order to replace the Special Utilisation Conditions stipulated by CIREA in 1990 and still in force.

There are no such obligations on the supply of unsealed sources. Once they have reached the end of their service lives, management of these sources is the entire responsibility of the user. Depending on the radionuclides used, there are two possible options: either transfer to a radioactive waste management facility (ANDRA), or management of radioactive decay prior to disposal in conventional waste treatment installations.

5 COORDINATION WITH FRENCH AND FOREIGN AUTHORITIES

With the aim of coordinating public authorities, ASN in 2008 sought to forge new ties and maintain existing links with the State's various departments involved in radioactive source monitoring and oversight duties. ASN therefore initiated exchanges with the General Directorate of Customs and Excise (DGDDI) and the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), with a view to signing collaborative agreements in areas of common interest.

With respect to international coordination, ASN issued or responded to bilateral or multilateral calls for bids, took part in conferences, mainly with the aim of boosting international and community harmonisation and carried out cross-inspections with its transboundary counterparts.

More especially, with regard to implementation of the code of conduct on the security of radioactive sources and the corresponding import and export guidelines, ASN continued to take part in the periodic exchanges between States organised by IAEA. These exchanges dealt in particular with the implementation by the various countries of the import and export guidelines and the adoption of a common stance to help with achieving a common understanding and harmonisation of practices.

ASN drew the Government's attention to the steps needed to bolster the State's organisation for guaranteeing source security.

ASN, together with IRSN and ANDRA, responded to a request from the Chinese regulatory body to organise a technical meeting to deal with sources of ionising radiations. This request was initiated because the Chinese NRSC had recently become the competent Authority in this field and entailed a visit from a delegation of

11 high-ranking representatives from the Chinese central (NRSC) and provincial authorities. This reflects China's firm commitment to setting up a robust system, with personnel competent in the fields of radiation protection and source surveillance.

With the aim of harmonising practices, ASN also took part in a cross-inspection with the German regulatory body concerning the practices of a German company which supplies devices containing radioactive sources to France.

At a seminar of the International Radiation Protection Association (IRPA) in October 2008, ASN presented the French position in the particular field of industrial gamma radiography.

6 OUTLOOK

In the field of regulating applications of ionising radiations in industry and research, ASN's aim is to work to ensure that the operators take full account of the risks involved in the use of ionising radiations. This problem is accentuated by the diversity and numbers of the parties involved. Recent incidents in France and serious accidents abroad, for example in the field of gamma radiography, demonstrate once again the need for scrupulous implementation of the regulations and stringent operations. ASN is therefore continuing with definition of its priority actions, while optimising use of its resources:

- the central level will in 2009 continue with supplier regulation, both through examination of the licensing files and through inspections within the organisations concerned;
- the regional levels, responsible for monitoring the users of radioactive sources or electrical appliances emitting ionising radiations, will continue with surveillance and checks at the users.

During the course of its regulatory activities, ASN must remain vigilant and determined concerning any deviations that could lead to events with serious consequences for workers or for the public. Following the incidents involving gamma radiography sources, it carried out awareness-raising operations for the gamma radiography professionals on two occasions, with regard to the importance of complying with radiation protection rules and launched specific, targeted inspections. ASN also considers that the public needs to be more precisely informed of its regulatory activities. Consequently, publication of the follow-up letters to the inspections carried out by ASN in the industrial and research sector will begin in 2009.

The action initiated in previous years will be carried on and supplemented in 2009 through:

- continuation of the work to revise the licences issued to the manufacturers and suppliers of radioactive sources and the actions undertaken concerning the research sector;
- application of the licensing system to electrical generators of ionising radiations used in industry and research;
- inspections carried out, particularly with those using and in possession of gamma radiography devices and high-level sources.

ASN aims to maintain closer ties with all industrial and research stakeholders and organisations. When issuing its licences, ASN will in particular be reinforcing its checks on the extent to which opting to use radioactivity is justified.

CHAPTER 10
INDUSTRIAL AND RESEARCH ACTIVITIES