

Since ionising radiation was discovered more than a century ago, medical applications have been one of its main uses. Whether for diagnosis or therapy, medicine employs various sources of radiation, produced either by electrical generators or by artificial radionuclides inside sealed or unsealed sources.

In medical applications of ionising radiation, the principle of dose limitation, one of the three fundamental principles of radiation protection, does not apply. Unlike the other types of applications, medical exposure is of direct benefit to the patient exposed, either for diagnostic purposes or for therapeutic reasons. Therefore, it is up to the practitioner to carry out case by case an assessment of the level of exposure to be applied to the patient in order to achieve the specified goal. However, the practitioner must first of all employ the principles of justification and optimisation.

Although the benefits and usefulness of medical applications have been established for many years now, they do contribute significantly to exposure of the population. They are the primary source of artificial exposure, behind natural exposure. This is why medical uses of ionising radiation are subject to a wide-ranging regulatory framework and the ASN is in this area developing specific activities, particularly with respect to installation monitoring.

The work that started in 2001 to overhaul the radiation protection regulations continued in 2005 with the publication of new regulations implementing the Public Health Code (protection of patients) and the Labour Code (protection of workers).

The ASN also focused on putting in place tools for assessing changes to radiation protection in the medical field and reinforcing the information available to health professionals concerning radiation protection regulations.

1 PRESENTATION OF MEDICAL ACTIVITIES USING IONISING RADIATION

1 | 1

Medical and dental radiodiagnosis

Radiodiagnosis is the discipline of medical imaging covering all techniques for morphological exploration of the human body using the X-rays produced by electrical generators.

Radiology is based on the principle of differential attenuation of X-rays by the organs of the human body. The information is gathered either on radiological film or more and more often on digital media allowing computer processing of the images obtained.

Radiodiagnosis, which is the oldest of the medical uses of radiation, occupies predominant place in medical imaging area, which now comprises various specialisations which have become increasingly independent as time has gone by. Technological change has also led to the development of imaging techniques which meet a wide variety of user needs.

The variety of types of radiological examination available for modern medicine should not however lead the practitioners to forget that they all involve irradiation of the patient. Therefore, the doctor must only prescribe the examination if it is part of a diagnostic strategy that takes account of the pertinence of the information looked for, the benefit to the patient, the irradiation of the patient and the possibilities of other non-irradiating investigative techniques. Section 1|5 of this chapter gives details concerning the exposure levels of patients during certain radiological examinations.

Medical radiodiagnosis

In the medical field, apart from conventional radiology, more specialised techniques allowing a broader field of investigation are also used.

•Conventional radiology

This uses the principle of conventional radiography and covers the vast majority of radiological examinations carried out. These examinations are primarily of the skeleton, thorax and abdomen and are part of what is called “sophisticated radiodiagnosis”, with reference to the performance of the generators used. Conventional radiology can be split into three main families:

- radiodiagnosis performed in fixed installations specifically built for the purpose;
- radiodiagnosis performed occasionally using mobile appliances, particularly at the patient’s bedside. This practice should be limited to patients who cannot be moved;
- radiodiagnosis conducted in the operating theatre as a tool to assist the surgeon. In this case, mobile X-ray generators equipped with image intensifiers output images onto a TV screen (radioscopy) for real-time guidance of the surgeon.

It should be noted that radioscopy devices without image intensifiers (simple radioscopy) are now prohibited by the regulation of 17 July 2003.

•Surgical radiology

They are radiological techniques which use radioscopy with image intensification and require special equipment allowing to replace certain surgical operations, in particular in cardiology (dilation of coronary arteries, etc.). They often require long-term exposure of the patients, who then receive high doses which can sometimes lead to radiation deterministic effects (cutaneous lesions, etc.). The surgical staff usually working in the immediate vicinity of the patient are also exposed to higher levels than during other radiological practices. Then, given the risk of external exposure for the operator and the patient, surgical radiology must be justified by clearly determined medical need and its practice must be optimised in order to improve the radiation protection of both operators and patients.



Operating theatre radiology appliance

• **Digital angiography**

This technique, which is used to explore the blood vessels, is based on digitisation of images before and after injecting a contrast medium. Computer processing masks the bone structures around the vessels by subtracting two series of images.

• **Mammography**

Given the composition of the mammary gland and the degree of detail sought for the diagnostic, high definition and perfect contrast are required for the radiological examination. This can only be achieved by special appliances working with low voltage.

These generators are also used for breast cancer screening campaigns.



Mammography appliance

• **Tomography**

Using a closely collimated X-rays beam, emitted by a generating tube rotating around the patient and a computerised image acquisition system, tomography appliances give a three-dimensional picture of the organs with image quality higher than that of conventional equipment, providing a more detailed picture of the organ structure.



Tomography appliance

When first used, this technique revolutionised the world of radiology, in particular in the neurological exploration area, but is today being rivalled by magnetic resonance imaging (IRM) for certain investigations. However, the new generation of appliances (multi-slice scanners) offer an extension of the investigative field of tomography, somewhat offset by the fact that these appliances deliver higher doses of radiation to the patients.

Overall, although tomography examinations only account for a small percentage of the total number of radiological tests, they contribute significantly to the exposure due to radiology.

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Dental radiodiagnosis

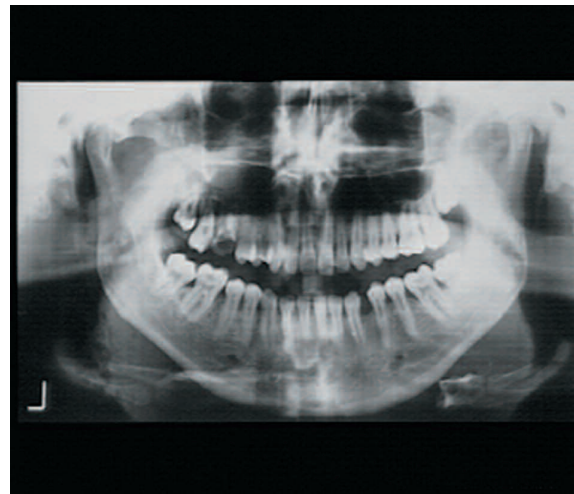
Of the radiological installations inventory, dental radiodiagnosis equipment occupies a dominant position, even if only three techniques are employed.

• Intra-oral radiography

Intra-oral type radiography generators are generally mounted on an articulated arm, to provide localised images of the teeth. They operate with relatively low voltage and current and a very short exposure time, of about a few hundredths of a second. This technique is increasingly frequently combined with a system for digital processing of the radiographic image which is displayed on a monitor.

• Panoramic dental radiography

Primarily used by dental specialists (orthodontists, stomatologists) and radiologists, panoramic radiography gives a single picture showing both jaws, by rotating the radiation generating tube around the patient's head for about ten seconds.



Panoramic dental radiography appliance and panoramic dental radiography image

• Cranial tele radiology

These generators are more rarely used by practitioners. They operate with a focus - film length of 4 metres, and are mainly used to take radiographic images for orthodontic diagnosis.

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Installation construction rules

A conventional radiological installation comprises a generator (high-voltage unit, radiation generating tube and control unit) and a stand for moving the tube and an examination table or chair. The general standard NFC 15-160, published by the Union technique de l'électricité (UTE), defines the conditions in which the installations must be fitted out to ensure human safety against the risks resulting from the action of ionising radiation and electrical current. It is supplemented by specific rules applicable to medical radiodiagnosis (NFC 15-161) and dental radiodiagnosis (NFC 15-163). In compliance with these standards, the walls of radiology rooms must be sufficiently opaque to radiation and may require the installation of reinforced lead protection. In the light of the changes to the radiation protection regulations, which have in particular led to a reduction in the exposure limits for both the general public and workers, a revision of these standards was initiated by the UTE in 2005. The ASN is taking part in the corresponding work, in partnership with the IRSN and the professional representatives concerned.

1 | 2

Radiotherapy

With surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. It uses ionising radiation to destroy malignant cells. The ionising radiation needed for the treatment is either produced by an electrical generator, or emitted by artificial radionuclides in a sealed source. A distinction is made between external (or transcutaneous) radiotherapy, with the radiation source placed outside the patient, and brachytherapy, in which the source is positioned in direct contact with the patient, inside or very close to the area to be treated.

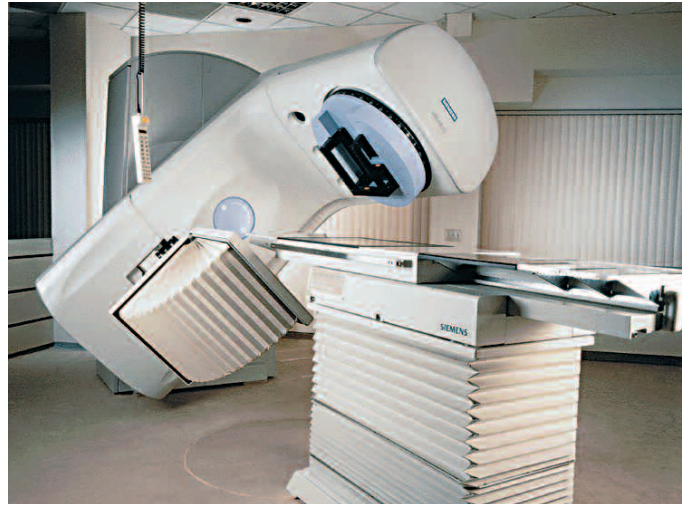
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External radiotherapy

The irradiation sessions are always preceded by preparation of the treatment plan which, for each patient, details the dose to be delivered, the target volume to be treated, the dosimetry, the irradiation beam ballistics and the duration of each treatment. Preparation of this plan, which aims to set conditions for achieving a high, uniform dose in the target volume while protecting sound tissues, requires close cooperation between the radiotherapy specialist and the person specialising in medical radiophysics (PSRPM), previously known as the radiophysicist.

Irradiation is performed either using particle accelerators producing photon or electron beams with an energy of between 4 and 25 MeV and delivering dose rates varying between 2 and 6 Gy/mn, or - albeit now to a lesser extent - telegammatherapy appliances equipped with a cobalt 60 source, the activity of which is about 200 terabecquerels (TBq). The number of these latter appliances is declining rapidly in France, where they are being systematically replaced by particle accelerators whose superior performance offers a wider range of treatments. Given the characteristics of these machines, they must be installed in rooms specially designed to guarantee radiation protection of the personnel, turning them into true bunkers (the ordinary concrete walls can vary from between 1 to 2.5 m thickness). A radiotherapy installation comprises a treatment room including a technical area containing the appliance, a control station outside the room and, sometimes, auxiliary technical premises.

It should be noted that experiments should shortly be conducted in France into new irradiation techniques (tomotherapy and radiosurgery). Section 4|4|1 of this chapter gives details on these changes, in which the ASN is keenly interested, in order to anticipate their consequences on radiation protection of both operators and patients.



Radiotherapy particle accelerator

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. A safety case must be produced for each installation by the supplier of the machine, together with the PSRPM and the person with competence for radiation protection (or the department with competence for radiation protection) of the establishment in which it is to be installed. This study defines the thicknesses and nature of the various protections required, which will be determined according to the conditions of use of the appliance, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below. This study should be included in the file presented to support the application for a licence to use a radiotherapy installation, examined by the ASN.

In addition, safety systems must indicate the machine status (operating or not) or must switch off the beam in an emergency or if the door to the irradiation room is opened.

1 | 2 | 2

Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours, specifically in the ENT field, as well as of the skin, the breast or the genitals.

The main radionuclides used in brachytherapy, in the form of sealed sources, are caesium 137 and iridium 192, which have definitively replaced the radium 226 needles or tubes used in the first half of the 20th century. These two radionuclides have half-lives of 30 years and 74 days respectively.

Brachytherapy techniques involve three types of applications.

Low dose rate brachytherapy, requiring patient hospitalisation for several days, gives dose rates of 0.4 to 2 Gy/h. The iridium 192 sources are used for interstitial applications (inside the tissues). The sources generally come in the form of wires of 0.3 to 0.5 mm in diameter, with a maximum length of 14 cm and which linear activity is between 50 MBq/cm and 250 MBq/cm. Endocavity techniques (inside natural cavities) use either iridium 192 wires or caesium 137 sources. In both cases, the sources remain in place in the patient for the duration of hospitalisation.

Sources are implanted in two stages and at two different locations: in the application room, where source catheters are fitted into the patient and their correct positioning is checked by radiological filming, and then in a room specially reinforced for radiation protection reasons, in which the radioac-



Iridium 192 sources used in low dose rate brachytherapy

tive sources are implanted. With this technique, it is possible to use a source applicator, in particular for the caesium 137 sources, thereby optimising personnel protection.

Low dose rate brachytherapy requires a room for storage and preparation of the radioactive sources, a room for radiological location and application, and at least 2 protected rooms for hospitalisation of patients implanted with sources.

Room protection must be determined on the basis of a caesium 137 source of 8,200 MBq or an iridium 192 source of 5,600 MBq placed in the centre of the patient's bed, which must be fixed in place.

In recent years, low dose rate brachytherapy techniques have been supplemented by the use of sealed sources of iodine 125 (half-life of 60 days) to treat prostate cancers. The iodine 125 sources, just a few millimetres long are permanently installed in the patient's prostate. Their unit activity is between 10 and 25 MBq and treatment requires about one hundred grains representing a total activity of 1,500 MBq, delivering a prescribed dose of 145 Gy to the prostate.

Medium dose rate pulsed brachytherapy uses dose rates of 2 to 12 Gy/h delivered by iridium 192 sources of small dimensions (a few millimetres), with maximum activity limited to 185 GBq. Each source is applied with a specific source applicator. This technique delivers doses identical to those of low dose rate brachytherapy, and over the same period, but given the higher dose rates, irradiation is split up into several sequences (pulses). The patient does not therefore carry the sources permanently, which is more comfortable and enables him to receive visitors. This technique, which is likely to



Iodine 125 sources used for prostate brachytherapy

be increasingly used, significantly improves the radiation protection of the personnel, who can now work with the patient without being exposed, once the source has been returned to the applicator's storage container. This technique can only be carried out in units which already carry out low dose rate brachytherapy; the room(s) set aside for hospitalisation of patients for whom this technique is well suited must have reinforced radiological protection based on an iridium 192 source of 185 GBq.

High dose rate brachytherapy uses an iridium 192 source of small dimensions (a few millimetres) and maximum activity of 370 GBq delivering dose rates higher than 12 Gy/h. A source applicator comparable to that employed for pulsed brachytherapy is used. The treatment times are very short (no more than a few minutes), unlike the previous techniques. Irradiation is carried out in a room similar to an external radiotherapy room, with the same safety measures. High dose rate brachytherapy is primarily used to treat cancers of the oesophagus and bronchus.



High dose rate brachytherapy appliance

1 | 3

Nuclear medicine

Nuclear medicine includes all uses of unsealed source radionuclides for diagnostic or therapeutic purposes. Diagnostic uses can be divided into in-vivo techniques, based on administration of radiopharmaceuticals to a patient, and exclusively in-vitro applications. As for radiology, paragraph 1|5 gives additional information on the patient exposure levels during the main nuclear medicine procedures.

1 | 3 | 1

In-vivo diagnosis

This technique consists in examining the metabolism of an organ with a specific radioactive substance - called a radiopharmaceutical - administered to a patient. The nature of the radiopharmaceutical, which is classified as a drug, will depend on the organ being examined. The radionuclide can be used directly, or fixed to a carrier (molecule, hormone, antibody, etc.). For example, table 1 presents some of the main radionuclides used in the various investigations.

Technetium 99m, delivered to nuclear medicine departments in the form of a generator, is by far the most commonly used radionuclide. Moreover, its short radioactive half-life of 6 hours and its limited gamma radiation energy (140 keV) are extremely favourable to the patient from the dosimetry viewpoint. The activity administered to a patient for an examination is a few hundred megabecquerels (MBq). Fluorine 18 is a radionuclide that emits positrons (511 keV, 2 hours half-life) and is increas-

Type of exploration	Type of radionuclide	Type of carrier
Thyroid metabolism	Iodine 123, technetium 99m	
Mycocardial perfusion	Thallium 201, technetium 99m	MIBI
Pulmonary perfusion	Technetium 99m	Albumin macroaggregates
Pulmonary ventilation	Xenon 133, krypton 81m, technetium 99m	Solid (carbon) or liquid (DTPA) aerosols
Osteo-articular process	Technetium 99m	Phosphonate
Oncology – search for metastasis	Fluorine 18	Fluorodeoxyglucose (FDG)

Table 1

gly widely used in nuclear medicine units for cancerology examinations.

The radioactive substance administered is located in the organism by a specific detector - a scintillation camera or gamma-camera - which consists of a crystal of sodium iodide coupled with a computer-controlled acquisition and analysis system. This equipment is used to obtain images of how the investigated organs are functioning (scintigraphy). As the images are digitised, quantification of the physiological processes is possible, as is a 3-dimensional reconstruction of the organs, using the same principle as for the X-ray scanner. The use of fluorine 18 requires that a gamma camera able to detect positrons and called a positron emission tomograph (PET) be employed. This is now coupled with scanner, forming a hybrid device called a PETSCAN.

Nuclear medicine is used to produce functional images and therefore complements the purely morphological pictures obtained with the other imaging techniques: conventional radiology, X-ray scanner, echography or magnetic resonance imaging (MRI).



Scintillation camera

1 | 3 | 2

In-vitro diagnosis

This is a medical biology analysis technique - without administration of radionuclides to the patients - for assaying certain compounds contained in the biological fluids, particularly the blood: hormones, drugs, tumour markers, etc. This technique uses assay methods based on immunological reactions (antibody - antigen reactions marked with iodine 125), hence the name RIA (RadioImmunoAssay). The activity levels present in the analysis kits designed for a series of assays do not exceed a few kBq. Radioimmunoassay is currently being strongly challenged by techniques which make no use of radioactivity, such as immuno-enzymology.

1 | 3 | 3

Metabolic radiotherapy

Some therapies require limited administration of radionuclides (< 740 MBq). They are for example designed to treat hyperthyroidism by administration of iodine 131, painful bone metastases by strontium 89 or samarium 153, and polyglobulia by phosphorus 32. Joints can also be treated using colloids marked with yttrium 90 or rhenium 186. As a general rule, these treatments do not require hospitalisation of the patient in the nuclear medicine department.

Other therapies require the use of far higher activity levels. This is the case with treatment of certain thyroid cancers after surgery. This is done by administering about 4,000 MBq of iodine 131 and the patients have to be hospitalised for several days in a special room in the nuclear medicine ward, until urinary evacuation of most of the radionuclide administered. The radiological protection of these rooms must be appropriate to the type of radiation emitted by the radionuclides. In the case of iodine 131, account must be taken of the gamma radiation from this radionuclide. The protection calculations will be made on the basis of a source of 5,550 MBq of iodine 131.

The year 2005 was marked in France by the start of biomedical research to experiment with new radiopharmaceuticals emitting high-energy alpha and beta radiation. Section 4|4|2 gives details on these experiments and their radiation protection consequences.

1 | 3 | 4

Nuclear medicine department organisation and operating rules

In the light of the radiation protection constraints inherent in the use of radionuclides in unsealed sources, the nuclear medicine departments must be designed and organised so that they can receive, store, prepare and then administer unsealed radioactive sources to the patients or handle them in a laboratory (case of radioimmunoassay). Provisions must also be made for the collection, storage and disposal of radioactive waste and effluent produced in the installation.

From the radiological viewpoint, the personnel are subjected to an external exposure hazard, in particular on the fingers, owing to handling of sometimes highly active solutions (the case with fluorine 18 and iodine 131), along with an internal exposure hazard through accidental intake of radioactive substances. The patients also eliminate radioactivity through their urine, which must be specially treated to minimise releases into the public domain. Finally, as we are here dealing with medical applications, the risk of infection is ever-present.

In these conditions, nuclear medicine departments must comply with specific construction and organisation rules, the main provisions of which - for the in-vivo diagnosis units - are as follows.

I Location and layout of premises

The premises of a nuclear medicine unit must be located away from the general circulation areas, clearly separated from premises intended for ordinary use, grouped so that they form a single unit allowing easy marking out of a controlled area, and categorised in descending order of radioactive activity levels. The controlled area will comprise at least the following:

- a changing area airlock for the staff, separating normal clothing from work clothing;
- examination and measurement rooms and rooms set aside for injected patients waiting for their examination (separate rooms should be provided for mobile patients and patients lying down);
- areas for storage and preparation of unsealed sources (hot laboratory);
- an injection room adjoining the hot laboratory;
- installation for delivery of radionuclides and storage of radioactive waste and effluent.

II Fitting out the controlled area

The thickness of the hot laboratory and injection room walls must be at least equivalent to 15cm of ordinary concrete. Floor coverings (to be continued up to skirting boards), the walls and the work surfaces will consist of smooth, impermeable, joint-free (no tiling) materials which can be easily decontaminated. The washbasin taps must not be hand-operated. The changing area airlock must have washbasins and a shower and the sanitation facilities reserved for injected patients must be connected to a septic tank, itself connected directly to the establishment's main sewer. The hot laboratory must be fitted with one or more shielded chambers for storing and handling radioactive sources, protecting the personnel against the risks of internal exposure and dispersal of radioactive substances.



Shielded chamber for handling unsealed radioactive sources

III Ventilation of the controlled area

The ventilation system must keep the premises at negative pressure, with air renewed at least five times per hour. It must be independent of the building's general ventilation system and foul air must be extracted with no possibility of recycling. The shielded compartments for storage and handling of radioactive products in the hot laboratory must be connected to independent extraction ducts fitted with filters.

IV Collection and storage of radioactive solid waste and liquid effluent

A room intended solely for storage of radioactive waste pending disposal must be provided. Similarly, liquid radioactive effluent must be sent from a small number of dedicated drainage points to buffer tanks which operate alternately as filling tanks and decay storage tanks. These tanks, of which there must be at least two, must be positioned above a safety leak tank.

1 | 4

Blood product irradiators

Blood products are irradiated in order to eliminate certain cells liable to lead to a fatal illness in patients requiring a blood transfusion. After this treatment, these products can be administered to the patients. This irradiation uses an appliance with built-in lead biological shielding, so that it can

be installed in a room which does not require additional radiation protection. Depending on the version, the irradiators may be equipped with one, two or three caesium 137 sources with a unit activity level of about 60 TBq. The blood bag is irradiated with an average dose of about 20 to 25 grays. Regional blood transfusion centres are equipped with this type of appliance.



Blood product irradiator

1 | 5

Medical exposure

Patient exposure to ionising radiation is differentiated from the other types of exposure (workers, population) because it is not subject to any strict limitations. Nonetheless, the justification and optimisation principles still apply. This is also the only case in which exposure is delivered for the direct benefit of the exposed persons, i.e. the patients. The worker and the population exposure consequences of the use of ionising radiation for medical purposes are mentioned in section 5 of this chapter.

The situation differs according to whether one considers patient exposure in the course of diagnostic applications (diagnostic radiology or nuclear medicine) or of external or internal radiotherapy: in the first case, optimisation is required, by delivering the minimum dose needed to obtain pertinent diagnostic information, while in the second, the dose needed to sterilise the tumour must be delivered, while preserving as much of the surrounding sound tissue as possible.

The dose received by the patient depends on the quality of the equipment used, what fully justifies retiring obsolete equipment and developing a quality control system for the medical appliances used. This concerns not only the irradiating equipment, but also those used for this exposure (if a radiological film viewer is defective, this could lead to increase the radiation doses to produce the films). The dose also depends on the nature of the procedures and the emission of radiation (X-ray tube, particle accelerator, unsealed source of radionuclides, etc.).

At present it is hard to gain a precise picture of overall exposure of medical origin, because the number of examinations carried out (per type) is still inadequately known and the doses delivered for the same examination may vary widely, depending not only on the performance conditions but also on the morphology of the patients. This is why, through its Action Plan for monitoring patient exposure to ionising radiation - PASEPRI (see chapter 1, point 3|4) the ASN has initiated a process to collect these data, with the assistance of the IRSN and the InVS. These 2 organisations therefore set up a survey unit with the purpose of collecting and analysing data. The work carried out was first of all to identify the various available sources of information, to update the available data on the volume and nature of the radiological examinations and to initiate targeted studies of scanners, neuroradiology and paediatric radiology.

Based on the initial results available after a year of operation of the survey unit, the number of radiological examinations carried out in France every year is somewhere between 61 and 74 million procedures, broken down as follows:

- 90% of the examinations made involve conventional radiology techniques;
- About 8% of examinations involve tomography;
- Nuclear medicine and surgical radiology each account for between 1 and 1.5% of the total number of examinations.

Starting from these data, the IRSN and InVS estimate that the average annual effective dose due to medical exposure per inhabitant in France, is somewhere between 0.66 and 0.83 mSv. Moreover, although conventional radiology accounts for 90% of the examinations conducted, its contribution to the annual effective dose is only 35%. Conversely, tomography examinations, which only represent 8% of the number of examinations carried out, account for 41% of the annual effective dose,

while surgical radiology (less than 15% of examinations) represents 15%.

Worldwide statistics, which need to be updated - (UNSCEAR 2000 report, volume 1) covering 1,530 billion inhabitants (1991-1996 data), indicate an annual effective dose per inhabitant of 1.2 mSv for radiology, 0.01 mSv for odontology and 0.08 mSv for nuclear medicine. In western Europe, for diagnostic radiology, the average annual effective dose per inhabitant is 0.33 mSv in the United Kingdom and 1.9 mSv in Germany.



Stamp representing A. Béclère, father of French radiology

The studies conducted so far generally show a wide variability in the doses delivered for a given examination. The choice of dosimetric parameter is thus very important. The range of doses delivered by medical exposure is fairly wide. For example, in radiology, measurements taken in the same conditions for a given examination performed in three hospitals (report by the Bonnin/Lacronique, OPRI and SFR mission, March 2001) revealed doses (doses at the entry surface on a phantom) varying by a factor of 1 to 3 for a lumbar examination (profile) or a factor of 1 to 10 for a cervical examination (profile).

In nuclear medicine, the activities administered vary widely from one department to another, from one Member State to another. Even if the doses are generally lower than in radiology, there are variations that cannot always be justified. For a pulmonary perfusion scintigraphy performed as part of the diagnosis of a pulmonary embolism, the activity administered can vary from 100 MBq (Netherlands) to 300 MBq (France), or an estimated delivered dose variation of 1.2 mGy to 3.75 mGy.

In order to improve knowledge of medical exposure and implement the principle of optimisation, 2005 saw work continue into the drafting, by the health professionals concerned, of prescription and procedure guides, based on a number of regulatory texts (see chapter 3, points 1|3|1 and 1|3|2) concerning:

- The diagnostic reference levels (regulation of 12 February 2004): radiology and tomography units must conduct annual dosimetry assessments of common radiological examinations carried out on “typical” patients, the results of these assessments then being compared with the reference levels. In the case of nuclear medicine, the levels administered to the patients will be recorded and compared with the activity levels recommended by the radiopharmaceutical’s notice of compliance. These levels, which are neither regulatory limits, nor optimum values, will constitute guidelines for implementing the principle of optimisation. They should not be exceeded if there is no technical or medical justification, but compliance with them does not obviate the need for continued optimisation. In order to ensure periodic updating of the reference levels, the IRSN collects the results of these annual assessments. It should however be noted that to date, only a limited number of radiology and nuclear medicine departments have forwarded their assessments to the IRSN.
- The obligation to fit a device on recently installed radiology appliances indicating the quantity of radiation produced during a radiological procedure (decree 2004-547 of 15 June 2004): this device will give the professionals concerned a clearer picture of the doses actually delivered, will make it easier to implement and assess the reference levels and thus help optimise the radiological practices.
- The training, duties and working conditions of persons specialising in medical radiophysics - PSRPM - (regulation of 19 November 2004): this is the first regulatory text precisely defining the training requirements for these specialists and the nature of their duties. This regulation also requires that all establishments using ionising radiation for diagnostic or therapeutic purposes draw up a plan specifying all of their medical radiophysics resources, in particular taking into account of the medical techniques employed, the resulting constraints and the number of patients treated. Application of this regulation will clarify the role of the PSRPM and strengthen their actions to obtain a clearer understanding of the doses delivered.
- Training of health professionals in patient radiation protection (regulation of 18 May 2004): the training programmes are spelt out in this regulation, in compliance with the requirements of article R.

1333-74 of the Public Health Code. This training is intended for medical and paramedical personnel responsible for carrying out procedures involving ionising radiation.

At the same time, the AFSSAPS in 2005 took a further decision concerning quality control procedures applicable to bone mineral density test installations and published two modifying decisions dealing with analogue mammography appliances. They complete those previously published concerning external radiotherapy units. These AFSSAPS decisions are wholly in line with the optimisation approach (see chapter 3, point 1|3|2).

2 INSTALLATIONS INVENTORY

2|1

Medical and dental radiology installations

Table 2 presents the inventory of medical and dental radiology appliances in service in 2005, established on the basis of the notifications by users of this type of equipment. In 2005, the number of radiological installations fell 8.1% in relation to 2004.

	Medical radiodiagnosis	Dental radiodiagnosis	Total
Private sector	8,470	31,880	40,350
Public and related sector	7,503	1,420	8,923
Total	15,973	33,300	49,273

Table 2

There is however a rise in the public sector part of the inventory, probably linked to the new notification procedure requiring hospitals to update the information they had previously submitted.

Table 3 presents the breakdown of radiology installations as of 31 December 2005, per category of appliances.

Medical and dental radiodiagnosis

	Private sector	Public and related sector	Totals	% change in
Light radiodiagnosis, including bone mineral density tests	1,303	2,956	4,259	+ 5,4 %
Sophisticated radiodiagnosis	5,162	4,042	9,204	- 7 %
Mammography	2,005	505	2,510	- 10,8 %
Dental radiology	31,880	1,420	33,300	- 9,7 %
Totals	40,350	8,923	49,273	- 8,1 %

Table 3

According to the information collected by the ASN, the radiology installations counted in the above tables and the tomography installations covered in point 2|2, are spread over about 4,000 radiology units, in which about 7000 radiology practitioners work, assisted by more than 22,500 electroradiology operators or similar. In the field of dental radiology, 40,000 dentists in 28,600 facilities share the use of the appliances listed above.

2|2

Tomography appliances

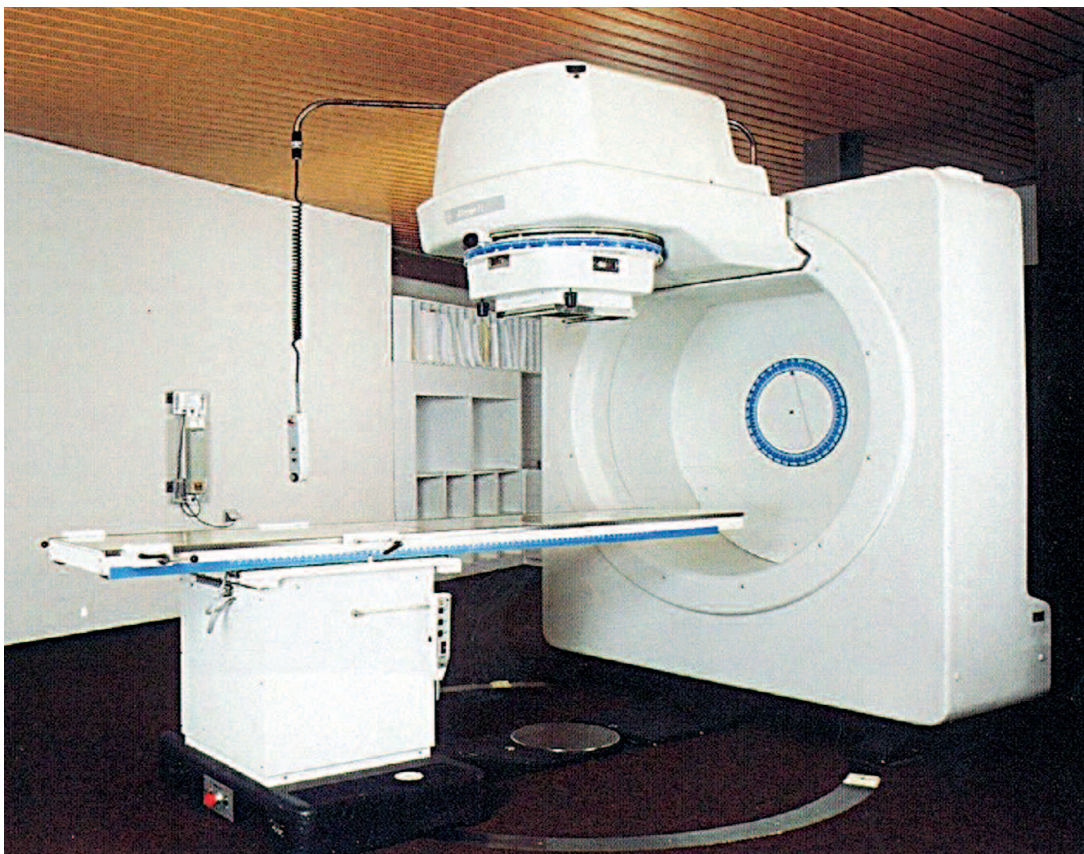
The French radiological inventory comprises 754 tomography installations, representing a 7.7% increase over 2004. It should be noted that this count includes appliances intended for radiotherapy simulation and that there are almost twice as many appliances in the public sector as in the private.

2|3

External radiotherapy installations

The trend, which has already been established for a number of years, continued in 2005 with a rising number of particle accelerators, now standing at 359 units (+2.5% in relation to 2004) and a regular fall in the number of telegermatherapy machines, which is now down to 34 (-27%).

These installations, along with the brachytherapy units mentioned in point 2.4 below, are used by about 600 radiotherapists (350 in the public sector and 250 in the private) who work in 179 radiotherapy centres (source: SFRO).



Telegermatherapy appliance

2 | 4

Brachytherapy units

With a total of 102 brachytherapy units, the downward trend evident over the past two years continued in 2005. Closure of the small units with limited brachytherapy activities was the reason for this drop. However, the breakdown between public sector (52) and private (50) remained stable.

2 | 5

Nuclear medicine units

With a total of 288 nuclear medicine units in service (comprising both in vivo and in vitro installations), the situation in 2005 remained on the whole stable in this sector. It should however be noted that the number of medical analysis laboratories using unsealed radioactive sources (radioimmunology laboratories) continued to fall. The public/private split between nuclear medicine units is 220 and 68 respectively. In 2005, 48 nuclear medicine units acquired positron emission tomography installations (PETSCAN cameras - PET camera coupled with a tomograph) using fluorine 18 in the form of fluorodeoxyglucose (^{18}F FDG).

According to information in the possession of the ASN, it would seem that about 550 specialist practitioners are today working in this field, to which should be added 1,000 physicians involved in the operation of nuclear medicine units (interns, cardiologists, endocrinologists, etc.).



Positron emission tomograph

2 | 6

Blood product irradiators

In 2005, 29 installations of this type were identified as operating in blood transfusion centres. Owing to the failure to replace the older appliances, and the concentration of blood product irradiation activities in a smaller number of facilities, 2005 saw a drop in the total number of appliances in relation to 2004.

3 REGULATORY PROVISIONS CONCERNING MEDICAL APPLICATIONS OF IONISING RADIATION

Chapter 3 of this report presented the current status of radiation protection regulations. Here we will simply recall the provisions concerning medical applications of ionising radiation, in particular the licensing and notification systems. However, the provisions concerning the protection of persons exposed for medical purposes and already detailed in chapter 3 will not be gone over again.

3 | 1

Notification or licensing of radiation sources used for medical purposes

The Public Health Code (articles R. 1333-17 to R. 1333-44) sets licensing and notification provisions concerning all nuclear activities, in particular those linked to medical and biomedical research applications of ionising radiation (articles R. 1333-17 to R. 1333-20 and articles R. 1333-21 to R. 1333-25), whether or not the establishments are subject to the regulations applicable to installations classified on environmental protection grounds (see article L. 1333-4 of the Public Health Code).

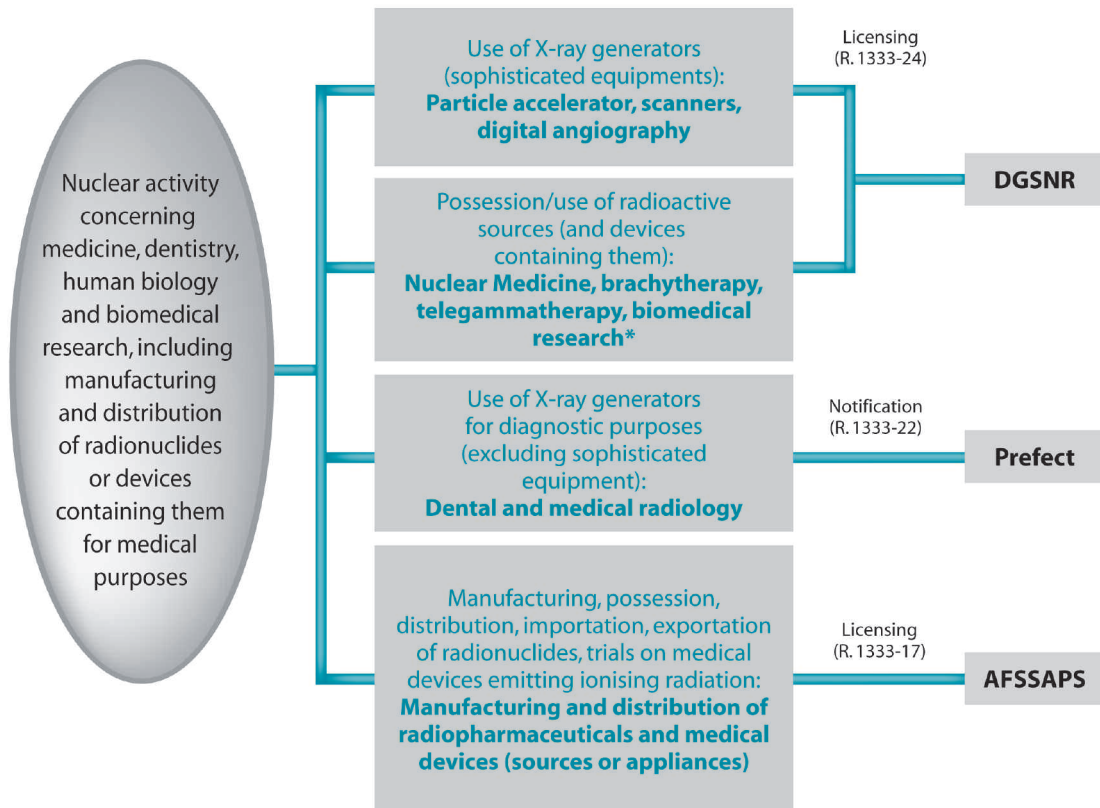
The following diagram presents the procedures governing the various medical and biomedical research applications, whenever it is relevant, these procedures do not replace those concerning sophisticated equipment as specified in articles L. 6121-1 to L. 6121-12 of the Public Health Code:

Finally, any incident or accident liable to be the cause of over-exposure of an individual must be immediately declared to the Prefect of the department and to the ASN. For this purpose, the ASN has a hot-line reserved for emergency situations (toll-free number: 0 800 804 135) accessible 24 hours a day (see chapter 8, point 1|13) but it can of course also be used for any radiological incident occurring in a medical installation.

In addition, article R. 162-53 of the Social Security Code, states that: "Practitioners and establishments using appliances generating ionising radiation or comprising the use of radionuclides or products containing them, for therapeutic or diagnostic purposes, may only carry out examinations or give treatment to persons covered by social security insurance if the appliances and installations have been declared or licensed as mentioned in articles R. 1333-22 and R. 1333-24 of the Public Health Code. Only those radiological examinations and radiotherapy treatments carried out using appliances and installations declared or licensed in the conditions laid out in the previous paragraph may be reimbursed or paid for".

Paragraph 3|3 describes the contents of the notification and licence application files specified in articles R. 1333-22 and R. 1333-24. The regulation of 14 May 2004, based on article R. 1333-44, specifies the practicalities for implementation of these procedures.

Radiation protection regulations applicable to medical activities



no exemption to notification or licensing procedures

*according to Public Health Code § L. 1121-1: trials or experimentation organised and performed on human to develop biomedical or medical knowledge

3 | 2

Radioactive source management rules

These rules, already presented in chapter 3, point 1|2|4, of course also apply to the medical and biomedical fields. They concern:



Cobalt 60 source for telegammatherapy

- the obligation to have a licence for all transfer, acquisition, possession or use of sources;
- preliminary registration of all source movements to the IRSN;
- book keeping by the beneficiary of the licence of detailed accounts for the sources in his possession, and their movements;
- immediate notification to the Prefect and the 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.

3 | 3

Notification or licensing procedures

3 | 3 | 1

Notification dossiers

The procedure involving notification to the department Prefect concerns the use of electric appliances generating X-rays for medical or dental diagnostic purposes - except for installations classified as sophisticated equipment (article R. 1333-22). Publication of the regulation of 14 May 2004 concerning the standard licensing and notification system defined in chapter V.I “Ionising radiation” of the Public Health Code, allows implementation of this procedure, which definitively replaces the approval procedure.

The notification is to be submitted on a form that can be downloaded from the ASN's website (www.asn.gouv.fr) or obtained from the DSNRs (Nuclear Safety and Radiation Protection Divisions). For each establishment using medical or dental radiology appliances, only a single notification mentioning all the radiological installations has to be provided. When the dossier is considered to be complete by the DSNR, the Prefect sends back to the declaring party an acknowledgement of notification of a radiodiagnostic installation, recalling the general conditions to which its operation is subject.

DÉCLARATION D'APPAREILS DE RADIODIAGNOSTIC MÉDICAL ET DENTAIRE

Je soussigné Nom : Prénom :
 Titre/Qualité :
 déclare les appareils de radiodiagnostic désignés dans la liste annexée (à-parte, nombre de pages :).

Si le déclarant est le praticien responsable des appareils, préciser sa spécialité :

Chirurgien Radiologue Gastro-entérologue Gynécologue Médecin généraliste
 Pédiatre Pneumologue Rhumatologue Cardiologue Chirurgien dentiste
 Docteur en chirurgie dentaire Médecin stomatologue Orthodontiste Médecin du travail Médecin de prévention
 Autres (préciser) :

1 - MOTIF DE LA DÉCLARATION

Première déclaration
 Renouvellement de la déclaration : N° de la déclaration antérieure :
 échéance quinquennale de la déclaration
 changement d'appareil adjonction d'appareil
 transfert de local modification substantielle du local
 Examens radiologiques donnant lieu à remboursements par les organismes de Sécurité Sociale : oui non

2 - ÉTABLISSEMENT

Secteur public ou assimilé Secteur privé à but non lucratif Secteur privé libéral
 Clinique Centre de médecine du travail ou préventive Centre de santé
 Cabinet privé individuel Cabinet privé collectif
 Centre hospitalier universitaire Centre hospitalier Centre régional de lutte contre le cancer
 Hôpital local Centre de soins - long séjour
 Autre (préciser) :

Utilisation hors établissement d'appareil(s) embarqué(s) sur des véhicules : oui non
 Nom (ou raison sociale) : N° :
 Rue :
 Code Postal : Ville :
 Tél : Fax : MEF :

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Direction générale de la sûreté nucléaire et de la radioprotection MINISTRE DE L'ÉCONOMIE, DES FINANCES ET DE L'INDUSTRIE
 MINISTRE DE LA SANTÉ ET DE LA PROTECTION SOCIALE
 MINISTRE DE L'ÉCOLOGIE ET DU DÉVELOPPEMENT DURABLE

Notification form for medical and dental radiodiagnostic equipments

After a five-year period, a further notification must be submitted. If, prior to expiry of the period of validity, significant modifications are made to the notification (change in or addition of appliance, transfer or substantial modification of the premises or change in the practitioner responsible), the Prefect must be immediately notified accordingly.

The notification dossier must comprise the reports of the inspections conducted, in application of articles R. 1333-43, R. 5211 and R. 5212-25 to R. 5212-32 of the Public Health Code and R. 231-84 of the Labour Code (protection of workers against the hazards of ionising radiation). If inadequacies are observed during these inspections, a report describing the remedial measures taken must be submitted along with the notification dossier.

The declared installations must be:

- equipped with a generator less than 25 years old (the case of medical appliances used for medical treatment) carrying CE labelling guaranteeing conformity with the essential health and safety requi-

rements mentioned in article R.665-12 of the Public Health Code, if they entered service after June 1998;

- fitted out in accordance with standards NFC 15-160, NFC 15-161 (medical radiology) and NFC 15-163 (dental radiology).

3 | 3 | 2

Licensing application dossiers

These dossiers concern the following installations:

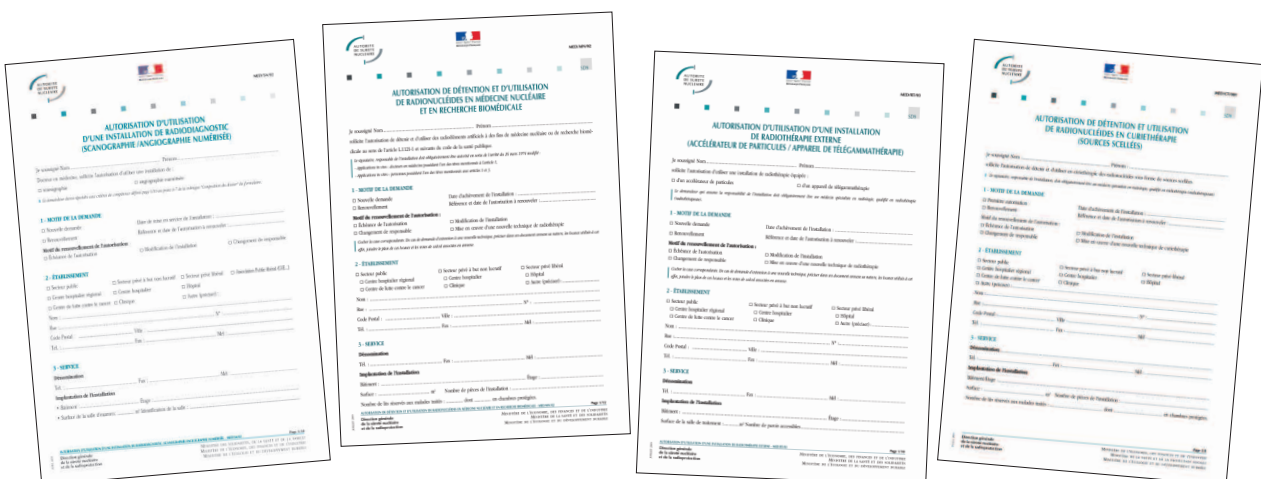
- X-ray tomography and digitised angiography;
- radiotherapy (particle accelerators, teletherapy and brachytherapy appliances);
- nuclear medicine;
- biomedical research on human beings in one of the above-mentioned disciplines, subject to a “Huriet law” biomedical research protocol, which are subject to prior licensing by the Minister for Health (article R. 1333-24 of the Public Health Code), valid for a maximum renewable period of 5 years, issued by the ASN to the practitioners who are responsible for them.

For each installation mentioned above, the corresponding dossier is to be drawn up using a form that can be downloaded from the ASN's website (www.asn.gouv.fr). These dossiers, accompanied by the required documents, are to be returned to the ASN for examination, either through the DSNR (scanner, digital angiography, radiotherapy), or the ASN (nuclear medicine, brachytherapy and biomedical research).

The licence is granted on the basis of criteria concerning necessity (in particular the case of installations classified as sophisticated equipment), the competence of the practitioner in charge, and conformity with the installation technical arrangement and layout rules and the radiation protection organisation. Furthermore, the appliances mentioned above may not be used once they are more than 25 years old.

In the case of nuclear medicine, particular attention will be given to the collection and disposal of the waste and radioactive effluent produced. For instance, the dossier must comprise a waste and effluent management plan for the entire establishment within which the nuclear medicine unit is located.

If biomedical research is performed in one of the above disciplines, the criterion of competence of the practitioners in charge of this research and the technical rules concerning the installations remain applicable.



Licensing application forms

4 2005 SUMMARY OF RADIATION PROTECTION IN MEDICAL INSTALLATIONS AND IMPORTANT EVENTS

4 | 1

Radiodiagnosis installations

The ASN, via the DSNRs, received about 4200 notifications of use for medical or dental radiodiagnosis appliances during the course of 2005.

4 | 2

Tomography, radiotherapy, nuclear medicine and blood product irradiation installations

The ASN issued 522 decisions (commissioning or renewal licences, cancellation notifications) according to the breakdown given in table 4.

Decisions	Particle accelerator	Telegamma-therapy	Brachy-therapy	Nuclear medicine	Scanner	Blood product irradiator	Angio-graphy	Contact-therapy
Total	111	10	37	123	172	15	52	2

Table 4

4 | 3

Important events in 2005

4 | 3 | 1

Serious radiotherapy incident at the Grenoble university hospital

In April 2005, the Grenoble university hospital submitted a notification to the ASN and the AFSSAPS concerning a serious incident which occurred in the first quarter of 2003 during radiotherapy treatment. This incident led to exposure of a patient to a dose about 20% higher than that initially planned for his treatment. This over-exposure was only detected in the patient in November 2004 further to a complication requiring surgery.

This incident, which is the first of this type declared to the ASN, was due to an anomaly in transmission of the computer data to the radiotherapy appliance used, a fact that was brought to light by the university hospital in May 2003 and corrected. The results of the investigations carried out show that the problem could only occur in a specific configuration on only one of the radiotherapy appliances in service between June 2002 (date the appliance was installed) and May 2003 (date on which the problem was corrected).

As soon as they became aware of this incident, the ASN and the AFSSAPS, together with the Isère DDASS, carried out investigations during the course of inspections in the university hospital radio-

therapy unit, to check the organisation of radiation protection in the preparation and performance of the treatment, to assess the IT system and monitor its conditions of use.

Following this event, the ASN and AFSSAPS sent a letter dated 26 April 2005 to all of the 180 French radiotherapy units in order to recall the main provisions concerning patient radiation protection and the regulatory obligations concerning equipment supervision, maintenance and inspection of radiotherapy installations. This circular can be consulted on the ASN's website (www.asn.gouv.fr).

4 | 3 | 2

Accidental irradiation in a fluorine 18 manufacturing unit in the Service Hospitalier Frédéric Joliot (SHFJ) in Orsay (Ile-de-France region)

Accidental irradiation of an employee occurred in March 2005 in the CEA's Service Hospitalier Frédéric Joliot (SHFJ) located in the Orsay hospital.

This incident occurred during production of a fluorine 18-based radiopharmaceutical used in nuclear medicine. After noting a malfunction in the automated manufacturing process, an operator carried out an inappropriate manual intervention which led to body and clothing contamination. This contamination involved irradiation of the operator's right forearm, which was given specialist medical treatment.

After being informed of this incident, the ASN inspected the SHFJ, bringing to light inadequacies in the design of the installation and in the organisation for dealing with radiation protection incident situations. The ASN only authorised continued operation of the installation after confirmation was received that effective corrective measures had been taken and that new permanent operational procedures were in place, to prevent such an incident happening again.

Ten other fluorine 18 production installations are in operation in France and, jointly with the AFSSAPS and the Labour Inspectorate, the ASN carried out a series of checks on these installations in order to verify their personnel radiation protection arrangements. Further to these checks, the ASN asked for various corrective actions to be taken, to improve operator radiation protection.

4 | 4

Changing medical techniques

The ASN is attentive to changes in medical techniques using ionising radiation, so that it can assess the consequences of their use in terms of radiation protection of personnel and patients. During the course of 2005, the ASN was informed of innovative radiotherapy development projects, with new radiotherapy appliances soon to be installed in France, and new radioactive tracers which are to be experimented in the field of nuclear medicine.

4 | 4 | 1

The new radiotherapy techniques

In addition to conventional methods of tumour irradiation, new techniques called tomotherapy and radiosurgery should shortly start being used in France.

Tomotherapy combines scanner and particle accelerator technologies. A photon beam of 6 MeV and 8 Gy/mn irradiates a tumour using techniques inspired by the helical scanner (complete rotation around the patient and breakdown of the volume to be processed into basic cross-sections, which

are irradiated). A multileaf collimator and modulation of the radiation intensity allow highly-localised irradiation of regions independently of each other. It is also possible to acquire images of the zone being irradiated and compare them with reference tomography images in order to improve patient positioning quality. This technique is currently employed in about fifty centres in the United States and Europe. Two devices of this type should be installed in France in 2006.

Radiosurgery consists in using a small particle accelerator placed on a robot arm with 6 degrees of freedom. By combining the robot's ability to move around the treatment table and the degrees of freedom of its arm, it is thus possible to use multiple, non-planar beams to irradiate small tumours that are difficult to access using conventional surgery and radiotherapy. At present, three centres in Europe (Belgium, Germany and Italy) are using this technique and one or two French teams should shortly be acquiring this equipment. Given the movement capabilities of the robot and its arm, the radiation protection of the treatment room does not correspond to the usual standards and will therefore require a specific study.

4 | 4 | 2

New tracers in nuclear medicine

The routine use in nuclear medicine of fluorine 18, in the form of fluorodeoxyglucose (¹⁸FDG), for cancerology purposes, has opened the door to research into development of new radioactive tracers intended for both diagnosis and internal radiotherapy. Other than fluorine 18 marking on new vectors, current work in progress concerns the use of other radionuclides such as rubidium 82, copper 64 or iodine 124 for diagnostic applications. In the field of internal radiotherapy, research is beginning to look at using high-energy alpha (astatine 211, bismuth 213, radium 223 or actinium 225) or beta (copper 67, yttrium 90 or lutetium 177) emitting radionuclides.

The use in nuclear medicine of at least some of these radionuclides - if their medical interest can be proven - will require that the radiation protection requirements associated with their use be taken into account as early as possible. Given the activity levels potentially involved (usually far higher than those normally employed in nuclear medicine), the characteristics of the radionuclides and the preparation and administration protocols as today made known to the ASN, exposure of the operator - particularly the hands - could reach or exceed the regulatory dose limits, which is of course unacceptable to the ASN.

In these conditions and pending the initial licensing applications, the ASN is combining a reminder of regulatory requirements with awareness raising programmes, in particular by encouraging the development of automated systems for preparation and/or injection of these radioactive products.

5 IMPACT OF MEDICAL INSTALLATIONS ON THE EXPOSURE OF PERSONNEL AND PUBLIC

The ASN currently has little data for assessment of the use of ionising radiation for medical purposes, other than that regarding worker exposure (exposure of patients was described in paragraph 1|5).

According to the data collected by the IRSN in 2004 (IRSN report on worker radiation protection, 2004 summary), about 135,000 people working with medical uses of ionising radiation - or 53% of the total number of monitored exposed workers, covering all activity sectors - were subject to dosimetric exposure monitoring. Medical radiology covers about 69% of the medical personnel exposed. In total, nearly 99% of the persons monitored in 2004 and working in medicine or dentistry received an annual effective dose of less than 1 mSv while 34 overshoots of the annual limit of 20 mSv were recorded (46 in 2003). These overshoots can be broken down as follows: 28 in medical radiology, 3 in

radiotherapy, 2 in dental radiology and 1 in occupational medicine. Inquiries are systematically carried out by the occupational medicine services in order to identify the origin of these individual cases.

In 2005, the IRSN's centralised system for collection and analysis of dosimetric data (SISERI) was launched. With the increasingly widespread use of operational dosimetry in the medical field, these tools will give a more detailed picture of exposure, better identify the origin of any cases of the regulatory limits being exceeded and highlight any abnormal situations more quickly.

Except in special circumstances, there is no specific surveillance of the impact of medical applications on the environment and the population. The available information concerns general surveillance of the environment carried out by the IRSN, in particular measurement of ambient gamma radiation, and overall no significant exposure level above the background radiation variations has been highlighted. However, checks on rivers or sewage plants in large towns occasionally reveal the presence above the measurement thresholds of artificial radionuclides used in nuclear medicine (iodine 131, technetium 99m). The available data on the impact of these discharges show that they are estimated at a few microsieverts per year for the most exposed persons (sewerage network staff) and that these radionuclides have never been measured in water intended for human consumption. However, so that more precise data is available on the impact of these releases, and at the request of the ASN, the IRSN is carrying out studies to determine the exposure of certain professional categories working in waste water treatment (sewerage network staff, treatment plant operators, etc.).

In the case of patients who have undergone a nuclear medicine test or treatment, the 21 January 2004 regulation requires that nuclear practitioners provide their patients with relevant information to limit exposure of persons in contact with them. Now, it is up to the nuclear practitioners and their representative bodies to draft a guide including all the recommendations to be given to the patients. Regular distribution of this information will help limit unnecessary exposure of those in the patient's entourage.

Apart from these measures related to nuclear medicine procedures, the gradual development of the ASN's radiation protection controls, allied with environmental monitoring targeted on certain installations and the use of appropriate computer models, should provide a clearer view of the impact of medical uses of sources of ionising radiation. These actions are part of multi-year programmes.

6 ASN VIEWPOINT ON THE PERCEPTION OF RADIATION PROTECTION IN THE MEDICAL FIELD

With the hindsight offered by several years of monitoring of medical installations and contacts with professionals in the medical and dental sectors, as well as the suppliers, installers and inspection organisations, the ASN has now sufficient information to assess the perception of radiation protection by professionals using sources of ionising radiation for medical purposes. The considerable diversity of the installations and medical practices means that radiation protection is dealt with in widely differing ways. The ASN encounters many kinds of situations, ranging from purely administrative radiation protection with the main purpose of declaring the use of a radiology installation or obtaining a licence, to the implementation within an establishment of a structured organisation in order to heighten the awareness and make all those concerned by the use of sources more responsible.

In addition, the radiation protection approach varies considerably depending on whether the ionising radiation is used for its therapeutic and functional imaging effects (dose or level administered) or simply to obtain radiological images.



W. Roentgen and the first radiography negative (Mrs Roentgen's hand)

In the first case, corresponding to the fields of radiotherapy or nuclear medicine, overall the radiation protection rules are known and accepted, provided that they do not constitute an obstacle to the development of medical practices and the performance of medical procedures. However, actual implementation of these rules may often be delayed by administrative, financial or technical constraints specific to hospitals.

In the second case, many users of radiodiagnosis appliances - although this number is now beginning to fall - still see radiation protection as a constraint imposed from outside, with consequences of an administrative (regulatory pressure), technical (obligation to make various installation or work procedure modifications) and financial (cost of modifications, checks, time required, etc.) nature that are felt to be excessive given the fact that the risks are not clearly quantified. Therefore this situation leads to delays in applying current radiation protection regulations.

However, this situation can be offset by information programmes and the work being done by various learned societies and professional bodies which, through high levels of sustained investment, are regularly helping to raise the awareness of those concerned by radiation protection.

These findings should therefore encourage the ASN to continue its efforts to develop supervision of application of the regulations as well as its training and information programmes with the professionals in the medical world, to ensure a continuous process of radiation protection improvement.

In August 2005, the ASN therefore published a letter intended for nuclear medicine professionals, recalling the current radiation protection regulations, together with recommendations designed to make them easier to implement. This document, which is added to that intended for radiotherapists (see point 4|3|1 of this chapter), is a response to a request from the Société française de médecine nucléaire et d'imagerie moléculaire (SFMNIM). It is available from the ASN's website (www.asn.gouv.fr).

To allow a more precise assessment of changes with respect to radiation protection of personnel, installations and patients, the ASN also defined a series of specific indicators.

These indicators will be collected as of 2006 during each inspection of medical or industrial installations conducted by the ASN. A summary of these data will be produced following the annual inspection programme and will be published. Table no. 5 below details the indicators selected, with the corresponding objectives.

7 OUTLOOK

With the creation of the radiation protection inspectorate in 2006, combined with continued growth in its resources, the ASN will be able to expand the development of long-term actions in the field of radiation protection supervision of medical installations, in particular on the basis of the findings regarding the current situation. These actions will more specifically be aimed at:

- from the radiation protection viewpoint, the ways in which new irradiation techniques can be used in radiotherapy, or new radioactive tracers can be used in nuclear medicine;
- the creation of a notification system for radiation protection incidents in medical installations, so that lessons can be learned from the data collected in this way;
- medical radiophysics, with each establishment containing a radiotherapy, nuclear medicine, tomography or surgical radiology unit drafting a plan organising this discipline within the establishment. The ASN will closely check that these plans exist and that the resources allocated to radiophysics are appropriate and operational;
- new radiation protection supervision actions in surgical radiology;
- implementing radiation protection assessment indicators in the medical field.

Table 5: radiation protection indicators

Indicators selected	Presentation of the indicator
Personnel radiation protection	
Presence of a person with competence in radiation protection (PCR) or a department with competence in radiation protection (SCR)	Strict minimum when attempting to organise radiation protection within an establishment
Performance of workstation studies	Proves that consideration is being given to the organisation of work and radiation protection
Implementation of operational dosimetry (whenever relevant) and transmission of results to SISERI	Provides the PCR and the personnel concerned with a tool for estimating the doses received. Through knowledge of the doses at the workstations, helps improve individual and collective radiation protection. Apart from the regulatory aspect, transmission of data to SISERI is one way of contributing to setting up a radiation protection organisation
Implementation of RP continuing training programmes	Contributes to raising the personnel's knowledge of radiation protection and is a tool allowing structuring of radiation protection for the long-term
Periodic inspections by approved organisations	Tool giving an outside view of the radiation protection system, enabling RP to be structured for the long-term
Overshooting of one of the annual exposure limits	Indicates serious inadequacies in optimisation and problems with controlling radiation protection
Installations radiation protection	
Administrative situation of the installation in good order (currently valid licence, notification submitted). The nuclear activity is covered, at least in part, by a licence (expiry date has not passed) or a notification	The ASN is thus aware of the installation and can carry out supervision, both administrative and in the field. Account taken of regulatory obligations confirming a minimum RP level.
Existence of a waste and radioactive effluent management plan (if unsealed sources)	Proves that an organisation has been set up for collection and then disposal of radioactive waste and effluent
Radiation protection of patients	
Presence of PSRPM in the units	Competence for determining and guaranteeing the doses delivered
Preparation of a radiophysics plan	Long-term consideration given to developing radiophysics in the establishment, allowing definition and then acquisition of tools for implementing the optimisation process
Creation of reference diagnostic levels (NRD) (if radiology or nuclear medicine)	Optimisation approach for identifying and then controlling the doses
Existence of quality control	Contributes to the optimisation process. Search for improved reproducibility of exposure quality and medical procedure safety