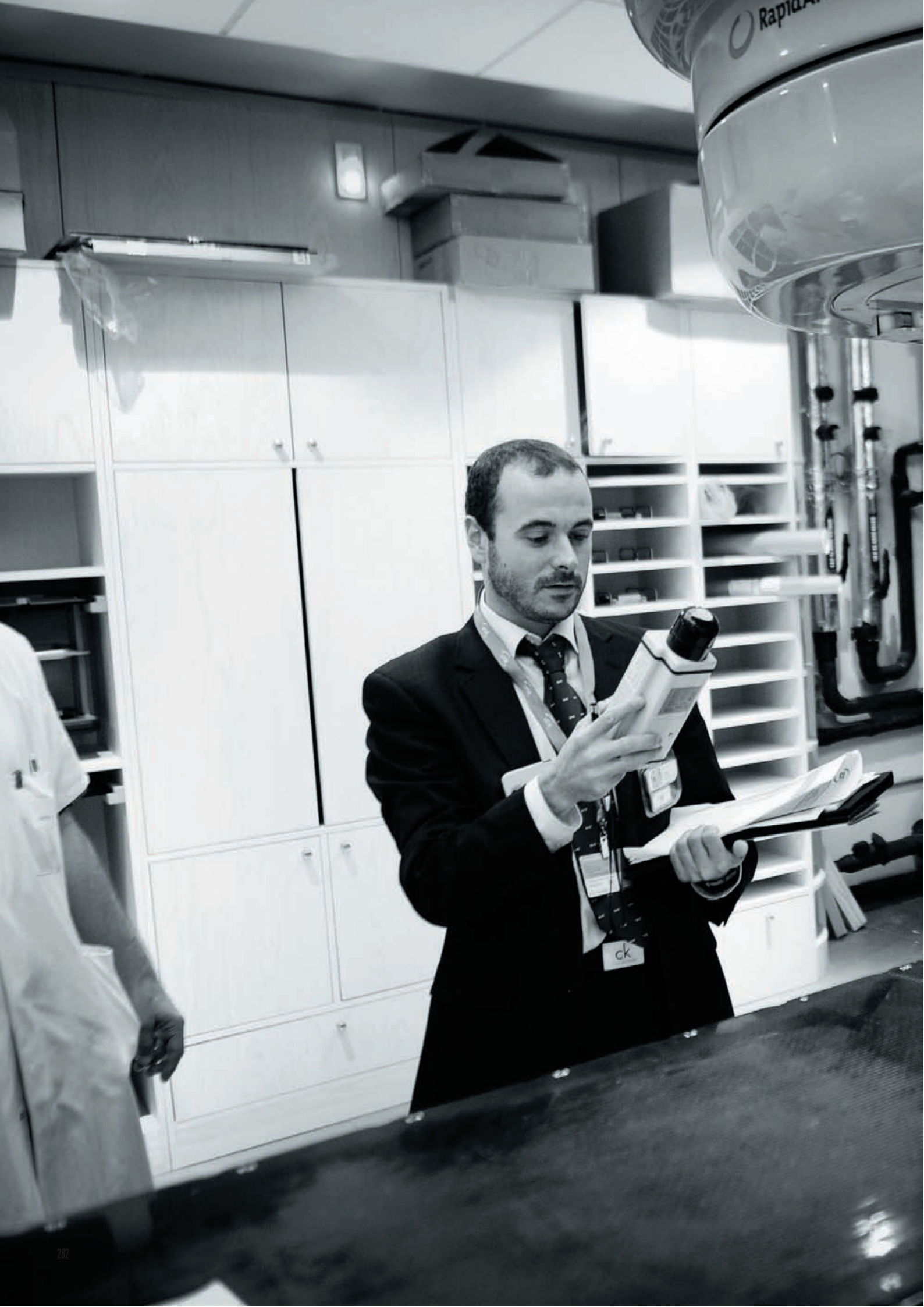
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Activities regulated by ASN

Chapter 9

Medical uses of ionising radiation

For more than a century now, for both diagnostic and therapeutic purposes, medicine has made use of a variety of sources of ionising radiation, produced either by electric generators or by radionuclides in sealed or unsealed sources. Even if their benefits and usefulness have long been medically proven, these techniques do however make a significant contribution to exposing the general public to ionising radiation. Behind exposure to natural ionising radiation, they represent the second source of exposure for the general public and the leading source of artificial exposure (see chapter 1).

Protection of the staff working in installations using ionising radiation for medical purposes is regulated by the provisions of the Labour Code. The medical facilities and devices emitting ionising radiation, including sealed and unsealed sources, must satisfy technical and administrative rules taken in application of the Public Health Code (see chapter 3).

In recent years, the technical regulations have been supplemented with the creation of a new set of regulations dedicated to patient radiation protection (see chapter 3). The principles of justification of procedures and optimisation of the doses delivered are the basis of these new regulations. However, contrary to the other applications of ionising radiation, the principle of dose limitation does not apply to the patient, since a certain dose - linked to the therapeutic or diagnostic strategy - is necessary to obtain a good quality image or deliver the desired treatment.

1 MEDICAL AND DENTAL RADIODIAGNOSIS INSTALLATIONS

1|1 Presentation of the equipment inventory

Radiology is based on the principle of differential attenuation of X-rays by the organs and tissues of the human body. The information is most often collected on digital media allowing computer processing of the resulting images, and their transfer and filing.

Diagnostic X-ray imaging is one of the oldest medical applications of ionising radiation; it encompasses all the techniques of morphological exploration of the human body using X-rays produced by electric generators. It occupies an important place in the field of medical imaging and comprises various specialities (conventional radiology, interventional radiology, computed tomography, angiography and mammography) and a wide variety of examinations (radiography of the thorax, of the abdomen and so on).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the patient's known medical history, the information sought, the expected benefit for the patient, the exposure level and the possibility of using other non-irradiating investigative techniques (see the French medical imaging good practices guide, chapter 3, new edition available in January 2013).

1|1|1 Medical radiodiagnosis

Conventional radiology

Conventional radiology uses the principle of conventional radiography and represents the large majority of radiological examinations performed if considered by number.

The examinations mainly concern bones, the thorax and the abdomen. Conventional radiology can be split into two main families:

– radiodiagnosis performed in fixed installations specifically built for the purpose;
– radiodiagnosis carried out on demand using mobile devices, at the patient's bedside for example. This practice must however be restricted to those patients who cannot be transported.

Digitised angiography

This technique, which is used to explore the blood vessels, is based on the digitisation of images before and after injecting a contrast medium. Computer processing removes the structures around the vessels by subtracting the pre-contrast images from the later ones.

Mammography

Given the composition of the mammary gland and the degree of detail sought for the diagnosis, high definition and perfect contrast are required for the radiological examination. This can only be achieved by special devices working with low voltage. These generators are also used for breast cancer screening campaigns.

Computed tomography (CT)

Computed tomography scanners use an X-ray beam emitted by an X-ray tube rotating around the patient and a computer-controlled image acquisition system, to produce a three-dimensional picture of the organs with image quality higher than that of conventional equipment, thus providing a more detailed picture of the organ structure.

Today, for certain medical indications, this technique is facing increased competition from magnetic resonance imaging (MRI). However, the technological developments made in recent years however, allowing dynamic volume acquisitions, have led to an extension of its investigative field and greater ease and speed of performance of these investigations. The negative side is that this technological development can lead to a multiplication of image acquisitions, which must be weighed up against the principle of optimisation and justification, and result in a large increase in the radiation doses delivered to patients.

Teleradiology

Teleradiology makes it possible to guide the performance of radiological examinations carried out in another location and to interpret the results, also from a distance. Data transmissions must be carried out in strict application of the regulations (relating to radiation protection and image production quality in particular) and professional ethics.

Essentially two practices are concerned:
– telediagnosis, which enables the doctor on the scene (e.g. an emergency doctor), who is not a radiologist, to send images to a radiologist for interpretation for diagnostic or therapeutic purposes. If necessary, the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes the responsibility for it;
– tele-expertise, whereby radiologists can exchange opinions by asking a remote expert radiologist ("teleradiologist") to refine and/or confirm a diagnosis and determine a therapeutic orientation or guide a remote examination.

The data transmissions are protected bidirectionally to preserve medical secrecy and image quality.

ASN inspection on the theme of interventional radiology at the Guingamp hospital centre – November 2012

Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure (radiologist or not), to the teleradiologist.

1|1|2 Interventional radiology

Interventional radiology concerns "all invasive diagnostic and/or therapeutic medical procedures, as well as surgical procedures using ionising radiation for per-procedural guidance, including monitoring[1]".

This involves techniques that use fluoroscopy with an image intensifier or flat panel detector and require special equipment, for example in surgical contexts or when performing vascular procedures (particularly in cardiology and neurology).

Interventional techniques using computed tomography are developing, due mainly to the technical progress in the equipment.

These techniques are used during diagnostic interventions (examination of coronary arteries, etc.) or for therapeutic purposes (dilation of coronary arteries, vascular embolisation, etc.) as well as during surgical procedures using ionising radiation to guide or monitor the surgeon's actions. They might require long-term exposure of the patients, who then receive high doses which can sometimes lead to radiation-related effects on tissues (cutaneous lesions, etc.). The staff are usually working in the immediate vicinity of the patient and are also exposed to higher dose levels than during other radiological practices. Under these conditions, in view of the risks of external exposure it entails, interventional radiology must be optimised to improve the radiation protection of operators and patients.

Interventional radiology facilities are used in rooms dedicated to interventional neurology, interventional cardiology and, more generally, vascular radiology. Radiology devices are also commonly used for fluoroscopy procedures in operating theatres in several specialised medical fields, such as digestive surgery, orthopaedics and urology.

ASN does not know the exact number of facilities in which interventional procedures are performed. The ASN regional divisions initiated actions to compare the information held by the health insurance offices and the Regional Health Agencies (ARS) in order to obtain a more accurate picture of the health-care activities concerned.

1|1|3 Dental radiodiagnosis

Intra-oral radiography

Intra-oral type radiography generators are generally mounted on an articulated arm and used to take 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 most often associated with digital systems for processing and filing the radiographic images.

1. Definition from the Advisory Committee for medical exposure (reporting to ASN).

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.

Cone-beam computed tomography

In the dental radiology field, the development of devices using a cone-beam computed tomography mode (3D) is continuing and the irradiation fields of view proposed by these devices are increasingly wide.

1|2 Technical rules for radiology and tomography installations

Radiology facilities

A conventional radiological facility comprises a generator (high-voltage unit, X-ray tube and control unit), associated with a support 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 procedures (NFC 15-161).

These standards stipulate that the walls of radiology rooms must afford sufficient radiological protection and may therefore require the installation of reinforced lead protection. In the light of the changes in radiation protection regulations, which have resulted in a reduction in the exposure limits for both the public and workers, these standards were revised and published in March 2011 (see box). Regulatory work is currently in progress to render enforceable the new standard published in March 2011.

In addition to complying with the above-mentioned standards, the devices must bear the CE marking, which has been mandatory since June 1998. This certifies that the device is in conformity with the essential requirements of health and safety mentioned in Articles R. 5211-21 to 24 of the Public Health Code. It should be noted that the 25-year limit on the lifetime of the generators was abrogated by the order of 1st December 2011, amending the order of 14th May 2004 concerning the general licensing and registration regime defined in chapter V-I "ionising radiation" of the Public Health Code. This duration had been set before the periodic quality checks on medical devices stipulated by a decision of the Director General of the ANSM (French national agency for medicines and health products safety) became mandatory. These checks ensure that the long-term performance of the medical devices is maintained. The regulations concerning medical devices also enable bans to be issued, as applicable, for any equipment that proves to be obsolescent.

Computed tomography facilities

Computed tomography facilities must be fitted out in accordance with the requirements of special standard NFC 15-161, which sets rules primarily for the dimensions of the examination room and for the radiological safety measures to be taken. A computed tomography device can therefore only be installed in a room with a surface area of at least 20m² and in which no linear dimension is smaller than 4 metres. The opacity of the walls, floor and ceiling of the room to ionising radiation must correspond to an equivalent

ASN inspection of the computed tomography facility on the theme of interventional radiology at the Guingamp hospital centre – November 2012

UNDERSTAND

Revision of standards NFC15-160, NFC15-161, NFC15-162 and NFC15-163

The standards in the NFC15-160 series relative to facilities for the production and utilisation of X-rays have been revised. These standards included general rules (NFC15-160) and specific rules for medical and veterinary radiodiagnostic facilities (NFC15-161), for roentgen therapy[2] facilities (NFC15-162) and for dental radiodiagnostic facilities (NFC15-163). The new standard NFC15-160 common to all medical radiology facilities, including computed tomography, dental radiology and veterinary radiology, introduces a method of calculating the required thickness of the protection screens in all facilities that use X-ray generators.

2. The roentgen facilities referred to in this standard are the radiotherapy facilities that use low-energy X-rays (produced at a voltage of less than 100 kV).

thickness of 0.2 to 1.5mm of lead, depending on the purposes for which the adjoining rooms are used. As at 31st December 2011, the French pool of radiological devices included 1109 computed tomography facilities. Furthermore, 126 CT scanners are dedicated exclusively to radiotherapy procedure simulation.

2 NUCLEAR MEDICINE

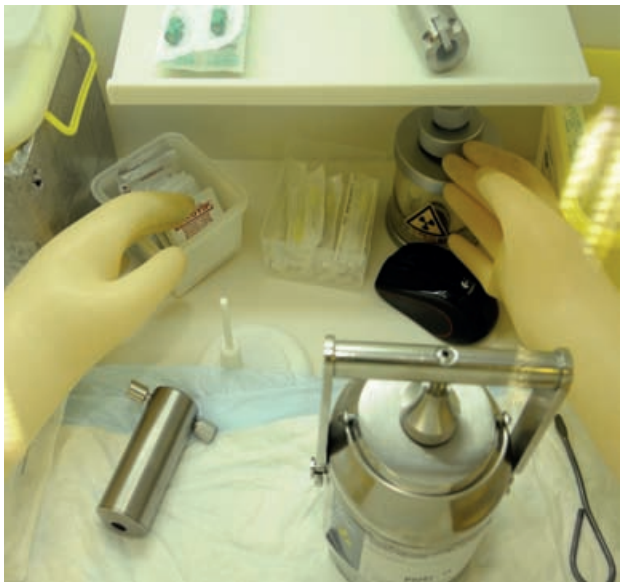
2|1 Presentation of nuclear medicine activities

Nuclear medicine includes all uses of unsealed radioactive sources for diagnostic or therapeutic purposes. Diagnostic uses can be divided into in vivo techniques, based on administration of radionuclides to a patient, and exclusively in vitro applications (medical biology).

This sector of activity comprises 217 nuclear medicine units with in vivo and associated in vitro facilities, and 41 biology laboratories independent of the nuclear medicine units.

On the whole, the number of nuclear medicine units practicing in vivo diagnosis and therapy has been stable for several years. At the end of 2011, 45% of the units were located in public facilities, 44% in private structures, 8% in private health institutions of collective interest (cancer centres) and 3% in joint public/private structures. At the end of 2011, the inventory included 106 positron emission tomography (PET) cameras, the majority of which are coupled to a computed tomography scanner (PET-CT). Forty-seven nuclear medicine units accommodate a total of 168 internal radiotherapy (brachytherapy) rooms.

Nuclear medicine comprises about 500 specialist practitioners, to whom should be added 1,000 physicians working jointly with the nuclear medicine units (internists, cardiologists, endocrinologists, etc.).



Handling unsealed sources under a hood in the nuclear medicine unit of the Oscar Lambret centre in Lille

2|1|1 *In vivo* diagnosis

This technique consists in examining the metabolism of an organ with a specific radioactive material - called a radiopharmaceutical - administered to a patient. The nature of the radiopharmaceutical depends on the studied organ or function. 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.

The radioactive substance – usually technetium-99m – administered by scintigraphy techniques is located in the organism by a specific detector called a scintillation camera or gamma-camera, which consists of a sodium iodide crystal (in most cameras) coupled with a computer-controlled image acquisition and analysis system. This equipment produces images of the functioning of the explored tissues or organs. As these are digitised images, the physiological processes can be quantified, along with a three-dimensional reconstruction of the organs (single-photon emission computed tomography or SPECT), using the same principle as for the X-ray scanner.

Fluorine-18, a positron-emitting radionuclide, is today commonly used in the form of a marked sugar, fluorodeoxyglucose (FDG), for examinations in cancerology. It requires the use of a scintillation camera that can detect positron emitters.

Nuclear medicine enables functional images to be produced. It is therefore complementary to the purely morphological images obtained using the other imaging techniques, such as conventional radiology, X-ray computed tomography, ultrasonography or magnetic resonance imaging (MRI). In order to make it easier to merge functional and morphological images, hybrid cameras have been developed: positron emission tomographs (PET) are now systematically coupled with a CT scanner (PET-CT) and more and more nuclear medicine units are acquiring gamma-cameras coupled with a CT scanner (SPECT-CT).

2|1|2 *In vitro* diagnosis

This is a medical biology technique for assaying certain compounds contained in biological fluid samples taken from the patient, such as hormones, drugs, tumour markers, etc., and it does not involve administering radionuclides to the patients. The technique uses assay methods based on immunological reactions

Table 1: Some of the main radionuclides used in the various nuclear medicine examinations

Type of examination	Radionuclides used
Thyroid metabolism	iodine-123, technetium-99m
Myocardial perfusion	thallium-201, technetium-99m
Pulmonary perfusion	technetium-99m
Pulmonary ventilation	krypton-81m, technetium-99m
Osteo-articular process	technetium 99m
Oncology – search for metastasis	fluorine-18

Solid waste storage room in the nuclear medicine unit, Brabois Hospital, Nancy CHU (University Hospital Centre)

(antigen-antibody reactions labelled with iodine-125), hence the name RIA (radioimmunology assay). The activities contained in the analysis kits designed for a series of assays do not exceed a few kilobecquerels (kBq). Radioimmunology is currently being strongly challenged by techniques which make no use of radioactivity, such as immuno-enzymology and chemiluminescence. A few techniques use other radionuclides such as tritium or carbon-14. Here again the activity levels involved are of the order of the kBq.

2|1|3 Targeted internal radiotherapy

Internal radiotherapy aims to administer a radiopharmaceutical emitting ionising radiation, which will deliver a high dose to a target organ for curative or remedial purposes.

Some treatments require patients to be hospitalised for several days in specially fitted-out rooms in the nuclear medicine unit to ensure the radiation protection of people visiting the patients and of the environment. The radiological protection of these rooms must be appropriate for the type of radiation emitted by the radionuclides.

This is particularly the case with the post-surgical treatment of certain thyroid cancers. The treatments involve administering about 4 GBq of iodine-131.Other treatments can be on an out-patient basis. Examples include administering iodine-131 to treat hyperthyroidism, strontium-89 or samarium-153 for painful bone metastases. Joints can also be treated using colloids labelled with yttrium-90 or rhenium-186. Finally, radioimmunotherapy can be used to treat certain lymphomas using yttrium-90 labelled antibodies.

2|1|4 Biomedical research in nuclear medicine

In recent years, research work to develop new radiopharmaceutical products has been growing in France and around the world. This primarily concerns positron emission tomography and targeted internal radiotherapy.

2012 saw the continuation of clinical tests relative to the use of various tracers marked with fluorine-17, gallium-68 and rubidium-82 in positron emission tomography (PET), and microspheres marked with yttrium-90 or vectors marked with lutetium-177 in targeted internal radiotherapy. New treatments are proposed in research, for example using radium-223, an alpha-emitter.

The use of new radiopharmaceuticals means that the radiation protection requirements associated with their handling must be integrated as early as possible in the process. Indeed, given the activity levels, the characteristics of certain radionuclides and the preparation steps involved, operator exposure – to their hands in particular – can be very high. For this reason, ASN has initiated awareness raising actions, notably by encouraging the development of automated systems for preparing or injecting these radionuclides.

2|2 Nuclear medicine unit organisation and operating rules

Given the radiation protection constraints involved in the use of unsealed radioactive sources, nuclear medicine units are designed and laid out so that they can receive, store, prepare and then administer unsealed radioactive sources to patients or handle them in laboratories (radioimmunology for instance). Provision is also made for the collection, storage and disposal of radioactive wastes and effluents produced in the installation, particularly the radionuclides contained in patients' urine.

From the radiological viewpoint, the workers are subjected to a risk of external exposure, in particular on the fingers, due to the handling of sometimes highly active solutions (as is the case with fluorine-18, iodine-131 or yttrium-90), and a risk of internal exposure through accidental intake of radioactive materials. In these conditions, the nuclear medicine units have to comply with specific layout rules, the main provisions of which are described below.

Location and layout of premises

The premises of nuclear medicine units are situated away from unrestricted access areas, and clearly separated from premises used for ordinary purposes. They are grouped together to form a single uninterrupted entity allowing ready delimiting of

controlled access areas that can be categorized in descending order of radioactive activity.

They comprise at least:
– an entry and changing area for the staff, separating normal clothing from work clothing;
– examination and measurement rooms, and rooms reserved for patients for the waiting period between injection of the radiopharmaceutical and taking of the images;
– rooms for storing and preparing the unsealed sources (radiopharmaceuticals handling room);
– an injection room adjoining the preparation room;
– facilities for reception of the radionuclides delivered and storage of radioactive waste and effluents.

Layout of premises

The walls are sized to ensure protection of the workers and the public in their vicinity. The floors, walls and worktop surfaces must be made of smooth, impermeable, seamless and easily decontaminable materials. The washbasin taps must not be hand-operated. The changing entry area must be equipped with washbasins and a shower. The sanitary facilities for the patients who have received an injection must be connected to a septic tank, itself directly connected to the establishment's main sewer. The radiopharmaceutical preparation room (the radiopharmacy) must be fitted with one or more shielded cells for storing and handling radioactive sources, offering protection against the risks of internal exposure and the dispersal of radioactive materials.

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 cells for the storage and handling of radioactive products in the radiopharmacy must be connected to independent extraction ducts fitted with filters.

Since 2010 ASN has been working on updating the design rules for nuclear medicine units (see box).

Collection and storage of radioactive solid waste and liquid effluents

The order of 28th July 2008 approving ASN resolution 2008-DC-0095 of 29th January 2008 lays down the technical rules to be followed for the disposal of waste and effluents contaminated by radionuclides.

Nuclear medicine units must have a room for storing waste contaminated by radionuclides pending its disposal. Contaminated liquid effluents are channelled to a system of storage tanks to allow radioactive decay prior to discharge into the sewerage network.

To facilitate application of the regulations, in 2012 ASN issued guide No.18 concerning the disposal of effluents and waste contaminated by radionuclides.

TO BE NOTED IN 2012

New design and fitting-out rules for nuclear medicine units currently under preparation

The progress in technologies and the development of new radionuclides have made it necessary to revise the order of 30th October 1981 concerning the conditions of use of artificial radioelements in unsealed sources for medical purposes. As part of its role in the development of the regulations, notably with technical resolutions, ASN set up a multidisciplinary working group to issue recommendations on the technical rules for the design, operation and maintenance of in vivo nuclear medicine facilities. The working group, coordinated by ASN, brought together professionals from various types and sizes of organisations and members of competent institutions. The group's report was presented to the Advisory Committee of experts in radiation protection for medical applications of ionising radiation (GPMED) in June 2012, which gave a favourable opinion on the recommendations. The draft ASN technical resolution currently under preparation will be subject to wide consultation in early 2013.

3 EXTERNAL-BEAM RADIOTHERAPY AND BRACHYTHERAPY

3|1 Description of the techniques

Alongside surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. Some 200,000 patients are treated each year. Radiotherapy uses ionising radiation to destroy malignant cells (and non-malignant cells in a small number of cases). The ionising radiation necessary for treatment is either produced by an electric generator or emitted by radionuclides in the form of a sealed source. A distinction must be made between external beam radiotherapy, in which the radiation source is placed outside the patient and brachytherapy, in which the source is positioned in direct contact with the patient, either in or close to the area to be treated.

At the end of 2011, the external beam radiotherapy installations comprised 444 treatment devices, including 422 isocentric linear accelerators (see points 3|1|1 and 3|1|3). These devices are installed in 174 radiotherapy centres, of which roughly half have public status and the other half private status.

There are 491 registered radiation oncologists (Radiotherapy Observatory, September 2011).

3|1|1 External-beam radiotherapy

Before the irradiation sessions take place, a treatment plan is always drawn up. For each patient, and in addition to the dose to be delivered, this plan defines the target volume to be treated, the irradiation beam setting and the dose distribution, as well as the duration of each treatment session. Preparation of this plan, which aims to set conditions for achieving a high dose in the target volume while protecting surrounding healthy tissues, requires close cooperation between the radiation oncologist and the medical physicist (also known as the radiological physicist), as well as the dosimetrists.

In the vast majority of treatments, irradiation is ensured using linear particle accelerators with an isocentric arm, emitting beams of photons produced at a voltage varying from 4 to 25 megavolts (MV) or electrons with an energy level of between 4 and 25 MeV and delivering dose-rates of from 2 to 6 Gy/min, although some latest-generation linear accelerators can deliver much higher dose-rates of up to 25 Gy/min.

For certain specific therapeutic indications (see point 3|1|3), a number of centres propose treatments that are made possible through the use of:
– a specific linear particle accelerator;
– a gammatherapy device equipped with more than 200 sources of cobalt-60 focused on a single point;
– a cyclotron producing proton beams.

Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method which aims to offer millimetre-precise, high-dose irradiation, using small beams converging in the centre of the target, for intra-cranial lesions that are surgically inaccessible. In stereotactic radiotherapy treatments, the total dose is delivered either in a single session or in a hypofractionated manner, depending on the pathology being treated. The term radiosurgery is used to designate treatments carried out in a single session.

This technique requires considerable precision when defining the irradiation target volume and the treatment has to be as conformational as possible.

It was originally developed to treat non-cancerous pathologies in neurosurgery (artery or vein malformations, benign tumours) and uses specific techniques to ensure precise localisation of the lesion. It is also more and more frequently used to treat cerebral metastases, but also for extracranial tumours.

This therapeutic technique uses three types of equipment:
– dedicated systems such as Gamma Knife® which directs the emissions from more than 200 cobalt-60 sources towards a single focal spot (four units are currently in service in three facilities), and CyberKnife® which consists of a miniaturised linear accelerator mounted on a robotic arm (see detail in point 3|1|3);
– dedicated linear accelerators offering dynamic irradiation mode (Novalis®, five units currently in service);
– "conventional" linear accelerators, providing dynamic irradiation mode and equipped with additional collimating systems (mini-collimators, localisers) to generate small beams.

Table 2: Breakdown of radiotherapy centres according to status in 2011

PRIVATE (excluding private health establishments of collective interest)	**91**
PUBLIC & Private health establishments of collective interest, including:	**83**
Hospital Centre	39
University hospital	20
Anti-cancer centre	20
Total	**174**

Source : ASN

Table 3: Breakdown of equipment in the centre

Isocentric accelerators	394
Dedicated accelerators (Novalis®)	5
Cyberknife®	5
Tomotherapy	13

Source : INCa data, 2011

ASN inspection during the commissioning inspection of a radiotherapy facility at the Franco-British Hospital Institute in Levallois-Perret – September 2012

3|1|2 Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours, specifically in the ear, nose and throat (ENT) field, as well as of the skin, the breast or the genitals.

This technique consists in implanting radionuclides, exclusively in the form of sealed sources (iridium-192 wires, considered to be unsealed sources, are a special case), either in contact with or inside the solid tumours to be treated.

The main radionuclides used in brachytherapy are caesium-137, iridium-192 and iodine-125.

Brachytherapy techniques involve three types of applications:

• Low Dose-Rate (LDR) brachytherapy:
– delivers dose-rates of between 0.4 and 2 Gy/h;
– using iridium-192 sources in the form of divisible wires, caesium-137 sources implemented using a specific source applicator. These sources are put into place for a limited duration;
– using iodine-125 sources in the form of seeds implanted permanently.

The iridium-192 sources implanted inside tissues take the form of wires 0.3 or 0.5 mm in diameter, with a maximum length of 14 cm at delivery and with an activity per unit length ranging from 30 MBq/cm and 370 MBq/cm.

The caesium-137 sources take the form of sealed sources 3 mm in diameter and 2 to 8 cm long. The brachytherapy unit must have a "library" of the various sources, corresponding to the types of applications the user wishes to employ. The sources are placed in a storage unit and transferred to the applicator system at the time of treatment.

Low dose-rate brachytherapy requires patient hospitalisation for several days in a room with radiological protection appropriate for the maximum activity of the implanted radioactive sources (rooms with radiological protection) where the patient stays for the duration of his or her treatment (except for brachytherapy of the prostate with seeds of iodine-125).

For the treatment of prostate cancers, iodine-125 sources are used. These sources (seeds), 4.5 mm long and 0.8 mm in diameter, are positioned permanently inside the patient's prostate gland. Their unit activity is between 10 and 30 MBq and treatment requires about a hundred seeds representing a total activity of 1 to 2 GBq.

Low dose-rate brachytherapy requires that the following premises be available:
– an application room, usually an operating theatre where the source carrier tubes (non-radioactive) are installed in the patient and their correct positioning is checked by X-rays or computed tomography imaging;
– an area for radioactive source storage and preparation.

Low dose-rate brachytherapy using sources of iridium-192 and caesium-137 is in the process of being phased out. The technique using sources of iodine-125 (prostate and ophthalmic brachytherapy), on the contrary, is in full development.

• Pulsed Dose-Rate (PDR) brachytherapy:
– delivers dose-rates of between 2 and 12 Gy/h;
– using iridium-192 sources in the form of a source 3.5 mm long, 1 mm in diameter and maximum activity of 18.5 GBq, implemented with a specific source applicator.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate for the maximum activity of the radioactive source used. It is based on the use of a single radioactive source which moves in steps, and stops in predetermined positions for predetermined times.

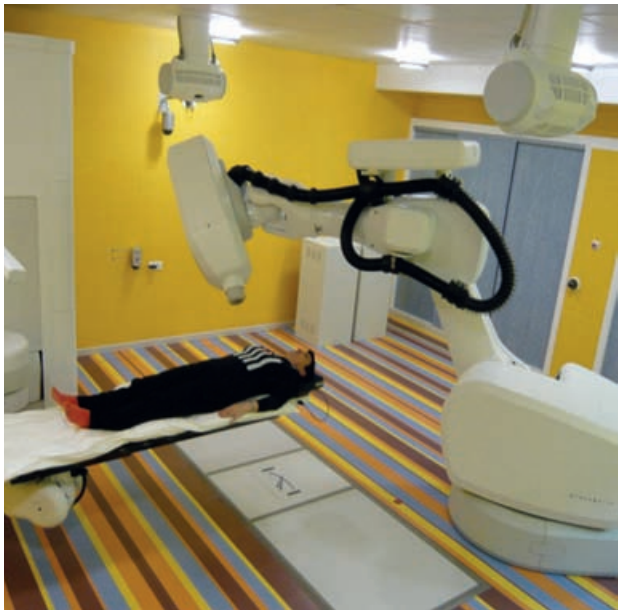
The doses delivered are identical to those of low dose-rate brachytherapy, but are delivered in sequences of 5 to 20 minutes, or sometimes even 50 minutes, every hour for the duration of the planned treatment, hence the name pulsed dose-rate brachytherapy.

Pulsed dose-rate brachytherapy offers a number of radiation protection advantages:
– no handling of sources;
– no continuous irradiation, which enables the patient to receive medical care without irradiating the staff or having to interrupt the treatment.

However, it is necessary to make provisions for accident situations related to the operation of the source applicator and to the high dose-rate delivered by the sources used.

• High Dose-Rate (HDR) brachytherapy:
– delivers dose-rates in excess of 12 Gy/h;
– using iridium-192 sources in the form of a source 3.5 mm long, 1 mm in diameter and maximum activity of 370 GBq, implemented with a specific source applicator.

This technique requires no patient hospitalisation in a room with radiological protection and is performed on an out-patient basis, in a room with a configuration comparable to that of an external beam radiotherapy room. The treatment is performed with an applicator containing an iridium-192 source and involves one or more sessions of a few minutes, spread over several weeks.



Accelerator on Cyberknife© robotic arm

Dedicated TomoTherapy© accelerator

High dose-rate brachytherapy is used mainly for gynaecological cancers, but also to a marginal extent for cancers of the oesophagus and bronchial passages. This technique is being developed for treatment of prostate cancers, usually in association with an external beam radiotherapy treatment.

3|1|3 Special radiotherapy techniques

Helical tomotherapy

As a complement to conventional methods of irradiating tumours, a technique called tomotherapy has been used in France since early 2007. Tomotherapy performs irradiation by combining the continuous rotation of an electron accelerator with the longitudinal displacement of the patient during irradiation. The technique employed is similar to the principle of helical image acquisitions obtained with computed tomography. A photon beam emitted at a voltage of 6 MV and a dose-rate of 8 Gy/min formed by a multi-leaf collimator enabling the intensity of the radiation to be modulated will allow irradiation of large volumes of complex shape as well as extremely localised lesions, which may be in anatomically independent regions. It is also possible to acquire images in treatment conditions and compare them with reference computed tomography images, in order to improve the quality of patient positioning.

Twelve devices of this type are installed in France.

Volumetric modulated arc therapy

Following on from intensity modulated radiation therapy[3] (IMRT), a new radiotherapy technique was recently developed and is being gradually introduced into France: volumetric modulated arc therapy. This technique, referred to differently (VMAT®, RapidArc®) depending on the manufacturer concerned, consists in irradiating a target volume by continuous irradiation rotating around the patient. Several parameters can vary during the irradiation, including the shape of the multi-leaf collimator aperture, the dose-rate, the rotation speed of the arm and the orientation of the multi-leaf collimator.

This type of treatment is performed using conventional isocentric linear accelerators that feature this technological option.

Robotic stereotactic radiotherapy

Stereotactic radiotherapy with a robotic arm consists in using a small particle accelerator producing 6 MV photons, placed on an industrial type robotic arm with 6 degrees of freedom, marketed under the name CyberKnife®. 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-coplanar beams to irradiate small tumours that are difficult to access using conventional surgery and radiotherapy. This technique enables irradiation to be carried out under stereotactic conditions, slaved to the patient's breathing.

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.

Seven installations of this type are in service in France in 2012, in Nancy, Nice, Lille, Lyon, Tours, Caen and Bordeaux.

Intraoperative radiotherapy

Intraoperative radiotherapy combines surgery and radiotherapy, performed concomitantly in the operating theatre environment. The dose of radiation is delivered to the tumour bed during surgical intervention.

3. For the duration of the session, the collimator leafs move while the beam is being emitted, thus modulating it in a complex manner.

In March 2011, the French National Cancer Institute (INCa) launched a call for proposals to support the installation of intraoperative radiotherapy equipment for the treatment of breast cancer patients. One of the objectives of this call for proposals is to carry out a medico-economic evaluation of radiotherapy treatments involving a small number of sessions compared with standard breast cancer treatments. Seven projects deploying an INTRABEAM® accelerator producing X-rays with an energy level of 50 kV were selected and installed between the end of 2011 and mid-2012.

3|2 Technical rules applicable to installations

3|2|1 Technical rules applicable to external-beam radiotherapy installations

The devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable bunkers (wall thickness can vary from 1 m to 2.5 m of ordinary concrete). A radiotherapy installation comprises a treatment room including a technical area containing the treatment device, a control station outside the room and, for some accelerators, auxiliary technical premises.

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 specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the person competent in radiation protection (PCR).

This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below the treatment room. This study should be included in the file presented to support the application for a licence to use a radiotherapy installation, examined by ASN.

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

3|2|2 Technical rules applicable to brachytherapy installations

The rules for radioactive source management in brachytherapy are comparable to those defined for all sealed sources, regardless of their use.

Low dose-rate brachytherapy

This technique requires the following premises:
– an application room, usually an operating theatre where the source carrier tubes (non-radioactive) are installed in the patient and their correct positioning is checked by X-rays or tomography imaging;
– hospitalisation rooms specially reinforced for radiation protection reasons, in which the radioactive sources are positioned and where the patient stays for the duration of the treatment;
– an area for radioactive source storage and preparation.

ASN inspection during the commissioning inspection of a radiotherapy facility at the Franco-British Hospital Institute in Levallois-Perret – September 2012

For certain applications (use of caesium-137 in gynaecology), a source applicator can be used to optimise staff protection.

In cases where permanent implant techniques are used (seeds of iodine-125 in particular for treating prostate cancer), the applications are carried out in the operating theatre with ultrasonography monitoring, and do not require hospitalisation in a room with radiation protection.

Pulsed dose-rate brachytherapy

This technique uses source applicators (generally 18.5 GBq of iridium-192). The treatment takes place in hospitalisation rooms with radiological protection appropriate to the maximum activity of the radioactive source used.

High dose-rate brachytherapy

The maximum activity used is 370 GBq of iridium-192, so irradiation may only take place in a room with a configuration comparable to that of an external beam radiotherapy room.

4 BLOOD PRODUCT IRRADIATORS

4|1 Description

The irradiation of blood products is used to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with an average dose of about 20 to 25 grays. Irradiation is ensured by a self-shielded device (radiological protection by lead), therefore it can be installed in a room which does not require additional radiation protection. Depending on the models, the irradiators are equipped either with radioactive sources (1, 2 or 3 sources of caesium-137 with a unit activity of about 60 terabecquerels - TBq) or with electrical X-ray generators.

4|2 Blood product irradiator statistics

In 2012, the French installations of this type totalled 30 irradiators in operation in blood transfusion centres, 13 with radioactive sources and 17 with electrical generators and X-ray tubes.

The policy to gradually replace the radioactive source irradiators by X-ray irradiators was initiated in 2009.

4|3 Technical rules applicable to installations

A blood product irradiator containing radioactive sources must be installed in a special room designed to ensure physical protection (fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, must be limited to authorised persons only.

5 THE STATE OF RADIATION PROTECTION IN THE MEDICAL FIELD

Radiation protection in the medical field concerns the patients receiving treatment or undergoing diagnostic examination, the health professionals (physicians, medical physicists, medical radiation technologists, nurses, etc.) using or participating in the use of ionising radiation, and also the population, such as members of the public moving around a health facility, or population groups that could be exposed to waste or effluents from nuclear medicine units. As of 2008, ASN began to prepare national reports synthesising the main lessons learned from its inspections.

As of 2008 updated syntheses are published on *www.asn.fr*. A new assessment of radiation protection in nuclear medicine units, based on the inspections carried out from 2009 to 2011 and a new appraisal of radiotherapy treatment safety based on the inspections carried out in 2011, will be published in 2013.

5|1 Exposure situations in the medical field

5|1|1 Occupational exposure

The risks for health professionals arising from the use of ionising radiation are firstly the risks of external exposure generated by the medical devices (devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed and unsealed sources (particular after administering radiopharamaceuticals). When using unsealed sources, the risk of contamination must be taken into consideration in the risk assessment (particularly in nuclear medicine).

The prevention of risks of exposure of health professionals to ionising radiation is required by provisions of the Labour Code concerning occupational radiation protection.

Inspection of the active dosimeter storage cabinet during an ASN inspection at the Guingamp hospital centre – November 2012

5|1|2 Exposure of patients

The exposure of patients to ionising radiation must be distinguished from the exposure of workers and the public insofar as it is not subject to a dose limit. The only principles applicable are those of justification and optimisation (see introduction to chapter 9).

The exposure situation differs depending on whether patient exposure is being considered for diagnostic or therapeutic applications. In the first case, optimisation is necessary in order to deliver the minimum dose required to obtain the appropriate diagnostic information or to perform the planned intervention procedure; in the second case, it is necessary to deliver the strongest possible dose needed to destroy the tumour cells while at the same time preserving the healthy neighbouring tissues as much as possible.

The examination and treatment procedures and the equipment settings play an important role in the application of the optimisation principle. Finally, the gradual implementation of patient radiation protection training for health professionals, which has been mandatory since 2004, is a key factor in progressing towards improving the radiation protection of patients in all fields.

Storage cabinet for the thermoplastic masks dedicated to each individual patient in a radio-therapy department

5|1|3 Exposure of the general public and environmental impact

With the exception of incident situations, the potential impact of medical applications of ionising radiation is likely to concern:
– the professional categories liable to be exposed to effluents or waste produced by nuclear medicine units;
– members of the public, if the premises containing installations emitting ionising radiation are not fitted with the required protection;
– persons close to patients having received a treatment or a nuclear medicine examination, particularly those using radionuclides such as iodine-131, or a brachytherapy.

Table 4: Different exposure levels from medical examinations using ionising radiation

	Type of examination	Adult exposure value (effective dose in mSv)
Conventional radiology		
	Thorax (front)	0.02
	Pelvis (front)	0.7
	Mammography	0.6
Computed tomography		
	Head	1.3
	Thorax	9
	Abdomen - Pelvis	10
	Heart (CT angiography)	8 to 30
Scintigraphy (diagnostic nuclear medicine)		
	Skeleton	4
	Thyroïd (^{99m}Tc)	0.5
	Lungs (ventilation and perfusion)	0.6 +1.1 or 1.7
	Cerebral (HMPAO)	3.6
	Myocardium with molecules marked with ^{99m}Tc	8
	Myocardium with 201Tl ^{201}Tl	23
	PET-CT (whole body)	10 to 20

(Source IRSN)

The available information concerning radiological monitoring of the environment carried out by IRSN, in particular measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the variations in the background radiation. On the other hand, radioactivity measurements in major rivers or wastewater treatment plants in the larger 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 indicate doses of a few tens of microsieverts per year for the most exposed individuals, in particular people working in the sewerage networks (source: IRSN study, 2005). However, no trace of these radionuclides has ever been measured in water intended for human consumption.

The physician's recommendations to patients after using radionuclides in nuclear medicine, have been the subject of specific work by the HCSP (French High Public Health Council), particularly for examinations and treatments using iodine-131, with the aim of harmonizing life-style advice to patients. The recommendations, which were published by ASN in 2007, concern the residual activity after hospitalisation (in the case of therapy using high activity levels) or the activity level administered if the patient receives iodine-131 without hospitalisation (exploration or treatment of hyperthyroidism).

5|2 Some general indicators

5|2|1 Authorisations and declarations

In 2012, ASN issued:
– 7,833 acknowledgements of receipt of declarations of medical and dental radiodiagnostic devices, of which nearly 67% concerned dental radiology devices;
– 639 authorisations (for entry into service, renewal or cancellation), of which 322 were in computed tomography, 177 in nuclear medicine, 111 in external-beam radiotherapy, 23 in brachytherapy and 6 for blood product irradiators.

5|2|2 Dosimetry of medical staff

According to the data collected by IRSN in 2011, 196,237 people working in sectors using ionising radiation for medical purposes, that is to say 57% of all exposed workers monitored, all activity sectors included, were subject to dosimetric surveillance. Medical radiology alone accounts for nearly 53% of the medical staff exposed.

In all, more than 98% of the health professionals monitored in 2011 received an annual effective dose below 1 mSv. Eight exceedances of the annual effective dose limit of 20 mSv and three

exceedances of the annual dose limit at the extremities (500 mSv) were recorded (in the interventional radiology sector).

5|2|3 Report on significant radiation protection events

Overall situation

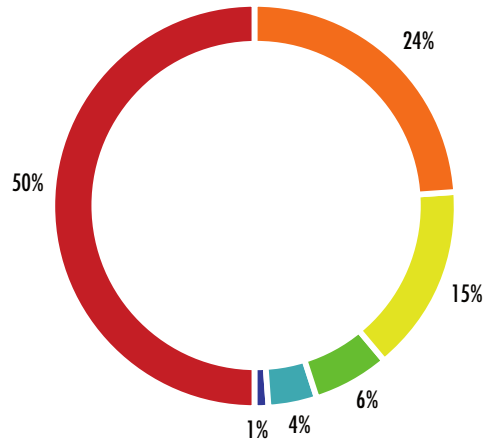
ASN was notified of 536 significant radiation protection events in the medical field in 2012. This number represents a 14% increase compared with 2011.

A significant increase is observed in notifications in the sectors of interventional radiology, nuclear medicine and computed tomography, even if one notification out of two comes from a radiotherapy department.

The reporting of significant radiation protection events in the medical field has been increasing since 2007, reaching an average of about forty notifications per month at the end of 2012.

About two-thirds of the radiotherapy departments declared at least one event in 2012.

Graph 1: Distribution of significant radiation protection events according to field of activity



Graph 2: Distribution of significant radiation protection events concerning workers according to field of activity

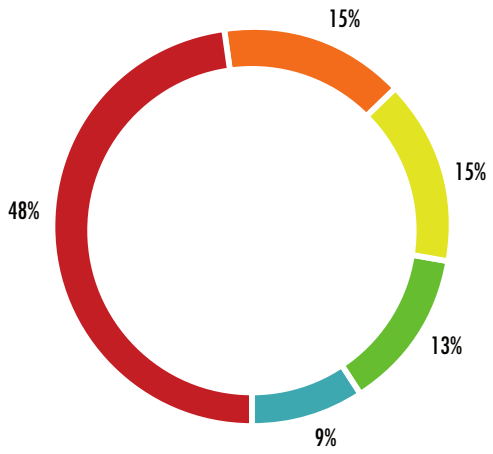
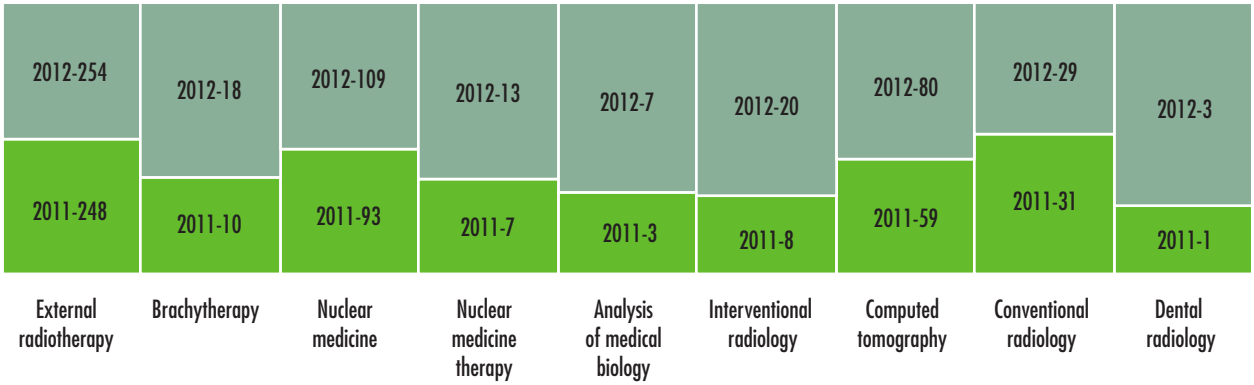


Table 5: Comparative volumes by activity of significant radiation protection events notified in 2011 and 2012



TO BE NOTED IN 2012

Event notified by the *La Cavale Blanche* CHU (University Hospital Centre) of Brest (Finistère *département*)

A nurse was contaminated by iodine-125 after handling a source applicator used for a prostate brachytherapy treatment. At the end of the procedure, the afterloader remained jammed in the applicator which, assumed to be empty, was then sterilised. Before returning the defective device to the supplier, the measurements taken by a contamination meter showed that one of the iodine seeds was still present in the applicator. The afterloader was then manipulated by a nurse in order to free the source.

The subsequent checks revealed contamination of the nurse's hands and of the floor of the room.

ASN has asked for increased rigour in the end-of-intervention checks, and particularly those relative to the use of appropriate detection means in order to detect any similar event more rapidly.

Significant radiation events concerning the workers (70 events)

The significant radiation protection events notified in 2012 concern all the fields of activity and are associated chiefly with:
– external contamination by fluorine-18 and technetium-99m, or internal contamination by iodine-131 or 125 in medical staff working in nuclear medicine and brachytherapy (see box),
– personnel exposure during an imaging examination with dosimetry results showing significant exposure but without exceeding the regulatory dose limits;
– significant exposure of the extremities of the operator (surgeon, radiologist);
– external exposure of radiotherapy workers after being shut in the treatment room during use of the accelerator.

Significant radiation events concerning patients (345 events)

The majority of notified events (75%) concerning patients come from a radiotherapy department. These events did not have serious health consequences for the patients.

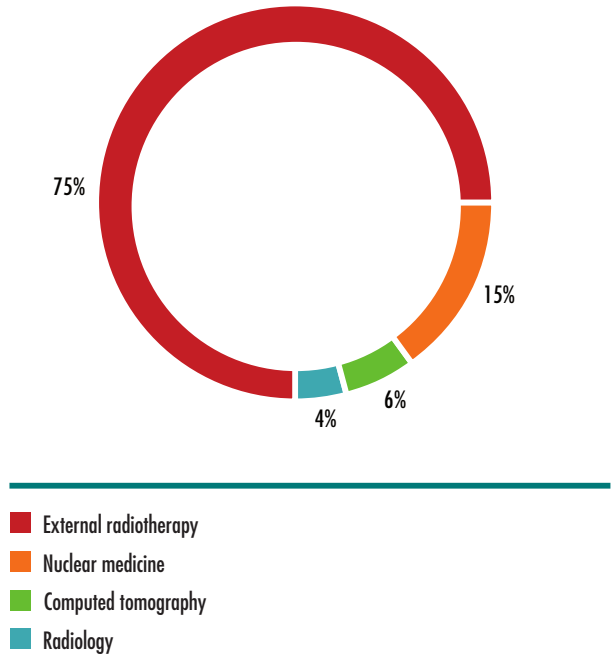
Increasing adoption of the procedure of notifying significant radiation protection events is being observed in nuclear medicine, witnessed by the one hundred or so notifications made in 2011 and 2012. Although the number of notifications remains low, those concerning patients are constantly increasing in radiology departments (computed tomography and interventional radiology), showing that the practice of notifying significant radiation protection events is starting to be adopted.

The types of events notified most often reveal errors in patient identity (similar names, lack of identity monitoring) or an error during the examination (location error, radiopharmaceutical administration error due to a lack of syringe labelling or an error in the sampled flask).

The notified events concerning the doses delivered to patients and the occurrence of radiation-induced deterministic events occur essentially in interventional radiology.

With regard more particularly to the significant radiation protection events notified in radiotherapy:

Graph 3: Distribution of significant radiation protection events concerning patients according to field of activity

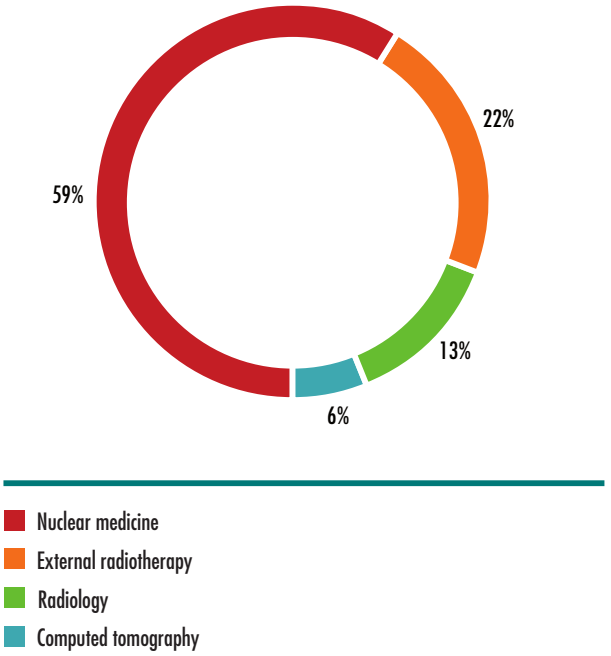


– 257 events concerning radiotherapy patients were declared in 2012. This number is stable compared with 2011;
– most of the events were due to a patient positioning anomaly or an error in patient identification, with no serious consequences for the health of the patient.
– 142 events were rated level 1 on the ASN-SFRO scale, which comprises 8 levels from 0 to 7. Quarterly reports of these level-1 significant radiation protection events are produced and published on www/asn.fr;
– three external beam radiotherapy events, notified in 2012, were rated level 2 on the ASN-SFRO scale (three in 2011). The incident notices are published on *www.asn.fr.*

The proportion of radiotherapy units having declared at least one event to ASN since the notification system was set up in 2007, is high (more than 90%). In 2012, 62% of the departments have declared at least one event per year.

Decay management tanks for contaminated effluents from the nuclear medicine unit at the Beauvais hospital centre.

Graph 4: Distribution of significant radiation protection events concerning sources according to field of activity



TO BE NOTED IN 2012

Event notified by the Gustave Roussy Institute of Villejuif (Val de Marne *département*)

Effluents from a radioactive decay tank were discharged into the collective sewerage system by the nuclear medicine unit to allow the continuation of iodine-131 treatments. 30 MBq of iodine-131 were thus discharged into the system.

The measurements taken by the system manager did not reveal any impact for the personnel working on the installations.

The abnormally high activity of the drained tank could be explained by a sealing defect in a valve which, although closed, could have allowed a low but continuous discharge of highly concentrated effluents into this tank.

ASN instructed the Gustave Roussy Institute management to repair the installations without delay. The institute has moreover undertaken to install a higher-performance tank management monitoring system and to study the feasibility of an alternative storage solution in the event of another tank failure.

Event notified by the Jean Perrin regional cancer centre in Clermont-Ferrand (Puy-de-Dôme *département*)

A drainage problem was discovered when cleaning the toilets of a room accommodating patients for radioactive iodine treatments. A plumber came to restore the drainage system further to the request for a maintenance intervention on the blocked toilets. The maintenance intervention caused flooding and radioactive contamination of several rooms when the system was drained. The rooms situated underneath the flooding had to be protected. The surface contamination of the rooms by iodine-131 was rapidly and completely removed.

The post-accident urine sample taken from the plumber revealed contamination. Further to this event, the Jean Perrin regional cancer centre implemented several corrective measures, including replacement of the incriminated pipe and the installation of suitable cleanout plugs in larger numbers, allowing maintenance interventions without draining the pipes.

Significant radiation events concerning sources, and radioactive waste and effluents (78 events)

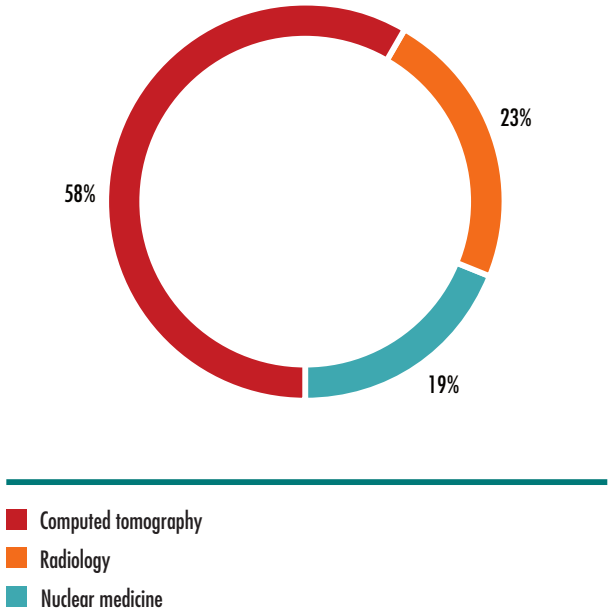
These significant radiation protection events are associated with the loss of radioactive sources or the dispersion of radionuclides (leaks of radioactive effluents from pipes or tanks, uncontrolled discharge of effluents into the collective sewerage network, removal of waste to an inappropriate disposal route).

Several events relating to leaks of radioactive effluents from nuclear medicine units were declared in 2012. They highlight the need to set up or to review the systems for monitoring the functioning of the drainage systems in the units, the majority of which are becoming outdated.

Medical exposure of women unaware of their pregnancy (86 events)

This concerns notification of exposure of the foetus in women who did not know that they were pregnant when they underwent a medical imaging examination. For the events notified in 2012, the doses received were without expected consequences for the foetus or the child after birth.

Graph 5: Distribution of significant radiation protection events concerning the exposure of unknowingly pregnant woman, according to field of activity



Synthesis of the significant radiation protection events notified in 2012

Analysis of the events notified to ASN in 2012 show that the medical activities that had the greatest consequences were:
– in terms of occupational radiation protection, the exposures in interventional radiology (external exposure of the operators, in particular exposure of the extremities) and in brachytherapy (radiation contamination with iodine-125 through failure of source containment);
– in terms of radiation protection of patients, notifications of events in interventional radiology with radiation-induced effects observed in patients having undergone particularly complex and long procedures;
– in terms of radiation protection of the public and protection of the environment, leaks of effluent containment systems and loss of control of radioactive waste in nuclear medicine and loss of control of sealed sources in brachytherapy.

With regard to the experience feedback from the analyses of notified events, ASN issued a letter to all the nuclear medicine units in 2012 concerning leaks in effluent pipes.

Two circular letters are moreover currently being prepared in brachytherapy and interventional radiology.

Since July 2011, a website provides an aid for the drafting of significant radiation protection event notifications in radiotherapy (*www.vigie-radiotherapie.fr*). This site, designed in partnership with the ANSM, with and for the radiotherapy professionals, helps them meet their notification obligations with regard to radiation protection and medical device surveillance. Since the website opened, almost 88% of the significant radiation protection event notifications have been drafted using this notification portal.

Lastly, it has been possible to build on experience feedback thanks to the rising number of notifications collected (more than 1,000 since 2007) and the analyses carried out by the centres. A periodic radiotherapy patient safety bulletin has been produced by the radiotherapy professionals and ASN. Bulletin No. 3 concerning the methods of analysing significant radiation protection events was published in 2012.

Patient safety bulleting No.3 of July 2012

5|3 Radiation protection situation in radiotherapy

Radiotherapy

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007. In view of the results of the inspections and the progress made in terms of treatment safety, as of 2012 radiotherapy centres will be checked every two years. An annual inspection frequency is nevertheless maintained for the centres with vulnerabilities in terms of human resources or organisation, and those who are behind schedule in ensuring compliance with ASN resolution 2008-DC-0103 of 1st July 2008. Moreover, particular attention is paid to departments having undergone major modifications (organisational or material), and centres implementing new techniques.

In the framework of the final report of the national committee for monitoring actions taken to improve the safety and quality of care in radiotherapy, which is coordinated by the INCa, ASN published in May 2012 the appraisal of its contribution to the Minister of Health's action plan.

Discussions between the ASN inspector and the personnel of the radiotherapy department in the Franco-British Hospital Institute in Levallois-Perret – September 2012

Stereotactic radiotherapy

Further to the publication of ASN deliberation 2011-DL-0025, ASN sent a letter to the various institutes and learned societies concerned by stereotactic radiotherapy and radiosurgery. As of 2012, the organisations contacted either integrated a specific teaching module on stereotactic radiotherapy or took measures to establish a complementary diploma in stereotactic radiosurgery.

ASN for its part began amending resolution 2008-DC-0103, which sets the quality assurance obligations in radiotherapy, so that the resolution's provisions also apply in medical centres that treat intra- or extra-cranial lesions by the delivery of a single or fractionated dose of ionising radiation under stereotactic conditions through ionising radiation beams produced by particle accelerators or by one or more radioactive sources situated externally to the patient. Publication of the resolution amending resolution 2008-DC-0103 is planned for early 2013.

On the other hand, two measures specified in deliberation 2011-DL-0025 have not yet been started. The measures in question are the review of the provisions of the Public Health Code concerning neurosurgery and the provisions applicable to radiotherapy, and the defining of the specific conditions of internal and external quality control of the equipment necessary for the implementation of stereotactic radiotherapy procedures.

5|3|1 Occupational radiation protection in radiotherapy

The inspections carried out in 2011 did not reveal any deviations from the provisions of the Labour Code as observed in the preceding years, regarding prevention of the risk of irradiation after being accidentally locked in the treatment room.

5|3|2 Radiation protection of patients in radiotherapy

Status of human resources in medical physics

The ASN inspections carried out in 2011 confirm the positive trend begun in 2008 with regard to the increased human resources deployed in the medical radiation physics field. The results of the inspections in 2011 show that a significant number of medical physicists were hired, following the increase in the number of training places decided on in the national radiotherapy plan.

The situation with regard to the organisation of medical radiation physics, especially in terms of the number of centres with too few medical physicists (12 centres at the end of 2009), has improved, although it is not yet fully satisfactory, because four of them had still to meet their additional staffing requirement as at the end of 2011, at the end of 2012, three centres still had only one medical physicist. This being said, in 2012. ASN observed no deviations from the obligation for a medical physicist to be constantly present during the treatment application time.

Implementation of a quality management system

Progress has been registered in the implementation and wider adoption of the management of safety and quality of patient care (ASN technical resolution 2008-DC-103). Nevertheless, the involvement of senior management in coordinating the management of safety and quality of care is still insufficient. Many centres need to further reinforce their safety culture and quality of care, in particular by formally drafting patient care practices and training the staff in risk analysis methods.

In general, the effort to draft formal practices and competences must be continued for many centres with regard to the delegation[4] procedures within the teams, particularly concerning the validation of the control images for patient repositioning during the treatments.

4. The transfer of medical procedures to other health professions is regulated by the steps taken pursuant to Act 2009-879 of 21st July 2009 on hospital reform, relating to patients, health and territories (HPST) in particular its Article 51 requiring the establishment of protocols.

National radiotherapy plan for 2007-2012

Management of risks and addressing malfunctions

Although internal notification of malfunctions is now in widespread practice, analysis of the causes and medium- and long-term monitoring of the improvement measures still need to be improved.

The *a priori* risk analyses provided for by technical resolution 2008-DC-103, which the radiotherapy centres are required to perform, are still not sufficiently carried out, particularly when new techniques are introduced. ASN considers that the radiotherapy centres should make such analyses a priority when new techniques are introduced, as a complement to the risk analyses performed by the manufacturers to obtain the CE marking.

5|3|3 Summary

To conclude, ASN is on the whole satisfied with the progress made by the centres and feels that its observations at the end of 2011 are encouraging. There has been a very real rise in awareness and reactivity within the profession with regard to radiation protection culture, formal drafting of practices and risk management in the treatment of patients by external beam radiotherapy.

ASN nevertheless draws attention to the spreading of new techniques such as volumetric modulated arc therapy and helical tomotherapy. It underlines the need to define the conditions of use of the new equipment and the new practices involved, particularly through prior analysis of the associated risks, and to identify the users' needs in terms of specific skills, training and good practices guides.

5|4 Radiation protection situation in nuclear medicine

A situation assessment of radiation protection in nuclear medicine units located within ASN's geographical area of competence (metropolitan France and French overseas *départements*), based on the inspections carried out in 217 units from 2009 to 2011, revealed the findings presented below.

5|4|1 Occupational radiation protection in nuclear medicine

The inspections carried out over the period from 2009 to 2011 show that the professionals are increasingly aware of their regulatory obligations.

Nevertheless, progress is still required in risk assessments and workplace studies, since 25% and 20% respectively of the departments had not carried them out on the date of the inspection. Likewise, internal radiation protection inspections are only carried out in full in 45% of the nuclear medicine units, and only half of the medical facilities have formalised the programme of radiation protection technical inspections in writing.

Lastly, progress is required in the coordination of prevention measures when outside contractors intervene in nuclear medicine units.

The 2012 update of the INRS (National Institute of Research and Safety for Prevention of Occupational Accidents and Diseases) radiation protection sheets for nuclear medicine, work that was carried out in collaboration with the professionals concerned, IRSN and ASN, should make it easier to implement the regulations concerning risk assessment, zoning and workplace evaluations.

The ASN inspections of nuclear medicine units will be continued in 2013.

5|4|2 Radiation protection of patients in nuclear medicine

The majority of the regulatory requirements relative to patient radiation protection are known and adhered to by nuclear medicine units, such as having a medical physicist and drafting medical radiation physics organisation plans (POPM), transmission of dosimetric readings for comparison with the diagnostic reference levels (DRL), inclusion of dosimetric data in the report, etc.).

Although the findings are on the whole satisfactory, some points still require improvement, such as training in patient radiation protection for all the professionals concerned, or the use of the DRLs to optimise the doses delivered to patients. It is also noteworthy that the recent ANSM approval in January 2012 of the first external quality control organisation for nuclear medicine diagnostic facilities should enable the units to implement these controls.

5|4|3 Protection of the general public and the environment

Today, almost all the inspected units have a contaminated waste and effluent management plan.

These documents are nevertheless incomplete with respect to the requirements of the order of 23rd July 2008[5]. The publication in March 2012 of the guide to the disposal of effluents and waste contaminated by radionuclides (ASN guide No.18) in order to detail the procedures for implementation of the order, should facilitate application of these regulations. Furthermore, 44% of the establishments with nuclear medicine units are not yet equipped with a fixed-station detection system for screening the waste intended for the non-radioactive waste disposal route. Moreover, the units have difficulties in complying with the decay tank outlet discharge values set by the order of 23rd July 2008, and the majority of units do not have a discharge permit issued by the sewage system manager (Article L. 1331-10 of the Public Health Code).

5|4|4 Summary

ASN continued the inspections of nuclear medicine units in 2012, and initiated or continued work on the regulations to improve radiation protection in this field of activity.

Work is thus in progress to update the design, operating and maintenance rules for nuclear medicine facilities on the basis of a risk-graded approach.

Moreover, a working group including all the stakeholders (heads of health care facilities, nuclear medicine professionals, wastewater treatment plant and sewerage system operators, administrations and regulating authorities concerned, technical experts) is going to be set up in early 2013 to issue recommendations on the conditions of discharge of radionuclide-contaminated effluents into the public sewerage system.

5|5 Radiation protection situation of patients in conventional radiology and computed tomography

In 2012, ASN continued the work started in 2010 and 2011 on the question of the increase doses delivered to patients undergoing medical imaging (an average increase of nearly 50% since 2002), especially in computed tomography (CT).

The deliberations of the ASN Commission on 14th June 2011 concerning the increase in the doses delivered to patients during CT and conventional radiology examinations, based on the conclusions of the seminar held by ASN on 16th September 2010 with all the professionals and organisations concerned, presented recommendations to achieve real control over the doses delivered to the patients.

ASN considers that the principle of justification of radiological examinations needs to be more effectively applied, so that each examination performed is actually useful, and that the doses delivered during the examinations are optimised, through greater quality assurance at all stages of the procedure.

ASN also underlines the need to continue the training and recruitment of medical radiation physicists for at least five consecutive years, so that their numbers are sufficient to meet the staffing requirements in medical imaging.

The health authorities and health professionals were notified of the measures identified by ASN.

Alongside the recommended measures for achieving better dose control, ASN had decided in 2011 to devote a part of its inspection programme to the radiation protection of CT patients. The results of these inspections were appraised in 2012.

With regard to the radiation protection of workers, this is considered to be satisfactory on the whole as concerns the designation of a PCR (person competent in radiation protection), risk assessments and zoning of the facilities, dosimetric monitoring of operators and the performance of external checks of radiation protection and internal environment checks.

Progress must nevertheless be made in the performance of workplace studies and the setting up of appropriate dosimetric monitoring of interventional CT procedures, in training in worker radiation protection, coordination of prevention measures in the event of intervention of teams from different legal structures and the settling of nonconformities discovered by an external radiation protection check. Thus, in nearly 10% of the facilities checked, the nonconformities identified in the inspection reports of the approved organisations were not resolved by the date that ASN performed its inspection.

Patient radiation protection is on the whole well integrated in the centres. The medical prescriptions are presented for the performance of the examinations, the prior examination history is tracked for patients registered in the inspected centre, the dosimetric data figure on the examination reports, the personnel are trained in the use of the equipment, if the machines features optimisation software, that software is used, and the machine maintenance operations and quality inspections are recorded in the maintenance register.

Improvements must nevertheless be made in the completeness of the elements substantiating the medical prescriptions, the training of the health professionals in patient radiation protection, the involvement of the physicists in the exposure optimisation process, the utilisation of the results of the diagnostic reference levels to optimise exposures, the performance of external quality inspections of the CT scanners, and putting procedures down in writing, particularly for the treatment of pregnant women.

Lastly, at European level, ASN participates in the initiatives of HERCA (Heads of European Radiological protection Competent Authorities) targeting:
– CT scanner manufacturers to improve the optimisation tools available on their equipment;
– European medical societies such as the European Society of Radiology, and international organisations such as the World Health Organisation (WHO) for questions relating to the justification of imaging examinations that use ionising radiation.

5. Order of 23rd July 2008 approving ASN resolution 2008-DC-0095 of 29th January 2008, setting the technical rules applicable to the disposal of effluents and waste contaminated by radionuclides, or liable to be so contaminated owing to a nuclear activity, implementing the provisions of Article R. 1333-12 of the Public Health Code.

5|6 Radiation protection situation in interventional radiology

During the last few years, significant radiation protection events have been notified to ASN following the appearance of lesions (radiodermatitis, necrosis) in patients having undergone particularly long and complex interventional procedures. In addition to these notifications which emphasise the major implications of radiation protection for patients, one must consider the notifications concerning workers whose exposure has resulted in exceeding of the regulatory limits.

Since 2009, the monitoring and regulation of radiation protection in interventional radiology has been a national priority for ASN.

The ASN Commission's deliberation of 14th June 2011 on improving radiation protection in interventional radiology, based on the GPMED's recommendations, underlines the strong implications of radiation protection in this field and recommends several actions that are necessary to improve it.

5|6|1 Occupational radiation protection in interventional radiology

The report on the inspections carried out in 2010 and 2011 confirms the 2009 observations. It shows that the radiation protection of workers is better integrated in fixed radiology facilities than in operating theatres where mobile devices are used.

Overall, the inspections revealed inadequacies in the risk assessments, workstation studies and in identification and delimitation of regulated areas. Incomplete use of active dosimetry and a lack of appropriate dosimetric monitoring, in particular of the extremities in the case of certain fluoroscopy-guided procedures, as well as an absence of medical monitoring of the practitioners, are also significant shortcomings.

For the PCRs (person competent in radiation protection), there are still methodological and organisational difficulties and they do not always have the means enabling them to perform their duties in full.

Inspection of protective aprons provided for workers during the ASN inspection on the theme of interventional radiology at the Guingamp hospital centre – November 2012

5|6|2 Radiation protection of patients in interventional radiology

On the whole, the findings of the inspections carried out in 2010 and 2011 are the same as in 2009. They reveal a lack of radiation protection culture in interventional radiology services. Shortcomings in the application of the principle of dose optimisation are observed in the setting of the machines, the protocols used and the practices. They result from insufficient operator training, both in patient radiation protection and in the use of the radiology devices, and are linked to a shortage of medical physicists and appropriate equipment. The lack of radiological protocols for most of the procedures performed in the operating theatre and an imperfect understanding of the doses emitted during the procedures contributed to a failure to apply the optimisation principle, creating potential risk situations.

5|6|3 Summary

ASN considers that urgent measures must be taken to improve the radiation protection of patients and workers in interventional radiology.

TO BE NOTED IN 2012

Event notified by the Lagny hospital centre (Seine et Marne *département*)

Necrosis appeared in a patient after six particularly long and complex iterative coronary angioplasties, for a chronic total occlusion (CTO).

IRSN carried out a dosimetric reconstruction and evidenced doses considerably higher than those published in the literature as causing the appearance of a tissular effect on the skin, and high dose levels for the lungs and heart (organs also situated in the irradiation field). The dose on the patient's skin was thus estimated at between 35 and 60 grays.

The analysis of this incident revealed deficiencies, firstly in the steps to optimise the machine settings, the protocols used and dose monitoring and recording, and secondly in the training in the use of the machine. Furthermore, the lack of knowledge of the successive doses delivered, and hence of the associated risk, meant that the patient was not subject to treatment follow-up monitoring which would have enabled the condition to be detected and treated at an early stage.

These measures must focus on increasing the number of medical physicists, operator training, quality assurance and the implementation of audits of professional practices.

The availability of PCRs and the means given to them must also be increased in order to make up for the insufficiencies observed, in particular in terms of risk assessment, workstation analysis, and the wearing of individual protective equipment and dosimeters, especially for monitoring doses at the extremities or the lens of the eye of the operator.

ASN also informed the HAS (French National Authority for Health) of the need for national recommendations for monitoring patients having undergone interventional radiology procedures that could lead to effects on tissues. These recommendations should be published in early 2013. Finally, ASN considers that regulatory measures should be taken to make it compulsory to install systems for estimating the delivered radiation dose during radiological procedures on existing radiology devices that do not have such systems.

In 2011, ASN also asked the learned societies and professional organisations representing the radiologists and non-radiologist practitioners (interventional cardiologists, vascular surgeons, neuro-surgeons, orthopaedists, etc.) who perform interventional radiology procedures, to step up their efforts with regard to training and the drafting of guides of good practice.

For procedures that are particularly long and complex, the good practices guides should detail the conditions of use of the devices according to the procedure, and establish local reference levels allowing application of the optimisation principle.

Owing to the inadequacies observed in radiation protection in the interventional radiology field, ASN is maintaining the national priority status it accords to the control of interventional radiology in its 2013 inspection programme.

6 OUTLOOK

The gradual improvement in the safety of radiotherapy procedures, observed by ASN through its inspections each year since 2007, must be continued in order to achieve good control of procedures and thus guarantee the radiation protection of the patients. In this new quality management culture, ASN will remain particularly attentive in its inspections to the recording and internal analysis of malfunctions - the key to permanent improvement and progress - and will endeavour to verify the balance between the procedures (formalising practices in writing) and their implementation. The centres with vulnerabilities in terms of human resources or organisation, and those who are behind schedule in complying with the requirements of ASN resolution of 1st July 2008, shall continue to receive particular attention, as will the centres implementing new treatment techniques.

Since 2009, ASN has been and remains concerned by the spreading of new techniques such as volumetric modulated arc therapy and helical tomotherapy without any specific oversight. It underlines the need to define the conditions of use of the new equipment and the associated new practices - particularly with regard to the prior risk assessments - and to identify the users' needs in terms of specific skills, training and good practices guides.

In the medical imaging field, following the publication of two deliberations in June 2011, jointly with the health administrations and the health professionals, ASN will organise in 2013 detailed monitoring of the steps taken to achieve true control of the doses delivered to patients in conventional radiology and in computed tomography, and to improve radiation protection in the field of interventional practices.

ASN will, in particular, remain highly attentive to the question of human resources and the corresponding skills, on the one hand to ensure compliance with the provisions of the Labour Code in operating theatres where radiology appliances are used and, on the other, to enable medical physicists to intervene in all fields of medical imaging, computed tomography and interventional radiology.

In the field of medical physics, the efforts made since 2007 to boost the numbers of medical physicists, must be continued in order to meet the medical imaging needs. In 2013, in collaboration with the SFPM (French Society of Medical Physics), ASN will publish two guides containing recommendations concerning firstly the involvement of medical physicists in medical imaging, and secondly the description of the organisation of medical physics (medical physics organisation plans) within health care facilities. More generally, ASN considers that the profession of medical physicist must be given full recognition, which from the regulatory aspect necessitates a clarification of the responsibilities of the medical physicists in the exercise of their duties in the areas of patient radiation protection and treatment safety.

Lastly, ASN actively participated in the work coordinated by the HAS (National Authority for Health) concerning the evaluation of clinical practices that expose individuals to ionising radiation for medical purposes. It will continue deployment of the clinical practices evaluation programmes in 2013.