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

Protection of the staff working in installations using ionising radiations for medical purposes is regulated by the provisions of the Labour Code. These regulations were updated in November 2007 (see chapter 3).

The installations themselves and their use are required to comply with specific technical and administrative rules, while the use of radioactive sources is subject to specific management rules contained in the Public Health Code, also updated in November 2007 (see chapter 3).

In recent years, the technical regulations have been considerably strengthened 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 foundation of these new regulations. However, unlike the other applications of ionising radiations, the principle of limitation of the dose delivered to the patient does not apply, owing to the health benefits derived by the patient, because a certain dose is required either to obtain a diagnostic quality image, or to obtain the desired therapeutic effect.

Since 2005, ASN has received a large number of radiotherapy event notifications. For some, no health consequences have as yet come to light, while others entail serious complications for the patients, even resulting in death in a few cases. In this context, ASN has since 2007 been inspecting all the radiotherapy centres, concentrating in particular on organisational and human factors. At the same time, in addition to publishing criteria for the notification of significant radiation protection events, ASN in conjunction with SFRO, developed a scale for rating the severity of events affecting patients undergoing a medical radiotherapy procedure.

1 MEDICAL AND DENTAL RADIODIAGNOSIS INSTALLATIONS

1 | 1 Presentation of the equipment pool

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

Radiodiagnosis, which is the oldest of the medical applications of radiation, is a discipline containing all the techniques for morphological examination of the human body using X-rays produced by electric generators. It enjoys pride of place in the medical imaging field and comprises various specialities (conventional or interventional radiology, computed tomography, angiography and mammography) and a wide variety of examinations (radiography of the thorax, 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 relevance of the information to be looked for, the

expected benefit for the patient, the anticipated exposure level and the possibility of using other non-irradiating investigative techniques (see medical imaging good practices guide, chapter 3).

1 | 1 | 1 Medical radiodiagnosis

Conventional radiology

This uses the principle of conventional radiography and covers the vast majority of radiological examinations carried out. The main subjects are the skeleton, thorax and abdomen. Conventional radiology can be split into three main families:

- radiodiagnosis performed in fixed installations specifically built for the purpose;
- radiodiagnosis carried out using mobile appliances, especially by the patient's bedside. This practice is however restricted to those patients who cannot be transported;
- radiodiagnosis in the operating theatre as a tool contributing to the satisfactory performance of interventional



Conventional radiology

procedures. In this case mobile X-ray generators fitted with a light intensifier are used, outputting images on a screen (radioscopy) that can be used in real time to guide the surgeon's hand.

Interventional radiology

These techniques use radioscopy with image intensification and radiography and require special equipment for the performance of operations which are either diagnostic (examination of coronary arteries, etc.) or therapeutic (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 interventional 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, interventional radiology must be justified by a clearly determined medical need and its practice must be optimised in order to improve the radiation protection of both operators and patients.

Digital angiography

This technique, which is used to explore the blood vessels, is based on digitalisation of images before and after injecting a contrast medium. Computer processing masks



Interventional radiology in the operating theatre

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.

Computed tomography

Using a closely collimated X-ray beam, emitted by a generating tube rotating around the patient and a computer-controlled 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 and three-dimensional picture of the organ structure.



Mammography appliance



Computed tomography appliance

When first used, this technique revolutionised the world of radiology, in particular in the neurological examination area, but is today being rivalled by magnetic resonance imaging (MRI) for certain investigations. However, the new generation of appliances (multi-slice scanners) enables the scope of investigation of computer tomography to be expanded, with easier and faster investigation. The counterpart can be a greater number of images being taken, which runs contrary to the principle of optimisation, thus leading to a significant rise in the doses of radiation delivered to the patients.

1 | 1 | 2 Dental radiodiagnosis

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.

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.

In the dental field, 2008 saw the continued development of volumetric 3D tomography, a technique derived from



Panoramic dental radiology appliance

conventional computed tomography, as well as the use of portable radiodiagnosis appliances. ASN will be defining the practical means of guaranteeing operator protection, based on the conclusions of the IRSN assessment of the risks of external exposure linked to the use of this new equipments.

1 | 2 Technical rules for radiology and tomography installations

Radiology installations

A conventional radiological installation comprises a generator (high-voltage unit, radiation generating tube and control unit), 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 radiations and electrical current. It is supplemented by specific rules applicable to medical radiodiagnosis (NFC 15-161) and dental radiodiagnosis (NFC 15-163).

These standards stipulate that 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. ASN, in partnership with IRSN and representatives of the professions concerned, is participating in this work - scheduled for completion 2009 - with the draft standards being made available for consultation by the UTE.

In addition to complying with the above-mentioned standards, the installations must be equipped with a generator

less than 25 years old (medical appliances used for medical care) and carrying the CE labelling that has been mandatory since June 1998. This certifies that the appliance is in conformity with the main health and safety requirements mentioned in articles R. 5-211-21 to 24 of the Public Health Code.

Tomography installations

Tomography installations 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 tomography appliance cannot therefore be installed in a room with a surface area of less than 20 m² and in which no linear dimension is less than 4 metres. The opacity of the walls (including floor and ceiling) of the room must correspond to an equivalent thickness of 0.2 to 1.5 mm of lead, depending on the purposes for which the adjoining rooms are used. In addition, tomography equipment more than 25 years old must not be used.

The French radiological pool comprises 1026 tomography installations (2008 figures). This figure includes appliances intended for radiotherapy simulation purposes.

Overall, in the field of radiodiagnosis, the profession in 2008 gave greater importance to radiation protection in daily practices, taking greater account of the safety of workers (person with competence for radiation protection, dosimetry monitoring of staff liable to be exposed, marking out of regulated areas, etc.), but also of the patient (optimisation, justification). ASN supports them in this move, in particular the radiologists, by placing a number of guidances at their disposal (regulations interpretation guides, etc.) and promoting good practices (good practice guide for medical imaging drafted under the supervision of the French Radiology Society).

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.

This sector comprises a total of 236 operational nuclear medicine units, containing both *in vivo* and *in vitro* installations (2008 figures).

The number of nuclear medicine units practicing *in vivo* diagnosis and therapy has been on the whole stable over the last three years. 60% of them are located in public or comparable structures and 40% are in private structures. After a period in which a number of the units acquired PET machines (2003-2006), the PET inventory has stabilised: in 2008, 71 are in service. The drop in *in vitro* diagnostic activity using radionuclides is continuing and in certain cases entails closure or merging of laboratories, or these laboratories being absorbed into nuclear medicine units.

Nuclear medicine involves about 500 specialist practitioners in this field, to which must be added 1000 physicians working in the nuclear medicine units (residents, cardiologists, endocrinologists, etc.).

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, which is classified as a drug, depends 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.

The radioactive material administered, usually technetium 99m, 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 these images are digitalised, the physiological processes can be quantified, along with a three-dimensional reconstruction of the organs, using the same principle as for the X-ray scanner.

Fluorine-18, a radionuclide that emits positrons with a half-life of 110 minutes, is today commonly used in the form of a sugar, fluorodeoxyglucose (FDG), for examinations in cancer treatment. It requires the use of a scintillation camera able to detect positron emitters in fact photons of 511 kW of dematerialisation of positrons, called a positron emission tomography (PET) machine.

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). In order to make it easier to merge functional and morphological images, hybrid appliances have been developed: PET machines are now systematically coupled with a scanner (PET-CT) and more and more nuclear medicine units are acquiring gamma-cameras coupled with a scanner (SPECT-CT).

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



Positron Emission Tomography machine in Tenon hospital, Paris

2 | 1 | 2 In vitro diagnosis

This is a medical biology analysis technique - without administration of radionuclides to the patients - for assaying certain compounds contained in biological fluid samples taken from the patient: hormones, drugs, tumour markers, etc. This technique uses assay methods based on immunological reactions (antibody - antigen reactions labelled 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.

2 | 1 | 3 Internal radiotherapy

Internal radiotherapy aims to administer a radiopharmaceutical emitting ionising radiations, which will deliver a

high dose to a target organ for curative or remedial purposes.

Certain therapies require hospitalisation of the patients for several days in specially fitted out rooms in the nuclear medicine unit, until most of the radionuclide administered has been eliminated through the urinary tract. The radiological protection of these rooms must be appropriate to the type of radiation emitted by the radionuclides. This is in particular the case with treatment of certain thyroid cancers after surgery, involving the administration of about 4,000 MBq of iodine 131.

Other treatments can be on an out-patient basis. 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 labelled with yttrium-90 or rhenium-186. Finally, radioimmunotherapy, which has appeared more recently, can be used to treat certain lymphomas using antibodies labelled with yttrium 90.

2 | 1 | 4 The shortage of technetium 99m

Since September 2008, the activities of nuclear medicine units have been seriously disrupted by problems with the procurement of technetium-99m generators, owing to the simultaneous shutdown of all the European nuclear reactors manufacturing molybdenum-99, which is the raw material for these generators. This problem is likely to continue through the first quarter of 2009.

Technetium 99m, which is the radionuclide used in about three-quarters of all nuclear medicine examinations (see



Handling of radioactive products in the Nantes university hospital nuclear medicine unit (Loire-Atlantique *département*) – September 2007

table 2), is produced by the radioactive decay of molybdenum-99 in a generator, followed by elution with physiological saline solution. The chemical form of this technetium-99m, its short radioactive half-life (6 hours) and its low gamma radiation energy, make it one of the most widely used radionuclides in nuclear medicine and one that entails the least irradiation for the patient. The activity administered to a patient for an examination is generally a few hundred megabecquerels (MBq).

The partial shortage facing the nuclear medicine units has been managed in various ways.

In some nuclear medicine units, where the quantities of technetium-99m administered were higher than strictly necessary, it had been possible to optimise the activity administered, in other words reduce them but without affecting the diagnosis. If this results in long-term optimisation of practices, this consequence can be considered positive in terms of radiation protection.

For certain examinations, it had been possible to replace the technetium-99m by another radionuclide (for example thallium-201 for cardiac scintigraphy or iodine-123 for scintigraphy of the thyroid). These replacements, which are not always possible and depend on the examination indications, usually however lead to higher exposure of the patient. The nuclear physician therefore has to assess whether the need for the examination is urgent enough to justify using these alternative radionuclides.

Other nuclear medicine examinations were replaced by alternative imaging techniques (radiology/scanner, MRI, ultrasounds). However, the diagnostic information obtained using these techniques is not always equivalent and the justification for performing alternative procedures using ionising radiations must be evaluated.

Finally, apart from the case of pulmonary embolism diagnosis, certain nuclear medicine examinations were postponed.

2 | 1 | 5 The new nuclear medicine tracers

In recent years, research has been under way in France and around the world, to develop new radioactive tracers. This primarily concerns positron emission tomography (PET) and internal radiotherapy.

The installation of numerous PET cameras has opened the door to research aimed at evaluating the advantages of new positron emitting radiopharmaceuticals. Considerable research is being carried out into molecules labelled with fluorine 18 (FLT, F-DOPA, F-MISO, FES, FET, F-choline, etc.), which could supplement FDG, so far the only tracer commonly used in PET. Research is also

being carried out into new positron emitting radionuclides. A clinical trial with gallium 68 (which has the advantage of being produced by a generator, in the same way as technetium 99m) is currently in progress. Projects concerning iodine 124 or rubidium 82 could also soon be started.

In the field of internal radiotherapy, most research in progress concerns radio-immunotherapy (use of antibodies labelled with a radionuclide) involving yttrium-90. Research in the near future could concern new radionuclides emitting beta radiation (lutetium-177 for example) or alpha radiation (radium-223, astatine-211, etc.).

The start-up of the Arronax cyclotron in Nantes, of which one role is to produce new radiopharmaceuticals, should lead to the development of new research.

The use of new radiopharmaceuticals in nuclear medicine means that the radiation protection requirements associated with their use must be taken into account as early as possible in the process. Given the activity levels involved, the characteristics of the radionuclides and the known preparation and administration protocols, exposure of the operators, particularly their hands, could reach or even exceed the dose limits set by the regulations. In addition to issuing a reminder of regulatory requirements, ASN has also initiated awareness raising programmes, in particular by encouraging the development of automated systems for preparation and/or injection of these radioactive products.

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 must be 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). Arrangements also need to be made for collection, interim storage and disposal of radioactive waste and effluents produced in the installation.

From the radiological viewpoint, the workers are subjected to a risk of external exposure, in particular on the fingers, owing to handling of sometimes highly active solutions (the case with fluorine-18, iodine-131 or yttrium 90 in radio-immunotherapy), along with a risk of internal exposure through accidental intake of radioactive materials. As the patients eliminate the administered radioactivity through their urine, special treatment of it is required in order to limit discharges into the public domain. In these conditions, the nuclear medicine units



Inspection by ASN's Nantes division in the Nantes university hospital radioactive waste area (Loire-Atlantique département) – September 2007

have to comply with specific layout rules, the main provisions of which are described below.

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 controlled areas, categorised in descending order of radioactive activity levels. They comprise at least:

- a changing entry area for the staff, separating normal clothing from work clothing;
- examination and simple measurement areas and waiting areas for the patients prior and after to examination;
- areas for storage and preparation of unsealed sources (radiopharmacy);
- an injection room adjoining the radiopharmacy;
- installations for reception of the radionuclides delivered and storage of radioactive waste and effluents.

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 radiopharmacy must be fitted with one or more shielded cells for storing and handling radioactive sources, offering protection against the risks of external exposure and 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 storage and handling of radioactive materials in the radiopharmacy must be connected to independent extraction ducts fitted with filters.

ASN has begun to look at revising the regulatory requirements resulting from the order of 30 October 1981, which specifies the conditions for use of artificial radionuclides in unsealed sources for medical purposes.

Collection and storage of radioactive solid waste and liquid effluents

The order of 28 July 2008 approving ASN decision 2008-DC-0095 of 29 January 2008 lays down the technical rules to be followed for the disposal of waste and effluents contaminated by radionuclides. This new text, drafted by ASN, means that the broad principles for contaminated waste and effluent management as previously introduced in circular DGS/DHOS 2001/323 of 9 July 2001 are now binding.

Generally speaking, nuclear medicine units have a room for interim storage of waste contaminated by radionuclides until disposal. Contaminated liquid effluents are however sent to a system of storage tanks prior to discharge into the sewerage network.

3 RADIO THERAPY

3|1 Presentation of radiotherapy techniques

With surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. 200,000 patients are treated every year. Radiotherapy uses ionising radiations to destroy malignant cells. The ionising radiations necessary for treatment are either produced by an electric generator, or emitted by radionuclides in the form of a sealed source. A distinction must be made between external 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.

The number of external radiotherapy installations is rising and now comprises 400 appliances located in 182 radiotherapy centres, half of which are public, while the other half are private (2008 figures). 667 radiotherapists are listed in the ADELI directory, of whom 42% are independent practitioners and 56% are salaried. 96 brachytherapy units are linked to these installations (2008 figures).

3|1|1 External 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 ballistics of the irradiation beams and the dose distribution (dosimetry), as well as

the duration of each treatment session. 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), also known as the medical radiological physicist, but also the dosimetrists.

Irradiation is carried out using either particle accelerators producing beams of photons or electrons with an energy level of between 4 and 25 MeV and delivering dose rates of between 2 and 6 Gy/min, or telegammatherapy devices equipped with a source of cobalt 60 whose activity level is about 200 terabecquerels (TBq), although the number of these devices is declining in France. They are gradually being replaced by particle accelerators, whose superior performance offers a more complete range of treatments.

Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method which aims to offer precise, high-dose irradiation, using mini-beams converging in the centre of the target, for intracranial damage that is surgically inaccessible. 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 localising techniques, such as the Leksell stereotactic frame for example,



Particle accelerator for radiotherapy



Use of a stereotactic frame for external radiotherapy

to ensure precise localisation of the damage. It is being increasingly used to treat cerebral metastasis.

This therapeutic technique has been in use in France since 1986, and employs three types of equipment:

- dedicated systems such as the Gamma Knife® using emissions from more than 200 Cobalt 60 sources focused on a single point. Three units are currently in service in two establishments;
- dedicated linear accelerators providing dynamic mode irradiation (2 units);
- “conventional” linear accelerators, providing dynamic mode irradiation and equipped with additional collimating systems (mini-collimators, localisers) to generate mini-beams. In 2008, 20 centres were using this type of equipment.

It is worth noting that ongoing technical developments concerning new equipment such as tomotherapy, or “robotic” radiotherapy, as well as developments in “conventional” accelerators associated with irradiation techniques slaved with breathing (gating) or with organ movements (tracking), enable this type of stereotactic irradiation to be used for extra-cranial damage.

3 | 1 | 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. Brachytherapy techniques involve three types of applications: low dose rate brachytherapy, medium dose rate pulsed brachytherapy, and high dose rate brachytherapy.

Low dose rate brachytherapy, which requires patient hospitalisation for several days, delivers dose rates of 0.4 to 2 Gy/h. The iridium 192 sources, placed inside the tissues, usually take the form of a wire 0.3 to 0.5 mm in diameter and no more than 14 cm in length, for which the activity per unit length is between 30 MBq/cm and 370 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.

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 30 MBq and treatment requires about one hundred grains representing a total activity of 1500 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 a small dimension iridium 192 source (a few millimetres), with maximum activity limited to 18.5 GBq. This 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



Insertion of an iridium wire for brachytherapy

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 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.

High dose rate brachytherapy uses a small source of iridium 192 (just a few millimetres) with a maximum activity of 370 GBq, delivering dose rates higher than 12 Gy/h. A source applicator similar to that for pulsed brachytherapy is used. The treatment times are very short (no more than a few minutes), unlike the previous techniques. High dose rate brachytherapy is primarily used to treat cancers of the oesophagus and bronchus.

3 | 1 | 3 The new radiotherapy techniques

New techniques called tomotherapy and extra-cranial radiosurgery (accelerator on robot arm) have been used in France since the beginning of 2007, in addition to conventional tumour irradiation methods.

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 acquisitions obtained with computer tomography. A photon beam of 6 MV at 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 damage 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. This technique is currently being used in nearly a hundred centres in the United States and Europe. Four devices of this type have been installed in France since the end of 2006 and have been used to treat patients since the first quarter of 2007.

Extra-cranial radiotherapy in stereotactic conditions with a robot arm, also called "robotic radiosurgery" consists in using a small particle accelerator producing 6 MV photons, placed on an industrial type 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-coplanar beams to irradiate small tumours that are difficult to access using conventional surgery and radiotherapy. This allows irradiation in stereotactic conditions that can also be 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.

At present, a number of European centres (Germany, Netherlands, Spain and Italy) are using this technique. Three installations of this type have been installed in France, i.e., in Nancy, Nice and Lille.

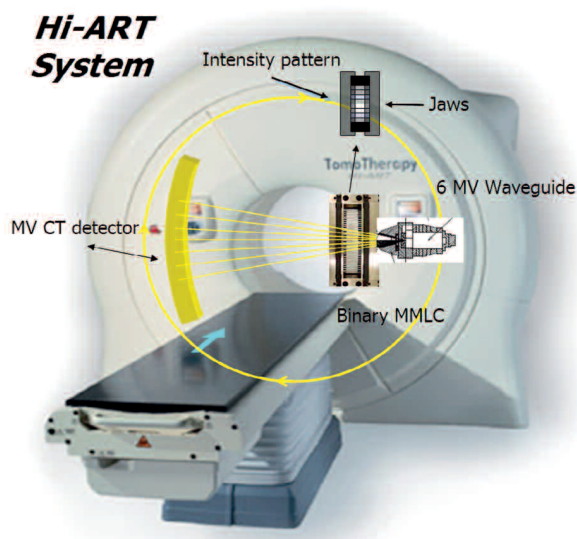
3 | 2 Technical rules applicable to installations

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

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

These machines must be installed in rooms specially designed to guarantee radiation protection of the personnel, turning them into true bunkers (the thickness of the ordinary concrete walls can vary from 1 m to 2.5 m). A radiotherapy installation comprises a treatment room including a technical area containing the appliance, a control station outside the room and, in the case of 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 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 unit with competence for radiation protection) of the establishment in which it is to be installed.



Tomotherapy appliance

This safety case defines the thicknesses and nature of the various protections required, which are 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 safety case 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) or must switch off the beam in an emergency or if the door to the irradiation room is opened.

3 | 3 | 2 Technical rules applicable to brachytherapy installations

Low dose rate brachytherapy

This technique requires the following premises:

- an application room, where the source carrier tubes (non-radioactive) are positioned on the patient and their correct positioning is checked by radiological 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.

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

Pulsed dose rate brachytherapy

This technique can only be used in units which already employ low dose rate brachytherapy. The rooms set aside for hospitalisation of patients receiving this treatment must have radiological protection appropriate to the maximum activity of the radioactive source used (generally 18.5 GBq of iridium 192).

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 radiotherapy room and fitted with the same safety systems.

4 BLOOD PRODUCT IRRADIATORS

4|1 Description

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 radiological 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.

4|2 Blood product irradiator statistics

In 2008, a total of 33 units of this type were in operation, primarily in the blood transfusion centres. However, the trend towards replacement of irradiators by X-ray machines, in particular to eliminate the constraints

involved in managing radioactive sources, has been confirmed since 2007.

4|3 Technical rules applicable to installations

The room in which the blood products irradiator is installed must be specifically dedicated to this appliance and be as isolated as possible, protected from all risk of flooding, short-circuit, explosion or traffic accident. It must be designed to prevent any possibility of break-in and any propagation of fire.

Access must be via a solid door equipped with an effective system automatically closing the door after it has been opened and only allowing access by authorised persons. If in a regulated area, the outside of the door must carry the appropriate radiation risk sign for the type of regulated area.

The irradiator control console must be fitted with a control key which is to be removed from the device and stored in a safe place under the responsibility of an individually designated person.



Blood products irradiator

5 SOURCE SUPPLIERS

Further to the expansion of its licensing competence to include source suppliers in the medical sector, the ASN will have an overview of the entire chain of health products containing radionuclides, from their manufacture up to their utilisation, an area that was already subject to ASN authorisation. The experience already acquired in industrial and research activities will be put to good use, taking account of the regulations which also apply to health products.

The health products supplier sector comprises 45 operators, split into 20 manufacturers and 25 distributors, with or without storage sites. It should be noted that 15 manufacturing sites for health products containing radionuclides in France are establishments that primarily manufacture 18-FDG and that a number of others are on the drawing board. The proximity between the production units and the user units is a necessary constraint linked to the short half-life of these drugs. The rising number of sites parallels the development of the indications for this type of molecule.

6 THE STATE OF RADIATION PROTECTION IN THE MEDICAL SECTOR

The potential dosimetric impact of medical installations concerns the patients undergoing treatment or examination, the health professionals (physicians, medical radiological physicists, electroradiology operators, nurses, etc.) using ionising radiations or involved in their use, but also the public, for example those living near installations, or population groups who could be exposed to waste or effluents originating in nuclear medicine units.

fact that the radiation protection regulations apply to them personally.

6 | 1 Radiation protection of the medical professions

6 | 1 | 2 Dosimetry

6 | 1 | 1 General indicators

The general radiation protection indicators contained in the 2007 report were not updated in 2008. During the course of the year, ASN focused on producing radiotherapy and nuclear medicine regional summaries, including these indicators which will be updated during the inspections. The results of these summaries will be published in 2009.

According to the data collected by IRSN in 2007 (IRSN report entitled “Worker radiation protection”, the exposure of nearly 145,000 people working in the sector using ionising radiations for medical purposes, or more than 49% of all the exposed workers monitored, all sectors included, was subject to dosimetric surveillance. Medical radiology covers about 64% of the medical personnel exposed. In total, more than 98% of the persons monitored in 2007 and working in medicine or dentistry received an annual effective dose of less than 1 mSv while an overdose exceeding the annual limit of 20 mSv was recorded on 18 occasions. In the field of medical activities, a single case

In 2008, the Lyon, Marseille, Dijon and Chalons divisions carried out targeted inspections in about one hundred radiology practices in the Picardie, Franche-Comté, Auvergne, Rhône-Alpes, Languedoc-Roussillon and Provence-Alpes-Côte d’Azur regions. This campaign showed that the majority of cases on the whole comply with radiation protection regulations, but that certain practices will need to take corrective measures quickly in order to make up for the shortcomings observed. For example, ASN is not always notified of appliances and the notifications are rarely updated. The appliance annual technical inspections are not always carried out and the radiologists inspected often seem to be unaware of the



Table of dosimeters used by the Nantes university hospital staff (Loire-Atlantique département) – September 2007

Situation of radiation protection in nuclear medicine units

ASN inspected nearly 90 nuclear medicine units in 2008 (or nearly 38% of all the units in France¹).

In terms of worker radiation protection, the steps taken by nuclear medicine units in recent years need to be continued, in particular with regard to evaluating the risks leading to the definition of regulated areas, workstation analyses enabling personnel to be placed in category A or B, the performance and traceability of radiation protection and ambient environment technical inspections, radiation protection training of workers, or the intervention specifications for outside companies.

With regard to radiation protection of patients, the situation varies widely from one unit to another: strong points and areas of progress were identified by the ASN inspectors. For example, despite the presence of a person specialising in medical radiation physics (in-house or from outside the establishment), the organisation of radiation physics still needs to be formally documented in most hospitals. However, other approaches have already been well incorporated into most units: for instance, 65% of nuclear medicine units² sent IRSN the dosimetric data needed to assess the diagnostic reference levels, at least once.

1. Including the overseas départements

2. Source: "Analysis of data concerning updating of the diagnostic reference levels for radiology and nuclear medicine. 2004-2006 results" / IRSN

of the annual dose limit at the extremities (500 mSv) being exceeded was identified (in the radiology sector).

Each overdose must lead to a significant event notification to ASN by the licensee of the nuclear activity. This triggers an individual investigation, jointly with the occupational physician and possibly in collaboration with the conventional safety inspectorate (circular of 16 November 2007 concerning coordination of the work of the radiation protection inspectors and the conventional safety inspectors with regard to the prevention of risks linked to ionising radiations).

6 | 1 | 3 Significant radiation protection events likely to affect medical workers

During the course of 2008, 15 significant radiation protection event notifications were sent to ASN, concerning individuals working in medical installations.

At the end of 2008, ASN was aware of a single notified event concerning an overdose by one quarter of a regulatory dose limit. This involved the isolated contamination of the end of an operator's index finger with carbon 11, during the preparation of a syringe for a PET examination, despite the fact that latex gloves were being worn. The exposure of the operator's index finger was assessed at somewhere between 50 and 250 mSv, which led ASN to rate the event at level 1 on the INES scale of radiation protection events.

Another event, due to the malfunction of an extractor fan in a shielded cell in a nuclear medicine unit, following a power cut, led to three workers being internally exposed to fluorine 18. Two events currently being investigated involve the exposure of nuclear medicine operators either from ingestion of thallium 201 or from splashing with fluorine 18 when handling a syringe.

Seven events involving the presence of staff in the treatment room (radiotherapy or scanner) during the emission of ionising radiations (three concerned maintenance personnel or residents) were also notified to ASN.

Finally, two events were notified as a result of abnormal dose values recorded on two passive dosimeters. Investigations are under way to determine the origin of the doses recorded.

6 | 2 Radiation protection of patients

Patient exposure to ionising radiations is differentiated from the other types of exposure (workers, population) because it is not subject to any limitations. This is also the only case in which exposure is delivered for the direct benefit of the exposed persons, i.e. the patients. The situation is different whether the patient is being exposed for diagnostic reasons (radiology or diagnostic nuclear medicine) or is receiving external or internal radiotherapy treatment. In the first case, optimisation is necessary by delivering the minimum dose necessary to obtain relevant diagnostic data, while in the second, the dose needed to

sterilise the tumour must be delivered, while maximising preservation of the surrounding healthy tissue.

Optimisation of the dose received by the patient depends on the quality of the equipment used, which for example 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 that used for this exposure: a defective radiological film viewer could lead to an increase in doses delivered in order to produce the films. On the whole, inspections carried out in 2007 showed that about 70% of the units exercised quality control of their appliances, while 12% had undertaken to set up a process of this type. The dose also depends on the nature of the procedures and the emission of radiation (X-ray tube, particle accelerator, unsealed radioactive sources, etc.).

6 | 2 | 1 Human resources (medical radiation physicist, training)

The optimisation process can be improved if a person specialising in medical radiophysics (PSRPM) is present in the unit to determine and guarantee the doses delivered. Overall, according to ASN sources, in 2007 only 64% of the units for which the indicators were recorded employed a PSRPM, all units included (radiotherapy, radiology, nuclear medicine). This overall figure indicates a shortage of staff with this qualification, in particular in radiology departments.

In radiotherapy units, the presence of the PSRPM during treatment is mandatory. An ASN survey was carried out at the beginning of 2007 to identify PSRPM needs in radiotherapy units. Overall, this survey showed the need for about 100 full-time equivalent PSRPM and about 100 full-time equivalent associated technicians (dosimetrists and electro-radiology operators).

6 | 2 | 2 Patient exposure from medical imaging

At present it is hard to gain a precise picture of overall exposure of medical origin, because the number of

EFOMP European Medical Physics News

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EFOMP Membership across Europe

The European Federation of Organisations in Medical Physics (EFOMP) was founded in 1980. The current membership covers 35 national organisations which together represent more than 6,600 physicists and engineers in the field of Medical Physics.

News from EFOMP:

Due to expiring terms there were some changes in the EFOMP officers board: Alberto del Guerra became past president and Renato Padovani's term as secretary general started, both at the beginning of 2006. Maria Wasilewska-Radwanska from Krakow/Poland was elected as the new chairman of the "Education, Training and Professional affairs committee" and Eduardo Guibelalde from Madrid/Spain was elected as the new chairman of the "committee on European Union Matters", both starting in 2007. The position of the honorary treasurer (Peter Sharp) was confirmed by the council in Malaga and prolonged for another 3 year term.

Don't miss the **EFOMP Congress** at Pisa in September 2007. See: <http://efomp-2007.dl.unipi.it>

Medical Physicists per million population
(data from EFOMP membership statistics 2007)

The countries which are members of EFOMP have a combined population of 870 million people, and the average number of medical physicists in these countries is currently 7.6 per million. However, there is a very wide range, from well below 1 per million, to over 30.

Did you know this?

PTW
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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 (see chapter 1).

Table 2 below presents the breakdown of the number of procedures and associated doses for conventional radiography, computed tomography, nuclear medicine and interventional radiology.

The studies conducted so far generally show a wide variability in the doses delivered for a given examination. 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

Radiotherapy situation in 2007

According to INCa, the number of Full Time Equivalent medical radiation physicists dedicated to radiotherapy was 378. Between 2006 and 2007, the number of FTE radiation physicists dedicated to radiotherapy grew by 7.6% nationwide and has risen by virtually 20% since 2004.

Source: INCa

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).

With regard to radiology and nuclear medicine, diagnostic reference levels (NRD) give a clearer picture of the doses delivered and thus allow better management of them. The first analysis of the results of the assessments of the ionising radiations doses delivered to patients during radiology and nuclear medicine examinations, submitted on 11 March 2008 by IRSN to ASN, at its request, underlines the inadequacies in application of the new regulations published in February 2004. In fact, only 65% of the nuclear medicine units, 8% of conventional radiology units and 17% of computer tomography units have

transmitted NRD data at least once during the course of the past three years (source: IRSN).

In nuclear medicine, the activities administered vary widely from one unit to another, from one country 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 1.25 mGy to 3.75 mGy.

6 | 2 | 3 Accidental irradiation of patients

The consequences of significant radiation protection events on the health of patients varies widely:

- they usually affect a single isolated patient, but can also concern cohorts (Épinal Hospital, Toulouse University Hospital)¹;
- they can lead to death (Épinal hospital, Lyon Sud University Hospital) or to serious or severe complications (Tours Hospital, Grenoble University Hospital)²;
- generally they do not become immediately apparent, requiring medical surveillance;
- there may not actually be any consequences because the event can, in certain cases, be compensated for in the subsequent treatment.

Once notified by the heads of the establishments concerned, through application of the radiation protection events notification guide (available at www.asn.fr), ASN:

- organises a reactive inspection, when necessary with the technical support of experts (IRSN, SFPM, SFRO, etc);
- disseminates operating experience feedback to the professionals;
- informs the health agencies (DGS, DHOS, Afssaps, InVS, INCa);
- informs the public after prior (mandatory) information of the patients by their radiotherapist, using the published severity scale updated in July 2008 (www.asn.fr).

During the course of 2008, ASN was notified of 214 significant events concerning patients undergoing therapeutic exposure. Most of these events (98%) occurred during an external radiotherapy medical process. The other events are the result of brachytherapy equipment malfunctions or undesirable events occurring during the preparation of brachytherapy sessions.

With regard to the radiotherapy events, the notifications received in 2008 come from 56 of the 180 establishments,



Guide of good practice for medical imaging examinations published by the French Radiology Society

1. See ASN 2007 report on the state of nuclear safety and radiation protection in France.
2. See ASN 2006 report on the state of nuclear safety and radiation protection in France.

Table 2: contribution to the individual dose from radiological and nuclear medicine procedures (source: IRSN)

Type of procedure	Approximate percentage of number of procedures	Contribution to individual mean dose
Conventional radiology	90%	36%
Interventional radiology	1%	17%
Tomography installations	8%	40%
Nuclear medicine	1%	7%

representing only 31% of the radiotherapy centres. Of these events notified to ASN, 6 were also notified to the French Health Product Safety Agency (AFSSAPS) under the medical devices vigilance system. About 58% of the events are random in nature: the error occurred for a single patient during a single session and took place during the treatment session without there being an error in the patient's technical file. However, more than one third of the events were systematic in nature, in other words linked to the presence of erroneous data in the patient's file and reproduced during each session until the error was detected. Finally, and more rarely, the events were due to errors in dosimetric characterisation of the equipment (calibration error for instance).

For all the external radiotherapy events, the origin was usually ascribable to human and organisational factors: defective organisation (failure of check-points, breakdown of communication between operators, etc.). However, 6 events were caused by an equipment operation anomaly.

In 2008, 4 significant events concerning patients exposed for diagnostic purposes, were notified to ASN. Three of them concerned an injection error during a nuclear medicine diagnostic examination. The fourth notification was linked to a suspected delivery of a higher than necessary dose during interventional cardiology procedures.

Furthermore, 9 events involving exposure of pregnant women during diagnostic examinations, before they were aware of their pregnancies, were notified to ASN in 2008. In all the cases, this exposure had no consequences for the foetus.

The majority of the events notified in 2008 had no consequences for patient health. With regard to external radiotherapy, 204 of the 208 events notified were rated 1 or lower. Four events were rated level 2 on the ASN-SFRO scale, as events causing or liable to cause a moderate alteration in an organ or function, and resulted in posting of an incident notification on ASN's website.



Meeting of the medical staff at Necker hospital in Paris – November 2006

Combined radiation protection and medical device vigilance events

In 2008, 6 external radiotherapy events involved both medical device vigilance and patient radiation protection. Investigations conducted jointly by AFSSAPS and ASN into events of this type revealed their complexity, both with regard to their analysis, which demands a high level of technical competence and the use of experts, and their management, in that the risk assessment cannot always identify the potential consequences for patient health. The methods for evaluating the dosimetric consequences can prove relatively complex, so the impact for patient health cannot always be quantified and it may prove difficult and time-consuming to identify all the patients concerned by the event if it happened some time in the past, thus affecting the organisation of the unit and the smooth running of the treatments in progress.

For the events notified in 2008 and likely to have consequences on patient health, checks were systematically requested on the files of all the patients being treated as well as all those for whom the technical file was being reviewed, regardless of the reason.

Based on this feedback, ASN and AFSSAPS will aim in 2009 to define investigative procedures designed to obtain a clearer understanding of the consequences of this type of event.

At an international level, ASN focuses on disseminating the experience acquired:

- through meetings both bilateral (Belgium, Switzerland, Ireland and Spain) and multilateral (Euratom and IAEA committees);
- by taking part in the working group set up by IAEA to prepare a scale for rating events concerning patients radiation protection.
- by taking part in WHO work initiated in 2008 on the radiation protection of patients ("Global Initiative on Radiation Safety in Health Care Settings");
- an international conference on radiotherapy treatment safety will be organised by ASN at the end of 2009, with the participation of IAEA, WHO and the European Commission.

6 | 2 | 4 Radiotherapy treatment security

In April 2008, ASN published the results of the inspections performed in 2007 in the radiotherapy centres, focusing on human and organisational factors. These results in particular revealed:

- that the preparation and performance of the treatment, and the corresponding responsibilities, appear to be well managed by the personnel, even though rarely contained in formally documented procedures;
- that individual post-treatment monitoring of the patients is generally well-organised;
- that there was a need to strengthen the radiation physics teams working in radiotherapy, in particular the medical radiological physicists, along with the oncology radiotherapists and medical electroradiology operators;

- that in-house inspections, in particular quality control of accelerators and checks on the preparation and performance of treatments, are indeed carried out by the centres, but in most cases are inadequately formally documented;
- that the analysis of the risks involved in radiotherapy, based on collection and analysis of undesirable events, is carried out in too few centres.

The screenshot shows the ASN website interface. At the top, the ASN logo is displayed with the text 'L'ASN assure, au nom de l'Etat, le contrôle du nucléaire pour protéger le public, les patients, les travailleurs et l'environnement. Elle informe les citoyens.' Below this is a navigation menu with links for 'Accueil', 'Plan du site', 'Lexique', 'Nous contacter', and 'Aide'. A search bar is visible on the left. The main content area features a 'COMMUNIQUÉ DE PRESSE' dated 'Paris, le 15 avril 2008'. The title of the press release is 'L'ASN dresse le bilan national de ses inspections dans les services de radiothérapie en 2007'. The text of the press release discusses the results of 180 inspections conducted in 2007 across France, highlighting areas of strength and weaknesses in radiotherapy services. It mentions that inspections were carried out by 11 territorial divisions of ASN and aimed to assess the safety of treatments, identify organizational weaknesses, and improve patient safety. Key findings include the need for better documentation of preparation and treatment steps, improved individual medical follow-up, and the necessity of strengthening physics teams and internal controls. The press release concludes by stating that the ASN report highlights a contrasted situation, with some centers having a well-advanced security culture while others need more work.

ASN presse release on the outcome of the events notified in the 3rd quarter of 2008 (www.asn.fr)

International conference on the radiation protection of radiotherapy patients

From 2 to 4 December 2009, with the support of IAEA, WHO and the European Commission, ASN is organising an international conference in Paris, on the subject of “Modern radiotherapy: advances and challenges in radiation protection of patients”.

The main objective of this conference is to present and analyse the steps taken to improve the safety of radiotherapy care, both domestically and internationally.

Presentations on specific subjects such as the treatment of complications, overexposure and individual radiation sensitivity, will be given by specialists from the fields concerned. A round-table on information of the patients and the public will also be held.

These results revealed a contrasting situation between the radiotherapy centres. There are some in which moves are being made to improve treatment safety, while in others, albeit fewer in number, there is an accumulation of organisational shortcomings which need to be addressed as a priority.

The inspections conducted in 2008

All the radiotherapy centres inspected in 2007 were revisited in 2008. ASN was thus able to follow-up the steps taken by the radiotherapy centres after the inspections made in 2007, giving priority to examining those centres in which inadequacies both in terms of human resources and organisation had been detected. On this occasion, ASN noted the positive proactive approaches supported by the French National Mission for Hospital Appraisal and Audit (MeaH), to improve treatment safety, in particular by setting up procedures to analyse the problems identified by the centres.

The conclusions of this second wave of inspections were transmitted to the Regional Hospitalisation Agencies (ARH) and forwarded to the support unit created by the French National Cancer Institute (INCa) at the request of the Minister for Health. The work done by this unit, in which ASN participated, led to the identification of nine centres for which the Minister for Health then requested immediate action to make up for the shortage of persons specialising in medical radiation physics.

For ASN, the situation in these nine centres must not however conceal the situation in other centres, where the available number of physicians and medical radiation physicists, but also the technical environment, makes it impossible for them to comply with all the regulations in force (order of 19 November 2004) and the future approval criteria published by INCa on 16 June 2008.

In 2009, ASN will focus and intensify its checks on particular topics such as the organisation of medical physics, management of the problems detected by the centres and the in-house inspection procedures.

6 | 3 The impact on the environment and the population

6 | 3 | 1 Dosimetric impact on the population

Barring special circumstances, there is no particular surveillance of the impact of medical applications on the environment and the population owing to its extremely diffuse nature. Except in the case of incidents, the potential impact could concern:

- specific 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 radiations are not fitted with the requisite protection;
- the entourage of patients who have received nuclear medicine treatment or examination involving radionuclides such as iodine 131.

The available information concerning radiological surveillance of the environment carried out by IRSN, in particular measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the background radiation variations. However, 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 microsieverts per year for the most exposed individuals, in particular the

Nuclear Safety Authority (ASN) regulatory actions in the field of radiotherapy

The inspections carried out by ASN in the medical field have included radiation protection of patients since 2005. From 2002 to 2005, ASN focused on publishing the new regulations necessary to transpose Directive 97/43/Euratom¹, while making inspection visits primarily to look at the radiation protection of the health professionals, the technical conformity of the installation with the stipulations of the licence and the radioactive source management rules.

The accidents that occurred in Épinal hospital (2004-2005) and the Rangueil hospital in Toulouse (2006-2007) as well as the other radiotherapy events of which ASN was notified after 2005, showed the importance of the role of human and organisational factors in the occurrence of incidents compounded, in certain cases, by bad practices such as a lack of supervision phases or insufficient operator training.

In this context, as in 2007, the inspection of all external radiotherapy centres, focusing on human and organisational factors, remained a top priority for ASN in 2008.

At the same time, ASN continued to strengthen the regulatory framework and enhanced information made available to the public concerning the inspections performed and the radiation protection events of which it was notified. These actions are part of the national action programme to improve the safety of radiotherapy treatment, placed under the responsibility of the Minister for Health.

The radiotherapy national measurements surveillance committee was set up on 15 December 2008. On this occasion, ASN recalled the urgent need to define interim operating criteria for the radiotherapy centres, enabling an acceptable level of safety to be attained, given the shortage of medical radiology physicists in many radiotherapy centres.

1. Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.

workers employed in the sewerage networks (IRSN 2005 study). However, no trace of these radionuclides has ever been measured in water intended for human consumption.

The recommendations that should be made by the physician after radionuclides are used in nuclear medicine were the subject of the work done by the “nuclear medicine” working group of the French High Public Health Council, in particular with respect to examinations and treatment using iodine 131. The aim was to harmonise the advice and lifestyle hints already dispensed by each physician. The work done was based on European recommendations but also on simulations and measurements taken in real-life situations. 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 administered if the patient receives iodine 131 without hospitalisation (examination or treatment of hyperthyroidism).

For protection of members of the public, the recommendations will be relatively undemanding, with the exception of particular situations (flights lasting longer than 7 hours, close working contact in particular with pregnant women

or children). For protection of family members, the recommendations made concern the partner and children under 10 years of age. The harmonised advice for everyday life, established according to the activity levels administered, will concern the length of time off work and the length of restrictions on contact between spouses and with children.

6 | 3 | 2 Significant events

In 2008, ASN was notified of three significant events involving the loss of a radioactive source. These concerned losses of iodine sources used in brachytherapy and nuclear medicine.

ASN was also notified of an event involving the discovery of sources. This concerned the discovery of five packages containing scintigraphy products (technetium) left by the roadside, following the theft of a transport lorry.

Finally, ASN was notified of five events involving the dispersion of radionuclides. Three of these cases concerned the dispersion of radioactive effluents from nuclear medicine units within the premises of the establishment.

7 OUTLOOK

With a cure rate of about 80% of patients treated, radiotherapy is a fully justified method for cancer treatment. However, in the light of the organisational weaknesses detected during inspections in certain radiotherapy centres, ASN, through its regional divisions, will in 2009 be maintaining its presence in the radiotherapy centres: particularly close attention will be given to increasing the numbers of medical radiological physicists announced by the Minister for Health and the gradual development of quality assurance, for which initial measures will become binding as of early 2010.

Domestically, along with the other stakeholders taking part in the radiotherapy national measurements surveillance committee, ASN is ready to help define interim operating criteria for the radiotherapy centres, enabling them to achieve an acceptable level of safety, given the shortage of medical radiological physicists in many of the radiotherapy centres. An appropriate legal framework, incorporating these interim criteria, needs to be defined

under the responsibility of the Minister for Health, given that a period of transition is inevitable before the numbers of radiological physicists and dosimetrists reach a satisfactory level.

In the radiology sector, based on recommendations from the new Advisory Committee for radiation protection in the medical sector, ASN will be updating the diagnostic reference levels, concentrating in particular on optimising the doses delivered in computed tomography and, together with the health agencies and the health professionals, will draw up a programme of actions to reduce exposure to ionising radiations for patients and personnel involved in interventional radiology practices.

Finally, after publication of the radiotherapy inspection follow-up letters on www.asn.fr in July 2008, ASN will pursue its goal of publishing all the follow-up letters concerning the radiation protection inspections conducted in the medical sector.