AUTORITÉ DE SÛRETÉ NUCLÉAIRE

ASN GUIDES

Guide 32

ALL FIELDS

In vivo nuclear medicine facilities: minimum technical design, operating and maintenance rules

Revised version of 10/02/2020

Preamble

The ASN collection of guides is intended for professionals concerned by the nuclear safety and radiation protection regulations (licensees, users or transporters of ionising radiation sources, general public, etc.).

The guides set out recommendations with the aim of:

- explaining the regulations and the rights and obligations of the persons concerned by the regulations;
- explaining the regulatory objectives and, as applicable, describing the practices considered by ASN to be satisfactory;
- giving practical tips and information concerning nuclear safety and radiation protection.

Application of these guides does not in any way reduce the responsibility of a Basic Nuclear Installation licensee with regard to the safety of its installation.

ASN Guide no. 32 was revised on 10 Februrary 2020.

Contents

1. INTRODUCTION

1.1. Regulatory context

The development of technologies, the use of new radionuclides and the graded approach to the risks of exposure to ionising radiation have led ASN to update the Order of 30 October 1981 on the conditions of use of artificial radionuclides in unsealed sources for medical purposes.

ASN Resolution 2014-DC-0463 of 23 October 2014 on the design, operating and maintenance rules applicable to in vivo nuclear medicine facilities, established in application of paragraph 5° of Article R. 1333-145 of the Public Health Code (CSP), approved on 16 January 2015 and published in the Official Journal of the French Republic on 27 January 2015, replaces the abovementioned Order of 30 October 1981, with the exception of the provisions of Articles 10 and 11 (reiterated below), whose application remains mandatory:

- the first two paragraphs of Article 10 relative to the particular conditions for in vivo facilities (while keeping the maximum dose equivalent rate of 25 µSv/h at 5 cm from the walls of the protective storage enclosure);
- Article 11 relative to in vitro nuclear medicine facilities.

This regulation was updated on the basis of a prior expert assessment report[1] and an opinion of the GPMED of 26 June 2012[2], which are accessible on the ASN website via the following link: ***http://www.asn.fr/Reglementer/Consultations-du-public/Archives-des-consultations-du-public/Conception-exploitation-et-maintenance-en-medecine-nucleaire-in-vivo***

The resolution underwent a consultation with the stakeholders (health authorities, learned societies, professional associations and hospital federations) during 2013, and with the public, on the ASN website.

The provisions of this resolution complement the general provisions of the Public Health Code as regards protection of the public and by the Labour Code as regards protection of workers, and more specifically:

- Decree 2018-434 of 4 June 2018 introducing various provisions with regard to nuclear activities;
- Decree 2018-436 of 4 June 2018 on the simplification of the maintenance and quality control procedures for certain medical devices;
- Decree 2018-437 of 4 June 2018 on the protection of workers against the risks due to ionising radiation;
- Decree 2018-438 of 4 June 2018 on the protection of workers against the risks due to ionising radiation to which certain workers are exposed;

[1] *Report of the Working Group "Fitting out in vivo nuclear medicine facilities " – January 2012. "Recommendations on the minimum technical design, operating and maintenance rules applicable to in vivo nuclear medicine facilities"*

[2] *Opinion of the Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED) concerning the orientations adopted in the working group report. 26 June 2012*

Other specific provisions called out by the texts mentioned below are also to be considered in the design and operation of these facilities:

- the Order of 15 May 2006 on the conditions of delineation and signalling of monitored and controlled areas and specially regulated or prohibited areas in view of the exposure to ionising radiation and the health, safety and maintenance rules imposed in them, amended by the order of 28 January 2020 on the conditions of delineation and signalling of monitored and controlled areas and specially regulated or prohibited areas in view of the exposure to ionising radiation and the health, safety and maintenance rules imposed in them;
- ASN Technical Resolution 2008-DC-0095 of 29 January 2008 on the technical rules applicable to the disposal of effluents and wastes contaminated by radionuclides, setting the requirements regarding the design of premises intended for the storage of waste and contaminated effluents, and for the transport of contaminated effluents;
- ASN Guide No. 18 on the disposal of effluents and waste contaminated by radionuclides, produced in facilities licensed under the Public Health Code (version of 26 January 2012);
- ASN resolution 2010-DC-0175 of 4 February 2010, specifying the technical conditions and frequencies of the inspections provided for in Articles R. 4452-12 and R. 4452-13 of the Labour Code (currently R. 4451-40, -41, 42, 44, 45 and -46, -47 and 48) and the Articles R. 1333-7 (currently R.1333-15) and R. 1333-95 (currently R. 1333-172) of the Public Health Code (amendment of this resolution to be issued on the technical verifications);
- ASN Resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules applicable to premises in which X-ray emitting devices are used, approved by Order of 29 September 2017, repealing ASN Resolution 2013-DC-0349 of 4 June 2013 setting the minimum technical design rules applicable to facilities in which X-rays produced by devices functioning at high voltage of less than or equal to 600 kV are present, approved by the Order of 22 August 2013;
- the Order of 8 February 2019 approving ASN Resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance obligations for medical imaging using ionising radiation;
- the Order of 26 June 2019 on the personal monitoring of worker exposure to ionising radiation.

This resolution does not apply to radioimmunoassay laboratories, but it does apply to centres conducting human subject research (HSR), even if it does not involve diagnostic procedures in the strict sense. For these research protocols, the radiation protection measures to be implemented for patients or workers are the same as those for a nuclear medicine service treating patients using procedures for diagnostic or therapeutic purposes.

1.2. Subject of document

Following the approval of ASN Resolution 2014-DC-0463 of 23 October 2014 setting the minimum technical design, operating and maintenance rules for in vivo nuclear medicine facilities, by the Order of 16 January 2015, this document aims to present in detail the articles of the abovementioned Resolution and this revision provides the opportunity to gives some details further to operating experience feedback and the IRSN referrals on different points.

The ASN services, at both central and regional division level, are there to provide the professionals concerned with any additional information.

1.3. Scope of application

This document concerns in vivo nuclear medicine and procedures carried out in the context of human subject research. This document is intended for employers, heads of nuclear activities, all professionals involved in nuclear medicine, particularly nuclear medicine physicians and other specialist physicians using radioactive sources occasionally, radiopharmacists, radiographers, hospital pharmacy dispensers, radiation protection advisers /radiation protection expert-officers in this area and any other person involved in the design of a nuclear medicine department (architect, etc.).

1.4. Document status

This document details the articles of the resolution.

For the purpose of the transposition of directive EURATOM 2013/59 relative to the basic radiation protection standards, amendments have been made to the Labour Code and the Public Health Code. Although these amendments do not call into question the abovementioned Resolution 0463, the references to the "L." and "R." articles of the Labour Code and the Public Health Code are updated in this version of the guide.

Furthermore, since Resolution 2014-DC-0463 came into effect, questions concerning its application have arisen, leading ASN, after obtaining the opinion of IRSN[3], to make position statements on various issues:

- the possibility, under certain conditions, of using the cell labelling room for other purposes than those for which it is supposed to be dedicated (for example, installation of a radiation-proof enclosure for certain occasional preparation operations);
- the possibility of sharing the ventilation ducts of several radiation-proof enclosures;
- the possibility of acquiring and using an independent unit for preparing and injecting doses of RPDs radiolabelled with fluorine-18 for PET examinations, without having a high-energy chamber in the service.

Alongside this, point 10 of Article 3 of Resolution 2014-DC-0463 concerning premises intended for contaminated effluents, has been supplemented with the findings of an ASN working group on the "Discharging of effluents containing radionuclides from nuclear medicine departments and research laboratories into the sewage networks" (the GTDE), with the proposed recommendations[4] and the provision by IRSN of a tool baptised "CIDRRE", a French acronym for "Calculating the impact of radioactive discharges in wastewater networks". CIDRRE provides a conservative estimate, for a series of radionuclides used in nuclear medicine, of the impact of radioactive discharges on the sewage network personnel and on workers involved in the removal and spreading of wastewater treatment sludges.

[3] https://www.irsn.fr/FR/expertise/avis/2019/Documents/avril/Avis-IRSN-2019-00073.pdf ***and*** https://www.irsn.fr/FR/expertise/avis/2019/Documents/mai/Avis-IRSN-2019-00117.pdf

[4] https://www.asn.fr/Informer/Actualites/Quinze-recommandations-sur-le-deversement-d-eaux-usees-faiblement-contaminees

2. BREAKDOWN OF THE RESOLUTION

The resolution is organised into several sections:

- the general principles (articles 1, 2, 3 and 4),
- the design rules:
  - the general principles (Articles 5, 6 and 7),
  - the general rules for the design of the premises (Articles 8, 9, 10, 11 and 12) and the equipment (Articles 13, 14 and 15),
  - the rules relative to the ventilation of the premises (Articles 16, 17 and 18),
- the general operating rules (Articles 19 and 20) and particular operating rules (21, 22 and 23),
- the miscellaneous and transient provisions (Article 24 – application time frames),
- an appendix containing definitions.

Resolution 0463 places the emphasis on the obligation to take into account the prevention of risks in the work place and the protection of workers against ionising radiation hazards as early as possible in the design (specifications preparation phase) or modification of the premises (Article 3), and throughout their operation. Article 4 reasserts the general principles of prevention, particularly for workers, and of optimising patient exposure, and applies these two principles by setting the requirements concerning the circulation routes of persons (workers and patients) and radionuclides (Art. 5).

The resolution nevertheless carries over several existing provisions:

- the regulatory provisions relative to the materials used in the nuclear medicine sector (Article 7) and the room dedicated to the handling of radionuclides (Article 9) which figured in the abovementioned Order of 30 October 1981;
- recommendations figuring in Circular Letter DGSNR/SD9/0921 of 5 August 2005 on the reminder of the regulations applicable to the holding and use of radionuclides in nuclear medicine, addressed to all the nuclear medicine departments, and notably the regulations concerning the layout of the rooms (Article 5), washbasins (Article 14), ventilation (Articles 16 and 17) and the use of transport equipment (Article 23). This resolution does not apply to *in vitro* diagnostic nuclear medicine. Only Article 11 of the Order of 31 October 1981 remains applicable. It contains in particular a requirement for the ventilation of the rooms which must allow at least 5 air renewals per hour.

The in vivo nuclear medicine facility is defined in the resolution appendix. It comprises the nuclear medicine sector defined in Article 3 of the Resolution (see below), and the rooms situated in non-regulated work areas as defined in the Labour Code, such as the reception desk, the secretariat, the waiting room for patients who are to be administered radionuclides, the offices (physicians, managerial staff, etc.) and the rooms situated outside the in vivo nuclear medicine sector used for the administration of radionuclides.

The full text of the resolution is reproduced below in the boxes. An explanation is provided below each article or group of articles.

Decrees, Orders, Circulars

GENERAL TEXTS

MINISTRY OF SOCIAL AFFAIRS, HEALTH AND WOMEN'S RIGHTS

Order of 16 January 2015 approving ASN Resolution 2014-DC-0463 of 23 October 2014 on the minimum technical design, operating and maintenance rules applicable to in vivo nuclear medicine facilities

NOR: AFSP1425839A

The Minister of Ecology, Sustainable Development and Energy, the Minister of Social Affairs, Health and Women's Rights, and the Minister of Labour, Employment, Vocational Training and Social Dialogue,

Having regard to the Environment Code, more specifically its Article L. 592-19;
Having regard to the Public Health Code, and more specifically its article R. 1333-43;
Having regard to the order of 30th October 1981 concerning the conditions of use of artificial radionuclides used in unsealed sources for medical purposes,

Order as follows:
Article 1– ASN Resolution 2014-DC-0463 of 23 October 2014 on the minimum technical design, operating and maintenance rules applicable to in vivo nuclear medicine facilities, in application of Article R. 1333-43 of the Public Health Code, appended to this Order, is approved.
Article 2– Articles 1 to 7 and 10 starting from its third paragraph, of the abovementioned Order of 30 October 1981 are repealed as from 1 July 2015.
Article 3 - The Director General for the Prevention of Risks and the Director General for Labour are responsible, each within their own field, for executing this Order, which will be published in the Official Journal of the French Republic.

Done on 16 January 2015.

Minister of Ecology, Sustainable Development and Energy For the Minister and by delegation: General Director for Risk Prevention P. BLANC	The Minister of Labour, Employment, Vocational Training and Social Dialogue, For and on behalf of the Minister: The Director General for Labour Y. STRUILLOU	The Minister of Social Affairs, Health and Women's Rights For the Minister and by delegation: General Director for Risk Prevention

APPENDIX

ASN RESOLUTION 2014-DC-0463 OF 23 OCTOBER ON THE MINIMUM TECHNICAL DESIGN, OPERATING AND MAINTENANCE RULES APPLICABLE TO IN VIVO NUCLEAR MEDICINE FACILITIES

ASN (Autorité de sûreté nucléaire), the French nuclear safety authority,

Having regard to the Environment Code, more specifically its Article L. 592-19;

Having regard to the Public Health Code, more specifically its Article R. 1333-43, its Articles L. 5126-1 to L. 5126-14 and R. 5126-1 to R. 5126-47;

Having regard to the order of 30 October 1981 on the conditions of use of artificial radionuclides used in unsealed sources for medical purposes,

Having regard to ASN Resolution 2008-DC-0095 of 29 January 2008 setting the minimum technical rules applicable for the disposal of effluents and wastes which are or could be contaminated by radionuclides due to a nuclear activity, taken in application of the provisions of Article R. 1333-12 of the Public Health Code;

Having regard to the results of the public consultation organised from 3 July 2013 to 2 September 2013;

Whereas the requirements of the Order of 30 October 1981 on the conditions of use of artificial radionuclides in unsealed sources for medical purposes must be updated to integrate technological developments and the use of new radionuclides;

Whereas the principle of optimisation defined in Article L. 1333-1 of the Public Health Code must be taken into account in the design of the facilities and during their operation in order to contribute to the protection any person who might have to stay in a nuclear medicine facility for any reason whatsoever;

Whereas the design rules for nuclear medicine facilities for the purposes of this resolution apply without prejudice to the rules on the design of the work rooms and their use set by the Labour Code, more particularly as regards the locker rooms and the rooms dedicated to the control panels of the devices emitting ionising radiation;

Whereas the results of the most recent studies, conducted to assess the risk of atmospheric contamination of the in vivo nuclear medicine facilities, call for new provisions with regard to the ventilation of the rooms;

Whereas this resolution applies in particular to the rooms of medical dispensaries located in in vivo nuclear medicine facilities, stipulated in Article L. 5126-7 [currently L. 5126-4] of the Public Health Code,

Hereby issues the following resolution:

3. TITLE I. GENERAL PRINCIPLES

Article 1

This Resolution sets the minimum technical, design, operating and maintenance rules applicable to in vivo nuclear medicine facilities, including in their biomedical research aspects.

Article 2

For the application of this Resolution, the terms marked with an asterisk are defined in the appendix.

Article 1 (**general information**)

Articles 1 and 2 define respectively the scope of application of the resolution and some of the terms used.

- The term "nuclear medicine facility" means the "rooms comprising the nuclear medicine sector, the rooms situated in non-regulated work areas as defined in the Labour Codes, such as the reception desk, the secretariat, the waiting room for patients who are to be administered radionuclides, the offices (physicians, managerial staff, etc.) and the rooms situated outside the in vivo nuclear medicine sector used for the administration of radiopharmaceutical drugs." (7th definition in the appendix).
- The term "nuclear medicine sector" means the "rooms intended for the holding and use of sealed and unsealed sources and devices producing X-rays for an in vivo nuclear medicine activity including diagnosis, therapy, cell labelling and human subject research, and excluding in vitro diagnosis. "The rooms concerned by this sector are detailed in Article 3.

Although not mentioned in the nuclear medicine sector, the premises dedicated to camera control panels (whether or not coupled to an X-ray emitting device) form part of the nuclear medicine sector. Reminder: independently of this resolution, ASN Resolution 2017-DC-0591 of 17 June 2017 applies to this room in the case of a single photon emitting computed tomography (SPECT) camera (including cadmium zinc telluride (CZT) detectors) or a positron emission tomography (PET) camera coupled with a CT scanner.

Biomedical research means human subject research as defined by Article L. 1121-1 of the Public Health Code [Act 2012-300 of 5 March 2012, amended by Ordinance 2016-800 of 16 June 2016 on human subject research, called the Jardé Act] even it these are not diagnostic or therapeutic procedures. Category 1 research is concerned here.

Article 3

Fitting out the in vivo nuclear medicine sector

The in vivo nuclear medicine sector comprises, to different extents, at least:

1° One or more rooms dedicated to the delivery and recovery of radionuclide generators containing a parent radionuclide;

2° One room dedicated to the handling* of radionuclides;

3° One room dedicated to the verification of radiopharmaceutical drugs, if applicable;

4° One room dedicated to cell labelling, if applicable;

5° One or more rooms dedicated to the administering of radionuclides*;

6° One or more rooms dedicated to the examinations performed after administering radionuclides to patients;

7° One or more rooms dedicated exclusively to patients waiting after having been administered radionuclides;

8° A toilet room dedicated to patients to whom radionuclides have been administered;

9° One or more rooms used for the storage of solid contaminated waste;

10° One or more rooms dedicated to the storage of radioactive effluents;

11° Internal targeted radiotherapy* rooms, if applicable.

This article lists the rooms of the in vivo nuclear medicine sector in which radionuclides (sealed and unsealed radioactive sources) are received or handled, and in which circulate patients to whom radiopharmaceutical drugs have been administered, and the rooms accommodating devices emitting ionising radiation (computed tomography (CT) scanner coupled with a camera for single proton emission computer tomography (SPECT), a semiconductor (CZT) camera or a positron emitting tomography (PET) scanner).

Pursuant to Article R. 4214-22 of the Labour Code, they are designed to enable the workers to carry out their tasks without risking their health, safety or well-being. A free space, within the workstation or in immediate proximity to it, must give the workers sufficient freedom of movement.

The term in vivo nuclear medicine sector means all the rooms mentioned, which form a whole, with the exception of:

- the internal targeted radiotherapy (ITR) rooms, which are most often situated in a hospitalisation unit;
- the room(s) dedicated to the storage of radioactive effluents, which are must often situated on a lower floor than the nuclear medicine sector or at a distance from this sector.

This implies in particular that the room dedicated to the manipulation of radionuclides (point 2°), whether it is within a nuclear pharmacy or not (see definition below), should be located within the nuclear medicine facility in order to meet the need to optimise the circuit for issuing radiopharmaceutical drugs and routing them to the points of administration to patients, by keeping it as short as possible.
It is possible to have several in vivo nuclear medicine sectors within a given medical centre: in this case each sector has the rooms mentioned in 1° to 9° of this article.

Details are given below for the following rooms:

- The room dedicated to the handling of radionuclides (point 2 of Article 3)

The term "room" means the room in which one or more items of equipment is (are) installed for preparing radiopharmaceutical drugs and preparing the doses to be administered to the patients.
In healthcare centres that have a medical dispensary authorised by the Regional Health Agency (ARS), all the steps of the radiopharmaceutical drug circuit (Article L. 5126-5 of the Public Health Code) and all the actions carried out within the RPD preparation room (or "nuclear pharmacy") are placed under the responsibility of a radiopharmacist.
Further details on the use of this room are provided in the explanatory paragraph of Article 9.

- The room dedicated to the verification of radiopharmaceutical drugs, if applicable (point 3 of Article 3);

Verifications must be carried out on the radiopharmaceutical drugs in accordance with the pharmaceutical baselines in all the facilities, in conformity with the summaries of the product characteristics (enforceable). The Good Preparation Practices (GPP) set by decision of the ANSM (formerly AFSSAPS) of 5 November 2007 applicable to medical centres that have a medical dispensary require that a room be dedicated to verification. In medical centres that do not have a medical dispensary, it is also recommended that these verifications be carried out in a dedicated room. These verifications must be carried out in a dedicated room. This is because it is not advisable to perform these verifications in the same room as the preparations (ambient radioactivity that could disturb the verifications and their interpretation, environmental class of the preparation room more difficult to achieve).

- The room dedicated to cell labelling [radioisotopic], if applicable (point 4 of Article 3)

The term "if applicable" means that this room must be set up if this labelling activity exists.
Details are provided in the paragraph concerning Article 11 taken up later on in this document (subject of the referral to IRSN).

- One or more rooms dedicated to the examinations performed after administering radionuclides [RPDs] to patients (point 6. of Article 3)

The dedicated rooms mentioned are the rooms equipped with a SPECT gamma, including the CZT cameras, or a PET scanner.
When these cameras are equipped with a CT scanner, the rooms accommodating them must also be in conformity with the abovementioned ASN Resolution 2017-DC-0591. This resolution is applicable to workplaces in which at least one device emitting X-rays is used, whether mobile or not, and is used permanently or frequently in the same room;

- One or more rooms used for the storage of solid contaminated waste (point 9 of Article 3)

One or more rooms used for the storage of contaminated solid waste must be installed within the medical centre. It is tolerated, depending on the organisation defined by the nuclear medicine department and approved by ASN during examination of the licence application file, for the service not to have a room reserved for solid waste on condition that:

- the waste is maintained in a shielded waste bin for 24 hours;
- the waste is removed the following day before the start of the activity, after checking the contact dose set to permit removal of the waste.
- One or more rooms dedicated to the storage of radioactive effluents (point 10 of Article 3);

Information on the contaminated effluents [and the storage rooms]:

The 15 recommendations of the final report[5] of the Working Group "Discharging into the sewage networks of effluents containing radionuclides from nuclear medicine departments and research laboratories" (GTDE) have been published with the main objectives of:

- allowing the updating of the contaminated effluents discharge licenses provided for in Article L. 1331-10 of the Public Health code and issued by the authorities responsible for managing the collective public sewage network;
- supplementing the waste and effluent management plans of nuclear medicine departments and research laboratories that use unsealed radioactive sources mentioned in Article R. 1333-16 of this code.

Their implementation will allow a better estimate of the impact of the discharges by considering:

- the radioactive sources held and used by the nuclear medicine departments or research laboratories;
- the conditions of management and disposal of these effluents in the centres in which these activities are exercised;
- the theoretical modes of exposure of the professionals involved in maintenance work on the sewage network structures and in the operation of urban wastewater treatment plants.

All this information can be usefully transmitted by the centre to the authority examining the discharge license. The impact can be estimated where necessary as an initial approach based on the CIDRRE methodology and digital tool developed by IRSN and also accessible on its website. ***https://cidrre.irsn.fr/***

With the publication of this report, ASN asks the nuclear medicine departments and research laboratories to update their waste and effluents management plan in accordance with the recommendations of the working group. It points out that the management plan must include the procedures for monitoring the discharged effluents in accordance with Article R. 1333-16 of the Public Health Code and ASN resolution 2008-DC-0095 of 29 January 2008 (mentioned as a reference at the beginning of this guide).

Furthermore, details are provided for the following premises which are not mentioned in ASN Resolution 2014-DC-0463:

- Locker rooms and showers.

The locker rooms of the nuclear medicine facility and the shower are no longer mentioned in the Resolution whereas they were mentioned in the Order of 1981. This is because the general provisions applicable to them are set in the general provisions of the Labour Code (Articles R. 4228-1 to 9).

Considering the showers of the internal targeted radiotherapy rooms, the head of activity is responsible for checking that the conditions of use of these rooms meet the regulatory requirements concerning the discharge of contaminated liquid effluents (see Article 5 of the Resolution 2008-DC-0095: In the case of discharges into a sewage network, the discharge conditions are set by the license specified in Article L. 1331-10 of the Public Health Code.

- The reception desk, the secretariat, the waiting room for patients waiting to be administered RPDs, the offices (physicians, managerial staff, etc.).

These rooms are not considered to be part of the rooms of the "nuclear medicine sector", which is a regulated area

[5] https://www.asn.fr/Informer/Actualites/Quinze-recommandations-sur-le-deversement-d-eaux-usees-faiblement-contaminees ***et*** https://cidrre.irsn.fr/

Other available information:
The INRS publications mentioned below can be a useful aid to the employer or project manager in the design or fitting out of the work rooms:
INRS Sheet FR3 – Applicable legislation - Reminder of the legislation concerning radiation protection in the medical field, September 2011
INRS Sheet FR5: Nuclear medicine. In vivo diagnosis excluding PET, December 2011
INRS Sheet FR6: Nuclear medicine. In vivo diagnosis by PET-CT or PET imaging with fluorine-18 and other positron emitters, March 2012
INRS Sheet FR8: Therapeutic nuclear medicine (internal targeted radiotherapy), September 2012
INRS folder: http://www.inrs.fr/risques/rayonnements-ionisants/ce-qu-il-faut-retenir.html

Article 4

Design and operational provisions

The nuclear medicine facilities indicated in Article 1 are designed, operated and maintained in compliance with the principles set out in Article L. 1333-1 of the Public Health Code - particularly the optimisation principle - which must be taken into account in the architectural and technical choices.

Article L. 1333-1 applies to the risks of persons being exposed to ionising radiation. The term "persons" includes the medical professionals. The design or fitting out of a nuclear medicine facility provides the ideal opportunity to apply the general principles of prevention set out in the Labour Code. In effect, the working, environment and safety conditions, and the work organisation are largely dependent on the way in which the buildings and rooms for accommodating the personnel are designed and built. Errors in design or fitting out can have an impact on the exposure of medical staff, patients or the public to ionising radiation.

The general radiation protection principles must be taken into account from the facilities design stage, particularly the ALARA ("As Low As Reasonably Achievable") principle, in order to limit the exposure of workers, patients and the public.
The informing and awareness-raising of the main project players, and the project managers and project owners in particular, must enable these principles to be taken into account.

4. TITLE II. DESIGN RULES

4.1. CHAPTER I. General design rules for the rooms and equipment

Section 1. General principles

Article 5

Layout of the rooms

The rooms of the in vivo nuclear medicine sector are designed and built such that:

1° The rooms mentioned in 1° to 9° of Article 3 are made up of a single block*;

2° The circulation areas are reserved for the persons involved in the activities of this sector;

3° The distribution of the rooms takes into account the risk of exposure of persons;

4° The circuit of patients to whom radionuclides have been administered and the radionuclides circuit are identified and defined such that the exposure to ionising radiation of any person who could be in this circuit is as low as reasonably achievable.

This article obliges the rooms of the in vivo nuclear medicine sector to constitute an individualised entity that is not crossed by circulation areas accessible to the public and to workers not concerned by this sector.

Without prejudice to the obligations set by the Labour Code, this layout must allow the optimisation of exposure to ionising radiation (patients, workers, public, environment).

In view of the radiation protection risks, the organisation of the rooms must take into account:

- the risks of exposure to ionising radiation of the various groups of people concerned;
- the planned activities (manipulation of unsealed radioactive sources, administering to patients, etc.) and the functional links between the activities;
- the movements of materials (unsealed radioactive sources, radioactive waste, etc.);
- the circulation of people (workers and patients).

The INRS publications (web folder "design of work places and situations" - ED 950 of September 2011 – and associated brochures relative, for example, to the circulation of persons) can be a useful guide for the employer or project owner, in the procedures for designing or fitting out work rooms (http://www.inrs.fr).

Article 6

The constraints in adjoining rooms

The rooms adjacent to the rooms of the in vivo nuclear medicine sector as defined in Article 3 are designed and built so that the exposure of persons to ionising radiation is as low as reasonably achievable.

This provision applies without prejudice to those set specifically in Article 5 of the "Zoning" Order of 15 May 2006 taken in application of Article R. 4451-27 (recodified in Article R. 4451-34 of the Labour Code by Decree 2018-437 of 4 June 2018) of the Labour Code which states that: "The head of the entity verifies in the buildings,

rooms or areas adjacent to the monitored or controlled areas, that the effective dose that could be received by a worker remains below 0.080 mSv/month".

Further to the publication of Decree 2018-437 of 4 June 2018 on the protection of workers against the risks due to ionising radiation, the "Zoning" Order of 15 May 2006 has been amended by the referenced Order of 28 January 2020.

Article 7

The materials used in the in vivo nuclear medicine sector

The materials used for the floors, walls, work surfaces and furniture of the in vivo nuclear medicine sector shall have no rough areas and shall be covered with an impermeable and smooth coating that allows decontamination.

Given the risk of contamination associated with the types of sources manipulated, such as splashes or breaking of a bottle or a syringe containing a radionuclide, all the surfaces of the nuclear medicine rooms must allow for optimal decontamination. The materials used must therefore form impermeable and smooth surfaces with no rough areas.

The following already existing provisions meet the aim of this article:

- the edges and connecting angles are rounded;
- the floor coverings rise up to form a skirting at the walls to prevent infiltrations of liquid or contamination under the floor, without joints or with bonded/welded joints. It withstands the weight of the devices and chemical cleaning products;
- the work surfaces are made with materials featuring continuous sills to retain liquids, without joints or with bonded/welded joints;
- all the cabinets and furniture in which radionuclides could be stored have a washable surface that is resistant to the chemical cleaning products.

Section 2. Rooms

Article 8

Delivery room

The room dedicated to the delivery and recovery of radionuclide generators containing a parent radionuclide is situated as close as possible to the room dedicated to the handling of radionuclides. This dedicated room is a closed room with secured access.

The dimensions and layout of this room, particularly its surface area and ceiling height, are such that they allow the delivery, recovery and safe storage of radionuclides.

This room is intended for the delivery of radionuclides, the recovery of the different types of radionuclide generators, and the handling of fluorine-18 transport packages if necessary.

Its location next to the room dedicated to the handling of radionuclides enables the movements of the radioactive sources to be circumscribed, and the movements and exposure to ionising radiation of any person who could be in the circuit of these sources in accordance with the provisions stipulated in the abovementioned article 5.

By a closed room we mean a uniformly closed room (a room closed by wire meshing is not suitable) and by secured access we mean an access point opened using a key, a code, etc.

The fitting out and characteristics of the room ensure the security of the sources during the delivery and recovery operations and prevent any risk of malicious acts or intrusion.
The dimensioning and fitting out of this room must be considered carefully taking into account the radiation protection of the workers who will be using it. They must have sufficient working space to carry out their tasks.

In practice, the departments send back the technetium-99m generators to the supplier, usually after a decay time allowing them to be transported in excepted packages (which implies a contact dose rate on the external surface of the package of less than 0.005 mSv/h).

It is tolerated for nuclear medicine departments that only perform PET scan examinations not to have a delivery room if the pot of fluorine-18 is delivered directly to the laboratory during opening hours. This point is studied when examining the licence application file.

Article 9

The room dedicated to the handling of radionuclides

The room dedicated to the handling of radionuclides is equipped with at least one radiation-proof enclosure ventilated at negative pressure to prevent the dispersion of contamination outside the enclosure and the room.

This enclosure is appropriate for the nature of the ionising radiation emitted by the radionuclides used and the activity level held. It is provided with extracted air filtration devices appropriate for the types of gases or aerosols that are or could be present in the enclosure.

Recycling of the air extracted from the radiation-proof enclosure is prohibited and the ventilation network of the enclosure is independent of that of the rooms.

Dedicating a room to the handling of radionuclides (or the preparation of RPDs), facilitates the containment intended to protect workers from the risk of exposure and the environment from the dissemination of contamination.

Containment is ensured by the radiation-proof enclosure which is ventilated and at negative pressure; there is no negative pressure requirement for this room. To ensure this containment, gloves must be fixed on the supports provided on the enclosure for this purpose; their sealing is checked and they are replaced in the event of a defect.

The requirement to limit the dose equivalent rate $\dot{H}^*(10)$ to 25 µSv/h at 5 cm from the walls of the protective storage enclosures for the different sources is maintained by the first two paragraphs of Article 10 of the Order of 30 October 1981 which remains in effect.

It is possible to use automated systems for filling syringes and injection, particularly for the handling of fluoride-18. The mobile devices that can carry out these steps are not considered to be radiation-proof enclosures as defined in the appendix of the resolution. Consequently, the ventilation requirements applicable to the radiation-proof enclosures do not apply to these mobile devices.

- Ventilation of radiation-proof enclosures (sharing ventilation systems)

It is possible to have several radiation-proof enclosures connected to the same ventilation system, on condition that:

- the system design guarantees the independence of the air extraction systems of the enclosures on the one hand and the rooms on the other, as required by ASN Resolution 2014-DC-0463;
- sharing in this way makes it possible limit the number of liquid and gaseous effluent discharge points, as provided for in Article 24 of Resolution 2008-DC-0095;
- measures are implemented to prevent the reflux of contaminated effluents within a network of extraction ducts connected to a single conduit, such as the installation of non-return valves as proposed in ASN Guide No. 18.

- PET scan examinations and independent dose preparation and injection units

Since ASN Resolution 2014-DC-0463 on nuclear medicine facilities was published, technologies have evolved, particularly for the performance of positron emitting tomography (PET) scan examinations. The technological changes in PET-CT examinations, through the reduction in acquisition times, has led to an increase in the number of daily examinations. It is thus perfectly common to perform some twenty PET scan examinations per day on one machine, or even more than thirty on some sites. The activity of the multiple-dose vials delivered has increased accordingly, regularly exceeding 10 GBq with 18-FDG. The handling of such activities implies putting in place radiation protection measures, and has led to the automation of radionuclide handling operations.

Independent units for the preparation and injection of radiopharmaceutical drugs without prior filling of syringes bring real benefits in reducing the exposure of the extremities of workers. As the only remaining source handling operations are the loading of the devices with a multiple-dose vial and the management (removal, placing in waste) of the injection kits after use, they allow a greater reduction in dose at the extremities than the dose fractionation enclosures, whether combined with injection systems or not. Furthermore, the use of a mobile injector limits the handling and transporting of heavy loads by the radiographers and therefore limits the associated risks. Nevertheless, for some devices the vial has to transferred from its shielded transport pot to a shielded vial holder appropriate for the controller.

As a result of the developments mentioned above, ASN has had to take into consideration two new situations:

- a department that has both a single-photon scintigraphy activity and a PET scan activity, wishing to acquire an independent injection unit for the PET scanner and a medium-energy shielded enclosure for the other preparations, but without a high-energy shielded enclosure,
- an entity performing only PET scan examinations and wishing to have an independent preparation and injection unit and completely dispensing with a radiation-proof handling enclosure, or even a room dedicated to the handling of radionuclides.

Following the opinion of IRSN, ASN considers that the use of independent preparation and injection units is possible if, should the unit be unavailable, the department opts for one of the following solutions:

- stop the positron emission tomography activity for the time necessary to solve the problem;
- have and use another independent preparation and injection unit;
- use a fixed-station fractionating unit (high-energy enclosure) and its associated injection mode;
- prepare the syringes manually in the high-energy enclosure and manually inject the radiopharmaceutical drug into the patient. This solution implies not only having appropriate radiation protection for the preparation of the doses to administer and routing the syringes to the injection unis, but also that the medical personnel performing these tasks have the skills to carry them out (training in and maintaining of the "manual" skills). It would also necessitate the delivery of vials containing a smaller quantity of radioactivity in order to reduce the exposure of the personnel during the preparation operations. Rather than using a low/medium-energy preparation enclosure, these degraded conditions mentioned in point d. can be justified:
  - in the light of the comparison of the results of the dose equivalent rate measurements with a vial of 18F-FDG in the high-energy handling enclosures, which are lower than in the low/medium-energy enclosures,
  - for reasons of radiation protection linked to the lower shielding performance of the low/medium-energy enclosures,
  - for reasons of the resulting transportation of syringes between geographically separated preparation sites and administration sites,
  - for reasons of securing the radiopharmaceutical drug circuit linked to the daily use of the low/medium-energy enclosure for numerous preparations of RPDs containing technetium (scintigraphy activities),
  - due to the necessity to calibrate the enclosure activity meter for the measurement of positron emitting radionuclides, in all the geometries for the planned uses, in addition to the calibrations for beta-emitting radionuclides. This could increase the risk of errors in the preparation of the doses to administer.

Nevertheless, on an exceptional basis, ASN could tolerate the preparation of syringes of fluorine-18 in low/medium-energy enclosures under the following conditions:

- inform ASN of the application of syringe preparation conditions for PET scan examinations in degraded mode,
- describe the work organisation put in place jointly with the daily scintigraphy activities (schedule, number of patients, etc.),
- limit the duration of work under these conditions to one or two days at the most in order to treat the patients present or called for appointments on these 2 days, the time necessary to find a technical solution or to repair the equipment,

- effectively wear a suitable dosimeter for the mode of exposure of the workers, particularly for measuring doses to the extremities (rings),
- take into account the overexposure associated with these manipulations in the individual assessment of the risks for the workers concerned.

Additional information on the RPD preparation and administration equipment:
The website of the SFMN (French Society of Nuclear Medicine) contains useful information for users on the joint work conducted by the SFPM (French Society of Medical Physics) and the SoFRa (French Society of Radiopharmacy) on the "Equipment for preparing and administering radiopharmaceutical drugs in nuclear medicine". The aim is to provide an exhaustive technology watch on the products available on the market that is validated by the suppliers themselves. The manufacturers are free to participate and respond and no critical analysis has been issued by the members of the working group.
The following are available:

- A blank Excel file that can be transmitted to the manufacturers for a request for proposals (RFP)
- The PDF files corresponding to the technical comparisons of the "unit RPD dose preparation enclosures" and the "independent RPD injection units" duly filled out by the suppliers.

This work serves to:

- Have fuller knowledge of the devices available on the market (to prepare for a purchase) and to keep track of their technological developments.
- Provide buyers and suppliers with a common benchmark for making objective comparisons of the devices available and to simplify RFP procedures.

Annual updating of this technology watch will be organised.
https://www.sfpm.fr/actualites/groupe-travail-equipement-preparation-administration-medicaments-radiopharmaceutiques

However, a facility exclusively performing PET scan examinations that acquires one or more independent injection units without having other fixed preparation devices, must nevertheless have a dedicated room in order to be able to work on its independent units (loading, unloading, failure, incident, etc.). It is not authorised to perform these operations in rooms dedicated to other activities (delivery, injection/waiting room, camera room, waste storage, etc.) or in circulation areas.
Whatever the case, for reasons of hygiene and observance of the ventilation principles, this room must be different from the radionuclide preparation room.

Methods of transport must be defined to allow the transportation of the unit vial holder between the unit itself and the preparation room. It is in the preparation room that the new vial must be loaded into the unit's vial holder (disinfection of septum, removal of flip-off, transfer behind shielding appropriate for the energy level), the loading of the vials into the unit's dedicated vial holder must also be carried out in compliance with the rules of hygiene and radiation protection.

Furthermore, in view of the growing number of PET scan examinations performed, the syringe preparation and manual injection skills of the personnel must be maintained for the PET scanner so that they can cope in the event of failure of the independent injection unit.

In accordance with Article R. 1333-136 of the Public Health Code, particular requirements may figure in the licenses issued by ASN for entities equipped exclusively with independent units for the preparation and injection of fluorine-18.

Reminder concerning the fixed RPD syringe preparation enclosures

For information, ASN circular letter of 22 May 2013 reiterates the recommendations concerning the radiation protection of patients administered radiopharmaceutical drugs (RPDs) prepared using automated systems (necessity to define and implement systematically, before any RPD administration procedure, check points applied by the medical staff to ensure that the right radiopharmaceutical drug with the right activity is administered to the right patient, particularly when using an automated system; performance of a risk analysis to ensure that all the steps of the process are mastered before it is effectively implemented, with this risk analysis including situations of malfunctions and operator training). The HAS guide of January 2013 supplements this information.

These recommendations are now incorporated in the requirements set out in the abovementioned ASN Resolution 2019-DC-660 on quality assurance in medical imaging.

Article 10

The waiting room for patients who have been administered radionuclides

The waiting room dedicated to patients to whom radionuclides have been administered, situated away from the circulation areas, is of an appropriate size for the number of patients treated, with separate waiting areas for adults and children.

Waiting in a circulation area is no longer permitted. A "common" waiting room for bedridden patients waiting for their injection and bedridden patients who have already received their RPD injection is not permitted.
The number of waiting rooms is adapted to the number of patients treated and the needs of the activity (e.g. booths where injected patients who are to undergo a PET examination can wait in a resting or lying position).

In existing departments licensed before 1 July 2015, if there are no separate waiting areas for adults and children, and pending major structural modifications, organisational measures can be taken to avoid having adults and children waiting in the same room (e.g. grouping children's scintigraphy examinations in half a day).

Article 11

The room dedicated to cell labelling

Without prejudice to the requirements for guaranteeing asepsis, the room dedicated to cell labelling by one or more radionuclides is equipped with a device fitted with a screen suited to the type of radiation emitted by the radionuclides and the activity held.

The "device fitted with a screen suited to the type of radiation emitted by the radionuclides used" can be a non-radiation-proof enclosure or hood. Consequently, Resolution 0463 does not impose any specific constraint

on the treatment of the air circulating in this device. In this type of room, only the general room ventilation requirements (Article 16) are applicable, that is to say a ventilation system that is independent of the rest of the building with no recycling of the air from the room. However, to ensure satisfactory environmental quality, to provide sufficient dexterity for these radiolabelling operations and to maintain preparation sterility, only a laminar air flow hood can be used.

ASN considers that the room in which the cell labelling is carried out does not necessarily have to be reserved exclusively for this activity. This is because the activity separation requirement stipulated in the ASN Resolution results from asepsis considerations (requirement for a high level of asepsis and sterility when performing cell labelling operations) and not from radiation protection considerations.
This being said, from the radiation protection aspect, if two work accessories (enclosure, hood) intended for different activities (RPD preparation in one and cell labelling in the other) are installed in the same room, these activities should not be carried out simultaneously. Use of this room on a "per campaign" basis can be envisaged. At the end of each campaign, the users must check that no contamination is present. This room, which would no longer be strictly dedicated to cell labelling, must be sufficiently large to allow the medical professionals to work comfortably and ensure their radiation protection.

Implementation of the provisions of Article 11 or ASN Resolution 2014-DC-0463 will be studied by the radiation protection inspectors on a case-by-case basis, depending on the organisational options envisaged by the nuclear medicine licence holders.

In accordance with Article R. 1333-136 of the Public Health Code, particular requirements may figure in the licenses issued by ASN for entities having a room shared between a radiolabelling activity and another activity.

Articles relative to internal targeted radiotherapy rooms

Article 12

Internal targeted radiotherapy rooms

The internal targeted radiotherapy rooms are single-patient rooms used exclusively for the hospitalisation of patients who have been administered radionuclides for therapeutic purposes. They are grouped within a hospitalisation unit in application of the principles defined in Article 5 of this Resolution.

The internal targeted radiotherapy rooms are equipped with a washbasin and toilet.

Article 16

General provisions relative to nuclear medicine sector rooms

All the rooms of the in vivo nuclear medicine sector must be ventilated by a ventilation system that is independent of the rest of the building. The recycling of air extracted from the in vivo nuclear medicine sector rooms is prohibited.

Article 18

Particular provisions relative to internal targeted radiotherapy rooms

The provisions of Article 16 also apply to internal targeted radiotherapy rooms.

These rooms are ventilated at negative pressure which ensures the containment* within the internal targeted radiotherapy room to protect people and the environment against the risk of contamination dispersion.

Article 21

Access to internal targeted radiotherapy rooms

Access to internal targeted radiotherapy rooms is restricted to those persons whose presence is justified.

The internal targeted radiotherapy (ITR) rooms are used in particular for the hospitalisation of patients who have received a dose of iodine-131 exceeding 800 MBq (according to the recommendations in 2010 of HERCA – the Heads of European Radiological Protection Competent Authorities).

If the ARS (Regional Health Agency) has authorised the therapeutic use of radionuclides in unsealed sources for cancer treatment, particular if ITR rooms are used, these rooms are subject to specific fitting out and layout provisions.

In view of recent studies which have demonstrated the regular contamination of the atmosphere of ITR rooms (of about a few hundred Bq/m3), new provisions concerning the ventilation and use of these rooms have been introduced in order to limit the risks of internal exposure of workers, the public (visitors) and between patients.

- The requirements regarding ventilation include a ventilation system for the ITR rooms that is independent of the rest of the building, the prohibiting of recycling the air extracted from the ITR rooms and the establishing of negative pressure;
- As regards the utilisation of the rooms, they must be reserved exclusively for ITR.

With regard to the fitting out of the rooms, the toilets must be connected to storage tanks that prevent direct discharge into the sewage network. Particular attention must be paid to the optimisation of the volumes of rinsing water in the urine compartment. It is to be noted that 60 to 80% of the iodine-131 activity administered to a patient is eliminated in the urine during the first four days following administration.

Recommendations may be made for treating patients by RPDs other than those based on iodine-131, notably lutetium-177, the use of which could increase rapidly.

No requirement has been set for the connection of the showers. Posters or hygiene advice given to the patients should limit the contamination of effluents from the showers.

Furthermore, in order to limit contamination of the workers and the dissemination of contamination outside the rooms, conditions of access to the rooms must be defined.

In order more specifically to allow access to the personnel responsible for cleaning the rooms (and not access to patients from other departments), the conditions stipulated in Decree 2018-437 of 4 June 2018 allow the delimiting of a monitored or controlled area to be lifted from the moment any risk of external or internal exposures is precluded. This decision, taken by the employer, cannot be made until the levels of exposure defined in Articles R. 4451-44 et seq. of the Labour Code have been verified.

Likewise, for the proper application of Article R. 4451-19 of the Labour Code and to avoid any dissemination of contamination, especially iodine-131, the GPMED has underlined in its opinion of 26 June 2012, the benefits of providing the workers concerned with "full protective clothing" before entering the ITR room (coverall, over-shoes, long gloves and, in the event of a major incident, a mask) must be examined. This recommendation "must be accompanied by enhanced awareness-raising for all the personnel, medical included, and specific enhanced training for each newcomer ".

As stipulated in Article R. 4451-19 of the Labour Code, when the measures taken in application of Article R. 4451-18 are unable to prevent a risk of contamination by radioactive substances or bringing aerosols into suspension or a significant gaseous release, the employer implements the measures that aim, among other things, to ensure the availability of the radiological monitoring devices, particularly at the exit from the work places concerned, and define in collaboration with the health professionals mentioned in the first paragraph of Article L. 4624-1 the appropriate procedures and means for decontaminating the workers.

The devices and the procedure applicable for their use and those required in the event of contamination of a person or an object must be available at the entrance to the ITR unit. On leaving the ITR room, the workers must check their hands, their feet and clothes which could have come into contact with contaminated objects.

Entry into effect of the requirements

The ITR rooms put into in service as of 1 July 2015 must meet the requirements of the abovementioned Resolution.

ITR rooms licensed before 1 July 2015 which did not meet the requirements of the Resolution were to be rendered compliant by 1 July 2018 at the latest.

Since 1 July 2018, ITR rooms can no longer be used for patients other than nuclear medicine patients, even if they are installed in another department, such as brachytherapy, or over specific periods. They must be reserved exclusively for ITR.

Section 3. Equipment

Article 13

Toilets dedicated to patients to whom radionuclides have been administered

The in vivo nuclear medicine sector is equipped with toilets reserved for the patients to whom radionuclides have been administered. These toilets are connected to a system that prevents direct discharge into the sewage network, in application of Article 20 of the above-mentioned ASN Resolution of 29 January 2008.

The number of toilets reserved for patients to whom radionuclides have been administered is defined according to the predicted number of examinations and treatments practised by the in vivo nuclear medicine sector.

Article 14

Washbasins and sinks

The in vivo nuclear medicine sector is equipped with at least one washbasin or a sink dedicated to contaminated liquid effluents and the washing of hands or contaminated equipment. This washbasin or sink is connected as directly as possible to the storage tanks in application of Article 20 of the abovementioned ASN Resolution of 29 January 2008.

Additional washbasins can be provided if necessary to take account of the places in which the radionuclides are handled and the distances between these places.

The washbasins are equipped with non-hand operable taps.

The conditions of disposal of the effluents are specified in ASN Resolution 2008-DC-0095 of 29 January 2008. ASN Guide No. 18 of 26 January 2012 details the conditions of application.
Storage tanks are installed upstream of effluent discharge into a sewage network. To avoid any radioactive cross-contamination via the taps, they are required to be of the non-hand operable type (controlled electronically or by the elbow or knee, etc.).

Article 15

Pipes

The pipes conveying the contaminated liquid effluents are designed such that they have no stagnation areas and they do not cross any rooms where people are likely to be present on a permanent basis.

The pipe layout is formalised in a plan. It illustrates in detail the contaminated liquid effluent collection circuit and the means of access to the pipe for maintenance and monitoring.

The pipes shall have no sections where liquid can lie stagnant (sufficient gradients, elbows), nor cross any rooms where people could be present on a permanent basis (habitual workstation, other department of the healthcare centre, etc.). The flow paths must be as direct as possible. The aim of these requirements is to limit

the exposure of persons (patients, workers and the public) by preventing the stagnation of contaminated effluents or the creation of deposits in the pipes.
The plan of the pipes must be kept up to date and available to the maintenance services if necessary, firstly to allow regular monitoring and secondly if any work is required on the pipes. As indicated in ASN Resolution 2008-DC-0095 on the management of contaminated waste and effluents, the pipes must be identified.
To prevent any malfunctions, the pipes are inspected to check their condition and the absence of leaks, both visually and using appropriate means, at least every six months.

4.2. CHAPTER II. Room ventilation rules

Article 16

General provisions relative to nuclear medicine sector rooms

All the rooms of the in vivo nuclear medicine sector must be ventilated by a ventilation system that is independent of the rest of the building. The recycling of air extracted from the in vivo nuclear medicine sector rooms is prohibited.

The provisions concerning the ventilation of the rooms must limit the dissemination of radioactive aerosols in all the nuclear medicine sector rooms indicated in Article 3. All these rooms must therefore be ventilated by a ventilation system that is independent of rest of the building in order to limit dissemination.

The requirements concerning the ventilation of the in vivo nuclear medicine sector rooms, the inspection and the maintenance of the ventilation systems, are set by:

- firstly the Labour Code, in which these rooms (like the ITR rooms) enter into the category of rooms with specific pollution, as defined in Article R. 4222-3. Consequently, they must comply with the requirements of Articles L. 4221-1, R. 4222-10 to 17 of this code. In addition, the other provisions of the Labour Code concerning the obligations of the employer (Articles L. 4121-1 to L. 4121-5), the obligations of the project manager (Articles L. 4211-1 to L. 4211-2), the aeration and sanitation of the workplaces (Articles R. 4212-1 to R. 4212-7) and their inspection (Articles R. 4222-20 to R. 4222-22, Order of 8 October 1987 on the periodic inspection of the aeration and sanitation systems of the workplaces and Order of 9 October 1987 on the inspection of the aeration and sanitation of the work places that can be required by the Labour Inspectorate);
- secondly the Good Preparation Practices (GPP) set by the ANSM (formerly AFSSAPS) decision of 5 November 2007, in cases where the radiopharmaceutical drug preparation room belongs to the health centre's medical dispensary, licensed by the Regional Health Agency (ARS). These GPPs are currently being revised.

They are supplemented by the requirements set in this Resolution with regard to the ventilation system and its functioning.
The prior provisions relative to the negative pressure in certain workplaces, to the hourly rate of air renewal and partial recycling of the extracted air are deleted, based on IRSN studies on the ventilation of nuclear medicine departments, and taking into account the opinion of the GPMED (Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation. The ventilation systems in which circulate fluids that could be contaminated must be independent and air recycling is prohibited, more

specifically to avoid of the reflux of contaminated air into the workplaces. Departments that partially recycle air must take compliance action.

The installation of non-return valves on the air extraction pipes is good practice and enables gaseous discharges to be controlled.
In view of the contamination risk, the requirements have been tightened for the ITR rooms (Article 18) and the rooms in which lung ventilation examinations are carried out (Article 17).

The INRS publications listed below (non-exhaustive list) can help the employer or project owner if applicable in the workplace design or fitting out procedure.

- INRS – Legal check-list TJ 5 (March 2019) – Aeration and sanitation,
- INRS Sheet ED 773: Workplace design. Obligations of project owners. Regulation (12/2011- Updated April 2016),
- INRS document ED 695: General ventilation principles (11/2015),
- INRS document ED 950 (September 2011). "Design of workplaces and work situations",
- INRS Sheet ED 91: Design of workplaces and work situations. Programming (07/2011),
- INRS Sheet ED 6008: The ventilation installation file (04/2007)-(Not updated since 2007).
- Integration of human factors in the design process, Briefing notes booklets ND 2192-191-03 (2003)
- Ergonomics and prevention in work situation design, Briefing notes booklets ND 2127-179-00 (2000)

Article 17

Particular provisions relative to lung ventilation examinations

Rooms in which lung ventilation examinations are carried must be equipped with a device for capturing aerosols as close as possible to the contamination source.

Recycling of the air extracted from the aerosol capturing device is prohibited and the ventilation network of this device is independent of that of the rooms.

A device for at-source capture of the gaseous effluents emitted during the lung examinations is moreover obligatory in the rooms in which such examinations are carried out. Recent studies effectively demonstrate that the atmosphere of the room used for lung ventilation examinations is regularly contaminated.

5. TITLE III. OPERATING RULES

5.1. CHAPTER I. General operating rules

Article 19

Circulation in the rooms

The rooms in which radionuclides are used and the circulation areas are always kept free of any clutter to prevent any contamination of objects, goods or equipment that might be situated there.

Access to the rooms in which radionuclides are present is limited to the people involved in the exercise of the nuclear activity and the patients and accompanying persons whose presence is justified.

Article 21

Access to internal targeted radiotherapy rooms

Access to internal targeted radiotherapy rooms is restricted to those persons whose presence is justified.

The utilisation of the rooms covers any activity, including the work necessary to allow the functioning of the nuclear medicine facility.

The first paragraph of Article 19 prohibits the presence of objects or equipment not necessary for the activity, occupying the floor or work surfaces, in order to avoid in particular the dissemination of contamination or any incident that they could cause.

The ASN Resolution indicates that the circulation of people within the nuclear medicine sector is restricted solely to persons involved in the exercise of the nuclear activity, the patients and the accompanying persons whose presence is justified (e.g. the parents of children treated in the department). Likewise, access to the ITR rooms is restricted solely to the persons concerned by the activity.

Article 20

The circuit of sources in the rooms situated outside the nuclear medicine sector

The paths taken by radionuclides and patients are designed such that the doses that could be received by persons during these journeys are maintained at the lowest reasonably achievable level.

Article 22

The use of radionuclides outside the in vivo nuclear medicine sector

The use of radionuclides outside the in vivo nuclear medicine sector must be strictly limited and is placed under the responsibility of a nuclear physician.

The justification for this practice must be formalised by a written protocol kept at the disposal of the inspectors mentioned in Article L. 1333-19 of the Public Health Code. This protocol defines the chosen organisation and describes the circuit followed by the sources.

Access to these rooms during the use of the sources is restricted to persons whose presence is justified.

All measures must be taken to limit any risk of accidental contamination.

The use of unsealed sources for nuclear medicine purposes elsewhere than in the rooms dedicated to this activity can only be accepted if it is justified.

Whenever sources are transported, the exposure of persons must be kept to the lowest level possible. Means of protection appropriate for the type of radiation must be used, such as lead-lined carrying cases, syringe shields, a trolley, etc.

The most common procedures that have to be carried out in operating theatres and/or necessitate recourse to fluoroscopy-guided interventional practices are:

- detection of the sentinel node by using an intraoperative probe, for breast and gynaecological cancers. The radiopharmaceutical drug labelled with technetium can have been administered several hours before the operation in the nuclear medicine department, with detection taking place in an operating theatre situated some distance from the NM department;
- synoviortheses (erbium-169 citrate, rhenium-186 sulphide, yttrium-90 citrate);
- treatments by intra-arterial hepatic injection (yttrium-90 microspheres);
- isolated limb perfusion in the case of soft tissue sarcoma of the limbs (technetium-99m);
- diagnosis of certain patients suffering from epilepsy necessitating the injection of the radiopharmaceutical drug labelled with technetium-99m at the time of the attack (this practice can only be carried out in the neurology department where the patients are hospitalised);
- injection of radiopharmaceutical drug labelled with fluorine-18 in the resuscitation unit (patients who cannot stay in the nuclear medicine department for the necessary resting time after receiving the injection and before undergoing the PET camera examination; these are exceptional but substantiated cases);
- paediatric procedures, etc.

A present, chromium-51 EDTA used for measuring the glomerular filtration rate in nephrology departments is no longer commercialised.

The responsibility mentioned in Article 22 falls upon the head of the nuclear activity, holder of the license, who must ensure that any use of sources outside the nuclear medicine department is done safely in compliance with the prevention and protection rules applicable to the use of ionising radiation.

The head of the nuclear activity must ensure that one or more procedures is/are drawn up and validated and describe(s):

- the justification of the practice;
- the workers handling the radionuclides (people concerned, training in radiation protection, classification of these people, dosimetric monitoring);
- the methods of delimiting the monitored or controlled areas, including at the place of use the radionuclides if applicable;
- the methods of transporting sources and waste within the building or between buildings on a given geographical site;
- the route followed by the sources within the centre, from the dedicated handling room to the radionuclide administration room (the criterion for choosing the route taken by the "transporter" is minimum frequentation rather than minimum distance travelled);
- the chosen organisation, indicating in particular the methods of checking non-contamination of the rooms and management of the waste produced.

5.2. CHAPTER II Particular operating rules

Section 1. Specific rooms

Article 21

Access to internal targeted radiotherapy rooms

Access to internal targeted radiotherapy rooms is restricted to those persons whose presence is justified.

See the details figuring with those relative to Article 19 (above).

Article 22

The use of radionuclides outside the in vivo nuclear medicine sector

The use of radionuclides outside the in vivo nuclear medicine sector must be strictly limited and is placed under the responsibility of a nuclear physician.

The justification for this practice must be formalised by a written protocol kept at the disposal of the inspectors mentioned in Article L. 1333-19 of the Public Health Code. This protocol defines the chosen organisation and describes the circuit followed by the sources.

Access to these rooms during the use of the sources is restricted to the persons whose presence is justified.

All measures must be taken to limit any risk of accidental contamination.

See the details figuring with those relative to Article 20 (above).

Section 2. Equipment

Article 23

Transportation of sources

Radioactive sources transport packages are available for the on-site transportation of sources between the room dedicated to the handling of the radionuclides and the various rooms for administering or checking them. The number of packages is appropriate for the frequency of source transport operations to be carried out.

For each package the dose equivalent rate H*(10) is less than 100 µSv/h at 5 cm from all the walls for the maximum activity of the radionuclide used in these devices.

The packages for on-site transport are closed and lined with an absorbent material to prevent dispersion of the radionuclide.

The transport requirements must ensure the safety of the sources during their transportation within the nuclear medicine sector and, if envisaged, within the medical centre for use outside the nuclear medicine centre.
The radioactive source transport package must provide maximum protection against the ionising radiation emitted. In application of Article 22 (preceding), the circuit of the sources from the handling room to the room in which the radionuclides are administered outside the in vivo nuclear medicine sector is described in a protocol.

This Article is applicable since 28 January 2015.

6. TITLE IV. MISCELLANEOUS AND INTERIM PROVISIONS

Article 24

This resolution shall be applicable, after its approval and its publication in the Official Journal of the French Republic, under the following conditions.

1° For facilities whose license is issued after 1 July 2015: as soon as this licence comes into effect;

2° For facilities already licensed on 1 July 2015:

- on this same date for Articles 3 to 11, 13, 14, 16, 17, 19 to 22;
- 1 July 2018 for Articles 12, 15 and 18.

However, in the case of a modification that could have a significant effect on the conditions of exposure of persons to ionising radiation, the facility is considered like a facility indicated in 1°.

After an interim phase and since 1 July 2018, all the requirements of this Resolution are now applicable to all in vivo nuclear medicine facilities.

The requirements relating to the design of the rooms and concerning:

- the layout of the waste room and the delivery room, which do not have to constitute a single block within the nuclear medicine sector,
- a waiting room reserved for children,

must be brought into compliance when the facility undergoes a modification, from the moment the current design of the facilities does not allow rooms to be allocated to these uses.
In the interim, organisational measures must put in place and described.

Article 25

The ASN Director General is tasked with implementation of this resolution, which will be published in the ASN Official Bulletin.

Done in Montrouge, 23 October 2014

The ASN Commission (*)

M. BOURGUIGNON J.-J. DUMONT M. TIRMARCHE

*Commissioners present at the sitting

Appendix 1

DEFINITIONS

Administration (or Administering) of radionuclides
Introduction of a radionuclide into the body of a patient by different routes, notably:

- by ingestion: administration by mouth (orally, or "*per os*") of a capsule or oral solution or through a foodstuff containing one or more radionuclides;
- by injection: administration by parenteral route (intravenous, sub-cutaneous injection, etc.). This mode of administration necessitates a needle or a catheter, with which the skin is pierced;
- by inhalation: administration of an aerosol or a gas via the respiratory tract.

Circulation areas
Areas in which people or radioactive sources are liable to move around within the in vivo nuclear medicine sector.

Internal targeted radiotherapy (ITR) room
Room intended for the patient undergoing a therapeutic procedure using a radionuclide and specially fitted out for reasons of radiation protection.

Containment
All the technical provisions for protecting workers, the environment and persons against the risk of dispersion of radioactive contamination. Static containment is ensured by obstacles materialised by the walls of a room or an enclosure, the sealing of which is guaranteed in normal circumstances, whereas dynamic containment is achieved by maintaining the direction and speed of air flow towards the areas where the level of contamination is the highest.

Distribution of the rooms
Division of space according to a desired functionality.

Radiation-proof enclosure
Enclosure with shielded walls and a specific ventilation system, designed to provide protection against external and internal exposure and to contain the radionuclides and unsealed sources handled inside it

Nuclear medicine facilities
Rooms comprising the nuclear medicine sector, the rooms situated in non-regulated work areas as defined in the Labour Code, such as the reception desk, the secretariat, the waiting room for patients before the administration of radionuclides, the offices (physicians, managerial staff, etc.) and the rooms situated outside the in vivo nuclear medicine sector used for the administration of radionuclides.

Rooms situated outside the *in vivo* nuclear medicine sector

Rooms adjacent to the nuclear medicine sectors, such as the reception desk, the secretariat, the waiting room(s) for patients waiting to be administered radionuclides, the offices, particularly the medical consultation offices which do not receive patients who have been administered a radionuclide, the resting rooms, meeting room, as well as the rooms in which sealed and unsealed sources are used for nuclear medicine procedures, such as the operating theatre, or the interventional radiology room and lastly the other rooms (e.g. other departments, residential rooms).

Handling

Operations consisting in handling radionuclides for the purpose of administering them to patients, such as placing a ready-to-use radiopharmaceutical drug in a syringe, reconstitution, preparation, etc.

Cell labelling with one or more radionuclides

Operations consisting, after taking blood from the patient and isolating formed blood elements (erythrocytes, platelets, leukocytes/polymorphonuclear leukocytes), in radiolabelling with a radionuclide. The radiolabelled cells are re-administered to the patient.

In vivo nuclear medicine sector

Rooms intended for the holding and use of sealed and unsealed sources and devices producing X-rays for an in vivo nuclear medicine activity including diagnosis, therapy, cell labelling and human subject research, and excluding in vitro diagnosis.

Single block

The term "single block" means an individualised entity that is not crossed by circulation areas accessible to the public. Domestic Security Code

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