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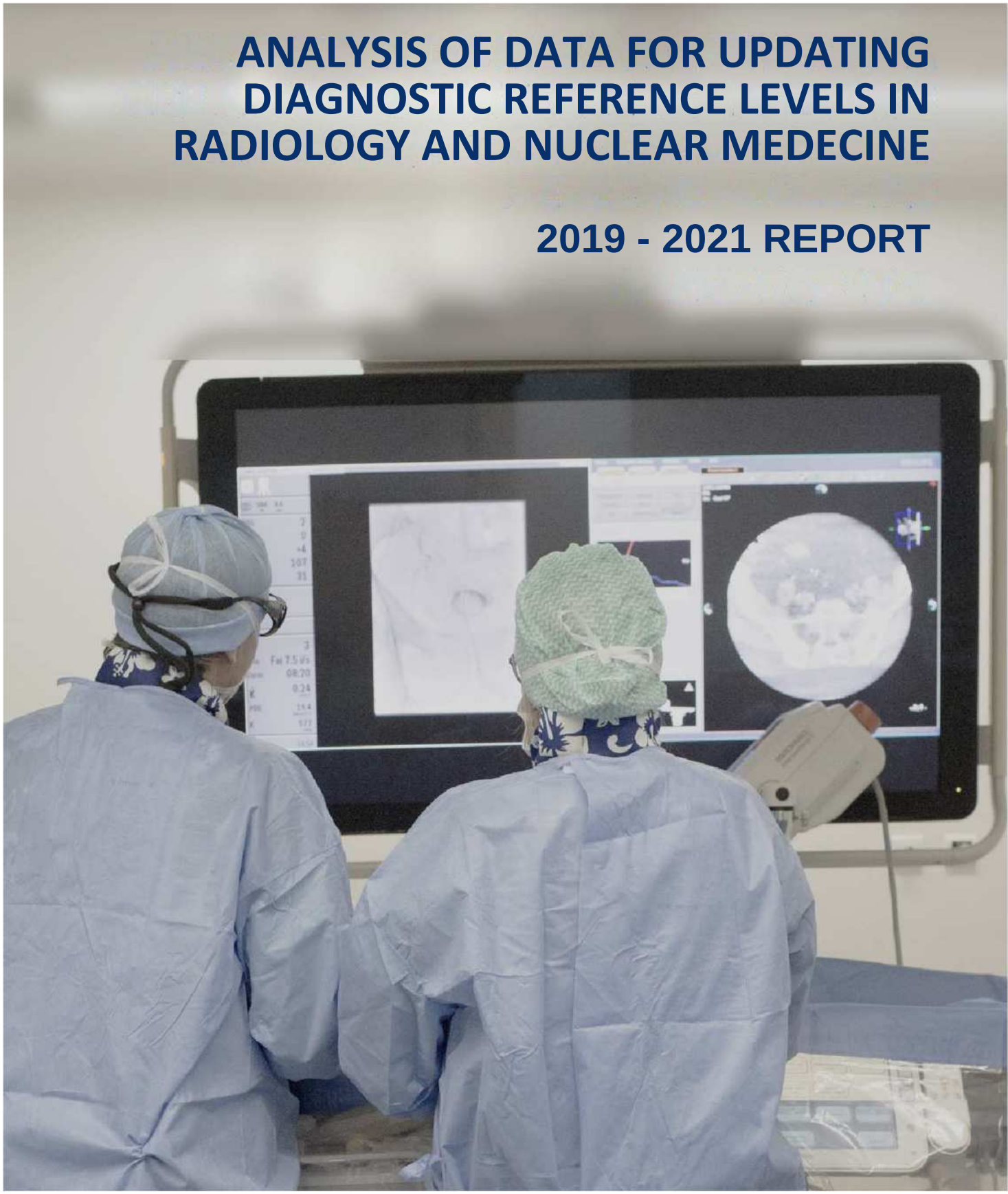
INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

ANALYSIS OF DATA FOR UPDATING DIAGNOSTIC REFERENCE LEVELS IN RADIOLOGY AND NUCLEAR MEDECINE

2019 - 2021 REPORT



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To fulfil these missions in these fields, IRSN:

- *carries out expert appraisals for the benefit of the authorities and, more generally, the public authorities;*
- *monitors the exposure of patients, medical staff, and the public;*
- *collects and analyses data to update diagnostic reference levels for practitioners.*

In support of these expertise and monitoring activities, in order to keep up to speed with all the latest scientific knowledge, the Institute conducts research programmes in collaboration with hospital teams and national, European, and international partners.

RESUME

En application de la réglementation relative aux niveaux de référence diagnostiques (NRD) et notamment la décision de l'ASN n°2019-DC-0667, les établissements de radiologie et de médecine nucléaire doivent transmettre annuellement à l'IRSN des données dosimétriques relatives aux actes d'imagerie dont ont bénéficié leurs patients. L'IRSN est chargé d'analyser ces données en vue de la mise à jour des valeurs des NRD.

Ce rapport présente les résultats de l'analyse des données recueillies sur la période 2019-2021. Ces résultats ont été comparés aux valeurs de NRD en vigueur depuis juillet 2019 afin d'examiner la nécessité d'une mise à jour.

Ce septième bilan de l'analyse des données françaises relatives aux NRD permet d'établir un état des lieux de la mise en œuvre des modalités introduites par la décision de l'ASN n°2019-DC-0667, en particulier en pédiatrie et en radiologie interventionnelle.

La participation des établissements apparait comme stabilisée autour de 50% pour la radiologie conventionnelle, et 90% pour la scanographie et la médecine nucléaire. La participation a été très importante pour la radiologie interventionnelle nouvellement introduite par la décision de l'ASN n°2019-DC-0667.

Chez l'adulte, l'analyse des données collectées de 2019 à 2021 montre que les valeurs du 75^{e} centile sont inférieures aux valeurs des NRD en vigueur dans tous les domaines : de 20 % à 30 % en radiologie conventionnelle, de 30 % à 54 % en radiologie interventionnelle, de 14 % à 60 % en scanographie et de 1 % à 22 % en médecine nucléaire. Cette analyse montre également une baisse globale des valeurs du 75e centile des indicateurs dosimétriques par rapport à la période 2016-2018, de 19 % en radiologie conventionnelle, 8 % en scanographie et 4 % en médecine nucléaire.

En pédiatrie, il est noté une augmentation du nombre d'évaluations exploitables reçues. Cependant, le nombre total de données reçues reste trop faible pour obtenir une robustesse statistique pour la majorité des examens.

Sur la base de l'analyse des évaluations dosimétriques transmises à l'IRSN au cours de la période 2019-2021, de résultats d'analyses complémentaires conduites par l'IRSN en collaboration avec les professionnels de santé et de la consultation de ces derniers, ainsi que d'avis d'expertise produits à la demande de l'ASN, l'IRSN formule les recommandations suivantes :

- du fait de la baisse globale des valeurs du 75^{e} centile des indicateurs dosimétriques réviser les valeurs de NRD dans tous les domaines, en priorisant la scanographie pour laquelle une évolution vers des NRD par indication clinique doit être envisagée ;
- faire évoluer la définition de certains NRD et les données collectées. Par exemple, en radiologie interventionnelle, ajouter le kerma dans l'air au point de référence comme indicateur dosimétrique complémentaire au PDS et au temps de scopie, en médecine nucléaire, définir un seul NRD en termes d'activité massique (MBq/kg) pour les examens qui s'y prêtent, et, en scanographie, faire évoluer les NRD pour prendre en compte les indications cliniques tel que déjà recommandé dans le précédent bilan ;
- définir de nouveaux NRD. Par exemple, en radiologie conventionnelle, créer un NRD pour la tomosynthèse mammaire et le CBCT dentaire sur la base des recommandations formulées par l'IRSN dans ses avis publiés fin 2021 et début 2023 respectivement. En radiologie interventionnelle, envisager de créer un NRD en rythmologie, et, en médecine nucléaire, engager une concertation avec les professionnels de santé sur la mise en place de NRD pour de nouveaux examens en particulier en TEP ;
- envisager la suppression des NRD associés à certains examens devenus peu fréquents, tels que la scintigraphie rénale au DTPA ainsi que la scintigraphie cérébrale à l'ECD et HMPAO en médecine nucléaire ou le rachis dorsal de profil en radiologie conventionnelle ;
- en pédiatrie, poursuivre les efforts pour la transmission des données.

ABSTRACT

In order to comply with the French regulations regarding the diagnostic reference levels (DRL), healthcare facilities performing medical imaging procedures are required to send samples of “patient” dosimetric data to the IRSN each year.

IRSN is responsible for analysing this data in order to update the DRL values.

This report presents the results of the analysis of dosimetric data over the period 2019-2021. Results are compared to DRL values defined by the regulations in force since July 2019 to examine the need for an update.

This seventh report on the analysis of French data relating to DRLs makes it possible to take stock of the implementation of the methods introduced by ASN resolution 2019-DC-0667, in particular in paediatrics and interventional radiology.

The participation of professionals appears to be stabilised at around 50% in conventional radiology and 90% in CT and nuclear medicine. Participation was very high for interventional radiology, newly introduced by ASN resolution 2019-DC-0667.

In adults, the analysis of the data collected from 2019 to 2021 shows that the 75th percentile values are lower than the DRL values in force in all areas: by 20% to 30% in conventional radiology, by 30% to 54% in interventional radiology, by 14% to 60% in CT, and by 1% to 22% in nuclear medicine. This analysis also shows an overall decrease in the 75th percentile values of dosimetric indicators compared to the period 2016-2018, by 19% in conventional radiology, 8% in CT, and 4% in nuclear medicine.

In paediatrics, an increase has been observed in the number of usable assessments received. However, the total quantity of data received remains too low to obtain statistical robustness for the majority of examinations.

On the basis of the analysis of dosimetric data transmitted to IRSN during the period 2019-2021 and the results of additional analyses conducted by IRSN in collaboration with health professionals, IRSN makes the following recommendations:

- Due to the overall decrease in the 75th percentile values of the dosimetric indicators, revise the DRL values in all areas, prioritising CT for which a move towards DRLs by clinical indication should be considered.
- Change the definition of some DRLs and the data collected. For example, in interventional radiology, add the air KERMA at the reference point as an extra dosimetric indicator alongside the dose area product and the radioscopy time; in nuclear medicine, define a single DRL in terms of specific activity (MBq/kg) for the examinations that lend themselves to it; and, in CT, upgrade the DRLs to take into account the clinical indications as already recommended in the previous IRSN report.
- Define new DRLs. For example, in conventional radiology, create a DRL for digital breast tomosynthesis and dental CBCT based on the recommendations proposed by IRSN in its notices published in late 2021 and early 2023 respectively. In interventional radiology, consider creating a DRL in rhythmology, and, in nuclear medicine, engage in consultation with healthcare professionals on the implementation of DRLs for new examinations, particularly in PET.
- Consider removing DRLs associated with certain examinations that have become infrequent, such as renal scans with DTPA, brain perfusion SPECT with ECD in nuclear medicine, and thoracic spine lateral radiographs in conventional radiology.
- In paediatrics, continue efforts to transmit data.

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INTRODUCTION

This document presents the report on IRSN's analysis of diagnostic reference levels data for the 2019-2021 period, in line with its mission under Article R.1333-61 of the French Public Health Code.

Diagnostic reference levels (DRLs) have been implemented in France since 2004 (1) based on the recommendations of ICRP publication 73 "Radiological Protection and Safety in Medicine" (2) and European Commission Guide RP109 (3), with a view to optimising doses in line with the requirements of Council Directive 97/43/Euratom (4) and then Directive 2013/59/Euratom (5).

DRLs are an indispensable and effective tool for optimising doses delivered to patients. They provide dosimetric indicators for the quality of practices and are intended to identify and monitor situations requiring improvement and quantify the effectiveness of an optimisation approach. They should not be confused with "dose limits" or "optimum doses".

The managers of conventional radiology, CT, and nuclear medicine facilities have to assess annually the doses delivered to their patients during diagnostic or interventional procedures in accordance with ASN resolution 2019-DC-0667 of 18 April 2019 pertaining to DRLs (6) currently in force. Analysing this data, by comparison of their median values with the DRLs in force, should enable professionals to situate their practice against a national benchmark and undertake improvements in the event that the value exceeds the DRLs without good reason. Conversely, particularly low exposures with regard to achievable dose values (AD) must also be questioned, and any reduction in the doses delivered must systematically be accompanied by an assessment of the quality of the images obtained in order to avoid any loss of diagnostic performance and any risk of performing unusable examinations. Healthcare professionals must submit the results of their dose assessments to IRSN.

IRSN is responsible for analysing the data submitted at a national level. It publishes a periodic report to present data collection and analysis methods and results. This analysis enables IRSN to put forward recommendations for updating the DRL regulations with a view to improving their application and effectiveness.

French regulations pertaining to DRLs have therefore been revised several times: first in 2011 (7) and more recently by ASN resolution 2019-DC-0667 (6) approved by the Order of 23 May 2019 (8). In particular, these regulatory changes have taken into account the recommendations made by IRSN in its previous reports (9–11).

This seventh report of the analysis of French data relating to DRLs covers the 2019–2021 period and is therefore the first report which takes place over a period of application of the latest aforementioned ASN resolution 2019-DC-0667. The report makes it possible to judge the effectiveness of the adaptations introduced by this resolution, in particular concerning the collection of data in paediatrics and the introduction of interventional radiology. It also allows IRSN to issue new recommendations with a view to continuous improvement of DRLs in France.

COLLECTION AND ANALYSIS OF DIAGNOSTIC REFERENCE LEVEL DATA

2.1 OVERVIEW OF REGULATIONS

In accordance with Article R.1333-61 of the French Public Health Code, for procedures which present, by the doses delivered or by their frequency, a radiation protection issue for patients, diagnostic reference levels (DRLs) are established and updated by the ASN, taking into account the results submitted to IRSN, which is responsible for collecting and analysing the data required for this periodic update. To this end, IRSN receives the results of dose assessments carried out from the activity managers (conventional radiology, interventional radiology, computed tomography, or nuclear medicine). Figure 1 below presents the principle for DRL implementation in France, and the roles of healthcare professionals, authorities, and IRSN.

ASN resolution 2019-DC-0667 of 18 April 2019 on DRLs (5), in force since 1st July 2019, specifies how to implement the collection and analysis of DRL data.

The dose assessments carried out annually by healthcare professionals must cover, for each device (CT and interventional radiology) or department (conventional radiology and nuclear medicine), two procedures appearing in the aforementioned ASN resolution. These assessments must include data on at least 30 patients per examination for all examinations, except in paediatrics and for image-guided interventional procedures for which only a minimum of 10 patients are required.

In paediatrics, dose assessments are mandatory if 5% of procedures performed on a medical device involve children (under 18 years of age).

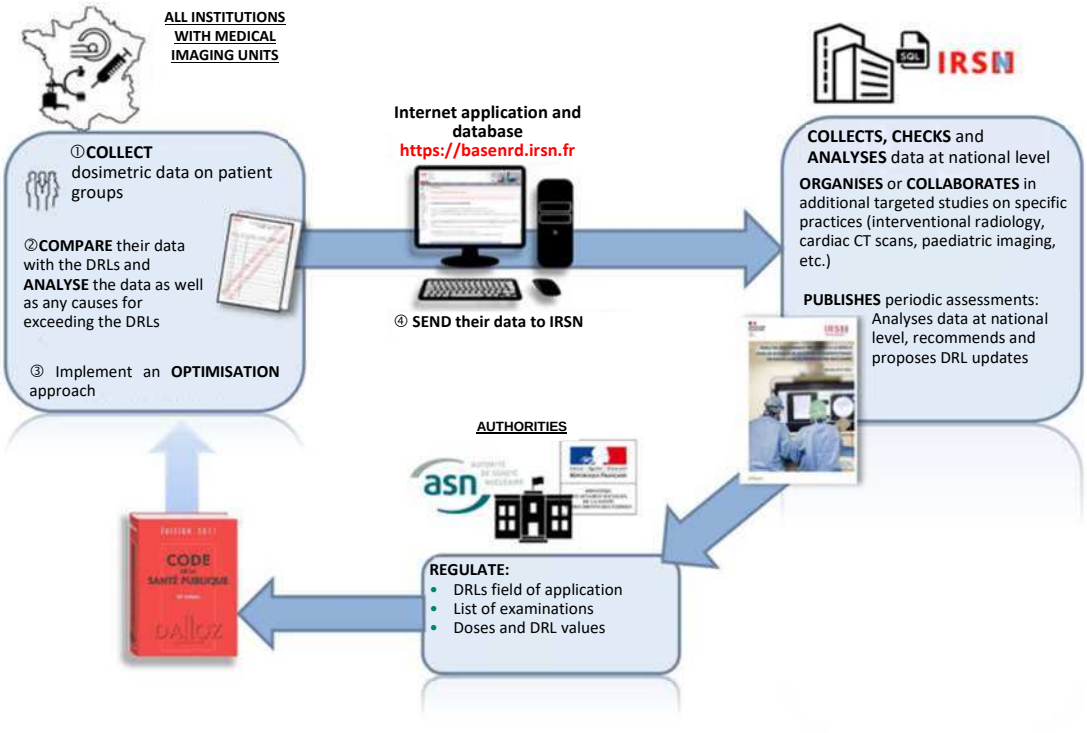

Figure 1: Principle for DRL implementation in France, roles of institutions with medical imaging facilities, authorities and IRSN.

2.2 NATURE OF DATA COLLECTED

Depending on the imaging type, data are collected for one or two DRL quantities:

- dose area product (DAP) for conventional radiology and orthopantomography;
- Mean glandular dose (MGD) for digital mammography;
- volume computed tomography dose index ($CTDI_{vol}$) and dose length product (DLP) for computed tomography;
- total activity and administered activity per body weight for nuclear medicine.

The result of the dose assessment is the median value of 30 (or more) values collected from groups of patients with the relevant dose values.

Patient morphology has a major impact on the dose delivered. Regulations therefore require patient height and weight to be recorded during dose assessments (see section 2.4).

In mammography and orthopantomography, dose is not assessed for a group of patients but with a single measurement on phantom performed during external quality control (12; 13): MGD and DAP respectively.

IRSN collects some parameters and information in addition to DRL quantities, in order to check the consistency of the data received:

- for conventional radiology: high voltage, filtration, focus-to-detector distance (FDD), detector technology and size;
- for computed tomography: high voltage and pitch (in helical mode);
- in interventional radiology: the radioscopy time, the air KERMA at the reference point, the number of radiography images, the mobile or fixed equipment, the use of rotational mode;
- for nuclear medicine: the radiopharmaceutical administered.

2.3 DATA COLLECTION

Collection methods

Since 2011, IRSN has collected data over the internet using an IT application (https://basenrd.IRSN.fr). The system has improved the quality of information submitted and facilitated discussions between IRSN and professionals, thanks to automatic checks during data entry.

In addition to its data entry and submission functions, the DRL application offers professionals the opportunity to compare their dose assessment median values to the DRL in force, as soon as they have finished entering their data. They can also view their data submission history to improve monitoring of the doses they deliver.

Data collection period

This report presents the analysis of the data collected for 2019, 2020 and 2021.

2.4 DATA ANALYSIS

Data validation criteria

Despite the automated checks performed by the DRL application during data entry, some data received by IRSN contain errors. Unrestrictive automated checking criteria for data consistency were selected in the app in order to avoid discouraging users who might have their data refused.

In this respect, each assessment submitted by institutions is checked by IRSN. Only data validated after verification are used for performing national-level statistical analyses.

For example, in computed tomography, the complementary DRL quantities combination, $CTDI_{vol}$ and DLP, can be used to check data consistency. This is because the $DLP/CTDI_{vol}$ ratio corresponds to the length exposed (length examined plus additional radiation (overranging) at the start and end of helical CT acquisition), which is characteristic of the acquisition performed. This makes it easy to identify, for example, a scan of the sinuses among brain examinations or an abdomen-pelvis acquisition in an assessment labelled "chest-abdomen-pelvis" due to an inconsistent acquisition length. Checking this parameter is fairly discriminating, which explains why there is a higher level of unused data than in conventional radiology (see paragraph 5.2 of this report).

Similarly, for interventional radiology, the DAP and K_{air}[1] pair of indicators (when the air KERMA is available, which is often the case) enables data consistency to be checked (see focus section in the "interventional radiology" chapter of this report). The DAP/K_{air} ratio corresponds to the average area of the field during the examination at the reference point. This area can be neither extremely small nor extremely large and an analysis of this ratio allows the presence of inconsistent data to be detected.

During checks, if some patient data appears inconsistent, the median values of the DRL quantities are recalculated to exclude them.

Selection of data for analysis

Despite the checks described in the preceding section, validated dose assessments may contain data errors or data that are considered not to represent current practices (abnormally high or low DRL quantities, patient morphology (BMI), acquisition lengths, etc.).

Data are therefore consolidated prior to analysis by applying the following criteria:

- for adult examinations, exclusion of patients:
  - aged under 15;
  - with a BMI of less than 18 or more than 35, except for nuclear medicine;
- for paediatric examinations, exclusion of patients:
  - aged over 18;
  - whose weight does not correspond to the selected category;
- in computed tomography: exclusion of patient examinations presenting particularly low or high acquisition lengths;
- in interventional radiology: exclusion of data with a particularly low or high DAP/K_{air} ratio;
- exclusion of data including fewer than 25 patients after application of the previously cited validation and selection criteria (or fewer than 10 data items for paediatric procedures and interventional radiology).

[1] K_{air} is the air KERMA at the reference point as defined by the IEC (14). No DRL is set by the regulations for this quantity. However, it is possible to transmit this data to IRSN, in addition to the DAP and the radioscopy time.

The age limit for paediatrics varies between 15 and 18 depending on sources, so broader criteria have been applied. For adult examinations, patients in the 15-18 age range have been accepted, since they were likely to have been examined following an adult protocol. For paediatric examinations, patients in the 15-18 age range have also been accepted if their weight falls within a defined category. It should be noted that selecting children by weight category is a more relevant criterion than by age.

In adult conventional radiology and computed tomography (except for the CT part of nuclear medicine examinations; see below), in which the volumes of data received are higher and the reduction in DRL quantities is most marked, the 75th and 50th percentile values have been calculated for each year, and it is the 2021 values that are presented for potential DRL updates. Nevertheless, all data (2019 to 2021) have been kept for producing the radiology and computed tomography histograms presented in the Annex to this report.

In nuclear medicine (including the CT part of nuclear medicine examinations), interventional radiology, dental radiology, and paediatrics (all fields), the 75th and 50th percentile values have been calculated for the entire 2019-2021 period, and not for each year individually. This is for the following reasons:

- lower volumes of data received (paediatrics, nuclear medicine, interventional radiology);
- slower change in doses delivered (nuclear medicine);
- less frequent dose assessments (orthopantomography, where data collection is associated with a five-year quality control).

The fact that data collected over a 3-year period are being analysed means that several dose assessments for a single examination from a single unit are available for the period. In order to avoid statistical bias linked to over-representation of units subject to several dose assessments over the 2019-2021 period, only the latest data received have been kept for calculating the 75th and 50th percentiles and presented in the histograms in the Annex.

In mammography, the DRL has no longer been applicable since 21 January 2021 following the entry into force of the new quality control procedures for digital mammography units (15), and so the data received over the incomplete period from 1st January 2019 to 20 January 2021 (the frequency for sending mammography data is five years) have not been analysed.

Statistical indicators

Median

National DRLs are based on the median values, per unit, of dosimetric data collected by healthcare professionals for groups of 10 or 30 patients. At local level, this median value needs to be compared to the DRL by healthcare professionals in order to assess their practice. At national level, the distribution of these unit median values is analysed to determine the 75th percentile.

By convention, in this report, the term median is used for a unit's representative dose value. For the national distribution of unit median values, the term 50th percentile will be employed to define the statistical measure used to establish the AD.

This convention also applies to nuclear medicine, where the national mean of mean unit activities previously used is replaced by the 50th percentile (national) of median activities (per unit).

75th and 50th percentiles

Conventional radiology, interventional radiology, and computed tomography

In conventional radiology, interventional radiology, and computed tomography, the DRL is defined as the 75th percentile of the distribution of results (dosimetric data median values) of dose assessments for a given examination. This is an alert level above which practices could be considered sub-optimal, or even abnormal, in terms of dose delivered to the patient.

In addition, the 50th percentile of the dose assessment results distribution is used to define the AD (see figure 2 below).

Nuclear medicine

In nuclear medicine, the 50th percentile of the medians per unit is used to define the DRL.

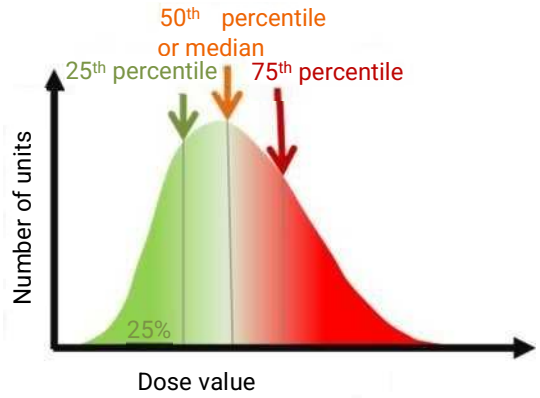

Figure 2: Definition of main statistical measures for dose data distribution for a given examination type.

75th to 25th percentile ratio

Medical imaging practices involve high degrees of disparity, with patient exposure levels that can vary by significantly for an apparently similar diagnostic performance.

Data heterogeneity is symptomatic of disparity in practices. In order to assess it, the results presented in this report, as with the previous report, are supplemented by a measure that is representative of dispersion of values: the 75th to 25th percentile ratio.

Presentation of analysis results

The results of analyses performed by IRSN on the data submitted by health professionals are presented for each of the medical imaging fields concerned: conventional radiology, interventional radiology, computed tomography, and nuclear medicine.

These results offer an assessment of the application of DRL regulations in establishments performing medical imaging procedures, through their participation in submitting data to IRSN.

The data breakdown submitted for the various examination types is also analysed and compared with the frequency of the medical imaging procedures in France. Although professionals had the freedom to choose the examinations they have assessed, this analysis assesses the representativeness of data collected with regard to national practices. The results for paediatrics are separated from those for adults.

The percentage of data submitted for each examination out of all the data received by IRSN for each imaging field is shown, together with the proportion of data that IRSN has been able to use.

Finally, analysis summaries are given in order to assess, for each examination, the positioning of statistical measures with regard to the DRLs and the results of the previous report. The results for paediatrics are, once again, separated from those for adults. It should be noted that when there are fewer than 10 assessments used per procedure, it is considered that the data volume is too small for the results to be discussed, and the positioning of the statistical measures with regard to the DRLs is not calculated.

Detailed analyses for each examination type are presented in the Annex of this report. The Annex includes the following for each examination where the amount of data collected allows analysis, and per dosimetric value (DAP, MGD, $CTDI_{vol}$, DLP, activity and administered activity per body weight):

- national distribution graphs for dose assessment results;
- a table of the main statistical measures;
- graphs presenting the change in the 75th and 50th percentiles in conventional radiology and computed tomography, and the 50th percentiles in nuclear medicine, since 2011.

When there are fewer than 20 assessments, these analyses are not detailed in the Annex to this report.

For better readability of this report, the titles of the types of examinations have sometimes been abbreviated, particularly in the figures (see Glossary).

For each of the areas, the results presented lead IRSN to issue recommendations for improving the DRL system.

2.5 CONSULTATION OF STAKEHOLDERS

The stakeholders (ASN, ANSM, ADF, AFTMN, CNPCV, G4, GACI, SFMN, SFPM and SoFRa) were consulted on 20 May 2022 to gather their feedback on the 2016–2018 report and present to them the initial results for the 2019–2021 period.

Certain comments received on this occasion have led IRSN to submit recommendations that are not necessarily directly related to the results of this report but which may also contribute to the improvement of the DRL system, in particular:

In interventional radiology, consider:

- the creation of DRLs for two rhythmology procedures considered to be the most irradiating: atrial fibrillation ablation and ventricular resynchronization (= triple or multisite cardiac stimulation); the “rhythmology” group of the Société Française de Cardiologie (French cardiology society) must be consulted to carry out this work;
- the introduction, in the long term, of interventional procedures performed under CT examination, in particular by engaging in reflection on interventional cardiology procedures (TAVI, mitral valvuloplasty) or interventional vascular radiology (peripheral vascular angioplasty, other procedures to be specified) performed in operating theatres or hybrid rooms, and not in dedicated radiology rooms.

In nuclear medicine:

- consider removing DRLs for examinations that have become too infrequent, as illustrated by the results of this report:
  - renal scans with DTPA,
  - brain scans with ECD and HMPAO;
- Define a single DRL in terms of activity per body weight (MBq/kg) for the examinations that lend themselves to it, rather than a combination of activity and activity per body weight as is currently the case;
- Consider the implementation of DRLs:
  - for new examinations, particularly in PET, such as:
    - brain PET with 18F-FDG,
    - PET with 18F-Choline,
    - PET with 18F-DOPA (brain, full body),
    - PET with gallium 68 (somatostatin receptors, PSMA);
  - in a second phase, for new scanning examinations, such as, for example:
    - dual-isotope (iodine-123 and 99mTc-MIBI) scans of the parathyroid glands,
    - brain scans with DaTSCAN;
  - for computed tomography acquisitions of the trunk and the full body combined with bone scans.

Recommendations from stakeholder consultation are specifically mentioned, in each relevant part of this report, where they arise.

FOCUS – PAEDIATRIC DRLs: THEIR SPECIFIC ISSUES

Problems with implementation of paediatric DRLs

Since DRLs were implemented under French regulations in 2004, IRSN has observed that the volume of data received each year for paediatric examinations has been extremely low. Over and above the fact that this presents a problem for updating DRLs, this data gap suggests that paediatric procedures may be subject to very little assessment.

Solutions implemented for increasing the use of DRLs in paediatrics

Following IRSN's observations and proposals, ASN resolution 2019-DC-0667 amended regulations in order to increase the assessment of paediatric procedures:

- the minimum number of dose assessments for children to be included has been reduced from 30 to 10, in order to encourage collection in institutions that perform a low number of paediatric examinations;
- the collection and analysis of one paediatric dose assessment per year is required when at least 5% of procedures performed on a medical device involve children.

Positive impact of the regulations in force since July 2019

Compared to previous years, the collection of data relating to 2020 and 2021 has developed positively. The number of institutions that sent paediatric data and the quantity of these data more than doubled in all areas between 2016–2018 and 2019–2021: in conventional radiology, the number of assessments submitted increased from 184 to 435 (+57%), in computed tomography from 91 to 202 (+55%), and in nuclear medicine from 31 to 111 (+72%).

Furthermore, the increasing deployment of patient dose management system software (DACS - Dose Archiving and Communication System) is contributing to the greater use of paediatric DRLs. By systematically recording DRL dose values used, DACS makes it easier to collect and analyse data for the least frequent procedures, such as paediatric procedures.

However, there are still not enough assessments to carry out a robust assessment of practices in this area

Despite this improvement, the number of assessments per examination remains insufficient overall: in conventional radiology, only 5 out of 16 examinations identified in ASN resolution 2019-DC-0667 received a sufficient number of assessments (more than 20) allowing for a detailed analysis, and in computed tomography only 3 out of 11 examinations. In nuclear medicine, all the examinations sent to IRSN included fewer than 20 assessments per examination and therefore could not give rise to a detailed analysis.

Under these conditions, in paediatrics, it remains difficult to assess the evolution of doses delivered in a robust manner. Therefore, IRSN recommends continuing efforts and encouraging healthcare professionals to submit data by reminding them that it is possible to collect data over a period of more than one year.

CONVENTIONAL RADIOLOGY

3.1 CONTRIBUTION OF DEPARTMENTS

For conventional radiology, the main institutions involved in radiography procedures are:

- the radiology departments of public and private healthcare institutions;
- private practices (radiology, pneumology, rheumatology);
- occupational health departments, municipal healthcare centres, prison healthcare departments, etc.;
- dental practices.

Conventional radiology (apart from dental practices)

The total number of conventional radiology departments or practices needs to be estimated in order to assess the contribution of departments. In the previous report covering the period 2016–2018, the estimate of the number of institutions performing conventional radiology procedures had been updated. The method for estimating the evolution of the annual participation of institutions carrying out conventional radiological procedures since 2004 had thus been adapted to present the participation rates using the estimated number of institutions based on a linear regression between the estimates for 2005 (5,100 institutions) and 2018 (3,000 institutions).

In keeping with this principle, figure 3 below indicates that, since 2016, approximately 50% of institutions performing conventional radiology procedures have complied with the regulatory provisions relating to DRLs. This means that the participation rate of institutions has still not increased in recent years.

It should be noted that the drop in the participation of institutions observed in 2011 is linked to the implementation of data transmission over the Internet that year. Furthermore, the apparent decrease in participation between 2014 and 2015 is probably attributable to stricter data collection conditions for 2015 (data transmission authorised until 31 January in 2015, as opposed to 31 March in 2014).

In conventional radiology, 68% of the data come from the private sector (Figure 5 below). According to IRSN estimates, three quarters of facilities are private institutions, and a third are public or non-profit institutions. Data source distribution therefore seems consistent with distribution of facilities and activity between the public and private sector.

Dental practices

For dental practices, the increase of new accounts on the DRL application, and therefore of healthcare professionals able to submit data, is presented in figure 4 below. Over the years, the number of new accounts continues to increase. At the end of 2021, the number of practices signed up (able to send data to IRSN) was 763. However, it should be noted that application accounts fell in 2021. Furthermore, it should be noted that, by the end of 2022, about 35% of practices signed up between 2014 and 2021 had never sent any data.

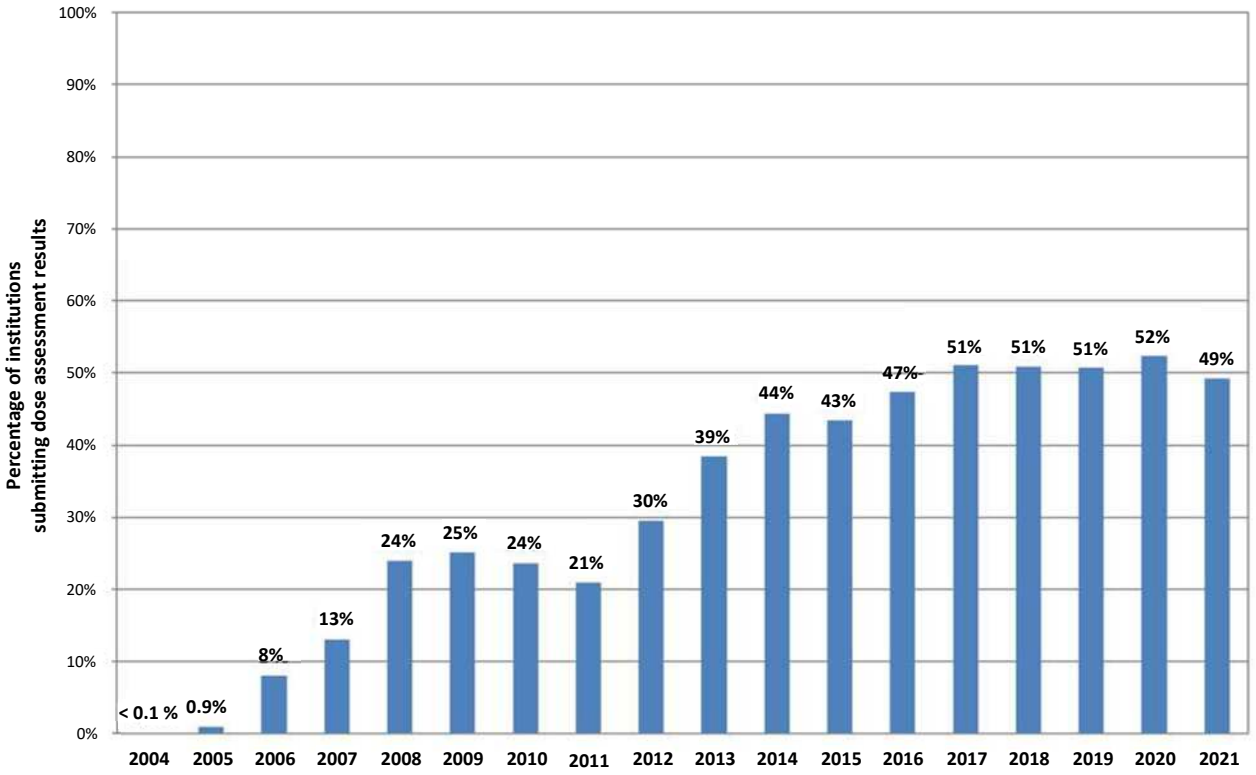

Figure 3: Change in annual participation of institutions performing conventional radiology procedures since 2004 (excluding dental).

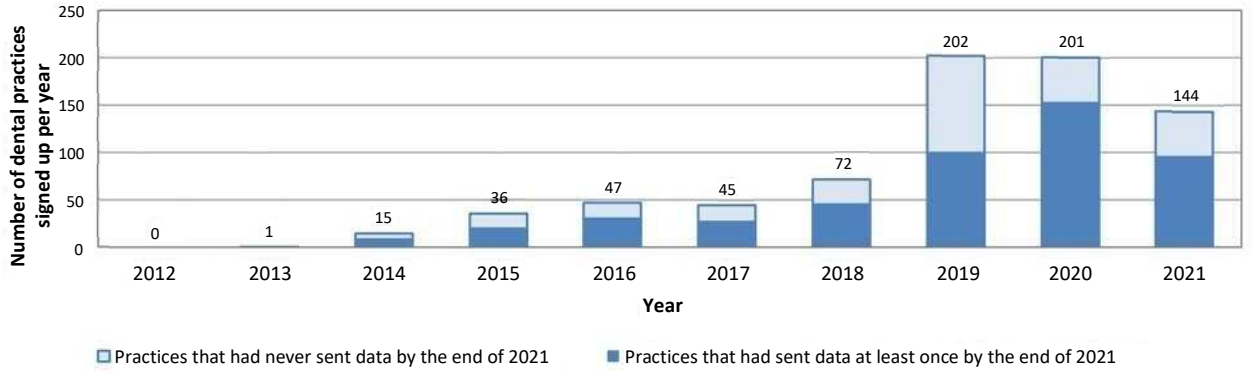

Figure 4: Number of new dental practice application accounts for the DRL application per year (creation of new accounts). The number of new practices signed up each year and the proportion of those that sent data at least once before the end of 2021 are represented.

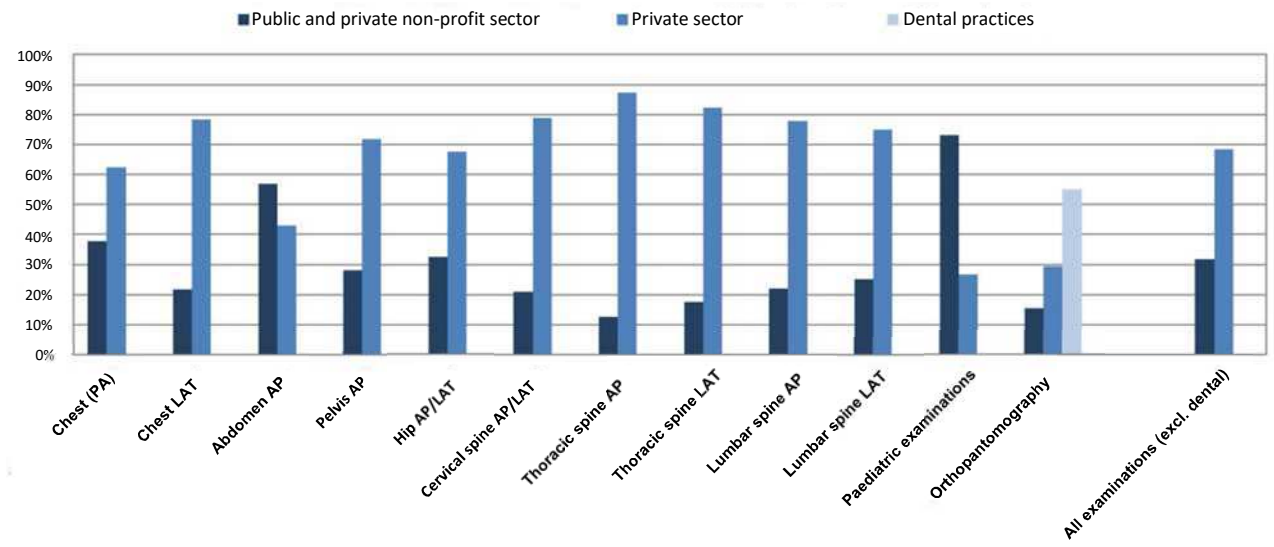

Figure 5: Source of data used for DRLs, over the period 2019–2021, according to the type of examination and sector of activity, in conventional and dental radiology.

3.2 DATA DISTRIBUTION BY EXAMINATION TYPE

Adult examinations

Figure 6 below shows the distribution of dose assessments, per examination type, submitted to IRSN by healthcare professionals from 2019 to 2021, together with the proportion of data that IRSN has been able to use.

For all examination types, except orthopantomography and mammography, the use rate for submitted data is over 90% or even 95%.

The use rate for orthopantomography is now around 80%, slightly up on the previous report (around 70%). This lower rate can mainly be explained by the fact that identical data submitted several times during the data collection period was not taken into account, for the reasons stated in the paragraph on “Selection of data” in chapter 2.4 above.

The distribution of examinations is almost equivalent to that observed in the previous report, with the exception of the proportion of orthopantomography and paediatric examinations, which increased by four points (5.1% to 9.1%) and two points (1.8% to 4%), respectively. It should be noted that the proportion of abdominal examinations dropped again in this report: from 4.7% (period 2016–2018) to 3.4% (period 2019–2021).

In adults, three types of examinations account for just over 40% of the data: frontal chest, pelvis AP and lumbar spine AP. This distribution appears to be consistent with the frequency of X-ray examinations carried out in France (16).

As stated previously, in mammography, the DRL as defined by ASN resolution 2019-DC-0667 has no longer been applicable since 21 January 2021, following the entry into force of the new methods of quality control of digital mammography facilities, and so the data received over the incomplete period were not analysed. For this reason, all dose assessments received are shown as not used in figure 6 below.

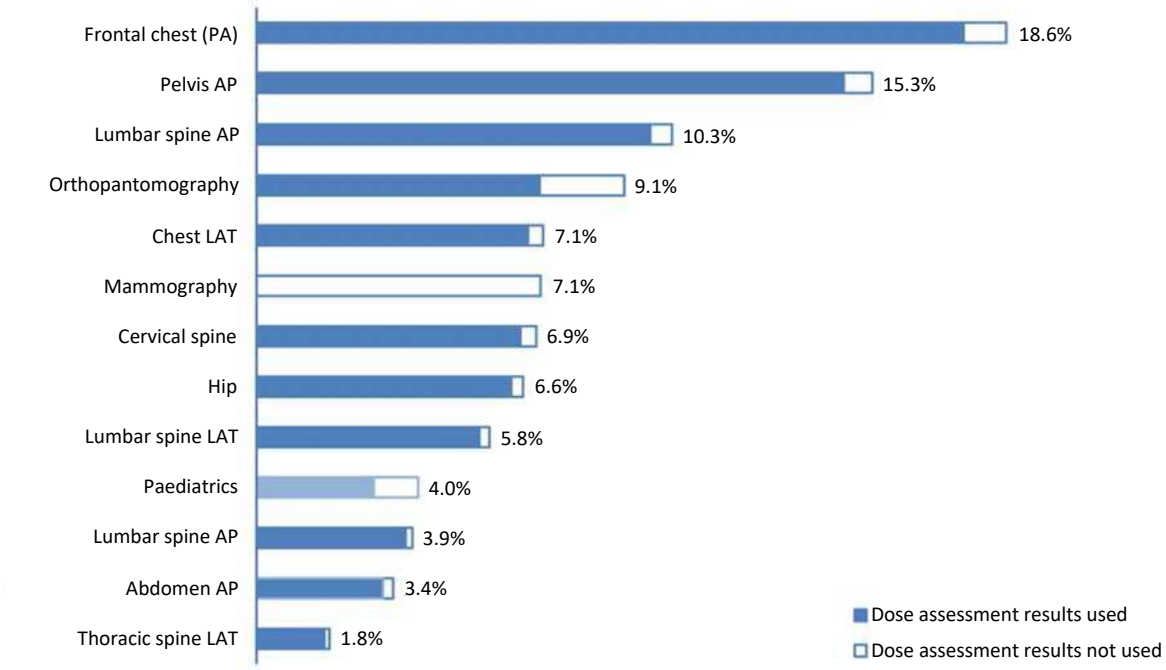

Figure 6: Percentage distribution by type of examination of radiography dose assessments for which results were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 10,860)

Paediatric examinations

The proportion of data concerning paediatrics is reduced, but to a lesser extent than in the previous report, with 4% of data submitted (see figure 6 above) compared to approximately 2% in the previous report (i.e., 435 assessments out of a total of 10,860 assessments submitted over the period, compared to 184 out of 10,343 over the previous report period), while approximately 10% of all the procedures carried out in France concern children (16).

Figure 7 below shows the distribution by type of examination, for children, of the dose assessments submitted to IRSN by healthcare professionals.

Examinations of frontal chest (PA) for children weighing 10 to 20 kg, total frontal spine AP (excluding wire chamber technology) and chest (AP) for children weighing 5 to 10 kg are the most frequently assessed procedures.

The changes brought in by ASN resolution 2019-DC-0667 have enabled the quantity of data received to be increased, compared to the previous report. However, the lack of data in paediatrics is still a major limitation to the establishment and regular updating of DRLs.

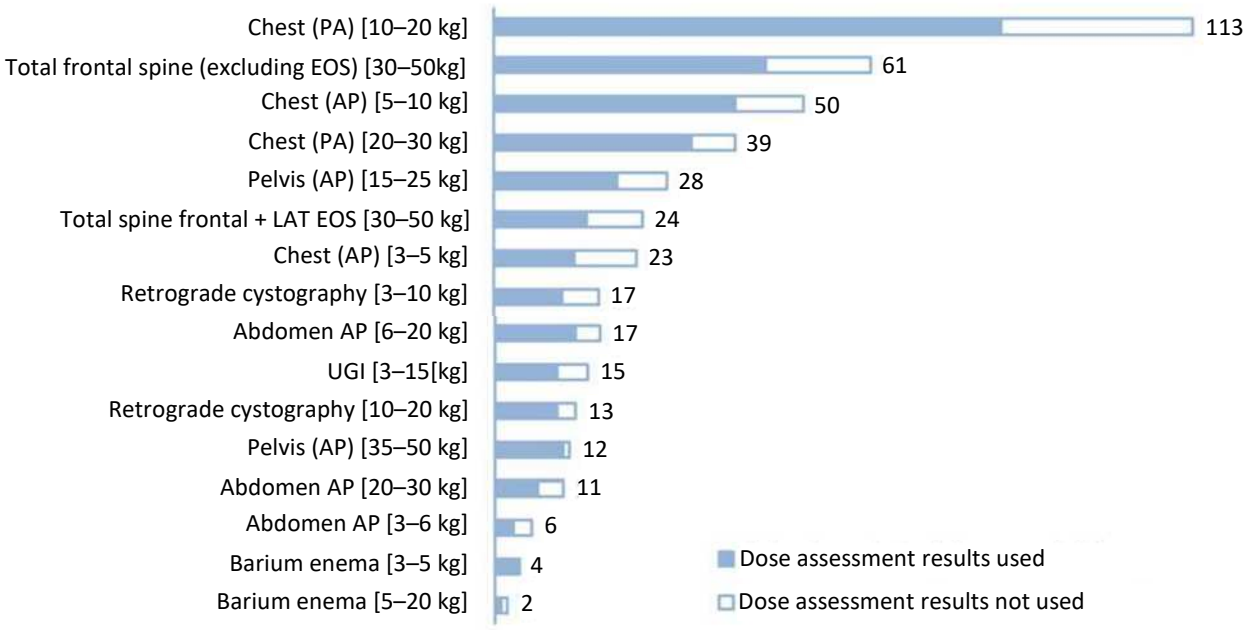

Figure 7: Distribution by examination type of the number of child radiography dose assessments for which results were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 435).

3.3 SUMMARY OF CONVENTIONAL RADIOLOGY RESULTS

Adult examinations

The results of the dose assessments submitted by conventional radiology professionals in terms of DAP are presented in table 1 below.

It shows:

- the number of assessments used for 2021 and the period 2019–2021 (N),
- patient median weight and BMI values,
- the DRLs and ADs in force (DRL and AD),
- the 75th percentile and 50th percentile values for data collected in 2021,
- the 75th to 25th percentile ratio for 2021,
- the position of the 75th percentile for 2021 with regard to the DRL in force (% DRL),
- the percentage of dose assessments data received in 2021 higher than the DRL in force (> DRL),
- the 2021 75th percentile variation with regard to the 2018 value stated in the previous report.

Table 2 below shows the specific results for orthopantomography.

The results are not presented for mammography, for the reasons stated previously.

Table 1: Summary of results of conventional radiology data analysis (excluding orthopantomography and mammography) by adult examination type, for 2021, expressed in terms of dose area product (DAP).

Examination type	N 2021 (2019-2021)	Median weight (kg)	Median BMI (kg/m²)	DAP (mGy.cm²)				P75/P25 ratio	% DRL	> DRL	Variation
				DRL	AD	P75	P50				
Chest PA	621 (1908)	70.5	24.8	200	150	155	110	2.16	-23%	10%	-16%
Chest LAT	259 (732)	70.0	24.7	550	400	408	290	1.95	-26%	6%	-17%
Abdomen AP	110 (341)	70.0	24.8	3400	2300	2586	1406	2.59	-24%	7%	-17%
Pelvis AP	503 (1585)	70.0	24.9	3800	2750	2708	1905	2.15	-29%	8%	-21%
Hip AP/LAT	231 (688)	70.0	25.2	1350	950	1069	731	2.17	-21%	10%	-10%
Cervical spine AP/LAT	248 (712)	69.0	24.5	400	250	270	170	3.00	-33%	6%	-17%
Thoracic spine AP	154 (403)	68.5	24.5	1000	750	764	582	2.14	-24%	10%	-15%
Thoracic spine LAT	58 (182)	69.0	24.8	1150	900	900	632	1.99	-22%	19%	-45%
Lumbar spine AP	366 (1063)	70.0	25.1	2700	1950	2042	1392	2.19	-24%	11%	-15%
Lumbar spine LAT	228 (602)	70.0	25.2	3900	2650	3088	2180	2.16	-21%	13%	-13%

Table 2: Summary of results of orthopantomography data analysis for 2021, expressed in terms of dose area product (DAP).

Examination type	N 2021 (2019-2021)	DAP (mGy.cm²)				P75/P25 ratio	% DRL	> DRL	Variation
		DRL	AD	P75	P50				
Orthopantomography	238 (765)	150	100	129	102	1.87	-14%	12%	-4%

Detailed analyses by examination type are presented in the Annex to this report in the form of datasheets. For each examination type for which the data collected can be analysed, these datasheets show:

- DAP distribution graphs for 2019–2021;
- a table with associated statistical data;
- changes in results since 2011.

Apart from the lateral thoracic spine examinations, the results show a drop of 10–20% in the 75th percentile values compared to 2018. Thus, the overall drop in the values of the dosimetric data observed over the period 2016–2018 (down 7% compared to 2013–2015) is confirmed and consolidated in this report (down 19% compared to 2016–2018). Lateral thoracic spine examinations, as in the previous report, are those for which the least number of dose assessments were analysed in 2021 (58 assessments in 2021; 30 assessments in 2018). In 2018, a 43% increase in the 75th percentile value compared to 2015 had been observed, but the representativeness of the result was questionable due to the low number of data. In 2021, the 75th percentile value was 900 mGy.cm², which is more than 20% lower than the DRL in force, and therefore returns to a value consistent with data from previous years (excluding 2018).

Overall, the 75th percentile values for 2021 were 20%-30% below the DRLs in force for all examinations. A revision of the DRLs could therefore be envisaged.

There is still a high level of data dispersion, with a 75th/25th percentile ratio of around 2 to 3. This result may raise questions about dose optimisation and associated image quality. However, it is not possible to discuss this result from the point of view of image quality. This is because, as stated in the previous report, the concept of image quality is complex, and subjectivity makes it difficult to assess. An assessment of the diagnostic performance of equipment needs to be associated with the system for optimising doses delivered to patients in order to ensure that it does not negatively impact examination quality. In particular, if local median values are below the achievable dose values (AD), image quality, rather than dose, should be considered as a priority in the optimisation process.

As stated previously, the detailed data analysis results for mammography are not presented. In this regard, IRSN conducted a study in 2020 and proposed to ASN, in its notice No. 2021–00193[2], a change in the method of collecting data and the DRL value in mammography, in order to better analyse the clinical practices of sites, as well as a new DRL for the rapidly expanding breast tomosynthesis technique (see dedicated focus).

[2] https://www.irsn.fr/sites/default/files/documents/expertise/avis/2021/Avis-IRSN-2021-00193.pdf

The number of assessments submitted for orthopantomography for 2019–2021 doubled compared to the previous assessment established for 2016-2018, rising from 371 to 765. It was therefore possible to produce an analysis for 2021. The 75th percentile in dental radiology in 2021 was very similar to that obtained for the previous report, and below the DRL by around 14%.

In line with what has been done in digital mammography and breast tomosynthesis, IRSN conducted, at the request of ASN, a study on the doses delivered with cone-beam computed tomography (CBCT) for dental radiology and proposed to ASN, in its notice No. 2023–00006[3], the implementation of a DRL for this increasingly used technique (see dedicated focus).

Paediatric examinations

The results of the dose assessment analyses for paediatric radiology are presented in table 3 below.

For each weight category, this table shows the number of assessments used (N) for 2019–2021, the minimum, median and maximum weight of children, the 75th percentile value (75th), the 50th percentile value (50th), the 75th to 25th percentile ratio and, for the examinations for which sufficient data have been collected, the position of the 75th percentile for the period with regard to the DRL in force (% DRL), as well as the percentage of dose assessments received over the period above the DRL in force (> DRL).

Only full spine AP examinations (excluding wire chamber technology) for children weighing 30 to 50 kg and chest AP examinations for the 5–10 kg, 10–20 kg and 20–30 kg categories include sufficient data in terms of DAP (more than 20 paediatric assessments) and may give rise to a detailed analysis (see Annex to this report).

Only abdomen examinations for the 3–6 kg and 20–30 kg categories as well as barium enema examinations for all categories had too few assessments (< 10) for the results to be discussed.

The child weight categories for the different examinations defined in ASN resolution 2019-DC-0667 have changed from the Order of 2011. It is therefore not possible to compare the results of the previous report established for the period 2016-2018. In addition, the weight categories defined for children in ASN resolution 2019-DC-0667 do not correspond to the weight categories defined at European level (17). A revision of these weight categories would allow comparisons to be made with the results of other European countries.

For chest AP examinations in children, the results are slightly lower than the DRLs set out in ASN resolution 2019-DC-0667, by around 6 to 8% for all categories except the 10–20 kg category. Approximately 20% of the submitted assessements are above the DRL.

For chest AP examinations of children in the 10 to 20 kg category, the result is around 20% higher than the DRL set out in ASN resolution 2019-DC-0667, with approximately 40% of the submitted assessments above the DRL. This may be explained by a difference concerning the institutions represented in the collected DRL data for the 5–10 and 20–30 kg categories. This is because the institutions submitting data for these two categories are mainly university hospitals specialised in or used to paediatric radiology, whereas this is not the case for the 10–20 kg category. This illustrates the need to disseminate good radiation protection practices for patients in institutions specialised in and/or used to paediatric radiology to all institutions treating children.

For full spine AP examinations, in the 30–50 kg category, the result is very slightly below the DRL set out in ASN resolution 2019-DC-0667, by around 2%, with just over 20% assessments above the DRL.

Conversely, full spine AP and LAT examinations with wire chamber technology gives a result well below the DRL set out in ASN resolution 2019-DC-0667, by around 20%, with no assessment above the DRL.

For pelvis (AP) examinations, in the 15–25 kg category, and for retrograde cystography, in the 3–10 kg and 10–20 kg categories, the results are well below the DRL, by around 40–60%. As the number of assessments submitted for retrograde cystography is still quite low (11 and 10, depending on the weight category), these results should be discussed with due caution. Furthermore, very high 75th and 25th percentile ratios were observed for these examinations, illustrating the heterogeneity of the results.

For Upper gastrointestinal series (UGI) , in the 3–15 kg category, the results are above the DRL by around 30%, with approximately 40% of the submitted assessments above the DRL and a 75th and 25th percentile ratio above 2.5. These results, as with retrograde cystography, illustrate a disparity in practices. It should be noted that these examinations cover several indications which do not result in the same dose level. It would probably be useful to refine this indication to better define a DRL accordingly.

[3] https://www.irsn.fr/sites/default/files/2023-02/Avis-IRSN-2023-00006.pdf

A new revision of DRLs in paediatric conventional radiology does not seem necessary in the short term. The results for full spine AP and LAT examinations with wire chamber technology and pelvis AP examinations for the 15–25 kg category, which are much lower than the currently applicable DRLs, could justify a lowering of the DRL; however, there are still insufficient data, and these need to be confirmed for the drafting of the next report that will cover the 2022–2024 data collection period. It is also necessary to monitor the evolution of the results of UGI and retrograde cystography examinations and to implement actions to encourage and standardise the optimisation of practices by the centres for these examinations, such as, for example, the development of a best practices guide by the healthcare professionals concerned. Indeed, it seems that some centres have implemented advanced approaches to optimising paediatric doses which could usefully be disseminated more widely.

Table 3: Summary of results of conventional radiology data analysis by paediatric examination type, in terms of dose area product (DAP) for 2019–2021

Examination type	Weight category (kg)	N 2019-2021	Median weight (kg)	DAP (mGy.cm²)			P75/P25 ratio	% DRL	> DRL
				DRL	P75	P50			
Chest	[3 - 5]	13	3.5	9	8.5	4.5	2.13	-6%	15%
	[5-10]	39	7.6	13	11.95	8.93	2.12	-8%	21%
	[10-20]	82	14.0	19	23	17	2.38	20%	40%
	[20-30]	32	24.0	35	33	25	1.71	-6%	22%
Pelvis (AP)	[15-25]	20	18.0	120	66	42	1.91	-45%	5%
	[35-50]	11	44.0	510	517	492	1.35	1%	27%
Abdomen AP	[3-6]	3	3.0	20	21	14	1.84	-	33%
	[6-20]	13	11.5	80	86	45	2.88	8%	38%
	[20-30]	7	24.1	280	221	218	1.35	-	0%
Full Spine AP (excluding wire chamber technology)	[30-50]	44	42.5	800	787	619	1.96	-2%	23%
Retrograde cystography	[3-10]	11	6.9	550	320	108	8.40	-42%	9%
	[10-20]	10	13.2	1000	385	347	2.14	-62%	10%
UGI	[3-15]	10	7.8	150	195	127	2.66	30%	40%
Barium enema	[3-5]	4	3.7	300	80	46	4.93	-	0%
	[5-20]	1	9.0	400	118	118	1.00	-	0%
Full spine AP+LAT (wire chamber technology)	[30-50]	15	42.0	850	660	392	2.56	-22%	0%

FOCUS – CONVENTIONAL RADIOLOGY

DRL IN DIGITAL MAMMOGRAPHY AND BREAST TOMOSYNTHESIS

See IRSN notice No. 2021–00193 of 3 December 2021[4]

At the request of ASN, IRSN - with the assistance of the relevant learned societies[5] - conducted surveys on the doses delivered to patients in 2D digital mammography (CR (computed radiography) and DR (direct radiology) systems) and breast tomosynthesis.

A collection of data on doses delivered in 2D digital mammography (DR systems only) and breast tomosynthesis was conducted from March to July 2021 among healthcare professionals.

The following indications were selected in the study on 2D DR mammography and tomosynthesis facilities:

- mammography in breast cancer screening campaigns;
- mammography for individual breast cancer screening (excluding campaigns);
- tomosynthesis procedures, regardless of their clinical indication.

Indications excluded from the scope of the study, because they do not systematically affect both breasts or may be additional examinations using different protocols and incidences of bilateral screening mammograms, were as follows:

- any magnifications and centred images;
- images of inflammatory breasts, symptomatic breasts, treated breasts, or prostheses;
- images taken during biopsies;
- examinations carried out by angiomammography.

The 2D CR systems do not have an MGD display, the dose indicator chosen for the study on 2D DR systems. This is why, an analysis of the data from external quality control reports for CR systems, submitted to IRSN by the ANSM in September 2021, was conducted.

The data used by IRSN for this study concerned:

- 80 CR 2D mammography facilities;
- 77 facilities and 5,300 patients for 2D DR mammography;
- 44 facilities and 3,009 patients for tomosynthesis.

The results of the IRSN study illustrate that, although tomosynthesis does not currently feature in organised breast screening campaigns, its use is tending to be expanded, and most equipped centres use it systematically for this type of screening. The 75th percentiles of MGD are 35% higher in tomosynthesis than in 2D DR mammography. These findings confirm the need to implement DRL in breast tomosynthesis.

MGDs clearly increase with compressed breast thickness in 2D CR / DR mammography and tomosynthesis. Therefore, an analysis of the indicators by breast thickness interval is necessary.

Furthermore, this study shows, in 2D DR mammography and tomosynthesis, extensive variability in the MGD recorded on patients according to the brand of mammography equipment:

- in 2D DR mammography, the 75th percentile of MGDs per patient ranges from 1 to 2.3 mGy;
- in tomosynthesis, the 75th percentile of MGDs per patient ranges from 1.4 to 2.9 mGy.

In 2D CR mammography, the MGD measured during external quality control varies little between mammography equipment brands.

[4] https://www.irsn.fr/sites/default/files/documents/expertise/avis/2021/Avis-IRSN-2021-00193.pdf

[5] Société Française de Radiologie, Fédération Nationale des Médecins Radilogues, Société d'Imagerie de la Femme, Société Française de Sénologie et de Pathologie Mammaire, Association Française du Personnel Paramédical d'Electroradiologie, Société Française de Physique Médicale

Whether in 2D CR/DR mammography or tomosynthesis, the results obtained in the IRSN study in terms of MGD are consistent with the recent literature on this subject. However, the small differences observed between the indicators obtained in the IRSN study and recent literature may be explained by the difference in method and sample size of the different studies.

The analysis of the 75th percentiles of threshold contrast visibility of the 2D CR facilities shows a lesser performance than for the 2D DR facilities (in the order of 25 to 50%), whereas the 75th percentile of the dose measured during external quality control in 2D CR mammography is about 20% higher than that of 2D DR mammography. With respect to the overall image quality visual score, given the high variability of visual score results with large standard deviations, the differences between brands are included in the ranges of variation. It is therefore difficult to compare the performance of the facilities on the criterion of visual score on an anthropomorphic phantom.

These results demonstrate the need to incorporate image quality in the delivered dose analysis. However, they also illustrate the difficulty of correlating the image quality on a test object for measuring the threshold contrast visibility with the image quality on an anthropomorphic phantom, let alone in clinical use.

These results also raise the issue, already stated in a previous IRSN notice (18), of the reduced performance of 2D CR mammography facilities which deliver more dose for a lower threshold contrast visibility than 2D DR facilities.

Currently, ASN resolution 2019-DC-0667 defines a single DRL for 2D DR and 2D CR digital mammography based on the mean glandular dose (MGD) measured during annual external quality control at 45 mm equivalent breast thickness. As IRSN's study shows that the MGDs vary according to the thickness of the compressed breast, it appears necessary to upgrade the DRL framework by extending the data collection to all breast thicknesses for 2D DR mammography and tomosynthesis facilities which enable dose readings to be taken on patients under clinical conditions. Therefore, IRSN recommends that facilities collect 2D DR mammography and tomosynthesis data every 3 years for at least 50 patients per facility, regardless of the thickness of the compressed breast. IRSN also recommends integrating, in addition to the mean glandular dose (MGD), the compressed breast thickness among the elements to be submitted to IRSN as part of the data collection required under the regulations. Lastly, IRSN recommends setting the DRL, regardless of breast thickness and incidence, at 1.7 mGy in 2D DR mammography and 2.3 mGy in tomosynthesis.

For 2D CR mammography facilities, the clinical and technical performance of these facilities is a topic of concern. IRSN recommends taking measures to avoid the commissioning of new 2D CR mammography facilities and encourage the replacement of facilities currently in operation.

FOCUS – CONVENTIONAL RADIOLOGY

DRL IN DENTAL CBCT

See IRSN notice No. 2023–00006 dated 11 January 2023[6]

At the request of ASN, IRSN, with the aid of professional bodies from the sectors concerned[7], conducted a survey in 2 phases, from May to July 2021, then from February to March 2022, on the doses delivered by CBCT in dental radiology examinations among all healthcare professionals using this technique, for the following nine indications:

- indications in adults:
  - single implant without guide, without sinus lift;
  - multiple implant with guide, without sinus lift;
  - jaw implant with sinus lift;
    - dental extraction: bilateral wisdom teeth;
    - single impacted tooth extraction;
    - periodontal assessment;
    - endodontics;
- indications in children:
  - impacted tooth in children aged approximately 12;
  - cleft palate in children aged approximately 8 to 10.

In light of feedback from previous surveys in three European countries, the dose area product (DAP) data associated with the parameters usually selected for a standard patient, in terms of morphology and indication, were collected.

228 dental and medical imaging institutions responded to the survey. However, the data used by IRSN only concern 150 institutions, 85% of which are in the dental sector, a proportion consistent with the national installed base of facilities. This is because the variable quality of the data collected required complex checking, and a large quantity of this data could not be used.

Statistical analysis of the data shows that, in the dental sector, the 75th percentile values of the DAP vary relatively little between the indications, at around 700 mGy.cm², except for periodontics and impacted teeth in children. In the medical imaging sector, the values are higher and more pronounced variations are observed between indications.

However, the size of the panel of institutions whose data has been used is small compared to the size of the installed base, estimated at at least 2,700 devices. Furthermore, even after verification, uncertainties persist for part of the data used, particularly for indications relating to several teeth (multiple implants and bilateral wisdom teeth, for example) or for which a significant unexplained discrepancy has been observed between the dental sectors and medical imaging (jaw implant, for example). Finally, in the absence of a regulatory quality control framework for devices used in CBCT imaging, it is not possible to guarantee that the DAPs displayed by the machines correspond to the reality of patient exposure.

Overall, the 75th percentile values for DAPs obtained in the CBCT French user survey are significantly higher than the DRLs in force in other countries such as Finland, the UK, Switzerland, and Sweden. The only exceptions are, on the one hand, Japan, whose DRL values are very high, and, on the other, endodontics examinations, for which the value of the Swiss DRL is close to the French result.

Considering all these elements and due to the previously detailed study limits and the insufficient number of data collected in paediatrics and for the periodontics indication in adults, IRSN therefore recommends keeping only three indications in adults: the single implant without guide and without sinus lift, single impacted tooth extraction, and endodontics. IRSN recommends expressing the DRL in terms of DAP, a value used in countries that have defined DRLs and already used for orthopantomography, and setting the same value (700 mGy.cm²) for the three indications chosen.

[6] https://www.irsn.fr/sites/default/files/2023-02/Avis-IRSN-2023-00006.pdf

[7] In the medical imaging sector: Société française de radiologie (SFR), Fédération nationale des médecins radiologues (FNMR), Société française de physique médicale (SFPM); in the dental sector: the Dental radiation protection commission (Commission radioprotection dentaire - CRD), incorporating the Association dentaire française (ADF), the Chirurgiens-dentistes de France (CDF), the Fédération des syndicats dentaires libéraux (FSDL), the Ordre national des chirurgiens-dentistes (ONCD) and the Union dentaire (UD)

In the absence of a regulatory quality control framework, particularly relating to the quality of the acquired images, IRSN does not consider it necessary, at this stage, to set ADs in addition to the DRLs. ADs are meant, in particular, to highlight the importance of maintaining sufficient image quality when doses become low.

During the expert appraisal which led to the publication of IRSN notice No. 2023–00006 of 11 January 2023, IRSN was faced with radiation protection issues linked to the use of dental CBCT systems: failure to comply with certain regulatory obligations, lack of knowledge of the possibilities of adjusting devices to optimise doses, errors in the documentation of certain manufacturers, and the need to formalise practices through protocols for performing procedures. Implementing DRLs for dental CBCT examinations would be of real aid to healthcare professionals for detecting unoptimised delivered dose levels.

With the aim of advancing radiation protection for patients in the dental field, IRSN therefore issued, in this notice, global recommendations that need to be implemented at the same time. Indeed, the establishment of new DRLs will only be meaningful if these recommendations, including those relating to the implementation of a quality control framework for dental CBCT, to the training of users of dental CBCT devices, and to the improvement of information provided by device manufacturers and suppliers, are implemented in parallel.

SUMMARY – CONVENTIONAL RADIOLOGY

Analysis of conventional radiology dose assessments shows:

- a still limited participation rate of radiology structures, stabilised at around 50%;
- an increase in the proportion of orthopantomography and paediatric examinations, which increased by 4 and 2 points respectively compared to the previous report;
- in adults:
  - the 75th percentile values of 2021 are 20 to 30% below the DRLs in force;
  - an overall 19% reduction in conventional radiology dose indicators compared to 2016–2018, which confirms the previously observed drop of 7% compared to 2013–2015;
  - still a high level of data dispersion, with a 75th/25th percentile ratio of around 2 to 3;
- in children:
  - the changes made in ASN resolution 2019-DC-0667 enabled an increase in the quantities of data received compared to the previous report; however, the lack of data in paediatrics still constitutes a major limit for the establishment and regular updating of DRLs;
  - for full spine AP and LAT examinations with wire chamber technology and pelvis AP examinations for the 15–25 kg category, results are well below the DRL;
  - for UGI and retrograde cystography examinations, very high ratios between the 75th and 25th percentile values, illustrating the heterogeneity of results and which may illustrate a diversity of practices and/or indications.

RECOMMENDATIONS – CONVENTIONAL RADIOLOGY

Analysis of conventional radiology dose assessments leads IRSN to make the following recommendations:

- in adults:
  - revise the DRLs;
  - monitor the evolution of data for thoracic spine LAT and possibly question whether to keep this examination within the DRL system, since it remains the examination with the lowest number of assessments submitted;
- in paediatrics:
  - monitor the evolution of the results of full spine AP/LAT examinations with wire chamber technology and pelvis AP examinations for the 15–25 kg category to potentially consider the revision of the DRLs of these examinations;
  - monitor the evolution of the results of UGI and retrograde cystography examinations and possibly revise, in the long term, the definition of these DRLs based on feedback received since 2019;
  - investigate the relevance of revising weight categories to fall into line with European recommendations and thus enable comparisons to be made;
  - continue to encourage the submission of paediatric data by reminding practitioners that it is possible to collect data for more than one year.

In addition, IRSN recommends:

- in mammography, revising the DRL for digital mammography and introducing a DRL for breast tomosynthesis taking into account the notice published by IRSN in December 2021 (19);
- in dental CBCT, introducing a DRL for certain indications taking into account the notice published by IRSN in January 2023 (20).

INTERVENTIONAL RADIOLOGY

4.1 CONTRIBUTION OF DEPARTMENTS

ASN resolution 2019-DC-0667 introduced DRLs for certain image-guided interventional procedures. These are therefore new procedures monitored over the period covered by this report. The main institutions concerned are those carrying out endovascular image-guided interventions (EIGIs), in cardiology and/or neuroradiology. To assess the participation of the departments in these specific areas, it is possible to draw on the "FINESS" files of the healthcare activity authorisations (21) and the "Open CCAM" database (22).

According to FINESS data, at the end of 2020 there were around 193 institutions performing interventional cardiology activities (excluding paediatrics and rhythmology) and around 41 institutions performing interventional neuroradiology activities.

On this basis, the interventional cardiology participation rate shows an increase from 46 to 70% year-on-year from 2019 to 2021, with 84% of institutions sending data at least once during this period. In neuroradiology, participation shows an increase from 61 to 85% year-on-year with a total of 100% of institutions sending data during this period. These positive results illustrate the degree of support from institutions for the DRL system. However, the results should be analysed with caution, given that the number of institutions carrying out these activities is not entirely known. The small number of institutions authorised to carry out interventional neuroradiology activities (41) should also be highlighted. Thus, even with 100% of institutions having sent data at least once over the period, the number of assessments in this area remains low (25 to 35 per year) and just within the limit of the 20 assessments necessary for the reliability of the results. The low number of assessments for a large proportion of the procedures has led to an analysis over the three-year period and not per year for the interventional radiology area in general.

For image-guided interventional procedures concerning areas other than cardiology and neuroradiology, the number of institutions concerned is difficult to establish as there is no dedicated activity designation in the healthcare activity authorisation files. For this reason, the contribution from departments illustrated in figure 8 below is presented as an absolute number and not as a percentage as in the other areas.

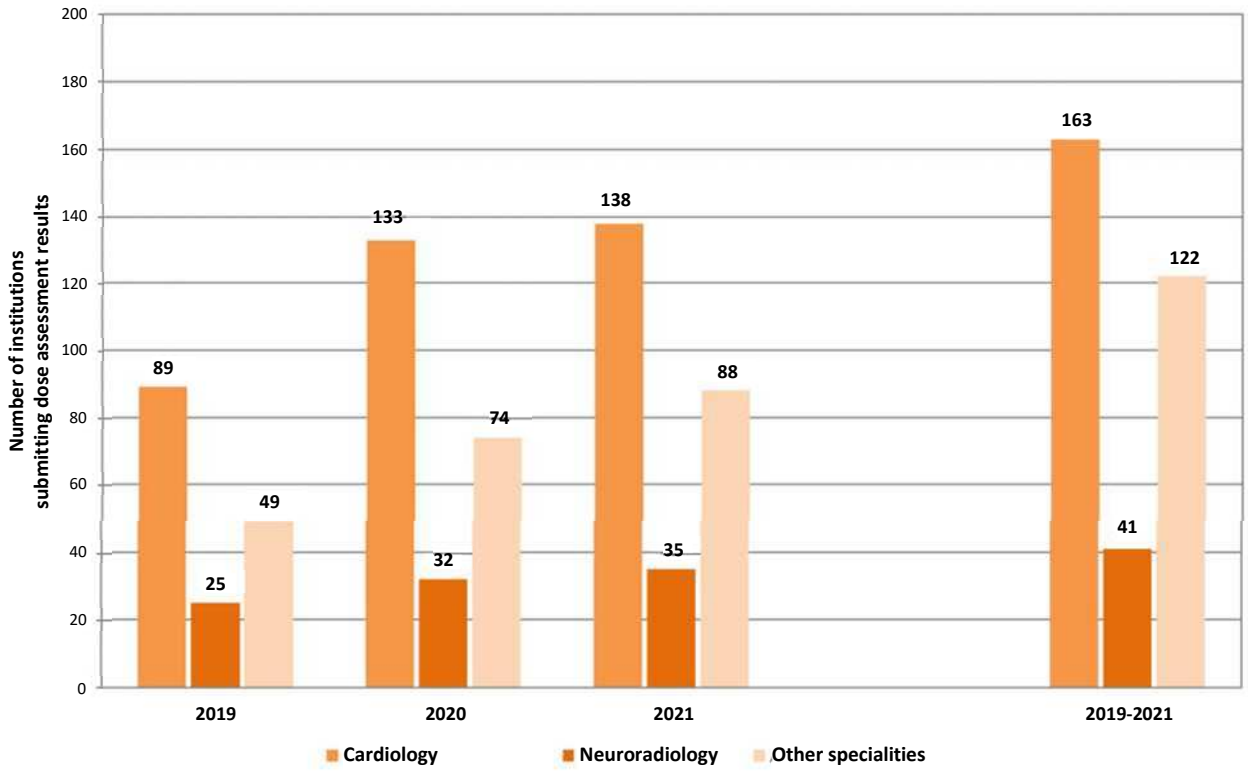

Figure 8: Number of institutions that have submitted dose assessments for interventional radiology, by area of activity.

4.2 DISTRIBUTION OF DATA BY TYPE OF PROCEDURE

Figure 9 below presents the percentage distribution, by type of procedure, of dose assessments submitted to IRSN by healthcare professionals from 2019 to 2021, together with the proportion of data that could be used by IRSN.

The rates of use of the submitted data are low; they range from approximately 50% for coronary angiography to 72% for biliary drainage with transcutaneous implanting of prosthesis. However, these low data use rates are not linked to data quality, but to the removal of "duplicates" to allow data analysis over a three-year period and not year by year. This is due, in the field of interventional radiology, to certain facilities being dedicated to certain specialities and specific procedures; hence, many institutions only perform a small number of types of procedures considered in the list of ASN resolution 2019-DC-0667. Therefore, many of them send data for the same procedures on the same facility every year. In this case, for the analysis over the three-year period, so as not to give more weight to one facility over another, only the assessment for the last year is kept. For example, for coronary angiography, out of a total of 550 submitted assessments, only 275 were used in this report. Of the 275 unused assessments, only 16 were not used for data quality reasons. This means that 259 assessments were not used due to the analysis over three years.

Coronary angiography and coronary artery angioplasty account for approximately 60% of the data. It is not possible to say precisely whether this distribution appears consistent with the frequency of the procedures carried out in France. This is because some of the procedures considered fall within the scope of therapeutic interventional radiology and are not analysed in the EXPRI study, which only concerns diagnostic activities (16).

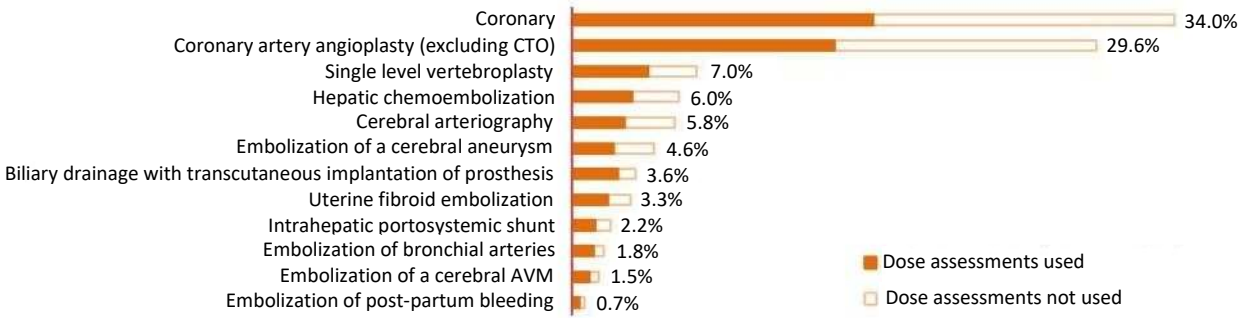

Figure 9: Percentage distribution by type of procedure of dose assessments in interventional radiology, the results of which were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 1,620).

4.3 SUMMARY OF INTERVENTIONAL RADIOLOGY RESULTS

The results of the dose assessments transmitted by interventional radiology professionals in terms of DAP, radioscopy time, and air KERMA at the reference point are presented in tables 4, 5 and 6 below. This is because, in addition to the DAP and the radioscopy time defined at regulatory level, it was possible, for each institution, to submit additional and optional data in terms of the number of radiography and air KERMA images at the reference point (see paragraph 2.4 of this report). As enough data was transmitted on the air KERMA at the reference point, these data could be analysed. Results for the number of radiography images are not presented because too many inconsistencies were found. The origin of these inconsistencies must be investigated in order to attempt to strengthen the reliability of the data submitted on this aspect for the next report.

For each of the procedures considered, the following are presented for 2019–2021:

- the number of assessments used (N),
- patient median weight and BMI values,
- the DRLs and ADs in force (DRL and AD),
- the 75th and 50th percentile values for the collected data,
- the 75th to 25th percentile ratio,
- the position of the 75th percentile with regard to the DRL in force (% DRL),
- the percentage of dose assessments data received over the DRL in force (> DRL).

Although the 75th percentiles of the radioscopy times are quite close to the DRLs set out by ASN resolution 2019-DC-0667, overall the 75th percentiles of the DAP are far below (between 30% and 54%). There may be several reasons for this:

- The SFPM study used for the determination of DRLs in interventional radiology (23; 24) was carried out on the basis of a data collection dating from the end of 2015 to January 2016; the DRLs in force are therefore based on already old data.
- In the SFPM study, the analyses were carried out based on the distributions of doses per patient and not on the distribution of medians per facility; the analysis of the median per facility is the analysis method used in the framework of the analysis reports carried out by IRSN every three years and which is recommended by the ICRP (25); this analysis method reduces the variations linked to each procedure (patient morphology, complexity of the procedure, etc.) and therefore the dispersion of data.

Given these results, IRSN recommends revising the value of DRLs in interventional radiology based on the results of this report.

The numerous data on air KERMA can be compared with the results of the SFPM and RAY ACT 2 studies (23; 24; 26). These data have proven to be very useful for data verification. IRSN recommends establishing, in addition, a DRL on this dose indicator based on the results of this report (see dedicated focus).

Table 4: Summary of results of interventional radiology data analysis by type of procedure in adults, for 2019 – 2021, expressed in terms of dose area product (DAP).

Examination type	N	Median weight (kg)	Median BMI (kg/m²)	DAP (Gy.cm²)				P75/P25 ratio	% DRL	> DRL
				DRL	AD	P75	P50			
Coronary angiography	275	76.0	26.1	38	21	20.0	14.6	2.00	-47%	1.5%
Coronary artery angioplasty (except chronic total occlusion)	240	77.0	26.3	80	45	40.7	28.6	2.09	-49%	2.1%
Cerebral arteriography (3 or more axes)	48	69.5	24.1	105	65	52.7	40.1	1.77	-50%	2.1%
Embolization of a cerebral aneurysm	38	67.0	24.0	190	130	129.8	96.2	1.80	-32%	0.0%
Embolization of cerebral arteriovenous malformation	16	71.0	24.2	285	170	199.8	152.3	1.69	-30%	6.3%
Hepatic chemoembolization	55	77.5	26.3	240	115	155.5	101.7	2.49	-35%	12.7%
Embolization of bronchial arteries	20	69.8	23.8	135	70	74.7	51.3	3.21	-45%	0.0%
Embolization of a uterine fibroid	33	64.5	23.5	130	55	59.5	35.5	2.11	-54%	0.0%
Embolization of post-partum bleeding	7	69.0	24.5	295	170	139.2	100.1	2.02	-50%	0.0%
Intrahepatic portosystemic shunt (IPS)	21	74.5	25.3	190	95	127.0	96.3	2.38	-33%	9.5%
Biliary drainage with transcutaneous implanting of prosthesis	42	66.3	23.3	45	20	23.5	17.5	3.23	-48%	4.8%
Vertebroplasty (1 vertebral level)	69	67.0	24.2	60	30	27.8	15.0	9.24	-54%	4.3%

Table 5: Summary of results of interventional radiology data analysis by type of procedure in adults, for 2019 – 2021, expressed in terms of radioscopy time.

Examination type	N	Median weight (kg)	Median BMI (kg/m²)	Radioscopy time (min)				P75/P25 ratio	% DRL	> DRL
				DRL	AD	P75	P50			
Coronary angiography	275	76.0	26.1	6	4	4.3	3.2	1.74	-28%	8.4%
Coronary artery angioplasty (except chronic total occlusion)	240	77.0	26.3	15	10	12.9	10.3	1.65	-14%	15.0%
Cerebral arteriography (3 or more axes)	48	69.5	24.1	13	8	12.6	10.2	1.74	-3%	25.0%
Embolization of a cerebral aneurysm	38	67.0	24.0	58	37	50.2	43.8	1.74	-13%	15.8%
Embolization of cerebral arteriovenous malformation	16	71.0	24.2	68	45	75.8	57.4	1.80	+11%	37.5%
Hepatic chemoembolization	55	77.5	26.3	27	18	26.7	21.7	1.80	-1%	21.8%
Embolization of bronchial arteries	20	69.8	23.8	38	25	26.2	24.1	1.23	-31%	5.0%
Embolization of a uterine fibroid	33	64.5	23.5	29	25	21.5	15.4	1.90	-26%	6.1%
Embolization of post-partum bleeding	7	69.0	24.5	25	15	20.1	18.9	1.45	-20%	0.0%
Intrahepatic portosystemic shunt (IPS)	21	74.5	25.3	39	25	28.6	21.5	1.61	-27%	4.8%
Biliary drainage with transcutaneous implanting of prosthesis	42	66.3	23.3	18	11	15.0	11.4	2.20	-17%	2.4%
Vertebroplasty (1 vertebral level)	69	67.0	24.2	9	6	6.9	4.1	5.02	-23%	11.6%

Table 6: Summary of results of interventional radiology data analysis by type of procedure in adults, for 2019 – 2021, expressed in terms of air KERMA at the reference point.

Examination type	N	Median weight (kg)	Median BMI (kg/m²)	K_{air} at reference point (mGy)				P75/P25 ratio
				RAY ACT 2	SFPM	P75	P50	
Coronary angiography	224	76.0	26.0	353	-	258.2	187.5	1.89
Coronary artery angioplasty (except chronic total occlusion)	196	77.0	26.3	920	-	626.0	448.0	1.96
Cerebral arteriography (3 or more axes)	38	69.8	24.1	-	720	364.4	261.6	1.64
Embolization of a cerebral aneurysm	30	67.1	24.0	-	2765	2258.6	1177.5	2.53
Embolization of cerebral arteriovenous malformation	14	70.5	24.1	-	3235	2154.7	1532.4	1.90
Hepatic chemoembolization	48	77.5	26.3	-	1000	935.2	586.7	2.28
Embolization of bronchial arteries	18	70.0	23.8	-	845	350.8	320.3	2.03
Embolization of a uterine fibroid	27	64.0	23.4	-	700	314.8	206.0	2.08
Embolization of post-partum bleeding	7	69.0	24.5	-	940	722.8	501.3	2.65
Intrahepatic portosystemic shunt (IPS)	17	74.5	25.5	-	810	717.2	292.2	3.24
Biliary drainage with transcutaneous implanting of prosthesis	32	65.9	23.3	-	310	140.9	102.3	2.87
Vertebroplasty (1 vertebral level)	43	68.0	24.2	-	610	358.6	224.0	4.25

The analyses per type of procedure are detailed in the Annex to this report in the form of datasheets. For each type of procedure for which the data collected enables an analysis to be made, these datasheets present:

- DAP, radioscopy time, and air KERMA distribution graphs for 2019–2021;
- a table showing the associated statistical data.

Given that these procedures were introduced in 2019 in the ASN resolution, it is not possible to analyse the evolution of results in relation to the results of previous reports.

Insofar as the 75th percentiles for 2019–2021 in terms of DAP are 30% to 54% below the DRLs in force, a revision of the DRLs appears necessary.

Significant data dispersion is noted, particularly for the DAP with a 75th/25th percentile ratio of 2 to slightly more than 3 (apart from vertebroplasty). The highest 75th/25th ratios are observed for therapeutic procedures. Differences in the complexity levels of interventions could explain a large proportion of these dispersions. The results for the radioscopy times appear to be less variable.

With regard to vertebroplasty, a $75^{th}/25^{th}$ ratio greater than 9 is observed. The reason for this is the submission of data for both mobile and fixed units. Separate data analysis leads to a 50^{th} percentile in terms of DAP that is 10 times higher for fixed units than for mobile units. Hence, under the term "vertebroplasty", different types of procedures performed on different units are grouped together, which leads to a very wide dispersion of data. In the future, it would certainly be advisable to better define this typology of procedure in order to refine the results.

Finally, ASN resolution 2019-DC-0667 currently requires the submission of data in interventional radiology for at least 10 consecutive adult patients and not for at least 30 patients as for the other areas. This choice to limit the quantity of data sent by the centres had been made when the aforementioned resolution was drawn up, in order to encourage the participation of the institutions. However, in order to reinforce the robustness of dose assessments, it would now be advisable to increase the minimum quantity of data required for dose assessments in interventional radiology. To this end, it would be interesting to study the relevance of a mass data transmission from DACS, even if the data were incomplete, since information on patient weights and sizes is rarely available in these databases. This study could be initiated in the field of interventional radiology and, if this principle proves satisfactory, it could be extended to the other areas.

FOCUS – INTERVENTIONAL RADIOLOGY

AIR KERMA AT THE REFERENCE POINT

Although this data is optional, a large proportion of the assessments submitted in interventional radiology specified the air KERMA values at the reference point (14) (60 to 100% of the assessments depending on the procedure).

These data, which are easily accessible, are very often used by professionals (medical physicists, doctors, etc.) as a means of alert, particularly as a complement to the DAP, the rationale for this being that, for procedures requiring small fields, the DAP can remain low while air KERMA at the reference point can be high. Users have therefore already become accustomed to looking at this dose indicator and have spontaneously submitted it to IRSN.

This indicator has proven to be very useful for IRSN in the context of data verification. The DAP/K_{air} ratio should approximate the average field area used during the procedure. Thus, data with an inconsistent DAP/K_{air} ratio were excluded from the analysis.

It is not possible to compare the results obtained with DRL values since this indicator is not defined in the regulations. However, it is possible to compare the results of this report with the results of the studies used to upgrade DRLs in interventional radiology, namely the RAY'ACT-2 study and the SFPM study (23; 24; 26).

For most procedures, the results in terms of air KERMA at the reference point (see table 6 above) are far below the results obtained during the SFPM and RAY'ACT-2 studies, in particular for the embolization of bronchial arteries and embolization of a uterine fibroid. This is also true for brain arteriography (3 or more axes), but for this procedure, a bias in the data is possible because some of the data transmitted may concern fewer than 3 axes. Similarly, for vertebroplasty, the data submitted to IRSN concern procedures carried out on mobile units or fixed units with very different dose levels. The same reasons as stated above for the results of DAP values can be put forward to explain the difference between the results of this report and the results of the RAY'ACT 2 and SFPM studies (data from studies that are recent or less recent; study of the distribution of doses per patient versus the median distribution of doses from the units).

IRSN therefore recommends establishing, in addition to the DRLs in terms of DAP and radioscopy time, a DRL on air KERMA at the reference point based on the results of this report.

SUMMARY – INTERVENTIONAL RADIOLOGY

Analysis of interventional radiology dose assessments shows:

- a high degree of participation by interventional cardiology and neuroradiology institutions since the introduction in 2019 of the DRLs newly defined in the regulations;
- 75^{th} percentiles for 2019–2021 that are 30% to 54% below the DRLs in force;
- a high level of data dispersion, particularly for DAP with a $75^{th}/25^{th}$ percentile ratio of around 2 to 3 (excluding vertebroplasty);
- an even higher level of vertebroplasty data dispersion with a $75^{th}/25^{th}$ percentile ratio, for DAP, higher than 9 due to the consideration of data relating to both mobile and fixed units;
- a large amount of data transmitted in terms of air KERMA at the reference point, which is very useful for data validation;
- inconsistent results in terms of the number of radiography images.

RECOMMENDATIONS – INTERVENTIONAL RADIOLOGY

Analysis of interventional radiology dose assessments has led IRSN to issue the following recommendations:

- revise the DRL values;
- monitor the evolution of the results of vertebroplasty procedures and, possibly, revise in the long term the definition of its DRL based on feedback since 2019;
- add the air KERMA at the reference point as an extra DRL quantity in addition to the DAP and the radioscopy time;
- investigate the origin of inconsistencies in the data in terms of the number of radiography images in order to make the data received for this indicator more reliable;
- consider increasing the quantity of patient data to be requested for each assessment submitted by studying the relevance of a mass data transmission from DACS without patient weights and sizes, with the aim of obtaining average data more representative of clinical practice;
- consider, from proposals of stakeholders consulted on the DRL system in 2022:
  - the creation of DRLs for two rhythmology procedures considered to be the most irradiating: atrial fibrillation ablation and ventricular resynchronization (= triple or multisite cardiac stimulation); the “rhythmology” group of the Société Française de Cardiologie (French cardiology society) must be consulted to carry out this work;
  - the introduction, in the long term, of interventional procedures performed under CT examination, in particular by engaging in reflection on interventional cardiology procedures (TAVI, mitral valvuloplasty) or interventional vascular radiology (peripheral vascular angioplasty, other procedures to be specified) performed in operating theatres or hybrid rooms, and not in dedicated radiology rooms.

COMPUTED TOMOGRAPHY

5.1 CONTRIBUTION OF DEPARTMENTS

For the 2019–2021 period, IRSN used the heavy equipment authorisation data available on the data.gouv.fr website to update the estimate of the total number of CT devices used for diagnostic radiology. According to these data, their number has continued to increase compared to the 2016–2018 period, from 1,184 devices in 2019 to 1,279 in 2021.

In addition, it should be noted that:

- insofar as CT examinations for simulation in radiotherapy do not fall within the scope of the DRLs, they are not therefore dealt with in this assessment;
- scanning acquisitions performed in positron emission tomography (PET) examinations are covered in the nuclear medicine section.

Dose assessments were submitted for around 90% of units in 2019–2021. Participation even exceeded 90% in 2020 (see figure 10 below). This increase of 5 points over 2020 is probably due to the changes made by ASN resolution 2019-DC-0667. This resolution requires an annual assessment of the doses of at least two procedures for each CT device, whereas previously this was the requirement for each institution; institutions with several CT scanners could therefore focus on only a fraction of the devices. However, this increase did not continue into 2021.

In computed tomography, distribution of data sources is balanced between the public sector and the private sector (see figure 11 below), except for the special case of paediatrics. This data source distribution is consistent with the distribution of scanners between the public and private sectors, which had been estimated at around 47% and 53% respectively in the previous report (27).

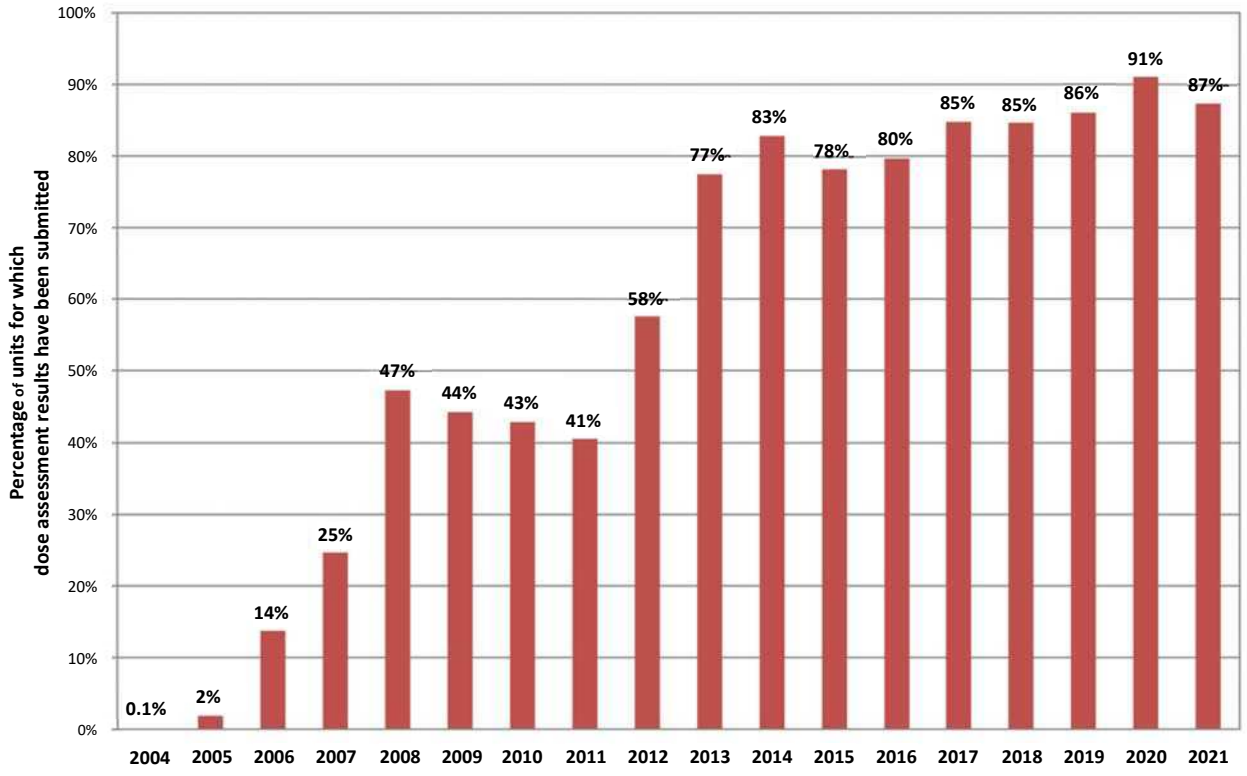

Figure 10: Change in annual participation of institutions performing computed tomography procedures since 2004.

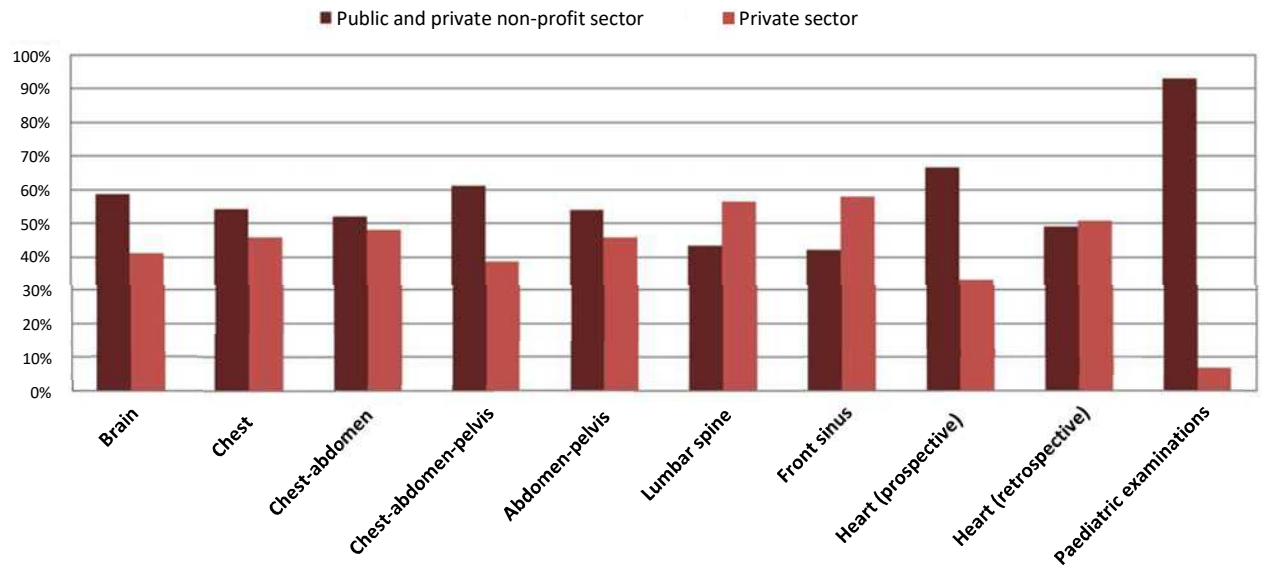

Figure 11: Source of data collected for computed tomography DRLs, for 2019–2021, according to the type of examination and sector of activity.

5.2 DISTRIBUTION OF DATA BY EXAMINATION TYPE

Adult examinations

Figure 12 shows the distribution, by percentage, of dose assessments submitted by professionals per examination type, together with the proportion of data that IRSN has been able to use.

The examinations with the greatest number of dose assessments are the brain, followed by the chest, and finally the abdomen-pelvis (AP) region. This moves the chest into second position, compared to third in the previous report. This could be an effect of the Covid-19 crisis, which led institutions to take a closer look at chest examinations.

For the examinations introduced by ASN resolution 2019-DC-0667 (front sinus, abdomen-chest, heart (retrospective), heart (prospective)), little data were transmitted, in particular for the two examinations of the heart and the abdomen-chest.

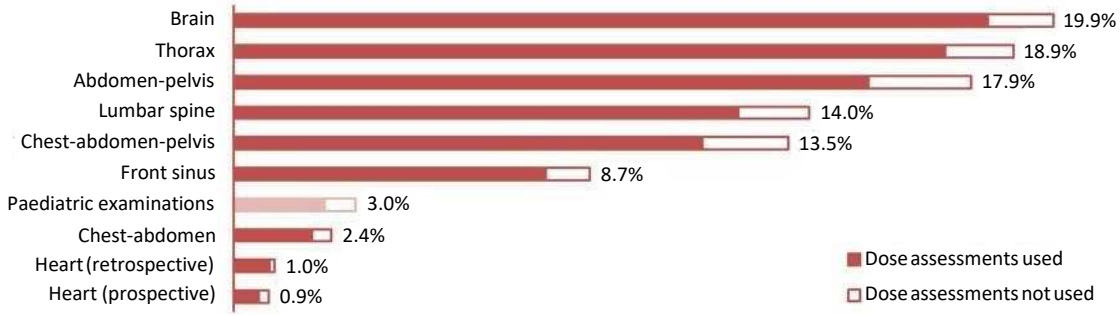

Figure 12: Distribution by examination type of computed tomography dose assessments for which results were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 6,697)

In total, around 88% of computed tomography data submitted to IRSN have been used for national analysis, which represents an improvement compared to the previous report, for which this percentage was around 80%.

The brain examination remains the procedure with the lowest rejection rate (around 9%) because the BMI criterion does not apply. The prospective heart and the chest-abdomen region are the examinations with the highest rejection rate (around 20% to 30%), which may be explained by the acquisition length validation criterion (see paragraph on data analysis in chapter 2.4 of this report).

Paediatric examinations

The number of paediatric CT assessments, although having increased compared to the previous report, is still very low with, on the one hand, fewer than 3% of all data relating to CT examinations (see figure 12), compared to 2% in the previous report, and only 7 to 37 dose assessments submitted to IRSN per examination type and weight category (see figure 13), compared to 1 to 17 assessments in the previous report. As in the previous assessment, brain and chest examinations are most frequently subject to dose assessments. Despite regulatory changes, the volume of data received still does not allow a robust assessment of practices at national level.

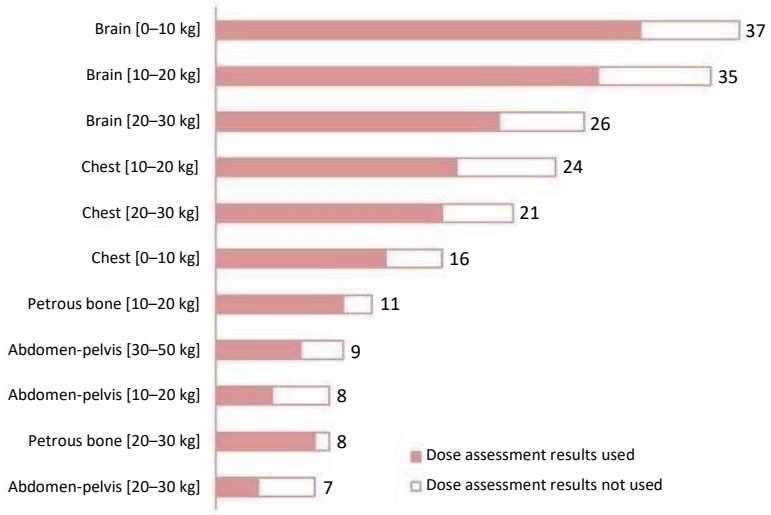

Figure 13: Distribution by examination type and weight of the number of child CT dose assessments for which results were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 202).

5.3 SUMMARY OF COMPUTED TOMOGRAPHY RESULTS

Adult examinations

Tables 7 and 8 below show the results of analyses of adult computed tomography data collected between 2019 and 2021, by examination, in terms of $CTDI_{vol}$ and then DLP.

These tables show:

- the number of assessments used for 2021 and the period 2019–2021 (N),
- the median weight and BMI values for patients associated with the collected data,
- the DRLs and ADs currently in force,
- the 75th and 50th percentile values for the data collected in 2021,
- the 75th to 25th percentile ratio for 2021,
- the position of the 75th percentile for 2021 with regard to the DRL in force (% DRL),
- the percentage of dose assessments data received in 2021 higher than the DRL in force (> DRL),
- the 75th percentile variation in 2021 compared to the 2018 value published in the previous report.

Table 7: Summary of adult computed tomography analyses, by examination, for 2021 data, in terms of volume computed tomography dose index ($CTDI_{vol}$). The last 4 examinations in the table are examinations newly introduced by ASN resolution 2019-DC-0667, with the calculations made for the 2019–2021 period and not for 2021 alone.

Examination type	N 2021 (2019-2021)	Median weight (kg)	Median BMI (kg/m²)	$CTDI_{vol}$ (mGy)				P75/P25 ratio	% DRL	> DRL	Variation
				DRL	AD	P75	P50				
Brain	431 (1,245)	70.0	24.7	46	40	39.6	36.6	1.17	-14%	2.8%	-3%
Chest	406 (1,176)	73.0	25.4	9.5	7.5	6.6	5.5	1.52	-30%	2.5%	-11%
Chest-abdomen-pelvis	295 (775)	70.5	24.9	11	9.5	9.1	7.8	1.34	-18%	3.7%	-10%
Abdomen-pelvis	389 (1,049)	71.0	25.0	13	11	9.5	8.2	1.35	-27%	1.0%	-6%
Lumbar spine	304 (834)	72.0	25.4	28	23	21.6	19.3	1.27	-23%	3.0%	-10%
Front sinus	(515)	70.0	24.7	14	-	6.9	5.5	1.56	-51%	1.0%	-
Chest-abdomen	(129)	71.0	24.8	11	9.5	8.6	7.4	1.33	-22%	3.1%	-
Heart (prospective)	(42)	74.8	25.0	26	18	16.2	10.5	2.43	-38%	4.8%	-
Heart (retrospective)	(59)	74.0	26.0	44	30	33.2	27.3	1.48	-25%	5.1%	-

Table 8: Summary of adult computed tomography analyses, by examination, for 2021 data, in terms of DLP. The last 4 examinations in the table are examinations newly introduced by ASN resolution 2019-DC-0667, with the calculations made for the 2019–2021 period and not for 2021 alone.

Examination type	N 2021 (2019-2021)	Median weight (kg)	Median BMI (kg/m²)	DLP (mGy.cm)				P75/P25 ratio	% DRL	> DRL	Variation
				DRL	AD	P75	P50				
Brain	431 (1,245)	70.0	24.7	850	725	734	673	1.19	-14%	3.5%	-1%
Chest	406 (1,176)	73.0	25.4	350	275	248	208	1.52	-29%	3.2%	-13%
Chest-abdomen-pelvis	295 (775)	70.5	24.9	750	650	620	534	1.33	-17%	3.7%	-10%
Abdomen-pelvis	389 (1,049)	71.0	25.0	625	525	475	408	1.38	-24%	2.1%	-3%
Lumbar spine	304 (834)	72.0	25.4	725	625	621	537	1.40	-14%	6.9%	-5%
Front sinus	(515)	70.0	24.7	250	-	101	81	1.56	-60%	0.4%	-
Chest-abdomen	(129)	71.0	24.8	550	475	415	359	1.37	-25%	2.3%	-
Heart (prospective)	(42)	74.8	25.5	375	325	259	171	2.28	-31%	7.1%	-
Heart (retrospective)	(59)	74.0	26.0	875	550	624	505	1.48	-29%	1.7%	-

For the examinations of the brain, chest, abdomen-pelvis, chest-abdomen-pelvis and lumbar spine, there was a 1% to 13% decrease in $CTDI_{vol}$ and DLP compared to the previous report.

The 75th percentiles for 2021 in terms of $CTDI_{vol}$ and DLP are below the DRLs in force since 1 July 2019 by 14 to 60% for all examinations considered. They are slightly lower than the AD for almost all examinations. Aside from the examinations of the chest and abdomen-pelvis, the examinations introduced by the 2019 ASN resolution (frontal sinus, chest-abdomen, prospective and retrospective heart) were mainly among those with the 75th percentiles the furthest below the DRLs. The downward trend of DRL quantities for this region seems more marked than for the brain, for instance. This downward trend could be explained by technological developments, and particularly the widespread use and improvement of iterative image reconstruction algorithms, with this type of algorithm being more effective on the abdomen-pelvis region than on the brain. In addition, institutions performing very low-dose examinations for specific indications on certain anatomical regions have submitted data leading to extremely low minimum doses compared to the previous report; this is the case in particular for the chest and lumbar spine, for example.

The quantity of data collected over the 2019–2021 period is satisfactory for the examinations of the brain, chest, abdomen-pelvis, chest-abdomen-pelvis, and lumbar spine since, for each of them, several hundred assessments were submitted. For the examinations introduced in the ASN resolution 2019-DC-0667 (frontal sinus, chest-abdomen, prospective and retrospective heart), only the frontal sinus examination accounts for more than 100 assessments. The data for these new examinations were therefore aggregated over 3 years in order to be able to make an analysis.

The results for each type of examination over the 2019–2021 period are detailed in the Annex to this report. The figures representing the change in the $CTDI_{vol}$ and DLP since 2011 show a continuous decrease of the 75th percentiles regardless of the type of examination.

As stated in the previous report, the DRL values of ASN resolution 2019-DC-0667 were established on the basis of data dating from 2015, and the drop in the decrease in the values of DRL quantities observed over the period 2016–2018 (12% compared to the period 2013–2015) is confirmed in this report (8% drop compared to the period 2016–2018 (excluding new examinations)). Overall, the results over the period were 28% below the DRLs. It therefore seems necessary to revise the values of computed tomography DRLs.

Furthermore, as illustrated in the previous report, defining DRLs by anatomical region leads to combining data that is very heterogeneous because they present significantly varying clinical objectives. A change in the definition of DRLs in computed tomography to DRLs by clinical indication must be considered.

To this end, device diagnostic performance assessment should be taken into account in the DRL framework in order to be able to ensure that the examination quality requirements associated with delivered doses are complied with. However, as outlined in the conclusions of the European EUCLID project (28), the assessment of image quality for the determination of DRLs based on a clinical indication is not a trivial task. International studies are needed to establish guidelines on image quality criteria relevant for the assessment of DRLs based on a clinical indication.

Paediatric examinations

Table 9 below shows the results of analyses of data submitted in terms of $CTDI_{vol}$ and DLP for the paediatric computed tomography examinations. The table shows the number of assessments used (N) over the 2019–2021 period, the median, minimum and maximum weights of patients concerned by the data collected, the value of the 75th percentile, the value of the 50th percentile, the 75th and 25th percentile ratio, and the percentage of dose assessments received over the period above the DRL in force (> DRL) and, for examinations for which sufficient data have been collected, the position of the 75th percentile over the period with regard to the DRL in force (% DRL).

As in the previous report, apart from the brain (all categories) and the chest (all categories), the number of assessments is too low (<10) for the results to be discussed. However, there was an increase in the number of assessments received for these examinations, which was in the order of 4 to 12 in the 2016–2018 report and which is 12 to 30 for the 2019–2021 report.

Only brain examinations for all categories contain sufficient data – over 20 assessments – and can be analysed in detail (see Annex).

Regarding the brain and chest, regardless of the weight category, the results in terms of $CTDI_{vol}$ are slightly lower than the DRLs of ASN resolution 2019-DC-0667, in the order of 0 to 12% according to the categories. As far as DLPs are concerned, this is not the case for all these examinations.

Consequently, it does not appear necessary to propose a possible adjustment of the DRLs in the short term. However, the weight categories defined for children in ASN resolution 2019-DC-0667 do not correspond to the weight categories defined at European level. A revision of this information would make it possible to draw comparisons with the results of other European countries (17).

Table 9: Summary of paediatric computed tomography analyses, by examination, in terms of volume computed tomography dose index ($CTDI_{vol}$) and dose length product (DLP).

Examination type	Weight category (kg)	N	Median weight (kg)	CTDIvol (mGy)						DLP (mGy.cm)					
				DRL	P75	P50	P75/P25 ratio	% DRL	> DRL	DRL	P75	P50	P75/P25 ratio	% DRL	> DRL
Brain	0 to <10	30	6.2	20.0	18.8	16.0	1.44	-6%	7%	320	297	259	1.49	-7%	10%
	10 to <20	27	13.0	22.0	21.9	20.8	1.27	0%	26%	360	399	364	1.19	11%	52%
	20 to <30	20	23.5	26.0	25.0	21.6	1.22	-4%	20%	470	450	415	1.18	-4%	20%
Petrous bone	10 to <20	9	16.0	43.0	46.3	34.72	1.49	-	33%	240	242	210	1.35	-	33%
	20 to <30	7	24.0	51.0	43.0	38.4	1.18	-	14%	330	245	229	1.49	-	0%
Chest	0 to <10	12	6.7	1.1	0.97	0.82	1.33	-12%	8%	20	17.7	14.3	1.45	-12%	17%
	10 to <20	17	15.0	1.3	1.20	1.00	1.62	-8%	18%	26	30.7	22.5	2.01	18%	35%
	20 to <30	16	23.3	1.4	1.39	1.05	1.88	-1%	19%	40	40.8	28.8	2.10	2%	25%
Abdomen-pelvis	10 to <20	4	13.3	2.0	1.39	1.25	1.24	-	0%	65	43	39	1.15	-	0%
	20 to <30	3	23.0	2.5	2.36	2.02	1.35	-	33%	95	89	77	1.34	-	33%
	30 to <50	6	39.3	4.0	3.91	3.51	1.22	-	17%	180	159	152	1.06	-	17%

FOCUS – COMPUTED TOMOGRAPHY

RADIATION PROTECTION OF CHILDREN EXPOSED TO CT SCANS

For several years, IRSN, along with the European scientific community, has been interested in paediatric radiation protection because children are particularly sensitive to the effects of ionising radiation compared to adults.

IRSN periodically analyses the exposure of the French population to ionising radiation due to diagnostic medical imaging examinations, in line with the missions entrusted to it under the Public Health Code. In addition to the study concerning the medical exposure of the general population during 2017 (16), IRSN conducted a specific study concerning computed tomography procedures in children under 16 years of age based on a representative sample of health insurance beneficiaries in France between 2012 and 2018 (29). Over this period, the number of CT procedures is constant, with an average of 14 scans per year per 1,000 children. However, a variation in the number of procedures per year per 1,000 children is observed depending on age: approximately 15 scans for those under 1 year of age; fewer than 10 between 1 and 9 years of age; then increasing to over 35 scans at 15 years of age. Finally, this study shows that children exposed to computed tomography had, for the vast majority, only one examination per year, and depending on the year, 11–16% of them had several.

Since CT and MRI (magnetic resonance imaging) have a large number of common indications and the recommendations of healthcare professionals are consistent with the transfer of certain CT procedures to MRI, a study of the evolution of MRI procedures was also carried out. This study shows that, unlike computed tomography, the annual frequency of MRI procedures increased significantly (+59%) over the study period.

Furthermore, IRSN also conducted an epidemiological study aimed at assessing the risk of radiation-induced cancer following exposure to a scan in childhood. Launched in 2009, the “Enfant Scanner” (“Child Scan”) cohort involved approximately 100,000 children exposed to a first CT scan before the age of 10, between 2000 and 2010. An initial analysis of approximately 65,000 children revealed low excess risk of brain tumours and leukaemia. The inclusion of additional children and the extension of cohort follow-up until 2016 confirmed the previously observed excess risks. These results were published in 2022 (30; 31).

In addition, at European level, a study was also conducted by the International Agency for Research on Cancer (WHO-IARC). This European project, called “EPI-CT”, was launched to quantify the excess risk of cancer associated with exposure to ionising radiation due to the performance of one or more scans in children and young adults. The study incorporated a cohort of 1 million children and young adults who received at least one CT scan in 276 radiology departments in Belgium, Denmark, France, Germany, the Netherlands, Norway, Spain, Sweden and Great Britain between 1977 and 2014. This study shows an excess risk of developing brain cancer after CT scans of the head in children and young adults; this risk increases as the cumulative dose increases (32). For 10,000 children that received a single CT scan of the head (estimated dose of 38 mGy on average), 1 brain cancer

attributable to exposure to ionising radiation is expected to be observed in the 5–15 year period following the examination[8].

As illustrated in this report, it should be noted that, with regard to the brain and the chest, the results in terms of $CTDI_{vol}$ in children are slightly lower than the DRLs of ASN resolution 2019-DC-0667, by up to 12%. Furthermore, according to data from previous IRSN reports, a downward trend has been observed since 2011 in the doses delivered by scanners for paediatric examinations of the brain, abdomen-pelvis, and chest (see figure 14 below). However, this reduction should be considered with caution because of the small quantity of data collected during these periods.

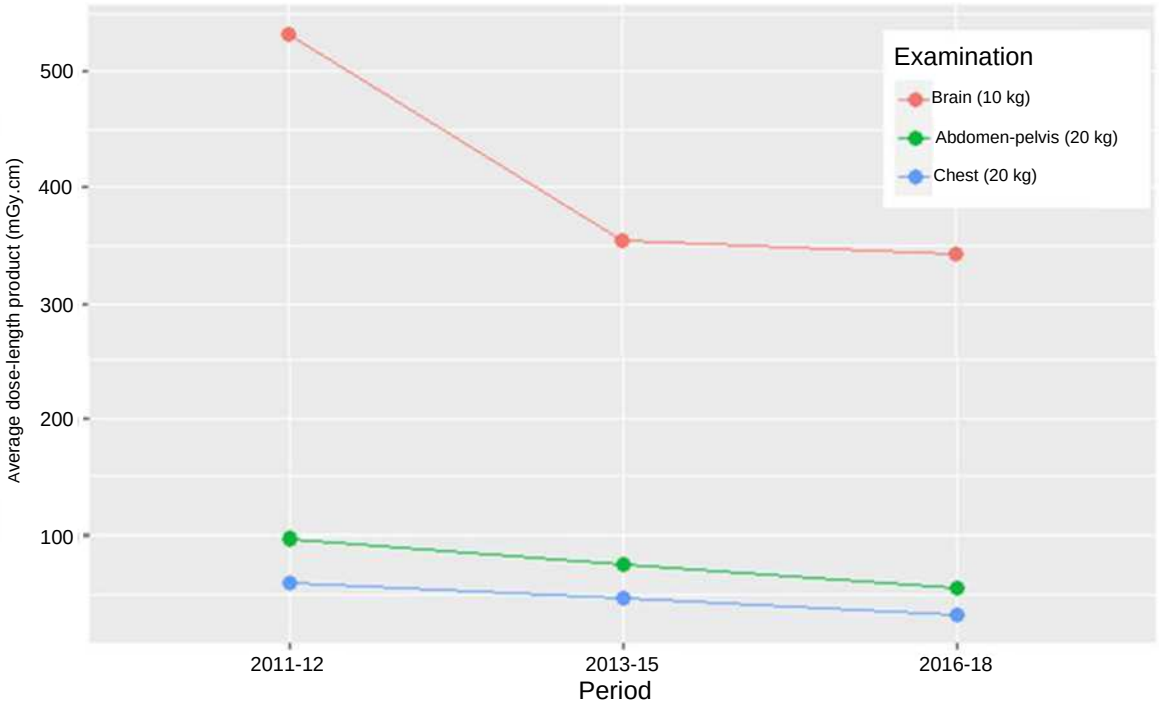

Figure 14: Development of dose values in computed tomography (dose length product) in children, for 3 anatomical regions (brain 10 kg, abdomen-pelvis 20 kg, and chest 20 kg) monitored as part of the DRL system

However, it can be emphasised that, owing to the period of performance of the CT examinations (prior to 2014) considered in the aforementioned "Enfant Scanner" ("Child Scan") and "EPI-CT" studies, the dose levels taken into account in these studies are higher than the dose levels delivered on average today for the same examination.

Be that as it may, these studies reinforce the importance of radiation protection rules for this particularly radiation-sensitive paediatric population, based on the principles of justification and optimisation of CT scans, as recapitulated in the WHO guide recently translated into French (33).

Finally, it should be recalled that in its 2018 report relating to the "fleet of scanners and recommendations relating to radiation protection in medical imaging" (34), IRSN found, in the field of paediatrics, an inconsistency in the system of reimbursement of imaging procedures that could favour radiological examinations to the detriment of examinations not using ionising radiation, such as MRI and ultrasound. Indeed, the CCAM provides for the application of "modifiers", which make it possible to evaluate certain specific circumstances for the performance of procedures. For paediatrics, there are modifiers, particularly in computed tomography, for children under the age of 5, which make it possible to evaluate the specific circumstances for the performance of the procedure. There are none for non-irradiating examinations such as ultrasound and MRI in paediatrics, while there is also the problem of the time required, particularly for sedation, for these techniques.

[8] https://www.irsn.fr/FR/Actualites_presse/Actualites/Pages/20221206_EPI-CT.aspx#.Y9jjV3CZPIU

SUMMARY – COMPUTED TOMOGRAPHY

Analysis of computed tomography dose assessments shows:

- a computed tomography institution participation rate that has risen to around 90%;
- for adults:
    - a distribution of examinations selected by professionals for dose assessments with chest examinations to the fore (2nd location in quantity of data submitted after the brain), probably due to the Covid-19 crisis;
    - a fairly small quantity of data submitted for the examinations introduced in 2019 by the latest revision of the ASN resolution on DRLs;
    - for all the examinations considered, the 75th percentiles for 2021 in terms of $CTDI_{vol}$ and DLP below the DRLs by 14% to 60%, and slightly below the ADs;
    - an overall decrease of 8% in computed tomography dose indicators compared to 2016–2018, which confirms the previously observed decrease of 12% compared to 2013–2015;
- in paediatrics:
    - a significant increase in the number of assessments received, but the low volume of data still does not allow a robust assessment of practices at national level;
    - for the brain and chest, slightly lower $CTDI_{vol}$ results than the DRLs, which is not the case for all categories in terms of DLP.

RECOMMENDATIONS – COMPUTED TOMOGRAPHY

Analysis of computed tomography dose assessments for 2019–2021 leads IRSN to make the following recommendations:

- plan, as a priority, for computed tomography DRL updates to take into account clinical indications;
- provide, for examinations for which a DRL per clinical indication would not be defined, a revision to DRL values in adults;
- in paediatrics:
    - study the relevance of revising weight categories in order to align with European recommendations and thus allow comparisons to be made;
    - continue to encourage healthcare professionals to submit data, by reminding them that it is possible to collect data over a period of more than one year.

NUCLEAR MEDECINE

6.1 CONTRIBUTION OF DEPARTMENTS

Nuclear medicine departments were surveyed based on information published by ASN. There were 231 nuclear medicine departments listed at the end of 2015; 236 at the end of 2017 (35); and 239 in 2021 (36).

Figure 15 below presents the change in the number of nuclear medicine departments that submitted dose assessment results for the years 2004 to 2021.

Participation has stabilised since 2014, with around 90% of departments having submitted data.

In nuclear medicine, as in the previous report, the distribution of data sources is balanced between the public sector and the private sector (see figure 16 below), except for the special case of paediatrics and brain perfusion. This data source distribution is consistent with the distribution of facilities between the public and private sector (35). For paediatrics and brain perfusion, data comes primarily from the public sector, which could be explained by the specific nature of this type of examination and a low data submission rate.

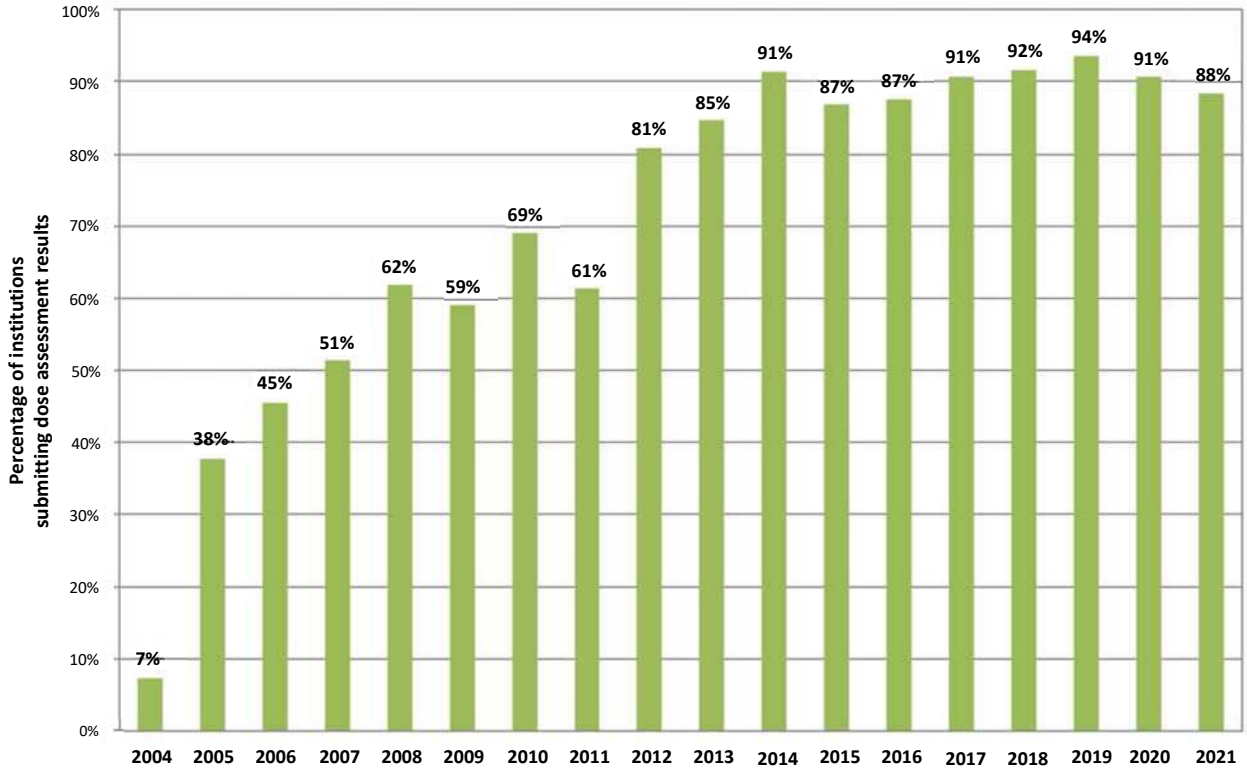

Figure 15: Change in annual participation of institutions performing nuclear medicine procedures since 2004.

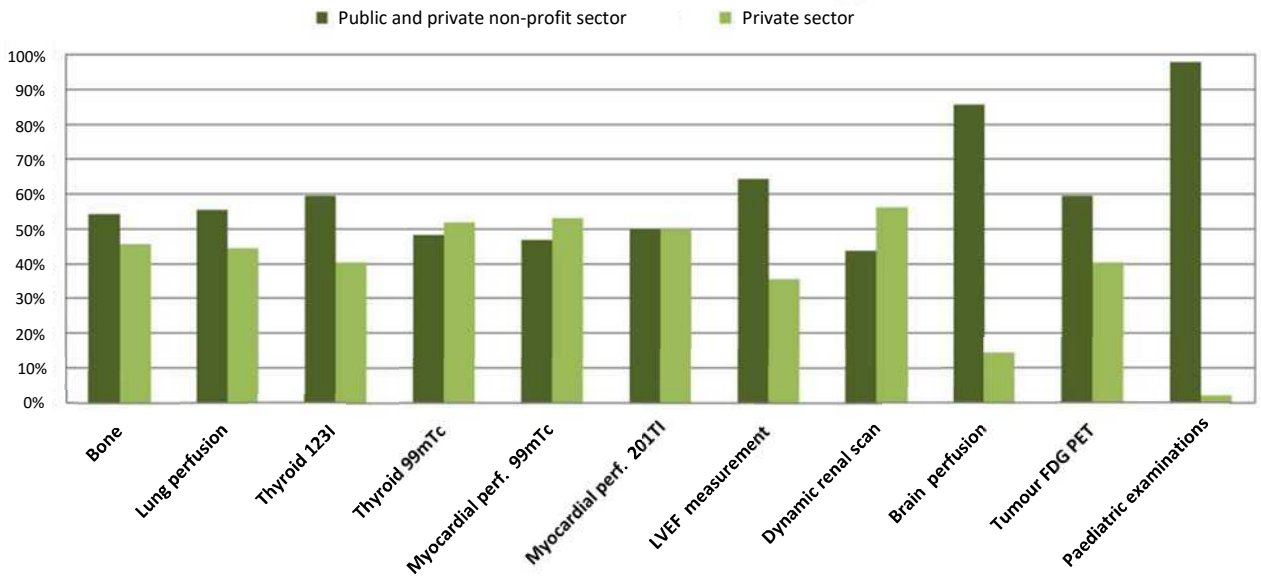

Figure 16: Source of data collected for computed DRLs, for 2019–2021, by examination type, in nuclear medicine.

6.2 DATA DISTRIBUTION BY EXAMINATION TYPE

Adult examinations

Figure 17 below shows the distribution of dose assessments submitted by nuclear medicine professionals to IRSN by examination type, in line with the list defined by ASN resolution 2019-DC-0667, together with the proportion of data that IRSN has been able to use.

Paediatrics is shown for all examinations in order to present the volume of paediatric data by comparison with all data submitted for nuclear medicine. It is detailed in the next section.

The number of dose assessments for PET examinations is now ahead of the number for bone scanning, which regularly accounted for the largest number of dose assessments since 2004. This is due to the fact that data are now received for the computed tomography part of the PET examinations, which increases the overall volume of data relating to these examinations (nuclear medicine part alone, computed tomography part alone, or both).

The number of assessments for ^{18}F-FDG PET and the paediatric examinations has thus increased by 4 points since the previous report in relation to the regulatory changes made by the 2019 ASN resolution.

Depending on the examination, the data use rate for the 2019–2021 period varies between 56% and 86%. The unused data submitted are almost exclusively redundant data (identical examination type and unit type). For statistical reasons and in order to avoid over-representation of some institutions, only the most recent dose assessment was taken into account for calculating the national indicators. This is particularly the case for ^{18}F-FDG PET, the examination for which the most data is received. Moreover, for the PET scan, some machines are managed by legal entities dedicated to this activity who submit data for this examination every year. Repeating assessments for the same examination over a 3-year period can still be useful for centres for monitoring doses delivered.

Dynamic renal scanning includes scans with DTPA and MAG3. However, renal scans with DTPA only represent 8% of the data received for this examination category, i.e., less than 1% of all data received for all nuclear medicine examinations combined. This low quantity of data received is undoubtedly linked to supply difficulties for this pharmaceutical product and the low number of examinations carried out. Furthermore, this examination represents little interest in dosimetric terms, so its removal could be considered from the list of examinations concerned by the DRLs. Similarly, the brain perfusion SPECT with ECD and HMPAO examinations were those that had the lowest number of dose assessments submitted. This is because brain examinations are increasingly performed using PET. Removal of this examination could also therefore be considered from the list concerned by the DRLs.

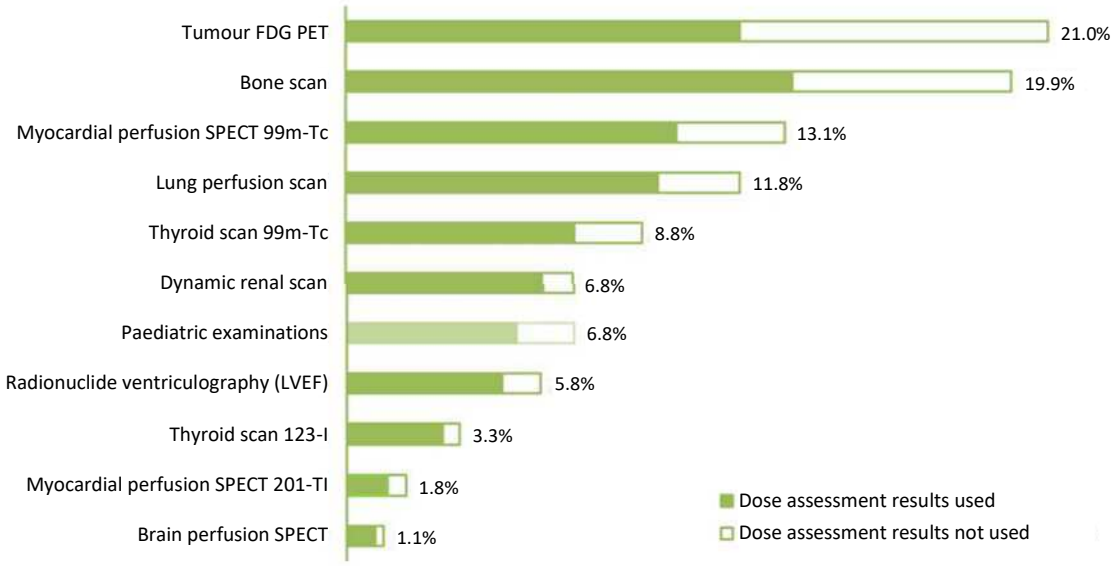

Figure 17: Distribution by examination type of nuclear medicine dose assessments for which results were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 1,642).

Paediatric examinations

The volume of assessments submitted for paediatric nuclear medicine remains very low, accounting for less than 6% of all data received. This number has, nonetheless, increased by 4 points compared to the previous report.

ASN resolution 2019-DC-0667 now makes it compulsory to carry out dose assessments when 5% of the procedures carried out on a medical device concern children (under 18 years of age). These new provisions have generated an increase in the quantity of data transmitted, but this remains insufficient for obtaining a robust analysis. The details of the data transmitted are shown in figure 18 below.

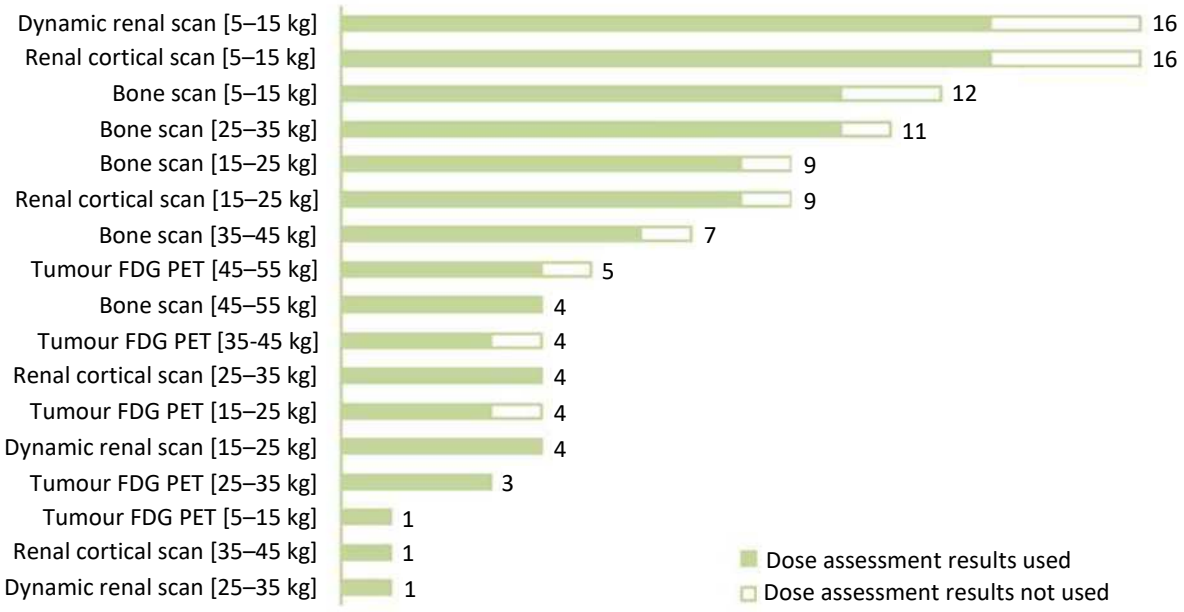

Figure 18: Distribution by examination of the number of child nuclear medicine dose assessments for which results were submitted to IRSN from 2019 to 2021 (total number of assessments submitted: 111).

6.3 SUMMARY OF NUCLEAR MEDICINE RESULTS

Adult examinations

Tables 10 and 11 below present the summary of analysis of data submitted for all nuclear medicine examinations subject to DRL regulations (except the CT part of PET examinations). Tables 12 and 13 present the results of the analyses of the data collected between 2019 and 2021 for the CT part of the PET examinations introduced by the 2019 ASN resolution in terms of $CTDI_{vol}$ and DLP, respectively.

These tables show, for the 2019–2021 period:

- the number of assessments used,
- the median weight for patients associated with the collected data,
- the DRLs in force,
- the 50th percentile values for the data collected [and the 75th percentile values for the CT part of a PET-CT with FDG procedure],
- the 75th to 25th percentile ratio,
- the position of the 50th percentile [or 75th percentile for the CT part of a PET-CT with FDG procedure] with regard to the DRL in force (% DRL),
- the percentage of dose assessments received for the period above the DRL in force (> DRL),
- and the 50th percentile variation for the period with regard to the 2018 value published in the previous report.

The results for each examination type for 2019-2021 are detailed in the report Annex.

It should be noted that, for dynamic renal scans with DTPA and brain perfusion SPECT scans with ECD and HMPAO, the position of the median with regard to the DRL in force cannot be used in this report because there are insufficient data.

For all other examinations, the analysis shows, over the 2019–2021 period, that the median values of the administered activities are 1 to 22% lower than the DRL in force. The same applies to the medians of the administered activities per body weight, which are 1 to 26% lower than the DRL in force. The largest deviations were noted for FDG-PET, with administered activities and administered activities per body weight being 22% and 26% lower than the DRLs in force.

The overall decrease in the values of the dose indicators observed over the period 2016–2018 (3% compared to the period 2013–2015) is confirmed in this report (4% compared to the period 2016–2018).

With regard to the CT part of the PET scans introduced by the 2019 ASN resolution, the results are also less than the DRLs in terms of DLP and $CTDI_{vol}$, whether for scans to mid-thigh or to the feet. The largest deviations are recorded for head-to-foot scanning, in the order of 30%.

Table 10: Summary of results of analysis of nuclear medicine data by adult examination type, for 2019-2021 data, in terms of administered activity.

Examination type	Radiopharmaceutical / protocol		N 2019-2021	Median weight (kg)	Administered activity (MBq)		P75/P25 ratio	% DRL	> DRL	Variation
					DRL	P50				
Bone	^{99m}Tc HDP/DPD		219	72.0	670	662	1.13	-1%	40%	+0%
Lung perfusion scan	^{99m}Tc MAA		153	72.5	225	194	1.49	-14%	35%	-7%
Thyroid scan	^{123}I (sodium iodide)		47	70.0	8	7.5	1.25	-6%	36%	-4%
	^{99m}Tc (sodium pertechnetate)		112	69.8	110	108	1.44	-2%	46%	+18%
Myocardial perfusion SPECT with stress test and/or pharmacological stimulation	^{99m}Tc MIBI/tetrofosmin	1 day/1st inj.	136	77.5	285	267	1.22	-6%	29%	-4%
		1 day/2nd inj.	136	77.5	785	760	1.23	-3%	38%	-1%
		2 days/1st inj.	26	79.3	615	550	1.45	-11%	23%	-12%
		2 days/2nd inj.	26	79.3	615	535	1.50	-13%	19%	-10%
	^{201}Tl (thallium chloride)	1st injection	20	75.5	110	101	1.44	-8%	20%	-5%
		Reinjection	18	75.5	37	35	1.66	-5%	33%	-5%
Equilibrium radionuclide ventriculography	^{99m}Tc human serum albumin/red blood cells		76	70.5	740	733	1.08	-1%	36%	-1%
Dynamic renal scan	^{99m}Tc MAG3		87	69.0	180	177	1.63	-2%	43%	-2%
	^{99m}Tc DTPA		9	68.0	255	168	1.41	-	11%	-32%
Brain perfusion SPECT	^{99m}Tc ECD		2	71.0	800	727	1.03	-	0%	+2%
	^{99m}Tc HMPAO		12	70.0	695	656	1.24	-	42%	-1%
Tumour FDG PET	^{18}F FDG		193	70.0	245	191	1.35	-22%	8%	-10%

Table 11: Summary of results of analysis of nuclear medicine data by adult examination type, for 2019-2021 data, in terms of administered activity per body weight.

Examination type	Radiopharmaceutical / protocol		N 20192021	Median weight (kg)	Activity per BW (MBq/kg)		P75/P25 ratio	% DRL	> DRL	Variation
					DRL	P50				
Bone	^{99m}Tc HDP/DPD		219	72.0	9.5	9.2	1.12	-4%	29%	-1%
Myocardial perfusion SPECT with stress test and/or pharmacological stimulation	^{99m}Tc MIBI/tetrofosmin	1 day/1st inj.	136	77.5	3.7	3.5	1.23	-6%	29%	-4%
		1 day/2nd inj.	136	77.5	10.3	9.7	1.21	-6%	33%	-3%
		2 days/1st inj.	26	79.3	7.7	7.0	1.52	-9%	27%	-5%
		2 days/2nd inj.	26	79.3	7.7	7.0	1.48	-9%	15%	-7%
	^{201}Tl (thallium chloride)	1st injection	20	75.5	1.4	1.38	1.45	-1%	40%	+2%
		Reinjection	18	75.5	0.5	0.48	1.58	-5%	17%	-1%
Tumour FDG PET	^{18}F FDG		193	70.0	3.5	2.6	1.24	-26%	6%	-14%

Table 12: Summary of analyses performed on the CT part of a full body PET-CT scan with FDG for scans to mid-thigh and foot in adults, for 2019–2021 data, in terms of volume computed tomography dose index ($CTDI_{vol}$).

Examination type	N 2019-2021	$CTDI_{vol}$ (mGy)				P75/P25 ratio	% DRL	> DRL
		DRL	AD	P75	P50			
PET-CT with FDG head to mid-thigh	100	7	5	5.5	4.7	1.36	-21%	4%
PET-CT with FDG head to foot	32	7	5	4.7	4.1	1.41	-33%	0%

Table 13: Summary of analyses performed on the CT part of a full body PET-CT scan with FDG for scans to mid-thigh and foot in adults, for 2019–2021 data, in terms of dose length product (DLP).

Examination type	N 2019-2021	DLP (mGy.cm)				P75/P25 ratio	% DRL	> DRL
		DRL	AD	P75	P50			
PET-CT with FDG head to mid-thigh	100	650	500	566.4	493.1	1.39	-13%	10%
PET-CT with FDG head to foot	32	1200	900	817.4	726.5	1.49	-32%	0%

Paediatric examinations

The results are presented in table 14 below.

There were dose assessments for seventeen examination types (taking into account weight categories). Only four of them represent 10 or more assessments submitted, thereby allowing the results of the statistical analyses to be discussed: renal cortical scans with ^{99m}Tc-MAG3 (5 to <15 kg), dynamic renal scans with ^{99m}Tc-MAG3 (5 to <15 kg), and bone scans with ^{99m}Tc-HDP/^{99m}Tc- DPD (5 to <15 kg and 25 to <35 kg).

For these four examinations, the analysis shows, over the period 2019–2021, differences between the median values of the administered activities compared to the DRL in force of between -17% and +20%.

Although, over the 2019–2021 period, more examinations led to assessments than in previous periods, the quantity of data received is still too low to have a clear vision of practices and to update the DRLs in force, despite regulatory developments concerning paediatrics.

Table 14: Summary of results of analysis of paediatric nuclear medicine data, by examination type.

Examination type	Weight category (kg)	N	Median weight (kg)	Administered activity (MBq)		P75/P25 ratio	%DRL	>DRL
				DRL	P50			
Dynamic renal scan	[5-15]	13	9.0	25	20.7	1.29	-17%	15%
	[15-25]	4	18.0	35	33.1	1.11	-	0%
	[25-35]	1	29.0	45	40.9	-	-	0%
	[35-45]	0	-	50	-	-	-	-
Renal cortical scan	[5-15]	13	10.0	20	23.9	1.57	20%	69%
	[15-25]	8	19.8	35	39.3	1.64	-	50%
	[25-35]	4	27.8	50	41.7	1.20	-	25%
	[35-45]	1	40.0	60	67.7	-	-	100%
Bone	[5-15]	10	11.3	95	103.6	1.09	9%	90%
	[15-25]	8	18.3	170	153.1	1.08	-	13%
	[25-35]	10	30.0	240	237.6	1.05	-1%	30%
	[35-45]	6	39.3	310	298.9	1.05	-	0%
	[45-55]	4	50.5	375	404.8	1.27	-	50%
Tumour FDG PET	[5-15]	1	12.9	40	68.7	-	-	100%
	[15-25]	3	20.0	70	70.2	1.07	-	67%
	[25-35]	3	29.5	100	100.8	1.17	-	67%
	[35-45]	3	40.5	125	124.5	1.20	-	33%
	[45-55]	4	50.0	150	140.4	1.26	-	50%

FOCUS - NUCLEAR MEDICINE

LUNG SCANS: 2022 SURVEY AND RECOMMENDATIONS

A lung scan is an examination that may include two phases: a ventilation scan using either technetium aerosols or krypton 81m and the lung perfusion scan. This examination may include either or both of these two phases. When technetium aerosols are used, the ventilation scan usually precedes the perfusion scan. The activity of ^{99m}Tc (macroaggregated albumin – MAA) administered for the perfusion scan needs, in this case, to be significantly high as to mask the ventilation signal (1:4 ratio between administered activities for ventilation and perfusion, according to SFMN recommendations (37)). This is not the case when the ventilation examination takes place in advance, or when it is performed using krypton 81m (the difference in energy of the gamma rays also allows simultaneous acquisition for ventilation and perfusion).

To date, only one DRL has been defined for lung perfusions scans at 225 MBq. The data received by IRSN aggregates examinations carried out with or without ventilation with ^{99m}Tc. The DRL thus determined is undoubtedly too high for procedures without ventilation or with ventilation using krypton 81m and is probably underestimated for procedures including ventilation with technetium 99m.

In the report published in 2020 for the period 2016–2018 (27), IRSN had recommended carrying out a specific study to distinguish between examinations performed with or without ^{99m}Tc ventilation in order to be able to propose a more relevant definition of the DRL currently in force. This study was conducted in summer 2022 by IRSN with the help of the relevant learned societies (AFTMN, SFMN, SFPM and SoFRA).

Collected data

The aim was to collect retrospectively or prospectively, from voluntary departments, series of MAA activities administered to adult patients (at least 30), distinguishing between the three procedures: perfusion after ventilation with technetium (Technegas, etc.), perfusion with ventilation with krypton, and perfusion alone.

Since the administered activities in lung scans are not dependent on the morphology of the patients, only the activity values (in MBq) were requested. Examinations involving patients who are minors (under 18 years of age), pregnant patients, and pulmonary shunt tests were excluded from the study.

There was a high degree of participation from nuclear medicine professionals: 94 institutions sent data, including 60% public or similar institutions (cancer centres included) (see figure 19 below). 72 institutions use technetium aerosols; 30 institutions use krypton; and one institution only performs examinations without ventilation. Some institutions use both krypton and technetium aerosols.

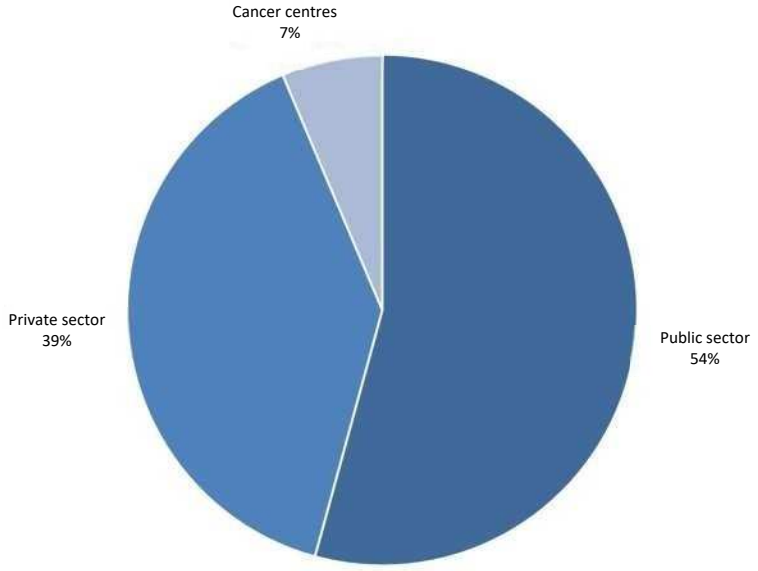

Figure 19: Breakdown of the types of institutions that responded to the survey

In order to have enough data for the survey, IRSN called in particular upon institutions using krypton, and the vast majority of these are public institutions (93%). This explains the slight over-representation of public institutions in this survey.

Results

Data analysis was performed to compare the MAA activities administered according to the type of procedure (see figure 20 below).

An analysis was also carried out, specifically for examinations without ventilation, in institutions also performing certain tests with ventilation, by separating out the users of krypton or technetium aerosols (see figure 21 below). The institutions using both Kr and Tc aerosols have been considered as users of Kr because in this case they use Kr more than Tc and for many of them Tc is only used as a "back-up". The greater dispersion of results for examinations without ventilation than for examinations with ventilation required more extensive analysis for this category.

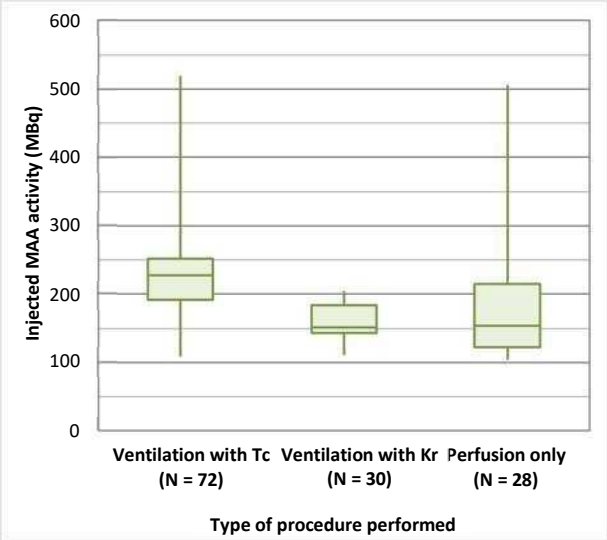

Figure 20: Distribution of administered median activities by type of procedure performed: ventilation with Tc, ventilation with Kr, or with no ventilation.

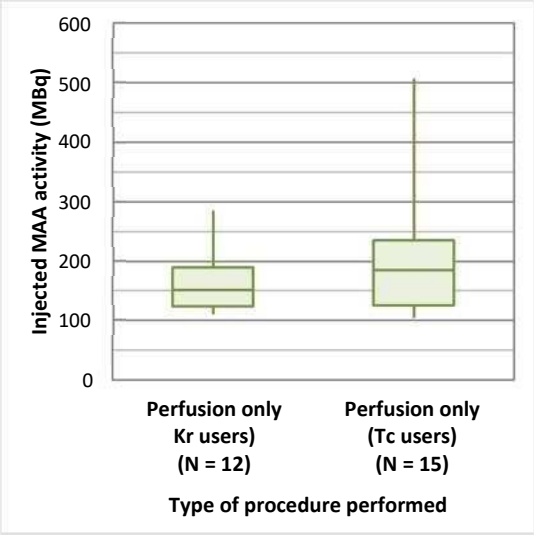

Figure 21: Distribution of administered median activities by type of procedure performed for examinations without ventilation for the usual users of Kr, and without ventilation for the usual users of Tc aerosols (institutions using both Kr and Tc aerosols were considered users of Kr)

Table 15: Summary of results of analysis of the distribution of administered median activities by type of procedure performed for examinations with ventilation with Tc, ventilation with Kr, or without ventilation, without ventilation for the usual users of Kr, and without ventilation for the usual users of Tc aerosols (institutions using both Kr and Tc aerosols were considered as users of Kr)

Indicator	*Examinations with ventilation with Tc*	*Examinations with ventilation with Kr*	*Examinations without ventilation*	*Examinations without ventilation for Kr users*	*Examinations without ventilation for Tc Users*
Number of institutions	72	30	28	12	15
Number of patients	4556	2294	924	358	526
50th percentile of administered activities (MBq)	228.1	150.7	153.5	151.5	185.6

The analysis of the data collected, presented in figure 20 above, shows that the 50th percentiles of the administered activities per institution, for examinations with ventilation with krypton or without ventilation, are very close to each other (2% difference) and in the region of 155 MBq, and much lower than the DRL in force (225 MBq). The median of the activities for examinations with ventilation with technetium is the region of 230 MBq, therefore slightly higher than the DRL in force, and higher than the 50th percentile of the data collected in 2019–2021 (194 MBq), for which the different types of procedures are not separated (see table 15 above).

These results therefore confirm the anticipated difference in terms of MAA administered activity between examinations with ventilation with technetium on the one hand, and examinations with ventilation with krypton or without ventilation on the other.

Separate analysis of the data from examinations without ventilation between the usual users of krypton and the users of technetium aerosols, shown in figure 21 above, shows that the latter inject, overall, higher activities (median of 186 MBq versus 152 MBq). Therefore, there seems to be room for optimisation for some of the users of technetium aerosols, who are accustomed to using higher MAA activities when performing examinations without ventilation.

Recommendations for updating the DRL in relation to lung scans

Based on the results of the survey, IRSN therefore recommends replacing the DRL in force with two new DRL values:

- 230 MBq for examinations with ventilation with 99m technetium,
- 155 MBq for examinations with ventilation with 81m krypton or without ventilation.

SUMMARY – NUCLEAR MEDICINE

Analysis of dose assessments in nuclear medicine shows:

- stabilised participation of departments since 2014, at around 90%
- a very low quantity of data for certain examinations (dynamic renal scans with DTPA and brain perfusion SPECT with ECD and HMPAO);
- median values of the administered activities less than the DRL in force in adults by 1 to 22%;
- an overall decrease of 4% in nuclear medicine dose indicators compared to 2016–2018, which confirms the previously observed decrease of 3% compared to 2013–2015;
- for CT acquisitions of PET examinations, results lower than the DRLs in terms of $CTDI_{vol}$ and DLP;
- too little data in paediatrics.

RECOMMENDATIONS – NUCLEAR MEDICINE

For nuclear medicine, IRSN makes the following recommendations:

- revise, based on the study conducted by IRSN, the DRL relating to lung perfusion scans by replacing the DRL in force with two new DRL values:
  - 230 MBq for examinations with ventilation with 99m technetium,
  - 155 MBq for examinations with ventilation with 81m krypton or without ventilation;
- in paediatrics:
  - study the relevance of revising the weight categories in order to align with European recommendations and thus allow comparisons to be made,
  - continue to encourage healthcare professionals to submit data by reminding them that it is possible to collect data over a period of more than one year;
- based on stakeholder consultation:
  - consider removing DRLs for examinations that have become too infrequent, as illustrated by the results of this report:
    - renal scans with DTPA,
    - brain scans with ECD and HMPAO;
  - define a single DRL in terms of activity per body weight (MBq/kg) for the examinations that lend themselves to it, rather than a combination of activity and activity per body weight as is currently the case,
  - reflect on the implementation of DRLs for new examinations, particularly in PET, such as:
    - brain PET with ^{18}F-FDG,
    - PET with ^{18}F-Choline,
    - PET with ^{18}F-DOPA (brain, full body),
    - PET with gallium 68 (somatostatin receptors, PSMA);
  - while prioritising the investigations to be carried out according to the frequency of implementation;
  - in a second phase, consider the implementation of DRLs for new scanner examinations, such as, for example:
    - dual-isotope (iodine-123 and 99mTc-MIBI) scans of the parathyroid glands,
    - brain scans with DaTSCAN;
  - consider the implementation of DRLs for CT acquisitions of the trunk and the full body associated with bone scans.

DRLs: SUMMARY, RECOMMENDATIONS AND PERSPECTIVES

7.1 SUMMARY:

From the analysis of the data collected from 2019 to 2021, IRSN highlights the following salient points:

- participation of structures still limited in conventional radiology to around 50%, and stabilised around 90% in computed tomography and nuclear medicine;
- strong mobilisation of healthcare professionals in the implementation of the new DRLs in interventional radiology;
- an increase in the quantity of data submitted in paediatrics but still insufficient to enable a robust analysis of practices in this field;
- DRL quantities below the DRLs in force in all adults examinations fields. The 75th percentile values (50th percentile for nuclear medicine) for 2021 are below the DRLs in force by:
    - 20% to 30% in conventional radiology,
    - 30% to 54% in interventional radiology,
    - 14% to 60% in computed tomography,
    - 1 to 22% in nuclear medicine,
- an overall drop in DRL quantities compared to 2016–2018 of:
    - 19% in conventional radiology,
    - 8% in computed tomography,
    - 4% in nuclear medicine,
- heterogeneities in the results that may illustrate a diversity of practices and/or indications, on the one hand in conventional paediatric radiology for UGI and retrograde cystography examinations, and on the other in adult interventional radiology for vertebroplasty.

7.2 RECOMMENDATIONS AND PERSPECTIVES

Based on the analysis of the dose assessments sent to IRSN during the 2019–2021 period, the results of additional analyses carried out by IRSN in collaboration with healthcare professionals, and consultation with these professionals, as well as expert opinions produced at the request of ASN, IRSN makes the following recommendations:

- **in paediatrics,** in all areas:
    - **continue efforts** to submit data, reminding practitioners that it is possible to collect data over a period of more than one year,
    - study the relevance of **revising weight categories** in order to align with European recommendations and thus allow comparisons to be made;
- **revise DRL values** in all areas, prioritising computed tomography;
- **monitor the evolution** of the results of certain procedures and, if necessary, ultimately review the definition of these DRLs based on feedback since 2019, in particular:
    - UGI and retrograde cystography in conventional paediatric radiology;
    - vertebroplasty in adult interventional radiology;
- **change** the definition of certain DRLs and the data collected:
    - in interventional radiology:
        - add the air KERMA at the reference point as an extra DRL quantity in addition to the DAP and the radioscopy time;
        - consider increasing the quantity of patient data to be requested for each assessment submitted. To do this, it will be necessary to study the relevance of a mass data transmission from DACS without patient weights and sizes, with the aim of obtaining average data more representative of clinical practice;
    - in nuclear medicine:
        - revise the DRL relative to lung perfusions scans by replacing the DRL in force with two new DRL values: 230 MBq for examinations with ventilation with 99m technetium and 155 MBq for examinations with ventilation with 81m krypton or without ventilation;

        - define a single DRL in terms of activity per body weight (MBq/kg) for the examinations that lend themselves to it.
    - in computed tomography: upgrade DRLs to take clinical indications into account;
- **define new DRLs,** in particular:
    - in conventional radiology:
        - in mammography, define a DRL in digital mammography based on clinical doses and no longer on the doses measured during quality control, and introduce a DRL in breast tomosynthesis taking into account the notice published by IRSN in December 2021 (16);
        - in dental CBCT, introduce a DRL for certain indications taking into account the notice published by IRSN in January 2023 (17);
    - in interventional radiology: consider, in consultation with healthcare professionals, creating a DRL for two rhythmology procedures considered to be the most irradiating procedures, and interventional cardiology procedures performed in operating theatres or hybrid rooms, and not in dedicated radiology rooms;
    - in nuclear medicine:
        - consider, in consultation with healthcare professionals, the implementation of DRLs for new examinations, particularly in PET, as well as, in a second phase, for new scanning examinations;
        - consider the implementation of DRLs for computed tomography acquisitions of the trunk and the full body associated with bone scans;
- **consider removing DRLs for some infrequent examinations,** such as renal scans with DTPA and brain scans with ECD and HMPAO in nuclear medicine or lateral thoracic spine examinations in conventional radiology.

Finally, as highlighted in IRSN notice 2020–00169[9] on image-guided radiotherapy, the implementation of a DRL type optimisation approach and the definition of dose index reference values for computed tomography acquisitions carried out as part of radiotherapy preparation could be considered.

7.3 CONCLUSIONS

This seventh analysis report on French diagnostic reference level data makes it possible to take stock of the implementation of the new modalities introduced by ASN resolution 2019-DC-0667, in particular in paediatrics and interventional radiology.

The results in terms of participation illustrate the degree of support from professionals in the field of interventional radiology for the DRL system.

The number of assessments submitted in paediatrics is increasing in all areas but remains insufficient for a robust analysis of practices. Continued efforts are required in this area.

Finally, the reduction in DRL quantities, which are below the DRLs in force for adults in all areas, illustrates a general downward trend in exposures and justifies a revision of DRL values. The implementation of this revision could be an opportunity to consider updating the list of examinations in consultation with the healthcare professionals concerned.

[9] https://www.irsn.fr/sites/default/files/documents/expertise/avis/2020/Avis-IRSN-2020-00169.pdf

GLOSSARY

Abbreviations

AD	Achievable dose
ADF	*Association dentaire française* (French dental association)
AFTMN	*Association française des techniciens en médecine nucléaire* (French association of nuclear medicine technicians)
AMM	Marketing authorisation (*Autorisation de Mise sur le Marché*)
ANSM	*Agence nationale de sécurité du médicament et des produits de santé* (French National Agency for Medicines and Health Products Safety)
AP	Anterior posterior
ASN	*Autorité de Sûreté Nucléaire* (French Nuclear Safety Authority)
ASP	Abdomen AP (*"abdomen sans préparation"*)
AVM	Arteriovenous malformations
BMI	Body mass index
CA	Chest-abdomen
CAP	Chest-abdomen-pelvis
CBCT	Cone-beam computed tomography
CCAM	*Classification Commune des Actes Médicaux* (common classification of medical procedures)
CDF	*Chirurgiens-dentistes de France* (Dental surgeons in France)
CLCC	Cancer centre (*Centre de Lutte Contre le Cancer*)
CNPCV	Conseil National Professionnel Cardiovasculaire (*French national cardiovascular professional council*)
CPD	Continuing professional development
CQE	External quality control
CRD	*Commission radioprotection dentaire* (French dental radiation protection commission)
CT	computed tomography
$CTDI_{vol}$	Volume computed tomography dose index
DACS	Dose Archiving and Communication System
DAP	Dose area product
De	*Dose à l'entrée* (entrance dose)
DGOS	*Direction générale de l'offre de soins* (Directorate general for healthcare services)
DLP	Dose length product
DOCS	*Dépistage organisé du cancer du sein* (Organised breast cancer screening)
DOPA	Dihydroxyphenylalanine
DRL	Diagnostic reference level
DTPA	Diethylene triamine pentaacetic acid
EANM	European Association of Nuclear Medicine
EC	European Commission
ECD	Ethyl cysteine dimer

FDD	Focus-to-detector distance
FDG	Fluorodeoxyglucose
FNMR	*Fédération Nationale des Médecins Radiologues* (French National Federation of Radiologists)
FSD	Focus-to-skin distance
FSDL	*Fédération des syndicats dentaires libéraux* (French federation of private dentist unions)
G4	*Conseil professionnel de la radiologie française* (French professional radiology council)
GACI	*Groupe athérome coronaire et cardiologie interventionnelle de la Société française de cardiologie* (French cardiology society, coronary atheroma and interventional cardiology group)
HMPAO	Hexa-methyl propylene amine oxime
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IRSN	*Institut de Radioprotection et de Sûreté Nucléaire* (French institute for radiation protection and nuclear safety)
LVEF	Left ventricular ejection fraction
MAA	Macroaggregated albumin
MGD	Mean Glandular Dose
MRP	Radiopharmaceutical(s)
ONCD	*Ordre national des chirurgiens-dentistes* (French national order of dental surgeons)
OPT	Orthopantomography
PA	Posterior anterior
PET	Positron Emission Tomography
PIR	Image-guided interventional procedures
PSMA	Prostate-specific membrane antigen
SFIPP	*Société Francophone d'Imagerie Pédiatrique et Prenatale* (French-language society for paediatric and prenatal imaging)
SFMN	*Société Française de Médecine Nucléaire et imagerie moléculaire* (French society for nuclear medicine and molecular imaging)
SFPM	*Société Française de Physique Médicale* (French society for medical physics)
SFR	*Société Française de Radiologie* (French society for radiology)
SoFRa	*Société française de radiopharmacie* (French society for radiopharmacy)
TAVI	Transcatheter aortic valve implantation
UD	*Union dentaire* (French dental union)
UGI	Upper gastrointestinal series
WHO	World Health Organisation

Titles of nuclear medicine examination types

Bone scan ^{99m}Tc	Bone scan with ^{99m}Tc MDP/HMDP/DPD
Lung perfusion scan	Lung perfusion scan with ^{99m}Tc-macroaggregates
Thyroid ^{99m}Tc	Thyroid scan with ^{99m}Tc
Thyroid ^{123}I	Thyroid scan with ^{123}I
Myocardial perfusion SPECT with ^{99m}Tc	Myocardial perfusion SPECT scans with stress test and/or pharmacological stimulation with ^{99m}Tc- MIBI/tetrofosmin (1^{st}/2^{nd} injections)
Myocardial perfusion SPECT with ^{201} Tl	Myocardial perfusion SPECT scans with stress test and/or pharmacological stimulation with ^{201}Tl-Chloride (1^{st}/2^{nd} injections)
LVEF	Equilibrium radionuclide ventriculographies (left ventricular ejection fraction measurement) with ^{99m}Tc-serum albumin/red blood cells
Dynamic renal scan	Dynamic renal scan with ^{99m}Tc-DTPA/^{99m}Tc-MAG3
Brain perfusion SPECT	Brain perfusion SPECT with ^{99m}Tc-HMPAO/^{99m}Tc-ECD
FDG-PET	Tumour FDG PET with ^{18}F-fluorodeoxyglucose

ANNEXES

Annexes to this report are available on the original report in French: rapport IRSN 2023 – 00333, Analyse des données relatives à la mise à jour des niveaux de référence diagnostiques en radiologie et médecine nucléaire. Via : https://www.irsn.fr/sites/default/files/2023-06/Rapport-IRSN-2023-00333-NRD.pdf

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Cover photo:

Julien Frandon, radiologist, and Hélène Mohammad, intern, during an embolisation of the prostatic artery in an interventional radiology room in the medical imaging department of the CHU in Nîmes. Sophie Brändström/Signatures/Médiathèque IRSN

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