MISSION
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IRSN
INSTITUT
DE RADIOPROTECTION
ET DE SÛRETÉ NUCLÉAIRE

Faire avancer la sûreté nucléaire

Analysis of data for updating diagnostic reference levels in radiology and nuclear medicine

2016-2018 Report

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FRENCH PUBLIC SERVICE EXPERT FOR NUCLEAR AND RADIATION RISKS

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RESUME

En application de la réglementation relative aux niveaux de référence diagnostiques (NRD - Décision ASN n°2019-DC-0667), les établissements de radiologie et de médecine nucléaire doivent transmettre annuellement à l'IRSN des données dosimétriques relatives aux examens d'imagerie dont ont bénéficié leurs patients. Les examens faisant l'objet d'une évaluation sont choisis librement parmi la liste fixée réglementairement. L'IRSN est chargé d'analyser ces données en vue de la mise à jour des valeurs des NRD.

Depuis le 1er juillet 2019, la réglementation relative aux NRD a évolué. Les nouvelles dispositions réglementaires s'inscrivent dans le contexte du renforcement des exigences relatives aux NRD au niveau européen. Elles prennent en compte les recommandations internationales les plus récentes en matière de NRD ainsi que les recommandations de l'IRSN émises dans ses précédents bilans. En particulier, de nouvelles dispositions ont été introduites dans la réglementation en 2019 pour améliorer le recueil et l'utilisation des NRD en pédiatrie.

Ce rapport présente les résultats de l'analyse des données recueillies sur la période 2016-2018. Ces résultats ont été comparés aux valeurs de NRD en vigueur depuis juillet 2019 afin d'étudier la nécessité d'une mise à jour.

Depuis 2014, la participation des professionnels à l'envoi de données apparaît comme stabilisée en scanographie et en médecine nucléaire autour de 85%. Compte tenu d'une révision de l'estimation du nombre d'établissements réalisant des examens de radiologie conventionnelle, jusqu'à présent fortement surévalué, la participation des professionnels de ces établissements est désormais évaluée à 50 %, contre 30 % précédemment. Elle reste faible.

Globalement, l'analyse des données recueillies sur la période 2016-2018 montre une diminution des valeurs des indicateurs dosimétriques dans tous les domaines par rapport à la période précédente d'analyse (2013-2015). La très grande majorité des valeurs se situe en dessous des NRD en vigueur depuis le 1er juillet 2019 (de l'ordre de 0 à 25 %). Ce constat peut s'expliquer par deux raisons dont il n'est pas possible de dissocier les influences : les évolutions technologiques d'une part, et l'optimisation des protocoles et la sensibilisation des utilisateurs aux bonnes pratiques d'autre part. Les écarts par rapport à ces nouveaux NRD restent cependant en général assez faibles et il ne paraît pas nécessaire de réviser les valeurs de NRD à court terme. Concernant la pédiatrie, les données transmises sont, comme par le passé, trop peu nombreuses sur ce bilan pour permettre une révision des NRD à court terme.

Les résultats présentés dans ce bilan de « transition », suite à la publication de la décision ASN n°2019-DC-0667, confirment le bien fondé de plusieurs évolutions réglementaires adoptées en 2019 :

- le retrait de la dose à l'entrée (De) comme indicateur dosimétrique en radiologie conventionnelle ;

- la suppression, du fait d'une pratique limitée, de la mammographie analogique ainsi que de 7 examens pédiatriques de médecine nucléaire de la liste des examens soumis au dispositif de recueil des NRD ;
- la révision des valeurs de NRD associées aux différents examens soumis au dispositif de recueil des NRD.

L'analyse des données recueillies sur la période 2016-2018, ainsi que l'évolution des pratiques d'imagerie, conduisent l'IRSN à formuler plusieurs recommandations concernant le dispositif NRD :

- en scanographie, faire évoluer la définition des NRD par région anatomique vers des NRD par indication clinique. La définition actuelle des NRD par région anatomique conduit à agréger des données hétérogènes car issues d'examens avec des objectifs cliniques divers. Sur la base de récents travaux aux niveaux national et européen, des NRD par indication clinique pourraient être définis et permettraient de disposer de valeurs spécifiques ;
- en mammographie, les évaluations dosimétriques ne consistent pas en des relevés d'indicateurs de dose déterminés sur des groupes de patients mais en des relevés d'un indicateur de dose mesuré sur fantôme lors du contrôle de qualité externe. Ainsi cette mesure peut se révéler assez éloignée des doses réellement délivrées en pratique clinique. Du fait de l'évolution à venir en 2021 des modalités de mesure de la dose moyenne à la glande lors des contrôles de qualité externes, une révision du NRD s'imposera. A cette occasion il conviendrait de repenser la définition du NRD afin de la rendre plus pertinente vis-à-vis de la pratique clinique ;
- ajouter la tomosynthèse mammaire à la liste des examens soumis au dispositif de recueil des NRD ainsi que la technique d'imagerie volumétrique par faisceau conique (CBCT), en radiologie dentaire, notamment pour les enfants ;
- associer une évaluation des performances diagnostiques des appareils à la démarche d'optimisation des doses délivrées aux patients afin de s'assurer que cette dernière ne nuise pas à la qualité de l'examen. En particulier si les valeurs médianes locales sont inférieures aux valeurs guides diagnostiques récemment introduites réglementairement, la qualité d'image, plutôt que la dose, devrait être considérée en priorité dans le processus d'optimisation.

MOTS-CLES

Niveau de référence diagnostique, dose, activité administrée, radioprotection, exposition patient, radiologie, scanographie, médecine nucléaire

ABSTRACT

Applying the diagnostic reference levels (DRL) regulations, healthcare facilities performing medical imaging procedures are required to send samples of "patient" dosimetric data to IRSN each year. IRSN is in charge of the analysis of this data in order to update the DRL values.

Since 1 July 2019, the DRL regulation has evolved. The new regulatory provisions are part of the strengthening of DRL requirements at European level. They take into account the most recent international DRL guidelines as well as IRSN previous recommendations. In particular, new requirements introduced into the regulation in 2019 are intended to improve the collection and use of DRLs in the pediatric field.

This report presents the results of the analysis of dosimetric data over the 2016-2018 period. Results are compared to DRL values defined by the regulations in force since 1 July 2019.

Since 2014, the participation of professionals appears to be stabilized in CT and nuclear medicine around 85%. It should be noted that, due to a revision of the estimate of the number of establishments performing conventional radiology examinations which have so far been highly overvalued, participation is now estimated at 50%, compared with 30% previously. This rate stays low compared to CT and nuclear medicine.

The analysis of data collected over the period 2016-2018 shows an overall decrease in the values of DRL quantities compared to the previous analysis period (2013 - 2015) for all modalities. The vast majority of values are below the DRLs in force since 1 July 2019 (in the range of 0 to 25%). This observation can be explained by two reasons from which it is not possible to separate the influences: technological developments on the one hand, and protocols' optimization and users' awareness of good practices on the other hand. Deviations from these new DRLs are generally quite small and there is no need to revise the DRL values in a near future. As in the past, the volume of collected data in pediatrics remains too small to allow short-term NRD update.

The results presented in this "transition" report, following the publication of ASN resolution 2019-DC-0667, confirm the legitimacy of several regulatory changes adopted in 2019:

- removing of the entrance surface dose (ESD) as a DRL quantity in conventional radiology;
- removing of screen-film mammography and 7 pediatric nuclear medicine examinations from the DRL study list;
- update of examinations DRL values.

The analysis of the data collected over the period 2016-2018, as well as the evolution of imaging practices, leads IRSN to formulate several recommendations regarding DRL:

- in CT, modify the definition of DRL by anatomical region to DRL by clinical indication. The current definition of DRL by anatomical region leads to the aggregation of heterogeneous data with various clinical objectives. Based on recent works at national and European levels, DRL by clinical indication could be defined in order to get specific values regarding clinical objectives;
- in digital mammography, dosimetric data are not determined on groups of patients but measured on a phantom during external quality control. Thus, this measurement may be quite different from the doses actually delivered in clinical practice. Due to upcoming changes in external quality control measurement of the average glandular dose, an adjustment of the DRL will be required. It might be the occasion to rethink the definition of this DRL in order to make it more relevant to clinical practice;
- add breast tomosynthesis and the CBCT technique in dental radiology, especially for children to the list of examinations submitted to the DRL regulation;
- associate diagnostic performance assessment to patient dose optimisation in order to ensure that dose optimisation does not impair examination quality. In particular if median values are lower than regulatory achievable doses (ADs) values, image quality, rather than dose, should be considered as a priority in the optimisation process.

KEY-WORDS

Diagnostic reference levels, dose, administered activity, radiation protection, patient exposure, diagnostic radiology, computed tomography, nuclear medicine.

INTRODUCTION

This document presents the report on IRSN's analysis of diagnostic reference levels data for the 2016-2018 period, in line with its mission under Article R.1333-61 of the French Public Health Code.

Diagnostic reference levels (DRL) were implemented in France in 2004 through the publication of a first order on DRLs in radiology and nuclear medicine (1). This order was based on the recommendations in 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).

In 2011, DRL regulations were revised by the French Order of 24 October 2011 (5). Then following the various IRSN reports (6; 7; 8), the advisory committee for medical exposure (GPMED) to the ASN developed recommendations on actions to improve the participation of imaging centres in collection of dosimetric data, and the analysis thereof, at a national level, as well as on changes to DRL regulations (9; 10). This work led to revision of the French DRL regulations launched in October 2015. Moreover, over the last few years, DRLs have been a central concern for European and international bodies. The European Commission funded a project on paediatric DRLs, PiDRL (11), which led to the publication of specific DRL guidelines for paediatric imaging (12). The ICRP also published a report on DRLs in 2017 (13). This publication is an additional source of both practical and methodological information and advice on these issues.

A new ASN resolution on DRLs (resolution 2019-DC-0667) (14) was approved by the French Order of 23 May 2019 (15) with a view to revising French DRL regulations. It takes into account most of the recommendations issued by IRSN in its previous reports (6; 7; 8), and aligns with the recent changes in international recommendations, in accordance with the reinforced DRL requirements set out in Council Directive 2013/59/Euratom (16). The diagnostic reference levels concept is therefore evolving. DRLs are an essential and effective tool for optimising doses delivered to patients. They serve as dose 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 management of conventional radiology, CT and nuclear medicine facilities has to annually assess the doses delivered to their patients during diagnostic procedures listed in the ASN resolution in force. Analysing this data, in comparison of their median values with the current DRLs, should enable professionals to situate their practice against a national reference and undertake improvements in the event that the value is over the DRLs without good reason. The recent introduction of achievable dose values (ADs)[1] should also encourage the long-term optimisation of doses. Exposures which are particularly low compared to the DRLs should be questioned, and any reduction in doses delivered should systematically involve assessment of the quality of images obtained in order to prevent a drop in diagnostic performance and any risk of performing unusable examinations. Once they have completed their analysis, professionals have to 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 in order to improve their application and effectiveness.

[1] ASN resolution 2019-DC-0667 pertaining to DRLs (14) provides professionals with a new level, designed to help set more ambitious goals than the DRL based on the 75th percentile. This new level is called "achievable dose", and is defined as the 50th percentile (or median value) of distributions.

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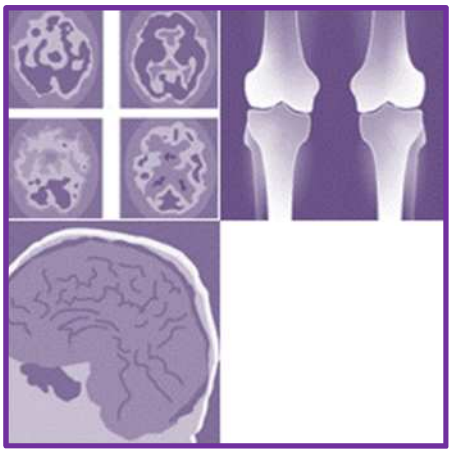

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WHAT'S NEW IN THE REGULATIONS

The French Decree of 4 June 2018 (17) transposing the requirements of Council Directive 2013/59/Euratom into the Public Health Code confirmed IRSN's missions regarding DRLs, previously defined by the Order of 24 October 2011 (5). 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. This DRLs are kept up to date by the French Nuclear Safety Authority (ASN), taking into account the results submitted to the French Institute for Radiological Protection and Nuclear Safety (IRSN). IRSN is responsible for collecting and analysing the data required for this periodic update. To this end, it receives the results of dose assessments from the operator or licensee. Figure 1 presents the principle for DRL implementation in France, and the roles of the professionals, authorities and IRSN.

IRSN had already put forward the following recommendations subsequent to previous diagnostic reference level data analysis in radiology and nuclear medicine:

- reconsider data collection and DRL definition methodology in paediatrics, in order to remedy the lack of data submitted to IRSN and supply professionals with DRLs on which to base their work;
- make DRL implementation obligations proportionate to the size of institutions, in order to avoid a situation in which some units never undergo dose assessments;
- analyse the data collected according to their median value, rather than the mean value, in accordance with international recommendations (12; 18);
- define a statistical measure for optimisation (50th percentile) in addition to the usual alert indicator (75th percentile);
- revise DRLs: list of examinations to be added or removed, numerical values (up or down);
- review dose values: remove entrance surface dose (ESD) and add administered activity per body weight
- take CT acquisition into account in nuclear medicine;
- include interventional radiology in the fields covered by the reference levels and make the collection and analysis of data mandatory, whenever possible setting national reference levels;
- introduce full examinations for conventional radiology and CT.

ASN resolution 2019-DC-0667 of 18 April 2019 on DRLs (14), in force since 1 July 2019, takes into account these recommendations and implements a number of changes for the implementation of the collection and analysis of DRL data compared to the Order of 2011 (5).

Changes introduced by ASN resolution 2019-DC-0667 (DRL)

Paediatrics

In paediatrics, the number of patients required has been reduced to 10 patients (formerly 30 patients, see focus below). Moreover, dose assessments have become mandatory if 5% or more of procedures are performed on children (under 18s). The number of paediatric procedures performed on a medical device is assessed as a percentage of the total activity performed on this device without limitation to the procedures listed in the annex of the resolution. If the number of procedures performed in paediatrics is over 5% of the total activity for a device, the activity manager must send data for a procedure and weight range on the list in the annex of the resolution, and for at least 10 patients. These modifications should improve the submission of data in this specific field.

Number of dose assessments

The number of dose assessments required is now:

- two per year and per device for computed tomography and interventional radiology;
- two per year and per department, with at least one dose assessment per unit every five years for conventional radiology.

These modifications make the implementation of DRLs proportionate to the size of institutions while avoiding a situation in which some units are never assessed.

Median value

Data collected must now be analysed using the median value for patient group doses rather than the arithmetic mean. The results presented in this report are therefore expressed using median values rather than mean values as in the previous report (see section on data analysis).

Achievable doses (ADs)

Achievable doses (ADs) have been implemented to supplement DRLs. DRLs have not been enough to encourage long-term dose optimisation in radiography and computed tomography. It is likely that in most cases, doses delivered could be optimised and brought significantly under the DRL (75th percentile) through fairly simple and cost-effective means, such as modifying acquisition parameters (high voltage, collimation, current, filtration, pitch, etc.). For example, an institution with modern equipment which offers a number of options for optimisation could set itself a more ambitious target than the DRL in force and apply the dose optimisation principle as much as possible. This is why the decision was made to provide professionals with an additional level which would help them set more ambitious targets than the 75th percentile DRL. This level is defined as the 50th percentile (or median value) of distributions (Figure 10). As mentioned in ICRP Publication 135 (13), if local median values are below the ADs, image quality, rather than dose, should be considered as a priority in the optimisation process.

List of examinations and associated DRLs

The list of examinations and associated DRLs was adjusted to take into account the report published in 2016 (8).

Body mass index

Adult patients must be selected according to body mass index (BMI), which must be between 18 and 35 kg/m^2.

Conventional radiology

For conventional radiology, since the requirement for units commissioned since 2004 to have a system providing information on the quantity of radiation produced, the majority of units allow the user to assess patient exposure directly using dose area product (DAP) data. In the report published by IRSN in 2016 (8), a large majority of assessments were using data expressed in DAP (80 to 90% of data collected) as opposed to data expressed in entrance surface dose (ESD). The dose expressed in De was therefore removed. Only the DAP is used now for dose assessments in this field. According to the recommendations issued by the Heads of the European Radiological Protection Competent Authorities (HERCA) in 2012 (19), DAP should be expressed in mGy.cm^2 and no longer cGy.cm^2

Nuclear medicine

In nuclear medicine for adults:

- the administered activity per body weight has been added. This addition makes it possible to focus on assessing the activity to be administered with regard to patient weight, while aiming to stay under the reference value for absolute activity.
- PET/CT acquisitions now have a DRL.

Image-guided interventional procedures

Image-guided interventional procedures are now covered, with the introduction of a DRL in the interventional field, including cardiology, neuroradiology and vascular surgery. The DRLs associated with these procedures are based on the results of two studies conducted by the French Society of Medical Physics (SFPM) (20) and the French College of Hospital Cardiologists (CNCH) (21).

Full procedure

DRLs for a full paediatric radiology procedure (a full procedure consists of all radiography and radioscopy acquisitions performed) were added under ASN resolution 2019-DC-0667. This is also the case with DRLs for image-guided interventional procedures, which have been defined for a full procedure including all radiography and radioscopy acquisitions performed.

Commitment of departments and system flexibility

In its last report (8), IRSN warned that the commitment of departments and the use of DRLs needed to be improved, in order to assess and optimise doses delivered in imaging. IRSN also drew attention to the need to make the regulation revision system more flexible for these technical aspects, so it can respond better to changes in practice and technologies. It is too early to say whether the latest ASN resolution will have a favourable impact on these two areas.

Changes introduced by ASN resolution 2019-DC-0660 (Quality assurance)

In its last report (8), IRSN recommended that the DRL system be integrated into a broader quality assurance approach for medical imaging. This has now been implemented. ASN resolution 2019-DC-0660 of 15 January 2019 established quality assurance obligations for medical imaging using ionising radiation. The collection and analysis of doses with regard to diagnostic reference levels must now be covered by a formal process under departments' quality management systems. This formal procedure requirement also contributes to the smooth running of the procedure optimisation process.

Still to be done

DRLs by indication: for computed tomography, it seems necessary to provide a DRL definition for each organ and/or clinical indication. In this regard, studies are currently underway in France (22) and Europe (23) with the goal of defining DRLs by indication rather than anatomical area.

Device diagnostic performance assessment: IRSN recommended that image quality assessment should be systematically associated with dose optimisation. This recommendation could not be taken into account in ASN resolution 2019-DC-0667, and remains to be integrated into regulations. Although the association of image quality with dose optimisation is not covered by the regulations, this aspect does need to be taken into account by professionals, who need to consider the quality of images obtained with regard to the doses delivered. In particular, if local median values are below the AD, image quality, rather than dose, should be considered as a priority in the optimisation process.

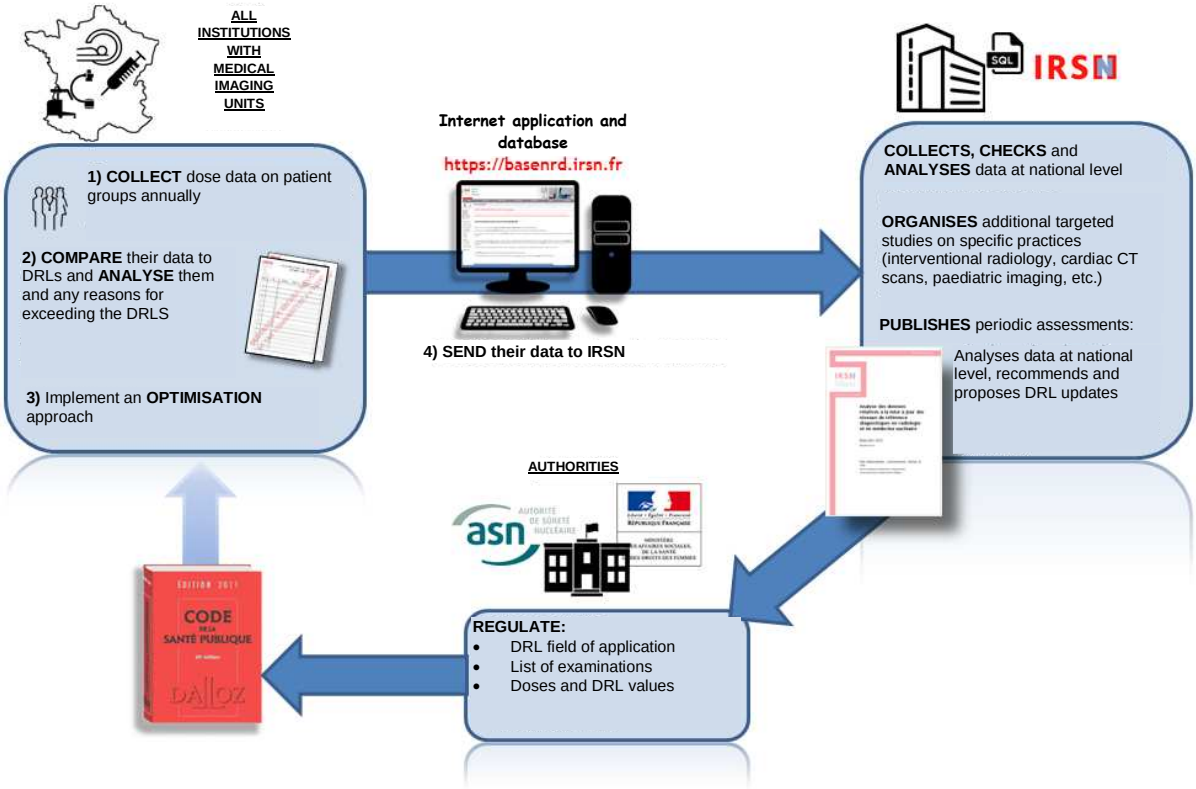


Figure 1: Principle for DRL implementation in France, and the roles of the professionals, authorities and IRSN.

FOCUS

The specific nature of paediatric DRLs

Problems with implementation of paediatric DRLs

Since DRLs were implemented under French regulations in 2004, IRSN notes 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 are probably subject to very little assessment. However, given the fact that children are more radiosensitive than adults, particular attention needs to be focused on justifying and optimising procedures for them, especially when these examinations are likely to be repeated in treating some diseases. Defining paediatric DRLs and their use by professionals for optimisation is therefore extremely important.

IRSN had already identified a number of causes for the low quantity of data received in earlier reports:

- in general (with the exception of specialist paediatric imaging departments), paediatrics only represents a low percentage of imaging professionals' work. Paediatric data is therefore harder to collect;
- segmentation by child weight or age group, which is absolutely essential for forming morphologically homogeneous groups, further complicates data collection;
- the French Order of 24 October 2011 set the minimum number of children per dose assessment at 30, as with adults;
- the French Order of 24 October 2011 required professionals to select at least 2 examinations per year for each imaging type, for adults or children.

A majority of professionals therefore preferred to focus on assessing adult examinations, for which it was easier to recruit patients. Since 2004, only 11% of institutions that have submitted conventional radiology data have sent paediatric data at least once. This proportion is 4% for computed tomography and 8% for nuclear medicine.

The problems encountered with paediatric DRLs in France are common to a number of countries, leading the European Commission to launch the PiDRL (11) project in 2013, with a view to establishing European DRLs for paediatrics. This led to the publication of European recommendations on DRLs for paediatric imaging in 2018 (12).

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 children to be included in a dose assessment was reduced from 30 to 10 in order to encourage collection in institutions that perform a low number of paediatric examinations;
- one paediatric dose assessment is required every year if at least 5% of procedures performed involve children.

This new regulation came into force halfway through 2019, but already seems to have had a positive impact on the data collection for 2019 (not yet completed at the time of writing). Both the number of institutions that have sent paediatric data, and the quantity of these data, have doubled in conventional radiology and computed tomography, compared with previous years.

Furthermore, the increasing deployment of patient dose management system is contributing to solving the problem of paediatric DRLs. By systematically recording DRL dose values used, it is making it easier to collect and analyse data for the least common procedures, such as paediatric procedures.

Studies performed for updating and completing paediatric DRLs

Given the low quantity of data on paediatric examinations collected over the years, IRSN has organised specific studies with imaging professionals in order to collect data for proposing a paediatric DRL update and improve knowledge of practices.

The first study was conducted with the French-speaking Society for Paediatric and Prenatal Imaging (SFIPP) and the French Society of Radiology (SFR) in 2016. Radiology departments that often perform paediatric examinations, or specialise in paediatric radiology, were surveyed to collect data on radiography procedures, procedures with opacification and CT procedures. The study showed that, despite the application of best practice, there was high divergence between participants with regard to doses delivered, especially for examinations with opacification. This confirms the importance of defining DRLs for this type of procedure. The study results served as a basis for the paediatric DRL updates in 2019 and were published in two articles (24; 25).

The second study was conducted with the French Society of Nuclear Medicine (SFMN) and the French Society of Medical Physics (SFPM) in 2016-2017. All entities performing nuclear medicine examinations were invited to send data for procedures performed on children. With regard to administered activities, the study showed that practices were close to the DRLs in force, which are based on EANM recommendations, and that there was no reason to change them. It also showed the importance of a DRL for renal cortical scans. However, data for CT acquisitions on some examinations (PET and bone scans) were too few for it to be possible to determine associated DRLs. The results of the study were presented at the 3rd French-speaking nuclear medicine days (26).

TYPE 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;
- average glandular dose (AGD) 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 big impact on the dose delivered. Regulations therefore require their height and weight to be recorded during dose assessments.

In 2018, only 6% of dose assessments results submitted to IRSN were assessed using the entrance surface dose (see Figure 2). This represents less than 20 assessments received in 2018 for each examination, except for chest PA and pelvis AP examinations for which around 30 assessments were received. Withdrawal of this DRL quantity in ASN resolution 2019-DC-0667 is therefore fully justified.

In mammography and orthopantomography dose is not assessed for a group of patients but with a single measurement on phantom (AGD and DAP respectively) performed during external quality control (27; 28).

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);
- for nuclear medicine: the radiopharmaceutical administered.

Moreover, additional analyses on these parameters which influence the dose delivered to the patient may be performed.

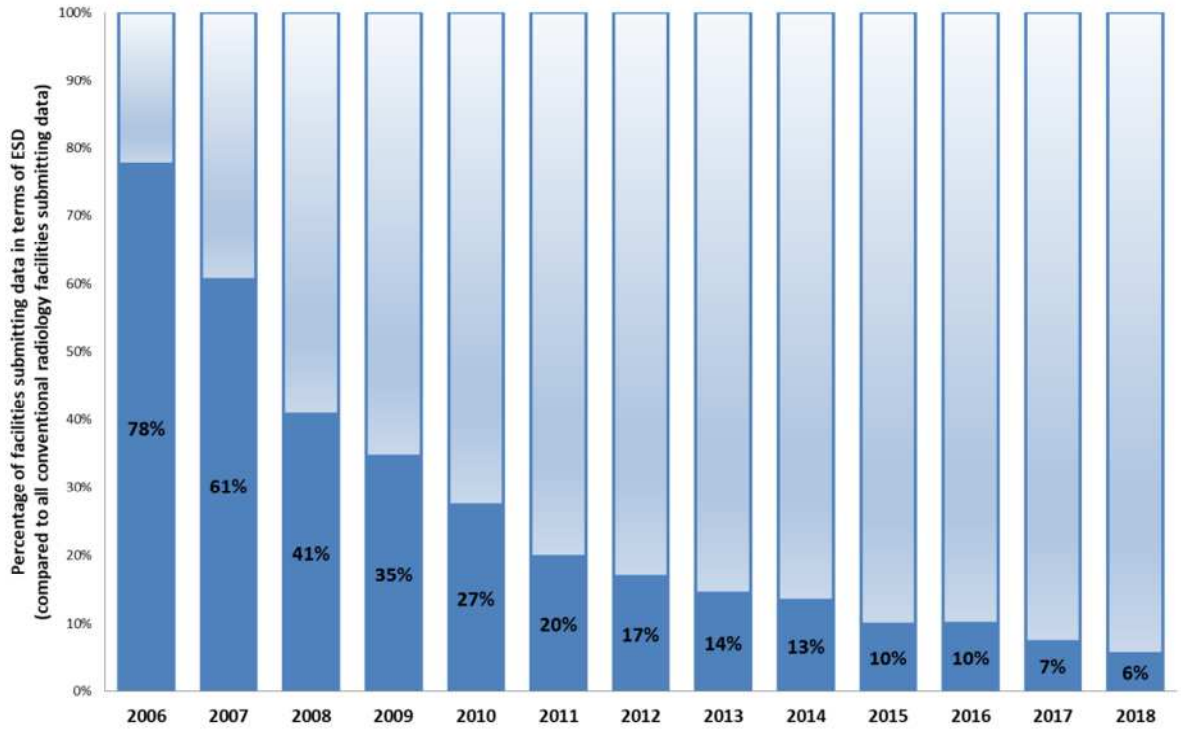


Figure 2: Change in the percentage of radiology facilities submitting data in terms of entrance surface dose (ESD) since 2006.

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, using 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.

A satisfaction survey on DRL data collection methods was sent to users in late 2018. The results of this survey are set out below in a special focus section.

FOCUS

Satisfaction survey on DRL data collection methods

In November and December 2018, IRSN carried out a satisfaction survey on DRL data collection methods. It covered the web application (https://basenrd.irsn.fr) used by professionals to submit their data, and the contact and information channels available (telephone line, email, website, etc.).

The survey also provided an opportunity for users to suggest upgrades and improvements that would make data reporting and monitoring easier.

Respondent numbers

Survey responses were anonymous. 352 individuals responded to the survey, representing around 16% of questionnaire recipients. The questionnaire was sent to people signed up on the DRL application with a valid email address in November 2018.

Table 1 shows respondent numbers. Most of them were radiographers (67%).

Over 80% of them had been using the application for at least 3 years.

The fields in which respondents worked are presented in Figure 3. This distribution is consistent with the distribution of fields associated with application DRL accounts, except for computed tomography, which is over-represented (52%, with only 33% of DRL accounts associated with a computed tomography device).

	Number of respondents	Distribution of respondents (%)
Radiologist / nuclear medicine physician	24	6.8%
Other physician	2	0.6%
Dental Surgeon	5	1.4%
Radiographer	235	66.7%
Medical physicist	43	12.2%
Radiopharmacist	2	0.6%
Other (para)medical or technical profession	32	9.1%
Administrative professional (secretary, etc.)	9	2.6%
Total	**352**	**100%**

Table 1: Profession of individuals who responded to the survey

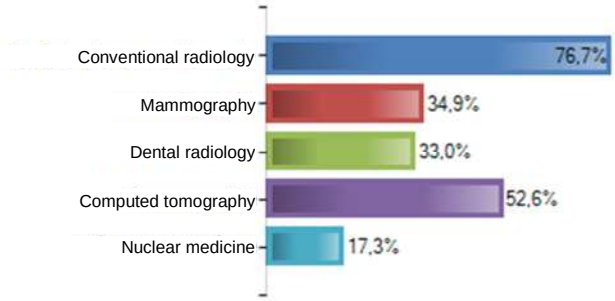


Figure 3: Distribution of responses by survey respondent field

Satisfaction regarding DRL application

For account creation and modification methods, 91% of respondents were satisfied or very satisfied with the ease of use of the application in terms of account creation, and 97% of individuals were satisfied or very satisfied with account validation lead times (see Figure 4).

Moreover, 98% of respondents were satisfied or very satisfied with DRL application availability.

For DRL data submission and validation, 89% of respondents were satisfied or very satisfied with ease of use of the application and 96% with submission validation response lead times (see Figure 5). Satisfaction with exchanges with IRSN during the data validation phase received similar results (95% of respondents were satisfied or very satisfied).

Finally, around 80% of respondents knew and used fairly regularly the application functions available (dose history and PDF printing of dose assessments).

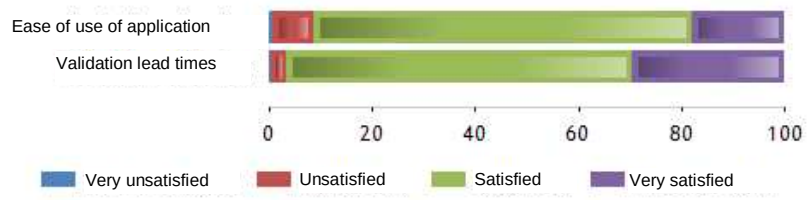


Figure 4: User satisfaction regarding account creation and modification

Figure 5: User satisfaction regarding DRL data submission and validation methods (dose assessments)

Satisfaction regarding contact and information channels

Around 30% of respondents had used the dedicated DRL telephone line (+33 (0)1 58 35 70 77) and around 60% had used the dedicated DRL email address (nrd@irsn.fr). Around 95% of them on average were satisfied or very satisfied with these services (see Figures 6 & 7).

IRSN also sends out emails several times a year to all DRL account holders to inform them of application upgrades, remind them of deadlines, etc. Around 99% of respondents said they read these emails and find them useful. 70% of them do not want these emails to be more frequent.

Finally, around 90% of respondents knew the DRL information website (http://nrd.irsn.fr). Some 98% of these respondents were satisfied or very satisfied with the content of this website (regulatory reminders, information on data submission, forms, datasheets).

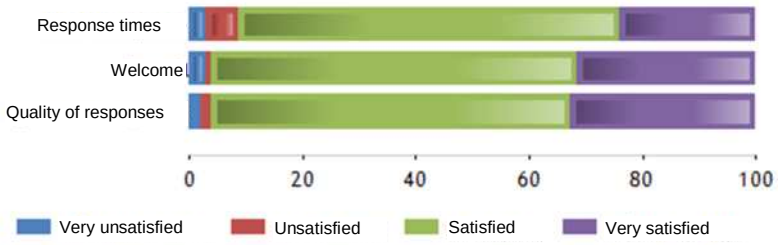


Figure 6: *User satisfaction regarding telephone line*

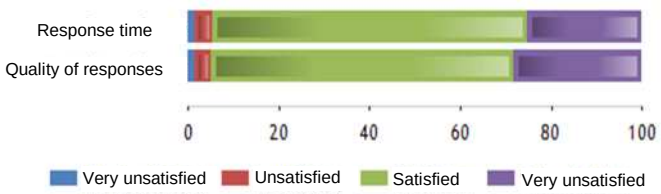


Figure 7: *User satisfaction regarding email*

Overall satisfaction and upgrade proposals

More generally, around 98% of respondents were generally satisfied or very satisfied with DRL data collection by IRSN (application, relations with IRSN, etc.).

Dissatisfaction expressed generally related to the ease of use of the application for assessment validation and account creation. With regard to account creation, some respondents did not like the fact that account validation has to be performed using a paper form, and that this means a certain validation lead time on the part of IRSN. For dose assessment validation, some respondents mentioned the time-consuming process of writing out the data by hand, or difficulties submitting .csv files. Some respondents would like there to be a simpler process using Excel spreadsheet data. Others also noted that the application is now somewhat dated, saying that they would like simpler more intuitive dashboards.

This feedback will be taken into account as much as possible in future application upgrades in order to make it easier to use.

Two of the upgrades suggested by IRSN in the survey were particularly positively received by respondents:

- graphical presentation of results and change in data over years;
- a dynamic comparison of data to national data by examination type, and according to generation of equipment, institution type, etc.

These aspects will also be taken into account in future application upgrades, from 2020, depending on the possibilities for technical development.

DATA COLLECTION PERIOD

In 2015, it was agreed with ASN that DRL reporting periods would go from 2 to 3 years. This report therefore presents an analysis of the data collected for 2016, 2017 and 2018.

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 were selected for data consistency in order to avoid discouraging users who might have their data refused.

Each assessment submitted by institutions is checked by IRSN. Only data validated after verification are used for performing national-level statistical analyses. The type of data required is described in the Appendices.

For computed tomography, the complementary DRL quantities combination, $CTDI_{vol}$ and DLP, can be used to check data consistency. 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”. Checking this parameter is fairly discriminating, which explains why there is a higher level of unused data than in conventional radiology. Figure 8 shows the $DLP/CTDI_{vol}$ ratio median values for 3 patient heights: 160, 170 and 180 cm (+/- 2 cm).

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

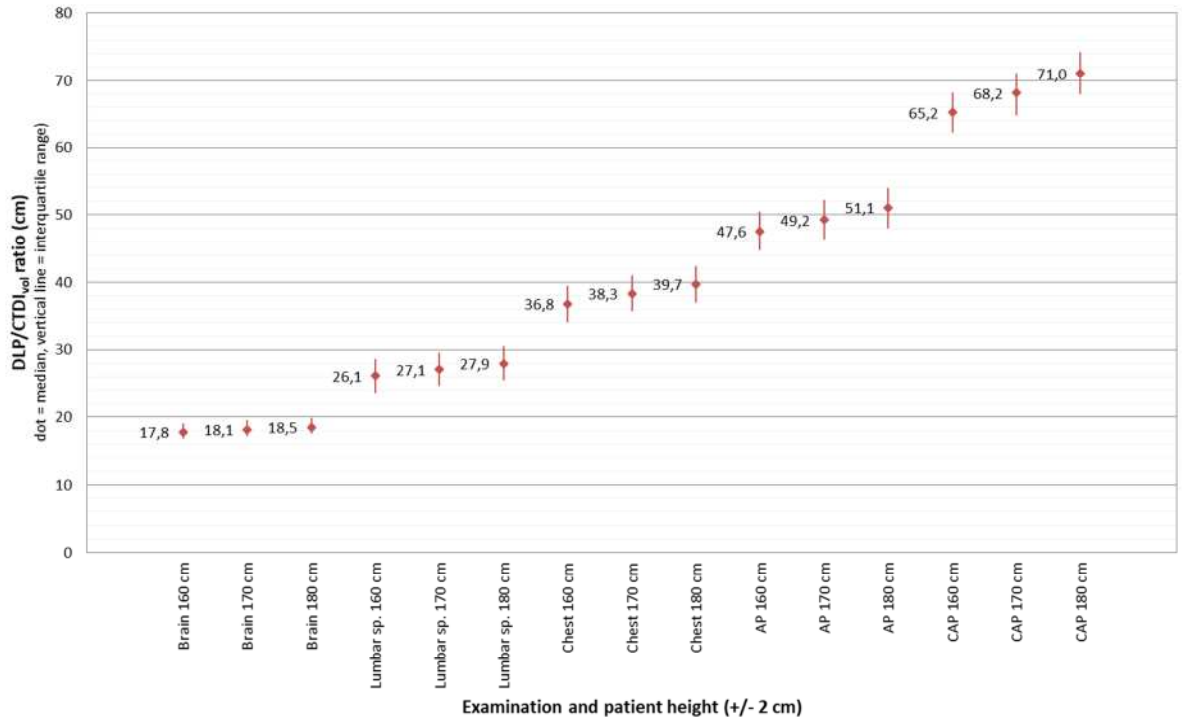


Figure 8: Median values of exposed lengths ($DLP/CTDI_{vol}$ ratio) by examination and different heights for all CT data received for the 2016-2018 period. The vertical line corresponds to the interquartile range (between the 25th and 75th percentile).

SELECTION OF DATA FOR ANALYSIS

Despite the checks described in the preceding section, validated dose assessments can contain data errors or data that is considered not to represent current practices (abnormally high or low DRL quantities, patient morphology, 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;
- exclusion of data including less than 25 patients after application of the previously cited validation and selection criteria.

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 more discriminating than age.

Since ASN resolution 2019-DC-0667 introduced a patient selection criterion based on their BMI, it was decided that this criterion would be applied to the 2016-2018 data retrospectively so that the results of analyses, which are intended to direct DRL updates, include this new requirement. Implementation of BMI filtering is the reason for the higher rates of unused assessments than in previous reports (see the sections focused on these different fields).

However, the BMI criterion has not been applied retrospectively to nuclear medicine data. In practice, administered activities are defined either as a function of weight, or independently of patient morphology.

In adult conventional radiology and computed tomography, 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 2018 values that are presented for potential DRL updates. Nevertheless, all data (2016 to 2018) have been kept for producing the radiology and computed tomography histograms presented in the Annex to this report.

In nuclear medicine, mammography, dental radiology and paediatrics (all fields), the 75th and 50th percentile values have been calculated for the entire 2016-2018 period, and not for each year individually. This is for the following reasons:

- lower volumes of data received (paediatrics, nuclear medicine);
- slower change in doses delivered (nuclear medicine, mammography);
- less frequent dose assessments (orthopantomography, where data collection is associated with a five-year quality check);
- the desire to perform analysis according to detector type used (mammography).

The fact that data collected over a 3-year period is 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 2016-2018 period, only the latest data received have been kept for calculating the 75th and 50th percentiles and presented in the histograms in the Annex.

STATISTICAL MEASURES

- ***From mean to median***

National DRLs were based on mean values (i.e. arithmetic means) of the dosimetric data collected for groups of 30 patients by professionals for each unit. Professionals were required to compare this mean value to the DRL in order to assess their practice. The distribution of these unit mean values was analysed in order to determine the 75th percentile.

For several years now, international recommendations encourage use of the median value to define a unit's representative value, rather than the mean, both for comparison with DRLs and for updating them (12; 13; 18; 29). This recommendation was integrated into French regulations by ASN resolution 2019-DC-0667.

What is the median?

The arithmetic mean of a series of values is equal to the sum of the values divided by how many there are. The median is defined as the central value which divides the series of values into two equal parts: half of the values are less than the median, and the other half are greater than the median. It also corresponds to the 50th percentile of the series (50% of values of a series are less than the 50th percentile).

By convention, in this document, 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 used 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).

Why the median?

The arithmetic mean is highly impacted by abnormally high or low values. For DRL data, these outliers can represent very specific clinical cases (patient morphology, complexity, etc.), or errors undetected during data collection and validation. The median, however, is much less sensitive to extreme values (see Figure 9). Using the median is therefore more representative of an institution's practice, and provides more relevant comparison with the DRL. On a national scale, it also improves the representativeness of DRLs, and given the international nature of the recommendation, makes comparison between countries much more relevant.

The previous IRSN report included an assessment of the impact of switching from mean values to median values (8). It showed a drop of 75th percentile values of around 5 to 10% with regard to the values calculated based on means for radiology and computed tomography. There is greater range of high values than low values (it is possible to perform examinations with a very high dose, but not with a very low dose, and low doses will always be greater than zero). In nuclear medicine, switching from mean to median values leads to differences of between –5% and +10% (8).

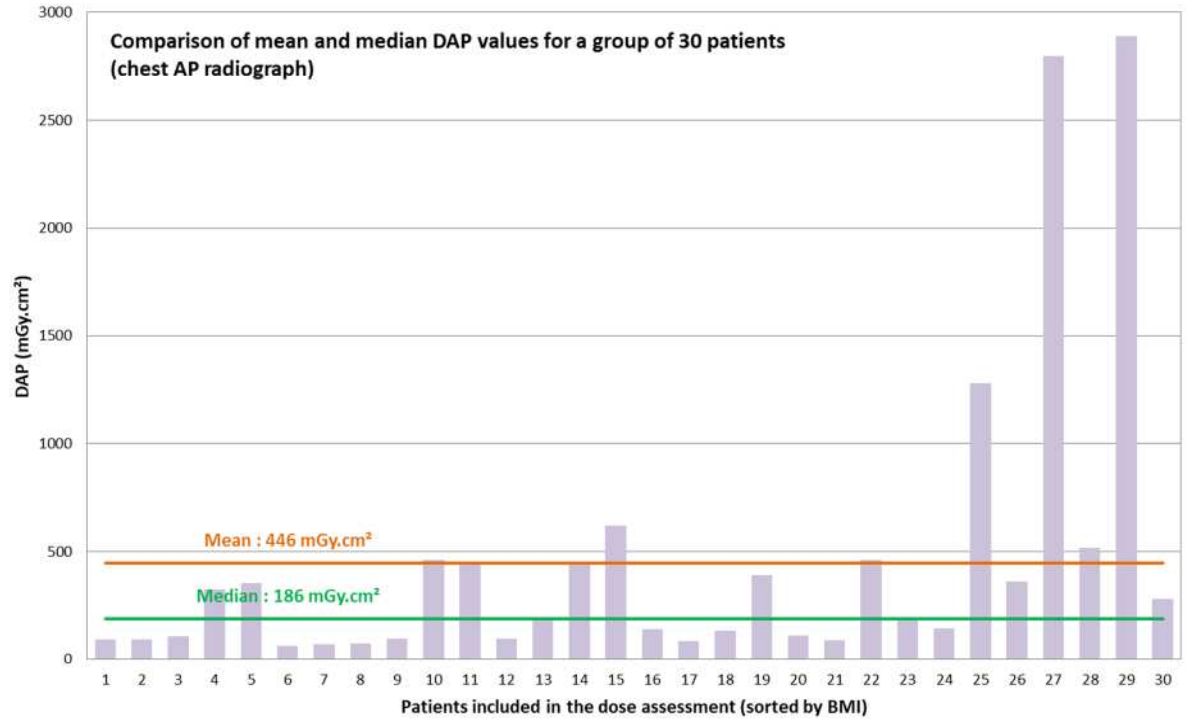


Figure 9: Comparison of mean and median values of DAP for a group of patients. The 3 outliers for patients 25, 27 and 29 increase the mean, making it less representative of the institution's general practice.

- ***75th and 50th percentiles***

Conventional radiology and computed tomography

In conventional radiology and computed tomography, the 75th percentile of the distribution of results (dosimetric data median values) of dose assessments for a given examination define its DRL. This is an alert level over which practices could be considered sub-optimal, or even abnormal, in terms of dose delivered to the patient. Given its international use, it remains an essential measure for DRLs.

In addition, the 50th percentile of the dose assessment results distribution is used to define the AD mentioned in the "what's new in the regulations" section (Figure 10).

Nuclear medicine

In nuclear medicine, the DRL was previously defined as the mean of the mean values. The 50th percentile of the median values is now used to define the DRL.

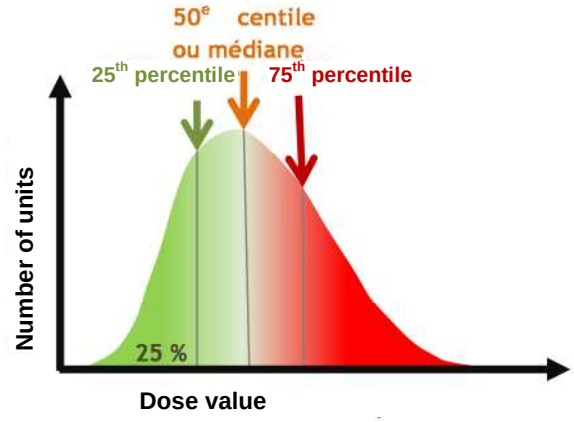


Figure 10: Definition of main statistical measures for dose data distribution for a given examination.

- ***75^{th} to 25^{th} percentile ratio***

Previous IRSN reports showed that medical imaging practices were involved high degrees of disparity, with patient exposure levels varying by several orders of magnitude 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 75^{th} to 25^{th} 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 covered by the French Order of 24 October 2011 in force during data collection between 2016 and 2018: conventional 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 assessed from the list in the Order of 24 October 2011, 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 in force since 1 July 2019 and the results of the previous report. The results for paediatrics are, once again, separated from those for adults.

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, AGD, $CTDI_{vol}$, 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 75^{th} and 50^{th} percentiles in radiology and computed tomography, and the 50^{th} percentiles in nuclear medicine, since 2011.

During the 2016-2018 period, data was only required to be assessed and submitted for the types of examination listed in the Order of 24 October 2011. IRSN analyses therefore only cover these. Nevertheless, ASN resolution 2019-DC-0667 restates the previous lists, with additional elements. This report provides updated values for the majority of adult examinations, which have been calculated in line with the new methods in force since 1 July 2019 (median values, selection by BMI). However, in paediatric radiology and computed tomography, a modification in patient weight categories means that the results obtained cannot be used to update the DRLs for newly defined examinations. Equally, data collection for the new examinations introduced, including interventional radiology, only began in July 2019. An overview of national indicators will not be available until at least the end of 2020. Since this is a sector with fewer units than for conventional radiology and computed tomography, it will probably be necessary to wait for several years of data in order to have data that is sufficiently statistically robust.

CONVENTIONAL RADIOLOGY

CONTENTS

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 previous IRSN DRL reports, this estimate was based on data provided by the French Nuclear Safety Authority (ASN). The total number of conventional radiology departments or practices subject to DRL regulations – declared users of X-ray generators for medical purposes who perform at least one of the types of examination specified by the DRL regulations – was then estimated at about 5,100 (excluding dental practices). This estimate had not been updated since 2005, because the national system for collecting information on imaging equipment that is not subject to authorisation is not strict enough, and numbers are not well known.

In December 2018, IRSN attempted to review the estimate based on a telephone directory extraction. This extraction used the key words “medical imaging”, “radiology”, “radiologist” and “hospital”. Extracted data was then consolidated in order to remove any redundant entries.

In this way, the total number of conventional radiology departments or practices was estimated at around 3000 at the time of extraction. The total number of departments and practices therefore appears to have decreased by around 40% over 13 years, and was therefore probably over-estimated in previous reports.

This new estimate impacts the participation results in the previous report by a factor of around 1.7 (5100/3000). The participation rate for this report can no longer, therefore, be directly compared with that of previous reports.

For the purposes of comparison with previous participation rates, Figure 11 on the change in annual participation of institutions performing conventional radiology procedures since 2004 has been adapted to present the participation rates determined using the number of institutions estimated in 2005, and the number of institutions estimated using linear regression between the 2005 and 2018 estimates.

Figure 11 shows that since 2016, around 50% of institutions performing radiography procedures have met DRL regulations. The participation rate therefore seems to be stabilising over recent years.

Please note that the 2011 dip in participation was linked to the implementation of internet data submission that year. Furthermore, the clear drop in participation between 2014 and 2015 can probably be attributed to stricter data collection conditions for 2015 (data could be submitted up to 31 January 2015, as opposed to 31 March in 2014).

In conventional radiology, 73% of data come from the private commercial sector (Figure 13). 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 practices able to submit data, is presented in Figure 12. Over the years, the number of new accounts is increasing. It should be noted that by the end of 2019, around 35% of practices signed up between 2014 and 2018 had never submitted data. Nevertheless, the very large increase (+75%) in the number of assessments submitted for orthopantomography examinations compared with the 2013-2015 reports is noteworthy.

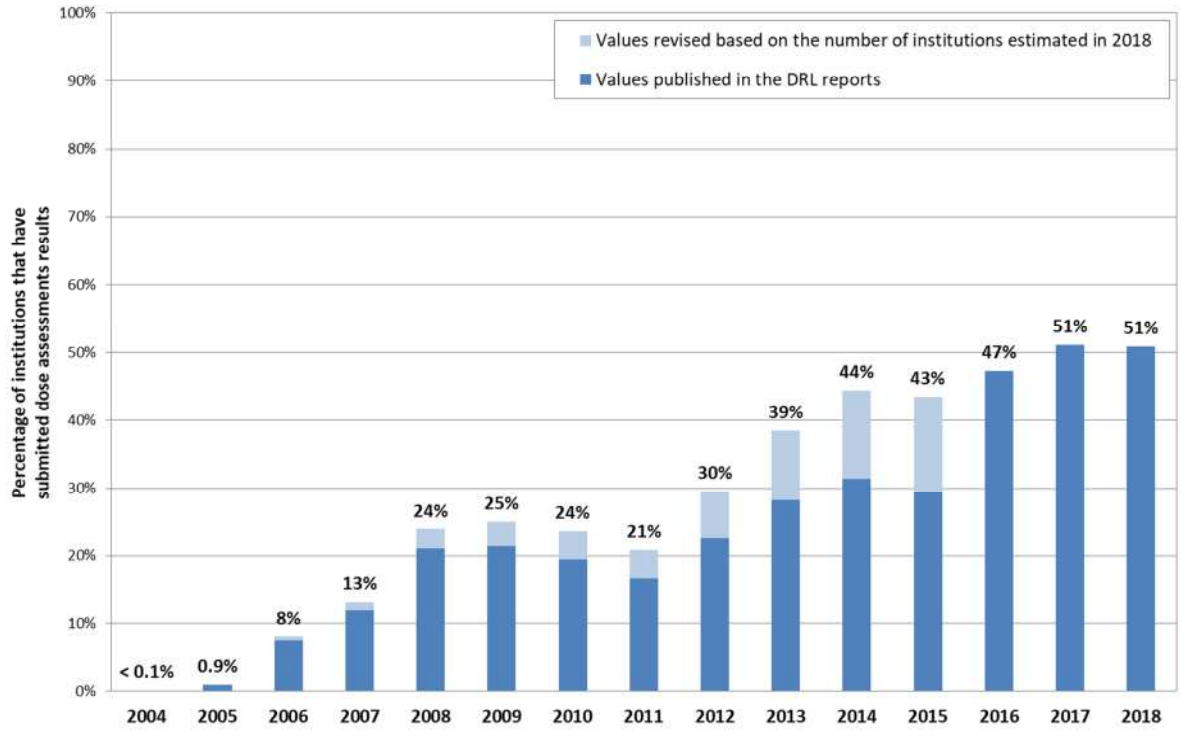


Figure 11: Change in annual participation of institutions performing conventional radiology procedures since 2004.

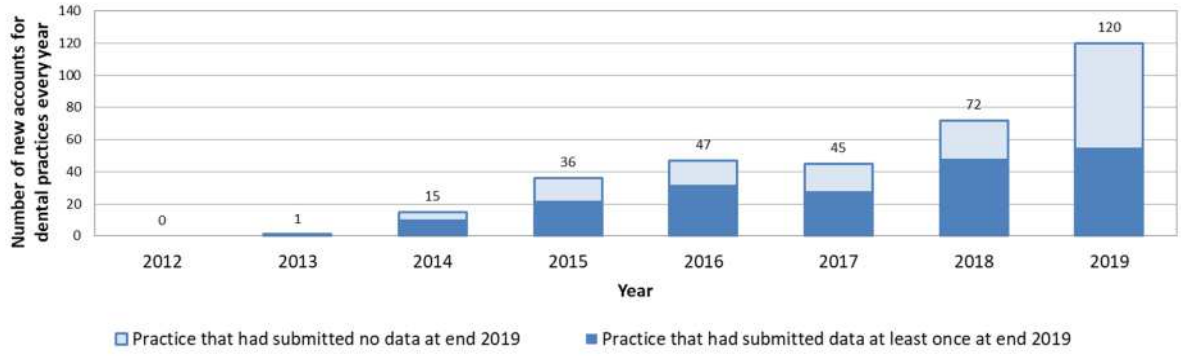


Figure 12: Increase of new DRL application accounts for dental practices. Represents the number of new accounts for dental practices every year, and the proportion of those who had submitted data at least once by the end of 2019. At end 2019, 336 dental practices had accounts and were able to send data to IRSN.

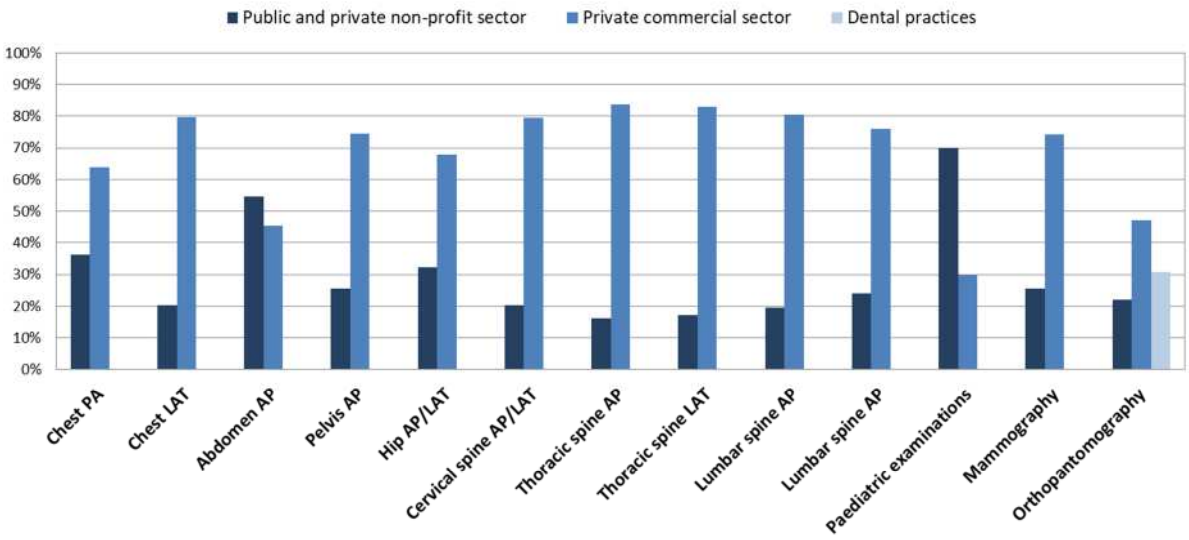


Figure 13: Source of data collected for conventional radiology DRLs, by examination type.

DATA DISTRIBUTION BY EXAMINATION TYPE

ADULT EXAMINATIONS

Figure 14 presents the distribution of dose assessments results by examination type submitted to IRSN from 2016 to 2018.

Procedure types are taken from the list in the 2011 Order, which goes unchanged in ASN resolution 2019-DC-0667. The percentage of data submitted for each examination type is shown, together with the proportion of data that IRSN has been able to use.

Paediatric procedures are covered in the next section, and are represented in Figure 14 by combining all examination types in order to measure the volume of paediatric data compared to all conventional radiology data submitted.

For all examination types, except orthopantomography and mammography, the use rate for submitted data is over 80%, and sometimes around 90% (Figure 14). These rates are lower than for the previous report, primarily because entrance surface dose (ESD) data have not been used. This represented 7 to 9% of data received, depending on the examination. Moreover, applying the new body mass index (BMI) criterion (see data analysis section) according to ASN resolution 2019-DC-0667 meant that a larger number of assessments were rejected than for the previous report, which used weight criteria for filtering data.

The use rate for orthopantomography is around 70%, and 60% for mammography. These lower rates are primarily due to the fact that identical data submitted several times over the collection period was not taken into account, as explained in the “data selection” section.

For screen-film mammography only 7 dose assessments results from 4 different devices were approved (compared with 780 assessments approved for mammography of all types). The removal of this examination in the new resolution is therefore fully justified, particularly given that this examination has no longer been authorised for organised breast cancer screening since February 2019.

As with the previous report, for adults, three examination types represent around 50% of data: chest PA, pelvis AP and lumbar spine AP. This distribution seems consistent with the frequency of radiography examinations performed in France (30).

Submission rates are virtually identical to the previous report, apart from the abdomen AP which drops from 6 to 4.7%, thoracic spine AP which drops from 4.1 to 3.5%, and orthopantomography which rises from 2 to 5.1% due to the significant increase in the number of assessments submitted as mentioned above.

The proportion of data for paediatrics is very low, with less than 2% of data submitted (184 assessments out of a total of 10,343 assessments submitted for the period), while around 10% of procedures in France are performed on children (30).

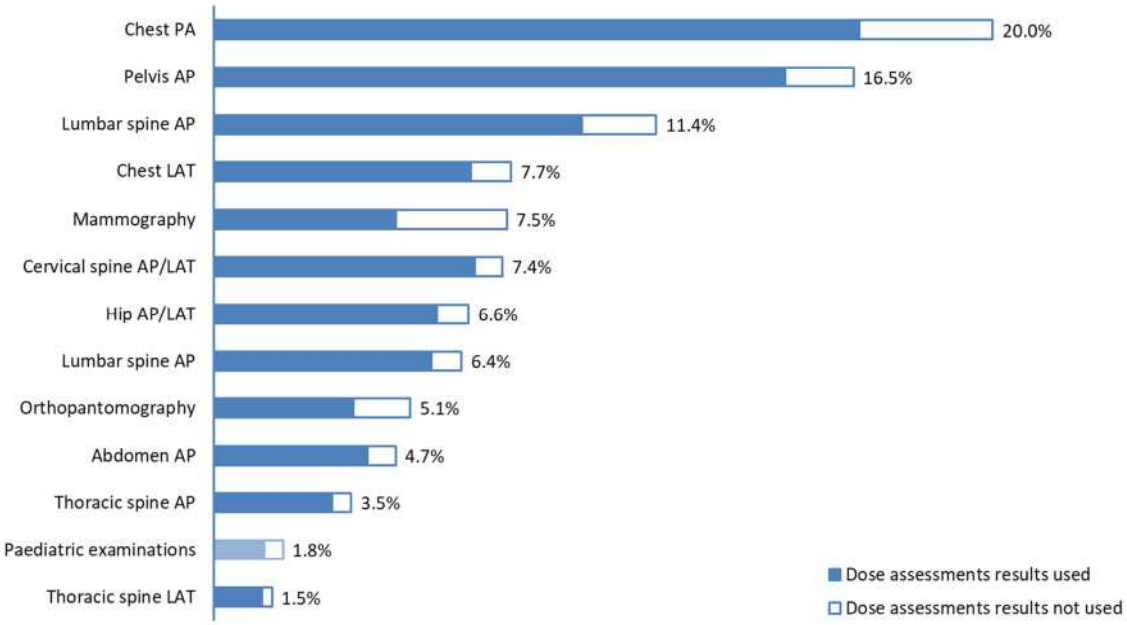


Figure 14: Percentage distribution by examination type of radiography dose assessments for which results were submitted to IRSN from 2016 to 2018 (total number of assessments submitted: 10,342).

PAEDIATRIC EXAMINATIONS

Figure 15 presents the distribution by examination type according to the Order of 2011, for children, of dose assessments results submitted to IRSN by professionals.

The same 3 procedure types are still assessed most frequently: frontal chest for children of 10 (AP) and 20 kg (PA), and pelvis for children of 10 kg (AP), but the amount of data remains very low.

As for previous reports, the lack of paediatric data presents a major difficulty for regularly setting and updating DRLs. The recurrent nature of this observation led to the implementation of specific targeted paediatric studies in collaboration with professionals (24; 25). The results of these studies were taken into account in ASN resolution 2019-DC-0667.

This ASN resolution makes dose assessments mandatory if 5% or more of procedures are performed on children (under 18s). These new provisions should improve the amount of data submitted and enable more reliable analysis in the next report. It is important to monitor this closely and check the effectiveness of these new measures.

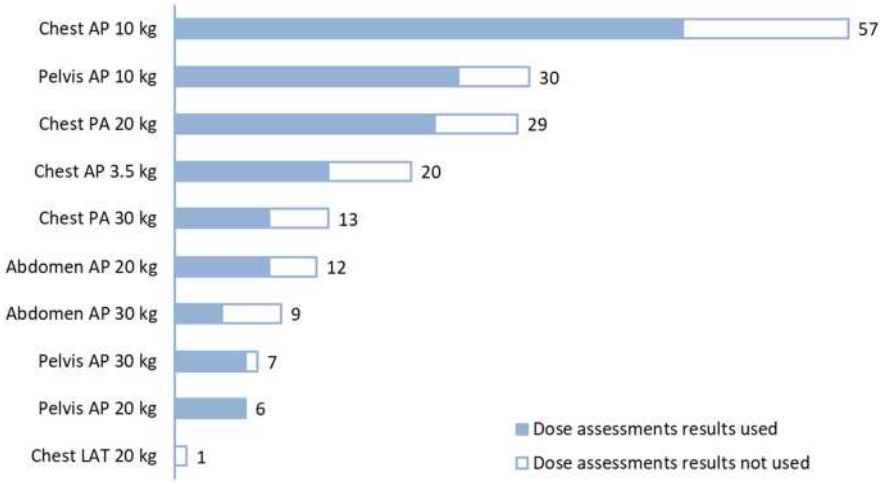


Figure 15: Distribution by examination type of the number of child radiography dose assessments for which results were submitted to IRSN from 2016 to 2018 (total number of assessments submitted: 184).

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 2.

It shows:

- the number of assessments used for 2018 and 2016-2018 (N),
- patient median weight and BMI values,
- the DRLs and ADs in force since 1 July 2019 (DRL and AD),
- the 75th percentile (75th) and 50th percentile (50th) values for data collected in 2018,
- the 75th to 25th percentile ratio for 2018
- the position of the 75th percentile for 2018 with regard to the DRL in force since 1 July 2019 (% DRL),
- the percentage of dose assessments data received in 2018 over the DRL in force since 1 July 2019 (> DRL)
- and the 2018 75th percentile variation with regard to the 2015 value published in the previous report.

All the data presented in Table 2 are for 2018. Only the number of assessments used is given for 2018 and the 2016-2018 period (N).

Table 3 shows the results for orthopantomography specifically (2016-2018 period).

Table 4 shows the results for mammography. These results are discussed in a focus section.

Table 2: Summary of results of conventional radiology data analysis (excluding orthopantomography and mammography) by adult examination type, for 2018, expressed in terms of dose area product (DAP).

Examination type	N 2018 (2016-2018)	Median weight (kg)	Median BMI (kg/m²)	DAP (mGy.cm²)				P75/P25 ratio	% DRL	> DRL	Variation
				DRL	AD	P75	P50				
Chest PA	565 (1719)	70.0	24.6	200	150	185	118	2.40	-8%	20%	-1%
Chest LAT	234 (684)	70.0	24.5	550	400	489	369	2.18	-11%	19%	-7%
Abdomen AP	128 (410)	70.0	25.0	3400	2300	3104	2118	2.02	-9%	18%	-8%
Pelvis AP	497 (1521)	70.0	25.0	3800	2750	3437	2340	2.22	-10%	20%	-9%
Hip AP/LAT	217 (593)	70.0	25.2	1350	950	1186	760	2.28	-12%	23%	-10%
Cervical spine AP/LAT	224 (695)	70.0	24.7	400	250	325	219	2.71	-19%	16%	-9%
Thoracic spine AP	82 (315)	70.0	24.7	1000	750	897	625	1.96	-10%	18%	-6%
Thoracic spine LAT	30 (129)	68.3	24.5	1150	900	1625	1021	2.46	+41%	47%	+41%
Lumbar spine AP	353 (979)	70.0	24.8	2700	1950	2405	1630	2.33	-11%	18%	-10%
Lumbar spine AP	201 (580)	70.0	24.8	3900	2650	3540	2200	2.34	-9%	19%	-9%

Table 3: Summary of results of orthopantomography data analysis for 2016-2018, expressed in terms of dose area product (DAP).

Examination type	N	DAP (mGy.cm²)				P75/P25 ratio	% DRL	> DRL	Variation
		DRL	AD	P75	P50				
Orthopantomography	371	150	100	129	97	1.96	-14%	13%	-5%

Table 4: Summary of results of mammography data analysis for 2016-2018, expressed in terms of average glandular dose (AGD).

Detector type	N	AGD (mGy)				P75/P25 ratio	% DRL	> DRL	Variation
		DRL	AD	P75	P50				
All digital detectors	484	1.6	1.3	1.54	1.26	1.45	-3.8%	19%	-2.5%
CR systems (photostimulable plate)	71	1.6	1.3	1.84	1.74	1.18	+15.0%	65%	+3.4%
DR systems	413	1.6	1.3	1.40	1.21	1.35	-12.5%	12%	+0.0%
Flat panel detectors	383	1.6	1.3	1.43	1.22	1.34	-10.6%	13%	-
Photon-counting detectors	30	1.6	1.3	0.7	0.58	1.29	-56.3%	0%	-

Detailed analyses by examination type are presented in the Annex in sheets. For each examination type for which the data collected can be analysed, these sheets show:

- DAP distribution graphs for 2016-2018;
- a table with associated statistical data;
- changes in results since 2011.

Results show a drop of 1 to 10% in 75th percentile values compared with 2015, except for the lateral thoracic spine (+43%). This is the examination for which the lowest number of dose assessments were analysed in 2018 (30 assessments), which casts doubt on the representativeness of this result. The value of the 75th percentile over the 3-year period is 1275 mGy.cm^2, which is closer to the DRL in force at 1 July 2019 (+10%) and is probably more representative (129 assessments). IRSN recommends monitoring changes in the 75th percentile for the lateral thoracic spine in coming years, in order to determine whether a revision of the DRL for this examination is required, or consider whether it is still worth including it in the list of examinations, given the low amount of data reported.

Apart from the lateral thoracic spine, the 75th percentiles for 2018 are 8% to 19% under the DRLs in force according to ASN resolution 2019-DC-0667, which is based on 2015 values which had been rounded up too much. Another revision of these DRL values does not seem necessary in the short term.

There is a high level of data dispersion, with a 75th/25th percentile ratio of around 2 to 2.70. This result raises 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. As stated in the previous report, the concept of image quality is complex, and subjectivity makes it difficult to assess. It is an underlying criterion that is not measured or taken into account in the current DRL framework. As stated above, 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 doses recently introduced in the regulations, image quality, rather than dose, should be considered as a priority in the optimisation process.

The results of mammography data analysis (Table 4) are discussed and detailed in a dedicated focus section. This analysis leads IRSN to suggest considering a change to the DRL concept for mammography, in order to better analyse sites' clinical practice and take into account the rapidly growing technique of breast tomosynthesis.

Although numbers of orthopantomography assessments submitted are increasing, there are still very few of them. In addition, external quality controls, the results of which are used for dose assessments, are performed every 5 years. It is therefore irrelevant to analyse 2018 alone. For this reason, analysis was performed over 3 years (2016-2018), including for the 75th and 50th percentiles (Table 3).

In line with recommendations for breast tomosynthesis, it could be useful to take into account cone-beam computed tomography (CBCT) for dental radiology, given the growing use of this technique and the sometimes high doses delivered, especially in paediatrics (31).

PAEDIATRIC EXAMINATIONS

The results of the dose assessment analyses for paediatric radiology are presented in Table 5.

For each weight category, this table shows the number of assessments used (N) for 2016-2018, the minimum, median and maximum weight of children, the 75th percentile value (75th), the 50th percentile value (50th) and the 75th to 25th percentile ratio.

As mentioned above, only frontal chest examinations for children of 10 (AP) or 20 kg (PA) and frontal pelvis for children of 10 kg (AP) have enough DAP data – over 20 assessments – and can be analysed in detail (see Annex).

Comparison with the DRLs defined in ASN resolution 2019-DC-0667 is complicated by the fact that the child weight categories for the various examinations have changed from the Order of 2011. To aid comparison, Figure 16 shows the 75th percentile value in terms of DAP for the 2016-2018 period, for abdomen, pelvis and chest examinations by child weight and in comparison with the DRLs in the 2011 Order and the 2019 ASN resolution.

With chest and pelvis examinations for children of 10 kg, results are slightly below the DRL in the 2011 Order. They results show a 5 to 15% downward trend compared with results for the 2013-2015 period.

For chest examinations, results are over the DRL in the 2019 resolution. This can be explained by a difference between the institutions included in the study performed (24) for updating DRLs in the 2019 resolution, and institutions represented in the national DRLs. In the DRL update study, the vast majority of institutions included were university hospitals specialised in or used to paediatric radiology, while the institutions involved in the national DRLs were more varied, including some more general institutions. IRSN recommends monitoring results on this examination in the next few years. The change in regulations means that more paediatric data is expected. They should make it possible to check whether or not the 75th percentile stays above the DRL. Depending on the results for this examination with more data, it may be appropriate to consider actions that will encourage centres to optimise practices and/or the need to readjust DRLs.

Table 5: Summary of results of conventional radiology data analysis by paediatric examination type, in terms of dose area product (DAP). (NB = newborns)

Examination type		Weight category (indicative age)	N	Weight (kg)			DAP (mGy.cm²)		P75/P25 ratio	Variation
				median	min	max	P75	P50		
Chest	AP	3.5 kg (NB)	13	3.8	3.0	4.7	9.7	7.0	3.23	-5%
		10 kg (1 y)	43	10.3	6.9	14.5	19	13	2.66	-17%
	PA	20 kg (5 y)	22	18.3	16.0	20.0	43	28	2.15	-10%
		30 kg (10 y)	8	28.3	25.5	30.9	35	29	2.55	+20%
Pelvis AP		10 kg (1 y)	24	7.2	5.7	10.5	29	19	2.63	-6%
		20 kg (5 y)	6	18.9	16.5	20.5	85	76	1.86	-48%
		30 kg (10 y)	6	29.2	28.0	30.0	171	154	1.24	-41%
Abdomen AP		20 kg (5 y)	8	20.0	17.5	21.9	196	87	2.93	-15%
		30 kg (10 y)	4	29.8	29.0	30.0	272	200	2.15	-10%

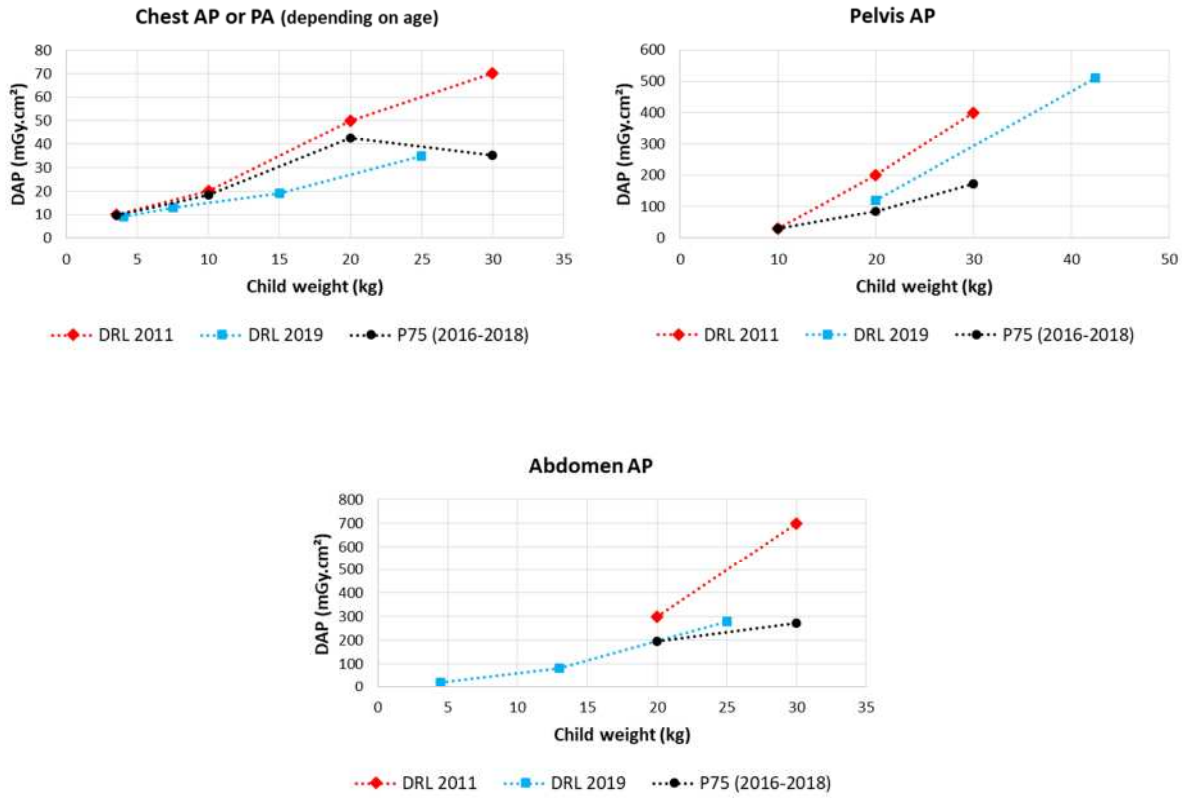


Figure 16: Comparison between the DAP 75th percentiles calculated for the 2016-2018 period and the regulatory DRL values set in 2011 and 2019 for chest, pelvis and abdomen radiographs. For the 2019 DRLs, the points are placed in the centre of the weight category intervals. Some 75th percentile values are calculated from very little data (chest 30kg, pelvis 20 and 30 kg, AXR 20 and 30 kg) and should therefore be used with care.

FOCUS

Influence of detector type on patient exposure in digital mammography

For mammography, the data submission rate has stabilised at 7.5% of conventional radiology assessments submitted since 2015. Around 85% of data submitted are from digital radiography (DR) systems (including flat panel detectors and photon-counting systems) and 15% are from computed radiography (CR) systems. This distribution is consistent with the distribution of mammography units monitored under regulatory quality controls by the French National Agency for Medicines and Health Products Safety (ANSM) (32).

Figure 17 shows the distribution of the average glandular dose (AGD) as a function of digital mammography detector type, and Table 4 specifies the 75th percentile values associated with each detector type. For DR, photon-counting systems have been separated out from flat panel detector systems in order to assess the impact of this difference on AGD.

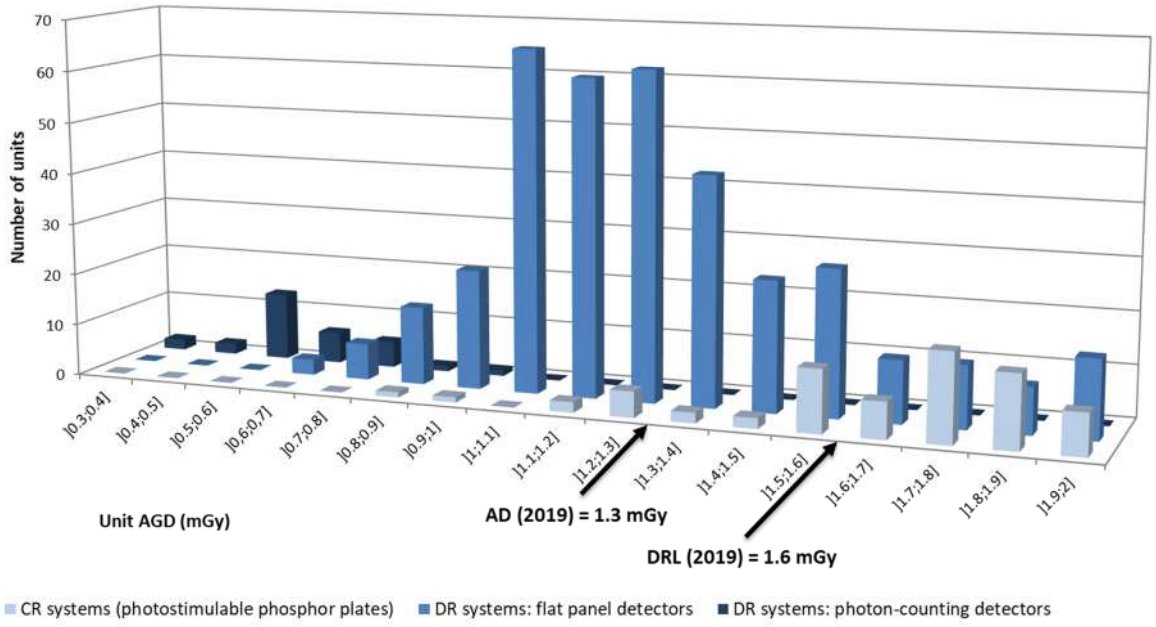


Figure 17: Distribution of the average glandular dose (mGy) as a function of digital mammography detector type.

This analysis by detector type shows that the 75th percentile for assessments on CR systems is above the DRL in force. More specifically, 65% of CR system assessments are over the DRL, as opposed to 13% for flat panel DR systems. No assessment for photon-counting DR systems is over the DRL in force. Digital radiography, and particularly photon-counting systems, remains the detection method involving the lowest level of patient exposure.

Optimisation of doses delivered to patients is even more important for mammography because this type of examination is part of organised breast cancer screening. These dose data must not be decorrelated from image quality and breast cancer detection performance. French National Cancer Institute (INCa) surveys from 2014 and 2017 on mammography performance as part of organised breast cancer screening show that the cancer detection rate was significantly higher with DR systems than with CR systems (33 ; 34). This is despite the fact that CR mammography systems have moved from powder imaging plate technology to needle imaging plates offering higher performance levels. CR detector systems therefore deliver higher doses and offer lower performance in terms of cancer detection rates in organised screening programmes. These results indirectly raise the question of technological obsolescence. It should, however, be specified that cancer detection rates are not solely linked to the technology used, but also the clinical practice of sites and the quantity of examinations performed for a specific method.

It should be noted that the AGDs submitted by centres are determined for an equivalent breast thickness of 45 mm. This dose is measured by external control bodies during the annual external quality check for 40 mm Poly(methyl methacrylate) (PMMA) systems as defined by ANSM. The values submitted are therefore not representative of the clinical practice of sites, but of system performance in given conditions. For performance checks, the AGD delivered for 40 mm PMMA under the conditions defined by ANSM must not exceed 2 mGy, or the unit is required to cease operations. This is why Figure 17 shows no value over 2 mGy, and the $75^{th}/25^{th}$ percentile is fairly low in mammography. ANSM AGD measurement methods have recently changed, and now require the use of polyethylene (PE) plates with the PMMA plates, so the 45 mm equivalent breast thickness no longer applies. They will enter into force from 22 January 2021 (35). The current DRL for digital mammography will no longer be able to be used after this date. The DRL for digital mammography therefore needs to be revised before 22 January 2021. This revision could offer an opportunity to consider changing the DRL concept for mammography, in order to better analyse sites' clinical practice. Moreover, breast tomosynthesis is not covered by current DRL regulations. The use of this technique is rapidly growing, and IRSN recommends that it be taken into account in future mammography DRL updates.

SUMMARY

Analysis of conventional radiology dose assessments shows:

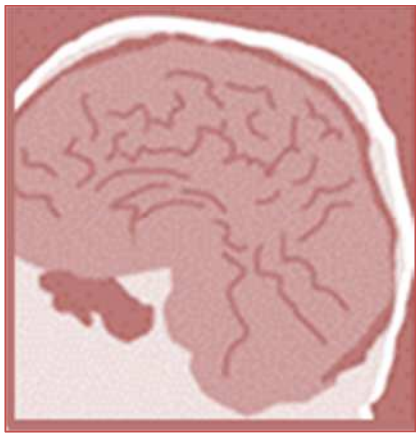
- a stable radiology participation rate of around 50%;
- a distribution of examinations selected by professionals for dose assessments comparable to the frequency of radiography procedures in France;
- an overall decrease in the DAP 75th percentiles for all adult examinations except the lateral thoracic spine (average 7% decrease since the previous report, excluding lateral thoracic spine examination results);
- overall positioning of DAP 75th percentiles below the DRLs in force on July 2019 (8 to 19%) for all adult examinations except the lateral thoracic spine;
- significant data dispersion, with a 75th/25th percentile ratio of around 2 to 2.70;
- in mammography: lower exposures for patients in units fitted with digital radiography detectors, especially photon-counting systems; the current digital mammography DRL will no longer be able to be used from 22 January 2021;
- in paediatrics: a major lack of data; positioning of the DAP 75th percentile over the DRL in force on July 2019 with regard to the frontal chest examination.

RECOMMENDATIONS

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

- DRL updates are not necessary in the short term, except in mammography;
- lateral thoracic spine: monitor change in the 75th percentile in coming years to prepare for a DRL revision for this examination, or consider whether it is still worth including it in the list of examinations;
- for mammography: the DRL needs to be revised before 22 January 2021. Plan to change the concept for this DRL in order to better take into account clinical practice, and to add breast tomosynthesis to the list of examinations;
- for dental radiology: add CBCT to the list of examinations, especially so as to be able to perform paediatric monitoring;
- for paediatrics: add orthopantomography to paediatric examinations; monitor and assess the effectiveness of measures taken to remedy the current lack of data; monitor the change in frontal chest examination results in order to check whether the trend of the 75th percentile over the DRL continues with more data, and understand why. Depending on results, implement actions that will encourage centres to optimise practices and/or readjust DRLs.

COMPUTED TOMOGRAPHY



CONTENTS

CONTRIBUTION OF DEPARTMENTS

The estimated total number of CT units covered by ASN resolution 2019-DC-0667 (i.e. used for diagnostic radiology) is 1,175 according to an IRSN study in September 2017 (36). There are now 750 more scanners than in 2004. This development has been taken into account by the various reports.

Some units are used for specific scanning techniques (simulation in radiotherapy, hybrid imaging in nuclear medicine), and do not fall within the scope of application of DRLs for 2016-2018.

Scanning acquisitions performed in positron emission tomography (PET) examinations have recently been included in the field of application of DRLs under ASN resolution 2019-DC-0667. This resolution came into force on 1 July 2019, and the data for these examinations are not covered by this 2016-2018 report.

Dose assessments were submitted for around 85% of units in 2018. Participation seems to have been stable at around 80-85% for the last six years (Figure 18).

In computed tomography, distribution of data sources is balanced between the public sector and the private commercial sector (Figure 19), 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 is fairly well known. From the 2015 DGOS data contained in the report by the Cour des Comptes published in 2016 (37), the proportion of public sector CT scanners can be estimated at around 47%.

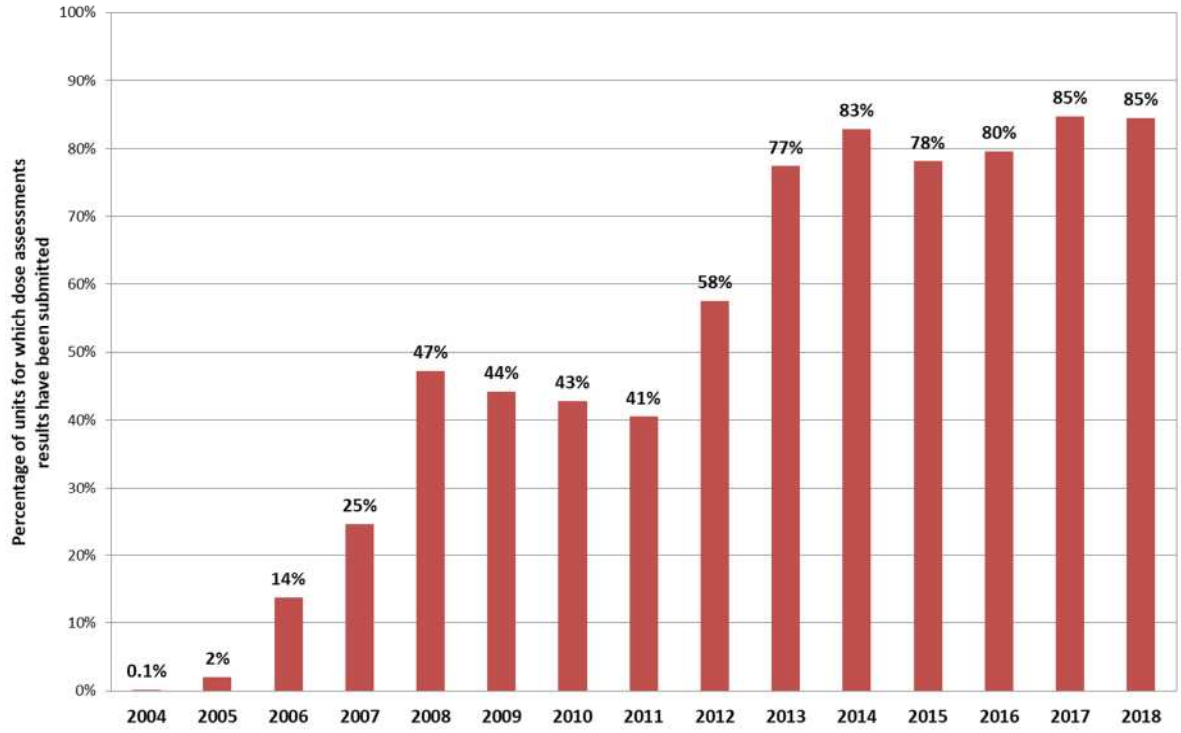


Figure 18: Change in annual participation of institutions performing computed tomography procedures since 2004.

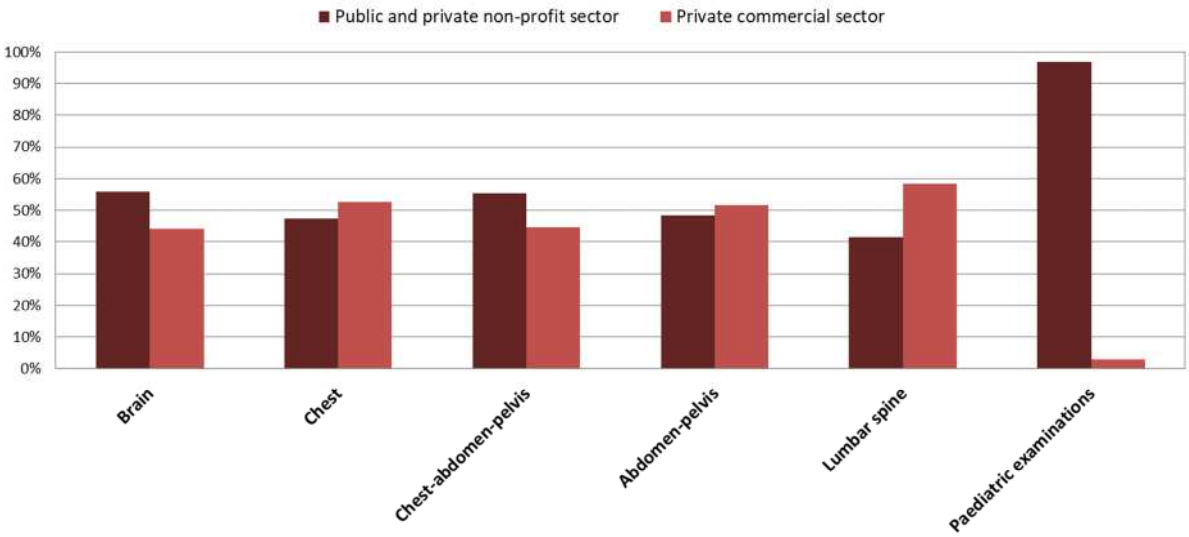


Figure 19: Source of data collected for computed tomography DRLs, by examination type.

DATA DISTRIBUTION BY EXAMINATION TYPE

ADULT EXAMINATIONS

Figure 20 shows the distribution of dose assessments submitted by professionals per examination type, in line with the list defined by the 2011 Order. It gives the percentage of dose assessments submitted for each examination, together with the proportion of data that IRSN has been able to use.

As with the observations of the previous IRSN report in 2016, the examinations with the greatest number of dose assessments are the brain, followed by the abdomen-pelvis region and the chest. The lumbar spine examination is also well represented. The chest-abdomen-pelvis examination is the least represented.

This distribution is consistent with national computed tomography activity (30).

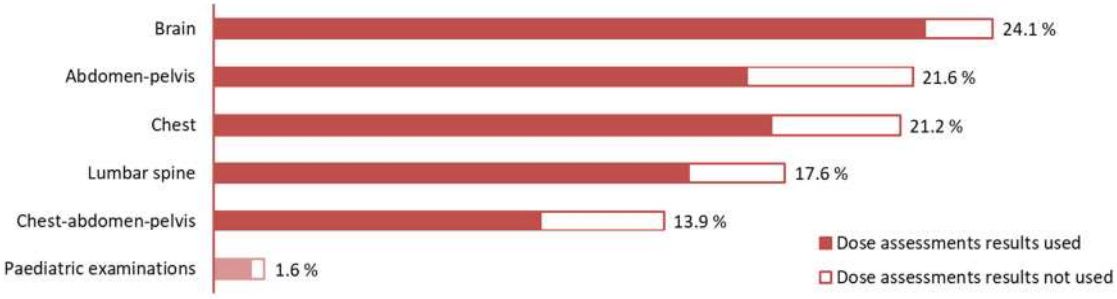


Figure 20: Distribution by examination type of computed tomography dose assessments for which results were submitted to IRSN from 2016 to 2018 (total number of assessments submitted: 5,860).

In total, around 80% of computed tomography data submitted to IRSN have been used for national analysis, while the two previous reports have had a stable rate of around 90%. The rejection rate is 5 to 10 points higher depending on the anatomical zones considered in this report than in the report published in 2016. This increase is due to the application of the new body mass index (BMI) criterion.

The brain examination remains the clinical indication with the lowest rejection rate (around 9%) because the BMI criterion does not apply. The chest-abdomen-pelvis region has the highest rejection rate (around 30%). This rejection rate can be explained by the application of the acquisition length validation criterion, as stated in the section on data validation criteria. It is not unusual for dose assessments submitted to contain data from abdomen-pelvis or chest-abdomen acquisitions in a chest-abdomen-pelvis procedure.

PAEDIATRIC EXAMINATIONS

The number of paediatric CT assessments is still very low, accounting for less than 2% of all CT examinations (Figure 20), and only seventeen dose assessments per examination type and weight category (Figure 21). As in the previous assessment, brain and chest examinations are most frequently subject to dose assessments. There is not always sufficient data to assess practices on a national level. As stated above, ASN resolution 2019-DC-0667 now makes dose assessments mandatory if 5% or more of procedures are performed on children (under 18s). These new provisions should improve the amount of data submitted and enable more reliable analysis in the next report. It is important to monitor this closely and check the effectiveness of these new measures.

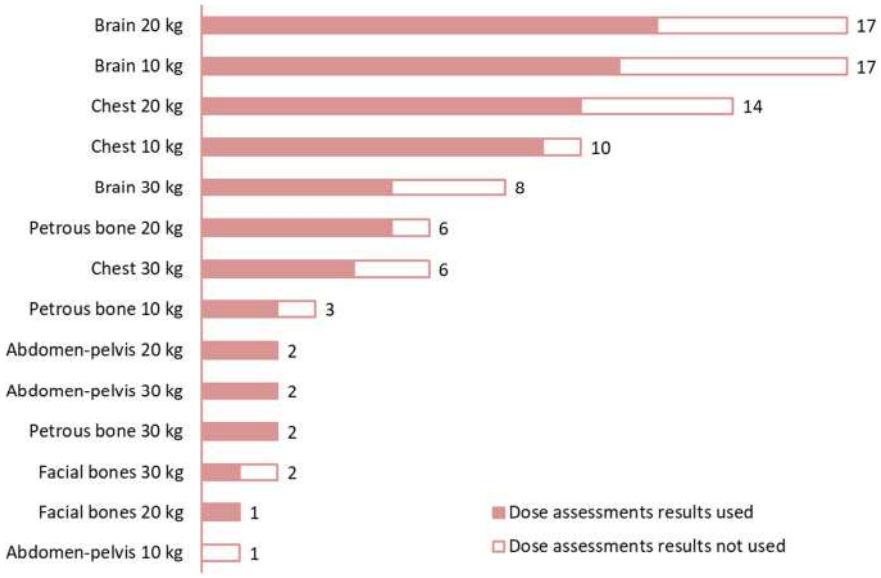


Figure 21: Distribution by examination type and weight of the number of child CT dose assessments for which results were submitted to IRSN from 2016 to 2018 (total number of assessments submitted: 91).

SUMMARY OF COMPUTED TOMOGRAPHY RESULTS

ADULT EXAMINATIONS

Tables 6 and 7 show the results of analyses of adult computed tomography data collected between 2016 and 2018, by examination, in terms of $CTDI_{vol}$ and then DLP.

They show:

- the number of assessments used for 2018 and 2016-2018 (N),
- median weight and BMI values for patients associated with the collected data,
- the DRLs and ADs in force since 1 July 2019 (DRL and AD),
- the 75th and 50th percentile values for the data collected in 2018,
- the 75th to 25th percentile ratio for 2018,
- the position of the 75th percentile for 2018 with regard to the DRL in force since 1 July 2019 (% DRL),
- the percentage of dose assessments received in 2018 over the DRL in force since 1 July 2019 (> DRL)
- and the 2018 75th percentile variation with regard to the 2015 value published in the previous report.

All the data presented in Tables 6 and 7 are for 2018. Only the number of assessments used is given for 2018 and the 2016-2018 period (N).

Table 6: Summary of adult computed tomography analyses, by examination, for 2018 data, in terms of $CTDI_{vol}$.

Examination type	N 2018 (2016-2018)	Median weight (kg)	Median BMI (kg/m²)	$CTDI_{vol}$ (mGy)				P75/P25 ratio	% DRL	> DRL	Variation
				DRL	AD	P75	P50				
Brain	422 (1284)	70.0	24.7	46	40	41.0	37.0	1.21	-11%	11%	-10%
Chest	337 (1007)	71.0	24.9	9.5	7.5	7.5	6.3	1.56	-21%	6%	-18%
Chest-abdomen-pelvis	207 (591)	70.0	24.7	11	9.5	10.1	8.5	1.34	-8%	15%	-7%
Abdomen-pelvis	354 (963)	72.0	25.1	13	11	10.1	8.9	1.35	-22%	3%	-18%
Lumbar spine	298 (858)	72.0	25.4	28	23	24.1	20.7	1.35	-14%	9%	-11%

Table 7: Summary of adult computed tomography analyses, by examination, for 2018 data, in terms of DLP.

Examination type	N 2018 (2016-2018)	Median weight (kg)	Median BMI (kg/m²)	DLP (mGy.cm)				P75/P25 ratio	% DRL	> DRL	Variation
				DRL	AD	P75	P50				
Brain	422 (1288)	70.0	24.7	850	725	742	675	1.21	-13%	10%	-11%
Chest	337 (1010)	71.0	24.9	350	275	286	240	1.58	-18%	7%	-16%
Chest-abdomen-pelvis	207 (592)	70.0	24.7	750	650	689	598	1.34	-8%	14%	-7%
Abdomen-pelvis	354 (966)	72.0	25.1	625	525	492	430	1.36	-21%	4%	-19%
Lumbar spine	298 (860)	72.0	25.4	725	625	654	564	1.38	-10%	13%	-9%

The 75th percentiles for 2018 in terms of $CTDI_{vol}$ and DLP are below the DRLs in force since 1 July 2019 by 8 to 22% for all examinations considered. They are closer to the AD than the DRL.

The $CTDI_{vol}$ and DLP have also dropped by 7% to 19% for all examinations compared with the previous report.

The quantity of data collected for the 2016-2018 period is satisfactory, because hundreds of assessments were submitted for each examination type.

Detailed results for each examination type for the 2016-2018 period are shown in the report Annex. The figures presenting the change in $CTDI_{vol}$ and DLP since 2011 show a continuous reduction of the 75th percentiles, for all examination types. DRL quantities are continuously dropping.

Lumbar spine:

For the lumbar spine, in the 2016 report (7), the 75th percentile in terms of DLP was 9% over the DRL set by the Order of 24 October 2011. Since this DRL was reviewed upwards in ASN resolution 2019-DC-0667, the 75th percentile in terms of DLP for the lumbar spine is now under the DRL in force and close to the AD as with other anatomical regions.

Abdomen-pelvis:

For the abdomen-pelvis, the 2018 75th percentiles for $CTDI_{vol}$ and DLP are even below the AD. Moreover, the downward evolution 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. This type of algorithm is more effective on the abdomen-pelvis region than on the brain, so this seems a plausible explanation for the results presented in the Annex.

As with conventional radiology, the computed tomography DRLs were recently revised with ASN resolution 2019-DC-0667 that came into force on 1 July 2019. The differences between the 75th percentiles and the DRLs in force are therefore less marked than in the 2016 report (8). They do not appear to need revising again in the near future. However, it should be recalled that new DRLs have been established on the basis of data from 2015. Given the downward trend observed in dose assessments for the short period of 2016-2018, they will need to be monitored closely.

Moreover, as shown in the focus section, defining DRLs by anatomical region leads to combining data that is very heterogeneous because they present significantly varying clinical objectives. Computed tomography DRLs could be updated for clinical indications. 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.

PAEDIATRIC EXAMINATIONS

Table 8 shows the results of analyses of data submitted in terms of $CTDI_{vol}$ and DLP for the paediatric computed tomography examinations defined in the 2011 Order. The table shows the number of assessments used (N), the median, minimum and maximum weights of patients associated with the data collected, the value of the 75th percentile, the value of the 50th percentile and the 75th and 25th percentile ratio. All data is for the 2016-2018 period. Only the 75th and 50th percentile values and the 75th/25th ratio are for 2018.

Apart from the brain (10 and 20 kg) and chest (20 kg), there are too few assessments (< 10) to be able to discuss results.

Comparison with the DRLs defined in ASN resolution 2019-DC-0667 is complicated by the fact that the child weight categories for the various examinations have changed from the Order of 2011. To aid comparison, Figure 22 shows the 75th percentile value in terms of DLP and $CTDI_{vol}$, for the 2016-2018 period, for brain and chest examinations by child weight and in comparison with the DRLs in the 2011 Order and the 2019 ASN resolution.

For brain (10 and 20 kg) and chest (20 kg), none of the dose assessments submitted are over the DRL set in the 2011 order in terms of $CTDI_{vol}$. Figure 22 shows that the results for the 2016-2018 period are slightly over the DRLs set in the 2019 resolution, in particular in terms of DLP for the brain examination. These values have been recently adapted with the introduction of ASN resolution 2019-DC-0667 on the basis of a study (25) presented in a special focus section, and it is too early to suggest DRL adjustments.

Table 8: Summary of child computed tomography analyses, by examination, for 2018 data, in terms of $CTDI_{vol}$ and DLP.

Examination type	Weight category (indicative age)	N	Weight (kg)			$CTDI_{vol}$ (mGy)			DLP (mGy.cm)		
			median	min	max	P75	P50	P75/P25 ratio	P75	P50	P75/P25 ratio
Brain	10 kg (1 y)	11	10.0	8.0	12.0	21.3	19.8	1.18	390	325	1.26
	20 kg (5 y)	12	18.8	16.0	20.5	26.7	24.1	1.25	479	448	1.12
	30 kg (10 y)	5	29.0	28.0	30.0	29.4	25.5	1.28	558	520	1.17
Facial bones	10 kg (1 y)	0									
	20 kg (5 y)	1	20.0	20.0	20.0	7.9	7.9	1.00	142	142	1.00
	30 kg (10 y)	1	35.0	35.0	35.0	10.5	10.5	1.00	193	193	1.00
Petrous bone	10 kg (1 y)	2	10.4	10.0	10.8	30.7	30.70	1.00	146	142	1.05
	20 kg (5 y)	5	19.0	19.0	21.0	43.9	43.9	1.04	290	231	1.34
	30 kg (10 y)	2	29.5	29.0	30.0	61.5	56.7	1.19	260	259	1.01
Chest	10 kg (1 y)	9	10.3	9.0	12.5	1.10	0.94	1.25	31.2	19.5	1.84
	20 kg (5 y)	10	20.0	16.6	22.5	1.30	1.21	1.27	33.3	31.2	1.30
	30 kg (10 y)	4	29.3	28.5	30.0	1.93	1.72	1.29	57.1	51.8	1.22
Abdomen-pelvis	10 kg (1 y)	0									
	20 kg (5 y)	2	19.0	18.0	20.0	1.79	1.63	1.23	59	56	1.12
	30 kg (10 y)	2	29.3	28.5	30.0	3.14	2.93	1.16	145	133	1.19

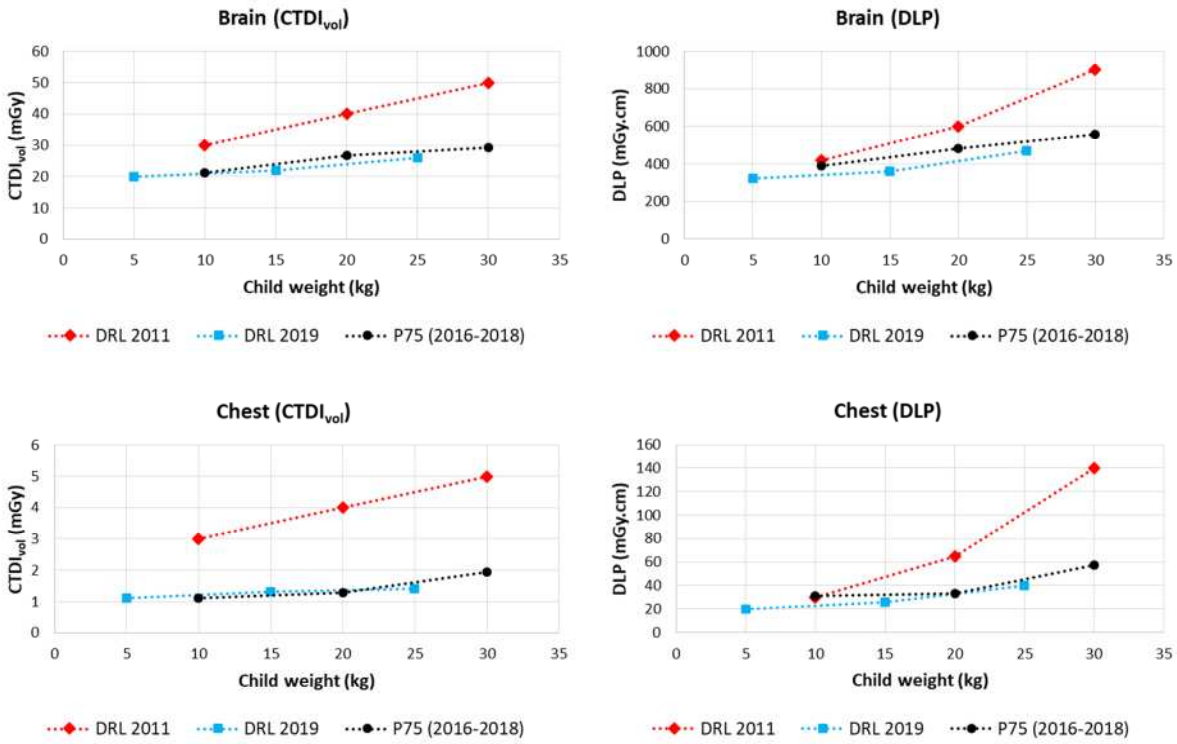


Figure 22: Comparison between the $CTDI_{vol}$ and DLP 75th percentiles calculated for the 2016-2018 period and the regulatory DRL values set in 2011 and 2019 for child brain and chest CT scans. For the 2019 DRLs, the points are placed in the centre of the weight category intervals. Some 75th percentile values are calculated from very little data (chest 10 and 30 kg, brain 30 kg) and should therefore be used with care.

FOCUS

Using clinical indications in computed tomography: case of chest examination

An SFPM working group that IRSN was part of recently studied doses delivered in computed tomography by clinical indication, and established significant differences for some anatomical regions depending on the indication, in particular the chest, in an article entitled "Patient dose evaluation in computed tomography: A French national study based on clinical indications" published in 2019 (22).

The working group analysed four groups of clinical indications for the chest: a) pulmonary embolism; b) chronic obstructive pulmonary disease (COPD), emphysema, and pneumothorax; c) infectious diseases and pneumonia and finally d) examinations to find pulmonary metastases. Figure 23 shows the distribution of volume computed tomography dose indices ($CTDI_{vol}$) for each group of indications for single acquisition examinations and BMI patients between 18.5 and 25 kg/m². There were significant differences, especially between the pulmonary embolism (a) and COPD (b) groups.

It is interesting to compare the results of the SFPM working group study with the results obtained by analysis of the data submitted to IRSN. For the chest, for example, data submitted to IRSN and presented in this report produce a median DLP of 240 mGy.cm, while in the SFPM study, median DLPs for patients with BMIs of between 18.5 and 25 kg/m² varied from 112 mGy.cm for COPD or pneumothorax examinations, to 203 mGy.cm for pulmonary examinations (Table 9).

This difference in results can be explained by a number of factors: the way in which the clinical indication is taken into account in the SFPM study, and the composition of the sample of institutions that took part in this study. Private institutions account for only 4% of institutions included in the SFPM study, whereas they account for 51% of institutions that submitted data to IRSN. This could explain the lower DLP values obtained in the SFPM study. A medical physicist was involved in most institutions included in the SFPM study, which leads us to assume that procedures are better optimised there.

This difference in results by clinical indication and the difference in the type of institution concerned are an excellent illustration of the advantages and disadvantages of implementing DRLs on a national scale. The organisation implemented for data collection has the advantage of offering good representation of institutions at national level. However, DRLs by anatomical zone cannot be used to distinguish between results on the basis of clinical indications. For example, as the SFPM study shows, pulmonary embolism is a very common indication, and it accounts for the chest examination that delivers the highest dose. However, COPD, emphysema and pneumothorax indications have lower image quality requirements and therefore involve lower doses. Setting DRLs for these clinical indications, for example, would make it possible to encourage institutions to establish specific protocols, if that is not already the case, and improve optimisation of doses delivered to patients.

The SFPM study results suggest that it could be possible to establish DRLs per clinical indication. Expectations for different indications are genuinely different, so implementing DRLs for indications could have a significantly positive impact on dose optimisation.

As mentioned in the previous report, the assessment and optimisation process for the dose delivered to patients within the DRL framework must not impair examination quality. This is an underlying criterion that needs to be taken into account in the DRL framework, particularly with a view to changing over to clinical indication DRLs in order to be able to check whether the image quality requirements associated with doses delivered are complied with.

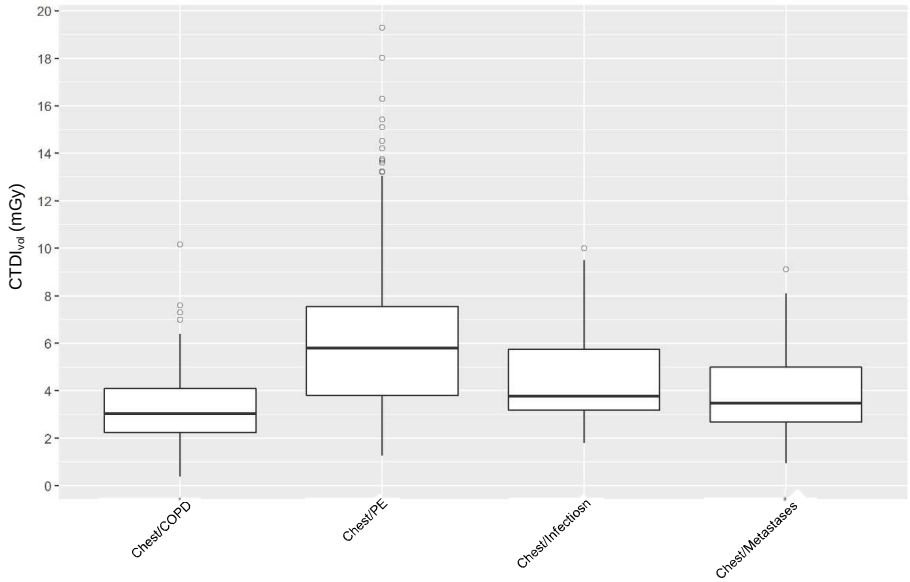


Figure 23: Distribution of $CTDI_{vol}$ values for 4 chest examinations (single acquisition) and patients with BMIs between 18.5 and 25 kg/m²: pulmonary embolism (Chest/PE), chronic obstruction or pneumothorax (Chest/COPD), infectious diseases or pneumonia (Chest/Infectious) and examinations to find pulmonary metastases (Chest/Metastases) (credit SFPM)

Examination type	N	DLP (mGy.cm)		P75/P25 ratio
		P50	P75	
Chest/COPD	61	112	185	2.4
Chest/PE	229	203	291	2.1
Chest/Infectious	60	145	227	2.1
Chest/Metastases	93	137	196	1.9

Table 9: results of SFPM study in terms of DLP (mGy.cm) for 4 chest examinations: pulmonary embolism (Chest/PE), chronic obstruction or pneumothorax (Chest/COPD), infectious diseases or pneumonia (Chest/Infectious) and examinations to find pulmonary metastases (Chest/Metastases) (credit: SFPM)

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SUMMARY

Analysis of computed tomography dose assessments shows:

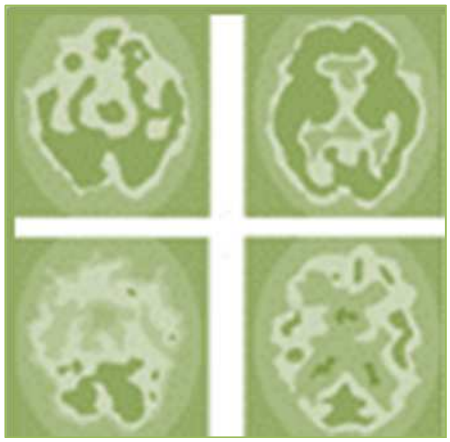
- a stable computed tomography institution participation rate of around 80% of facilities since 2013, reaching 85% in 2017 and 2018;
- a distribution of examinations selected by professionals for dose assessments comparable to the frequency of CT procedures in France;
- a regular decrease in the 75th $CTDI_{vol}$ and DLP percentiles for all examinations (average around 12% since the last report);
- overall positioning of $CTDI_{vol}$ and DLP 75th percentiles closer to the AD than the DRLs in force since 1 July 2019 for adult examinations;
- a major and ongoing lack of data in paediatrics;

RECOMMENDATIONS

Analysis of computed tomography dose assessments leads IRSN to make the following recommendations:

- DRL updates are not necessary in the short term, but they should continue to be monitored;
- plan for computed tomography DRL updates to take into account clinical indications;
- associate diagnostic performance assessment of equipment with the patient dose optimisation system;
- for paediatrics: monitor and assess the effectiveness of measures taken to remedy the current lack of data.

NUCLEAR MEDICINE



CONTENTS

CONTRIBUTION OF DEPARTMENTS

Nuclear medicine departments were surveyed based on the French Society of Nuclear Medicine and Molecular Imaging (SFMN) directory of nuclear medicine departments and the information published by ASN. There were 231 nuclear medicine departments listed in late 2015, and 236 in late 2017, fitted with 162 positron emission tomography (PET) scanners and around 475 gamma cameras (38).

Figure 24 presents the change in the number of nuclear medicine departments that submitted dose assessment results for 2004 to 2018.

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

In nuclear medicine, the distribution of data sources is balanced between the public sector and the private commercial sector (Figure 25), 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 (38). For paediatrics and brain perfusion, data comes primarily from the public sector. This could be explained by the specific nature of this type of examination and a low data submission rate (Figure 25).

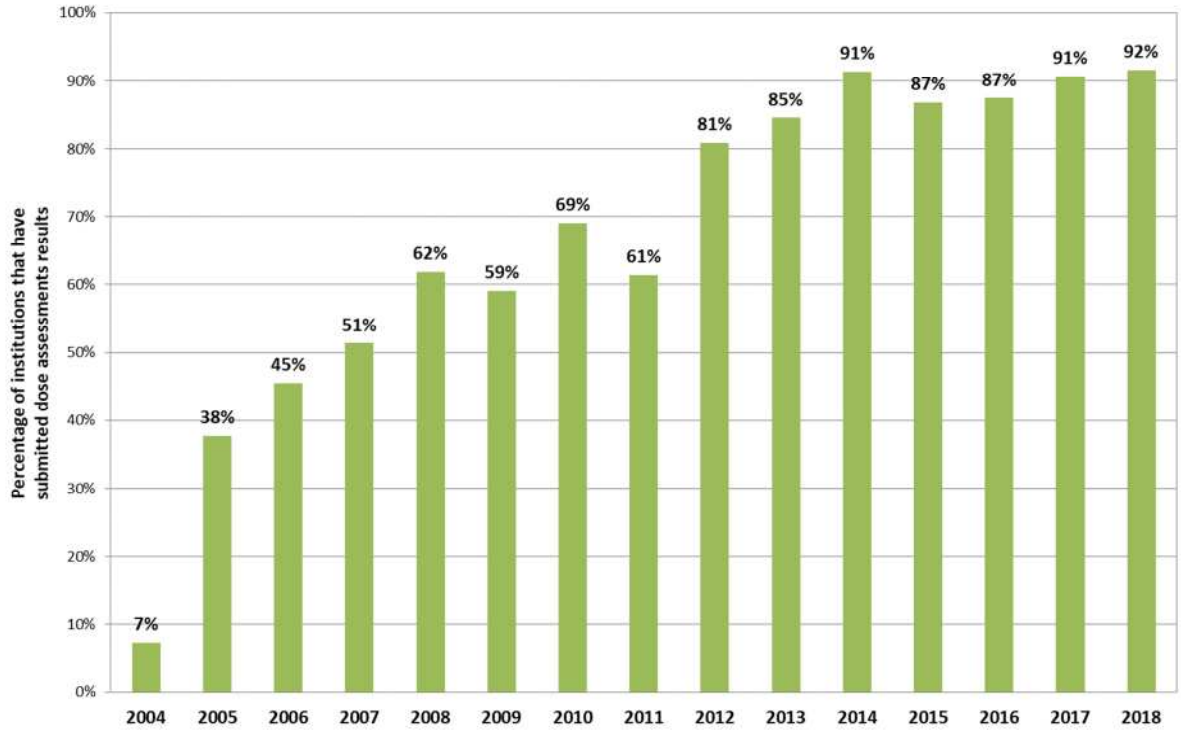


Figure 24: Change in annual participation of institutions performing nuclear medicine procedures since 2004.

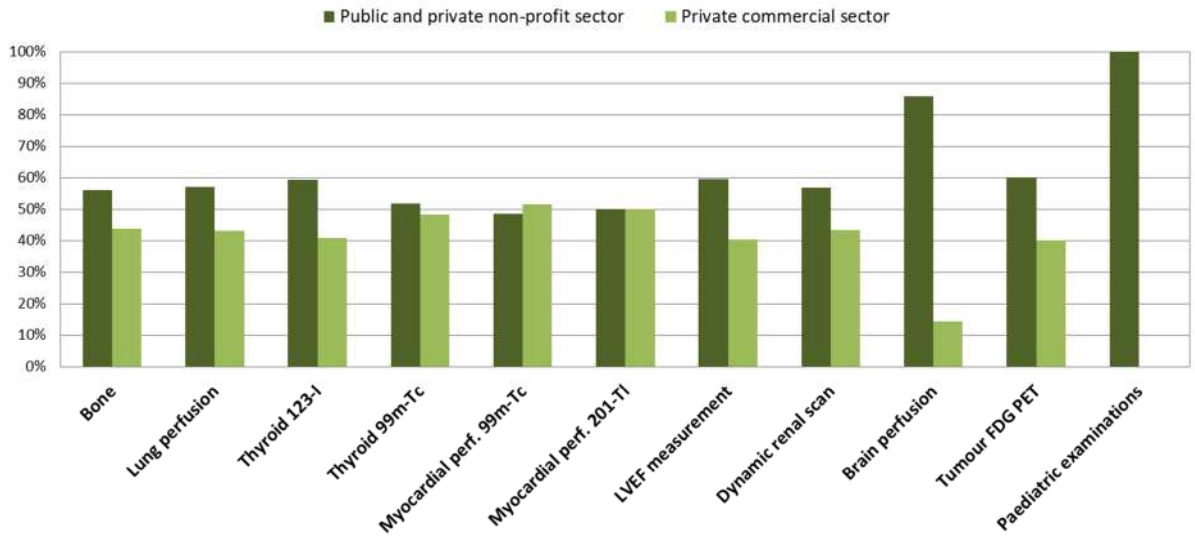


Figure 25: Source of data collected for computed DRLs, by examination type, in nuclear medicine.

DATA DISTRIBUTION BY EXAMINATION TYPE

ADULT EXAMINATIONS

Figure 26 shows the distribution of dose assessments submitted by nuclear medicine professionals to IRSN by examination type, in line with the list in the Order of 24 October 2011. It gives the percentage of dose assessments submitted for each examination, together with the proportion of data that IRSN has been able to use.

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

Since 2004, the examination which regularly has the biggest number of dose assessments has been bone scanning. The number of assessments for ^{18}F-FDG PET has increased 3 points since the previous report, which is consistent with the increase in the number of these devices. Myocardial perfusion SPECT (^{99m}Tc), lung perfusion and thyroid (^{99m}Tc) scans have been assessed in similar proportions to 2013-2015. The distribution of data by examination is consistent with the frequency of examinations performed in France in 2012 (30).

By examination, the data use rate for the 2016-2018 period varies between 75% and 87%, except for bone and ^{18}F-FDG PET scans (66%). 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 bone scans and ^{18}F-FDG PET, the examinations 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.

It should be noted that for the 2016-2018 period, a little over 90% of nuclear medicine departments that do not exclusively perform PET examinations performed a bone scan dose assessment.

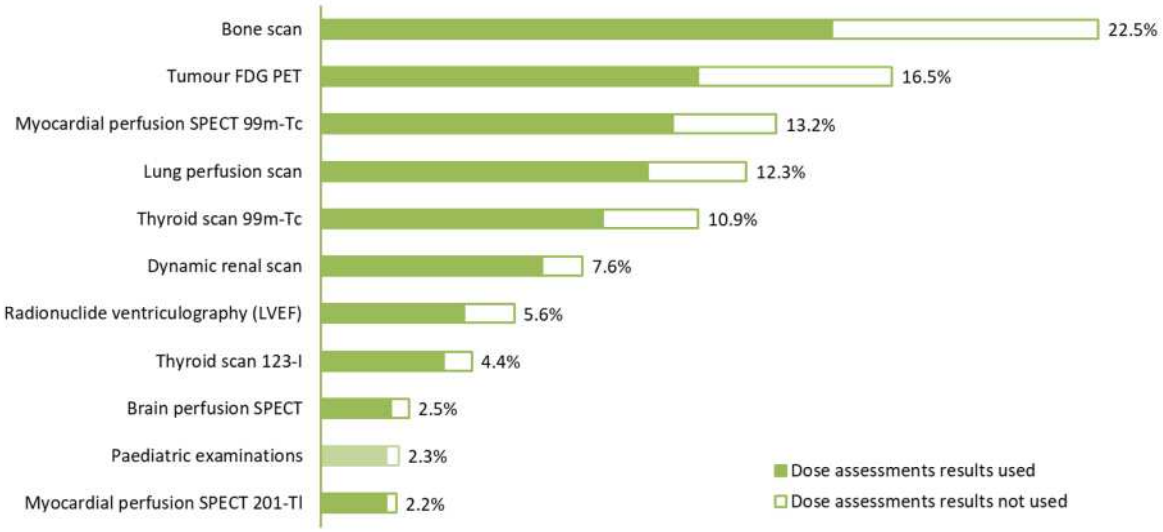


Figure 26: Distribution by examination type of nuclear medicine dose assessments for which results were submitted to IRSN from 2016 to 2018 (total number of assessments submitted: 1373).

PAEDIATRIC EXAMINATIONS

The volume of assessments submitted for paediatric nuclear medicine is very low, accounting for less than 3% of all data (Figure 27). This number has dropped by around 30% compared to the 2013-2015 report. A detailed breakdown of the data submitted is shown in Figure 27.

There is not enough data to properly assess practices at a national level. As stated above, ASN resolution 2019-DC-0667 now makes dose assessments mandatory if 5% or more of procedures are performed on children (under 18s). These new provisions should improve the amount of data submitted and enable more reliable analysis in the next report. It is important to monitor this closely and check the effectiveness of these new measures.

Out of the 10 examinations (without taking weight category into account) listed in the 2011 Order, dose assessments were not performed for 6 of them:

- lung perfusion scan
- thyroid scan with ^{99m}Tc
- radionuclide ventriculography
- dynamic renal scan with DTPA
- brain perfusion SPECT with ECD
- brain perfusion SPECT with HMPAO

Moreover, just one institution submitted data for thyroid scans with iodine 123.

The recent removal of these 7 examinations in the new resolution is therefore fully justified.

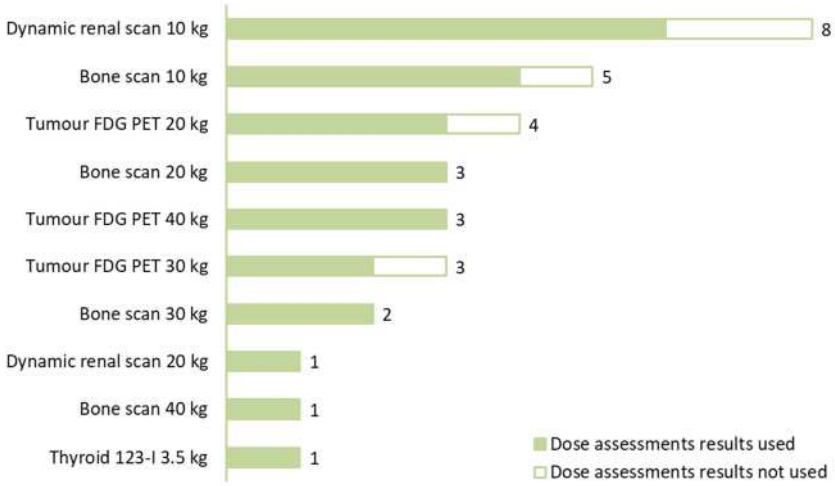


Figure 27: Distribution by examination of the number of child nuclear medicine dose assessments for which results were submitted to IRSN from 2016 to 2018 (total number of assessments submitted: 31).

SUMMARY OF NUCLEAR MEDICINE RESULTS

ADULT EXAMINATIONS

Tables 10 and 11 present the summary of analysis of data submitted for all nuclear medicine examinations subject to DRL regulations.

They show, for the 2016-2018 period:

- the number of assessments used,
- the median weight for patients associated with the collected data,
- the DRLs in force since 1 July 2019 (DRL),
- the 50th percentile values for the data collected,
- the 75th to 25th percentile ratio,
- the position of the 50th percentile with regard to the DRL in force since 1 July 2019 (% DRL),
- the percentage of dose assessments received for the period over the DRL in force since 1 July 2019 (> DRL)
- and the 50th percentile variation for the period with regard to the 2015 value published in the previous report.

Detailed results for each examination type for 2016-2018 are shown in the report Annex.

It should be noted that for dynamic renal scans with DTPA and brain perfusion SPECT scans with ECD, the position of the median with regard to the DRL in force since 2019 cannot be used because there is insufficient data.

For other examinations, except for the thyroid scan with ^{99m}Tc and the tumour FDG PET scan, analysis for the 2016-2018 period shows that median values of the administered activities and administered activities per body weight are comparable to the DRL in force (differences of between -7 and +2%) and are relatively stable compared with the previous report.

For the FDG-PET scan, administered activities and activities per body weight are below the DRLs in force by 13 and 14% respectively. This could be due to technological developments such as increasing use of the time of flight (TOF) technique identified in the previous report (8), and departments' commitment to optimising doses delivered to patients.

For thyroid scans with ^{99m}Tc, the median value of administered activities is 17% below the DRL in force. This is primarily due to the fact that the DRL in force was increased in ASN resolution 2019-DC-0667 compared with the value in force for the 2016-2018 period. The median value is 16% down on the 2015 value. This shows that although the DRLs set in 2004 and 2011 were lower than actual values used in practice, there was room for optimisation. For this examination, Figure 85 (see Annex) presents the results of the median values of administered activities by assessment and shows two very clear peaks at 80 and 110 MBq. This illustrates the fact that some departments use the maximum values recommended by the marketing authorisation (80 MBq maximum), while others use SFMN recommendations (39) (maximum value 110 MBq).

For lung perfusion, the distribution of median administered activities by assessment (Figure 81 in the Annex) presents peaks that correspond to activities that are multiples of 37 MBq: 111, 148, 185 and 222 MBq. It therefore seems that many professionals choose whole multiples of millicuries (mCi) for administered activities. Lung scans may include two phases: a ventilation scan using either technetium aerosols or krypton 81m and the lung perfusion scan. They can include either or both these two phases, and the ventilation scan generally precedes lung perfusion. If ^{99m}Tc (aerosols) is used for the ventilation examination, the activity of ^{99m}Tc (albumin macroaggregate) administered for the perfusion scan needs to be significantly higher in order to mask the ventilation signal (count rate 4 times higher than for ventilation, according to SFMN recommendations (40)). This is not the case when the ventilation examination takes place in advance, or when it is performed using krypton 81m. It would be interesting to carry out a specific study to separate out protocols with and without a prior ^{99m}Tc ventilation examination, which are currently combined in the data received.

Similarly for PET scans, there are peaks in 0.5 MBq/kg steps at 2.5, 3 and 3.5 MBq/kg (Figure 112). And for bone scans (Figure 78), results show 2 clear peaks at 9 and 10 MBq/kg. This illustrates the differing practices of departments, which can be explained by the difference in devices performance.

Table 10: Summary of results of analysis of nuclear medicine data by adult examination type, for 2016-2018 data, in terms of administered activity.

Examination type	Radiopharmaceutical / protocol		N	Median weight (kg)	Administered activity (MBq)		P75/P25 ratio	% DRL	> DRL	Variation
					DRL	P50				
Bone scan	^{99m}Tc HDP/DPD		203	72.0	670	662	1.13	-1%	42%	-1%
Lung perfusion scan	^{99m}Tc MAA		130	73.0	225	209	1.36	-7%	45%	-6%
Thyroid scan	^{123}I (sodium iodide)		49	70.0	8	7.8	1.41	-3%	47%	+1%
	^{99m}Tc (sodium pertechnetate)		112	69.0	110	91	1.45	-17%	37%	-16%
Myocardial perfusion SPECT with stress test (dynamical or pharmacological)	^{99m}Tc MIBI/tetrofosmin	1 day/1st inj.	121	78.0	285	279	1.20	-2%	43%	-2%
		1 day/2nd inj.	118	78.0	785	769	1.21	-2%	41%	-2%
		2 days/1st inj.	19	81.5	615	625	1.56	+2%	53%	+2%
		2 days/2nd inj.	18	81.8	615	597	1.66	-3%	50%	-2%
	^{201}Tl (thallium chloride)	1st injection	26	78.8	110	107	1.51	-3%	38%	-2%
		Reinjection	21	79.0	37	37	1.59	+0%	43%	+1%
Equilibrium radionuclide ventriculography	^{99m}Tc human serum albumin/red blood cells		57	71.0	740	737	1.25	-0%	47%	-0%
Dynamic renal scan	^{99m}Tc MAG3		80	68.0	180	181	1.64	+0%	53%	+2%
	^{99m}Tc DTPA		8	68.5	255	248	1.68	-3%	25%	-2%
Brain perfusion SPECT	^{99m}Tc ECD		3	70.0	800	712	1.07	-11%	0%	-12%
	^{99m}Tc HMPAO		25	70.0	695	662	1.48	-5%	44%	-4%
Tumour FDG PET	^{18}F FDG		150	70.0	245	212	1.33	-13%	26%	-12%

Table 11: Summary of results of analysis of nuclear medicine data by adult examination type, for 2016-2018 data, in terms of administered activity per body weight.

Examination type	Radiopharmaceutical / protocol		N	Median weight (kg)	Activity per BW (MBq/kg)		P75/P25 ratio	% DRL	> DRL	Variation
					DRL	P50				
Bone scan	^{99m}Tc HDP/DPD		203	72.0	9.5	9.2	1.17	-3%	38%	-0%
Myocardial perfusion SPECT with stress test (dynamical or pharmacological)	^{99m}Tc MIBI/tetrofosmin	1 day/1st inj.	121	78.0	3.7	3.6	1.23	-2%	38%	-1%
		1 day/2nd inj.	118	78.0	10.3	10.0	1.20	-3%	40%	-3%
		2 days/1st inj.	19	81.5	7.7	7.4	1.47	-4%	42%	-4%
		2 days/2nd inj.	18	81.8	7.7	7.5	1.39	-3%	44%	-2%
	^{201}Tl (thallium chloride)	1st injection	26	78.8	1.4	1.36	1.50	-3%	35%	-1%
		Reinjection	21	79.0	0.5	0.48	1.52	-4%	14%	+2%
Tumour FDG PET	^{18}F FDG		150	70.0	3.5	3.0	1.35	-14%	25%	-14%

PAEDIATRIC EXAMINATIONS

There were dose assessments for 10 examination types (taking into account weight categories). None of them represent more than 10 assessments submitted. It is therefore not possible to perform statistical analyses. The results are shown in Table 12, but are not discussed.

The quantity of data received remains too low to provide a clear overview of practices and update current DRLs, which are based on European Association of Nuclear Medicine (EANM) recommendations from 2007.

In order to remedy this situation revealed in the previous report, a survey (26), presented in the paediatrics focus section, of all nuclear medicine departments was carried out by the SFMN, the SFPM and IRSN targeting the most common paediatric examinations (bone, renal and PET scans) in late 2016 and early 2017. Around 80 sites replied. The results showed that median administered activities in France were roughly at the DRL level in force. FDG administered activities were, like the DRLs, over 40% lower than the EANM recommendations for oncology PET scans. However, for DMSA renal scans, not covered by the DRLs until now, the administered activities in France were significantly over European recommendations.

Given the low differences, the DRLs in force for administered activities did not need to be updated in ASN resolution 2019-DC-0667. However, the survey confirmed the need for a DRL for renal cortical scans, and this was added to the list of paediatric examinations in the ASN resolution published in 2019. The DRL value for this examination corresponds to the European recommendations in order to encourage departments to optimise.

Finally, the survey showed a general homogeneity in practices at national level. However, the activities administered by some centres presented significant differences from the majority of centres. Implementing DRLs should make it possible to limit these unusual practices.

Table 12: Summary of results of analysis of child nuclear medicine data, by examination type.

Examination type	Classe de poids (kg)	N	Median weight (kg)	Administered activity (MBq)		P75/P25 ratio	> DRL
				NRD	50^{e}		
Rein dynamique MAG3	10 kg	6	9.5	25	22	1.15	0%
	20 kg	1	19.5	35	30	1.00	0%
Squelette	10 kg	4	11.0	95	119	1.29	100%
	20 kg	3	19.0	170	162	1.12	33%
	30 kg	2	29.0	240	231	1.01	0%
	40 kg	1	40.0	310	290	1.00	0%
TEP FDG	20 kg	3	19.0	70	77	1.26	67%
	30 kg	2	29.8	100	101	1.03	100%
	40 kg	3	39.0	125	129	1.02	100%
Thyroïde 123I	3.5 kg	1	3.7	-	1.2	1.00	0%

FOCUS

Influence of CZT technology on administered activities for myocardial perfusion SPECT

Detector technology with CZT (cadmium-zinc-telluride) semi-conductors started to be used in nuclear medicine around fifteen years ago, and improves the detection performance and resolution of imaging devices. Cardiac-centered cameras were the first CZT nuclear medicine imaging devices. Their specific geometry made it possible to improve detection performance by hugging the shape of the patient's chest, and limit the size of CZT detectors, which are much more expensive than conventional detectors. Large-field CZT cameras then came in fitted with planar CZT detectors, and more recently multiple mobile CZT detectors (radial and swivel motion). According to the ASN data published following a survey of nuclear medicine professionals, around 10% of cameras were fitted with CZT detectors in 2017 (38).

Figure 28 and Table 13 show the impact of camera type on administered activities during myocardial perfusion scans with ^{99m}Tc. Figure 28 shows the distributions, by camera type, of the median values of the total activities per body weight administered to patients (combination of both injections under stress and at rest) for the 2016-2018 period as a function of camera type, showing cardiac-centered CZT cameras and conventional scintillation cameras (Anger type). No dose assessment was received for a large-field CZT camera. The camera model used was identified for 92% of data received via an email survey of professionals, since this information is rarely included in data received.

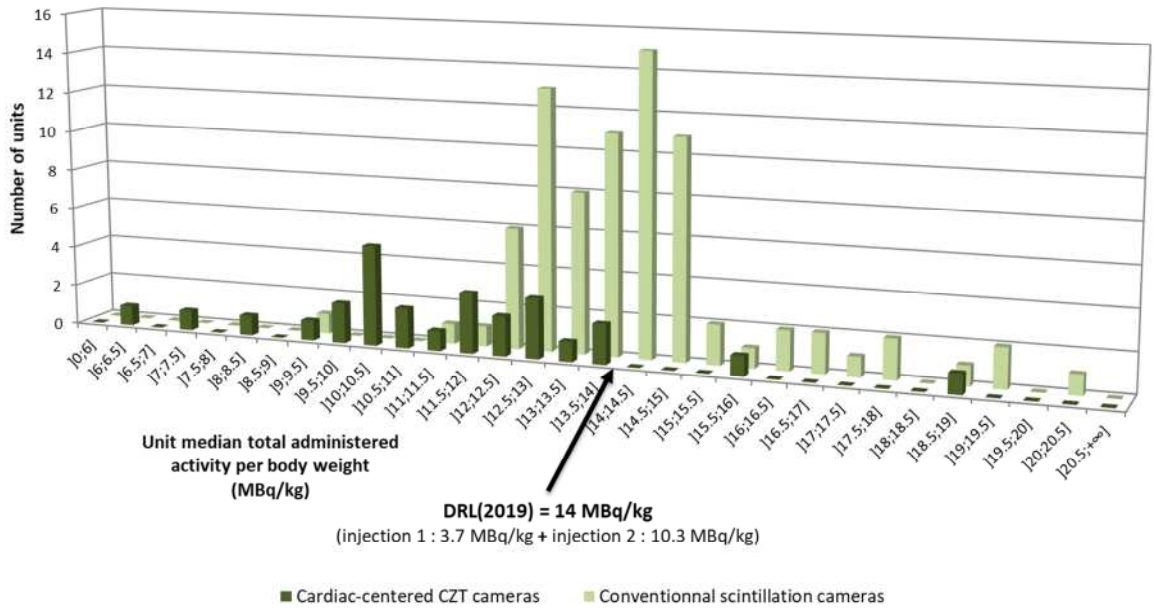


Figure 28: Distribution by camera type of median total activities per body weight administered for myocardial perfusion SPECT scans with ^{99m}Tc (protocol with 2 injections on 1 day). Only data for cameras whose type could be identified and that include the activities for both injections were included.

Table 13 shows a difference between the two types of camera: the 50th percentile of the total administered activity per body weight for caradiac-centered CZT cameras is about 2.5 MBq/kg lower than those of conventional cameras. However, there are disparities between users of the same type of camera. For conventional cameras, the total administered activity per body weight is close to SFMN recommendations (14.7 MBq/kg for the 2 injections combined) and the DRLs (14 MBq/kg for the 2 injections combined) in a large majority of units (around 80% are between 12 and 15 MBq/kg); however, lower, and especially higher, values are observed. For around 70% of CZT cameras, the administered activity per body weight is within the range of the EANM recommendations (10 to 14 MBq/kg) published in 2019 (38), with a peak around 10 MBq/kg. Practices seem a little less homogeneous with these more recent devices than with conventional cameras. This can be explained by the lack of official recommendations when the data was collected, and the unit's recent arrival in some institutions, which probably means that it had not yet been used to its full potential. Finally, whatever system is used, as for all scintigraphy scans, the administered activity and examination duration are linked, and the balance between these two parameters differs between institutions.

Table 13: Statistical data, by camera type, associated with the distribution of median total activities per body weight administered for myocardial perfusion SPECT scans with 99mTc (protocol with 2 injections on 1 jour). Only data for cameras whose type could be identified and that include the activities for both injections were included.

Examination type	Radiopharmaceutical protocol	Camera type	N	Total activity per BW (MBq/kg) (sum of the 2 injections)			
				Min	P50	Max	P75/P25
Myocarde avec épreuve d'effort et/ou stimulation pharmacologique	^{99m}Tc MIBI/tetrofosmin 1 day - 2 injections	conventionnal scintillation camera	81	9.3	13.9	20.2	1.14
		cardiac-centered CZT camera	27	6.0	11.3	18.7	1.27

SUMMARY

Analysis of nuclear medicine dose assessments shows:

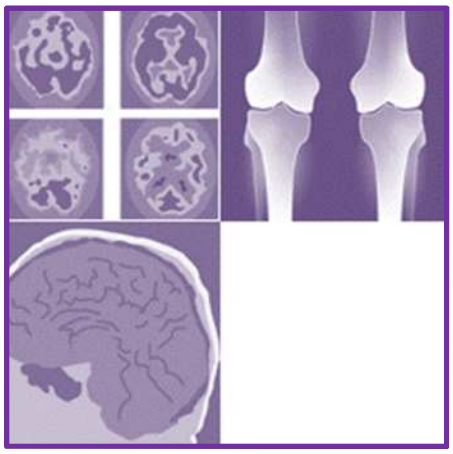
- a participation rate for nuclear medicine departments that has been stable at around 90% since 2014;
- a distribution of examinations selected by professionals for dose assessments that is consistent with the frequency of nuclear medicine procedures in France;
- general stability of administered median activities, except for downward trends for thyroid scanning with 99mTc and tumour FDG PET (average of all examinations, decrease of around 3% since the previous report);
- administered median activities generally close to the DRLs in force since 1 July 2019 except for thyroid scanning with 99mTc and tumour FDG PET, for which median activities are significantly below the DRLs in force;
- results illustrating disparities in practice of the various nuclear medicine departments;
- a major lack of data in paediatrics;

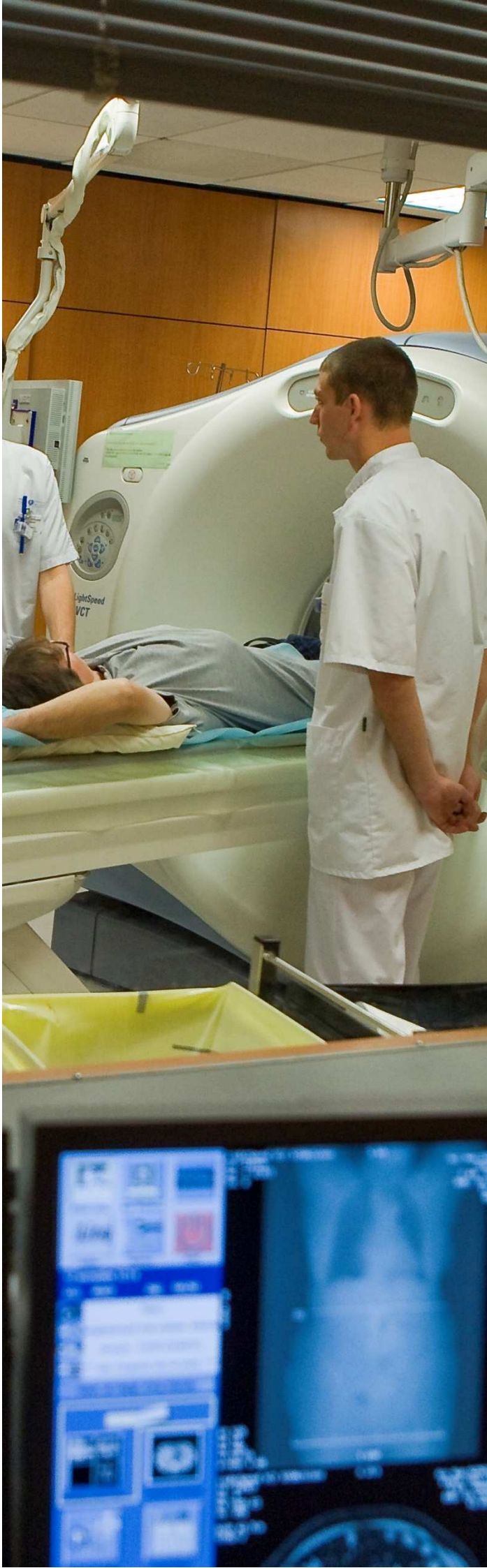
RECOMMENDATIONS

Analysis of nuclear medicine dose assessments leads IRSN to make the following recommendations:

- perform a specific lung perfusion scan study to distinguish between examinations performed with or without ^{99m}Tc ventilation;
- for paediatrics: monitor and assess the effectiveness of measures taken to remedy the current lack of data.

DRLs: PERSPECTIVES, SUMMARY AND RECOMMENDATIONS





CONTENTS

The first goal in analysing DRL data is to provide information to the authorities with a view to periodically updating the DRLs and, more broadly, understand implementation of the optimisation approach and the state of practice, from a dosimetry perspective, on a national level.

Since 2004, the implementation of DRLs in France has been contributing to significantly improving understanding of patient exposure in medical imaging.

In general, DRLs help professionals consider their practice from a dosimetry perspective. National-level data collection and analysis makes it possible to assess:

- implementation of professional recommendations;
- the impact on doses of replacing imaging equipment with new technologies on a national level.

With regard to national assessment of practices, from a dosimetry perspective, the current data collection and analysis system seems to be operating well. There is a significant volume of data. The conventional radiology participation rate is, however, disappointingly low (only 50% of institutions). Apart from the special case of paediatrics, the report could be considered representative of the situation in France with satisfactory representation of the various types of medical imaging institutions (public, private commercial or non-profit).

With regard to the assessment of practice at institution level, IRSN's exchanges with its contacts in imaging institutions have regularly given it the opportunity to understand the value of DRLs as an information and alert tool on imaging performance, and the consistency of protocols from a dosimetry perspective.

The main sources of dose optimisation weaknesses that the collection and analysis of DRL data made it possible to identify in departments are:

- protocols that are unsuitable for the type of patient examined (adult/child);
- abnormal technical parameter values: automatic exposure, high voltage (kV), current (mAs), etc.;
- equipment malfunctions: automatic exposure control, detector.

Some institutions repeat dose assessments for the same examination type within a short period of time (weeks/months). This may be due to the identification of a sub-optimal practice during the first assessment. The second assessment a short while afterwards can be used to measure the effectiveness of actions implemented.

It should be noted that a study on the change in exposures for institutions performing two dose assessments for the same type of examination for the same unit, at a two-year interval, in 2013 and 2015, was carried out in the previous report (8). This study showed that doses were almost always lower on the second assessment. This demonstrates the effectiveness of the DRL system for optimisation when it is implemented in institutions.

PERSPECTIVES

DRLs have now been implemented in France for more than fifteen years. Some problems have been dealt with and others should be in the near future thanks to application of ASN resolution 2019-DC-0667. There is, however, room for some additional improvements.

Analysis of data collected over the 2016-2018 period shows a decrease in DRL quantities in all areas, which could offer justification for changing regulations. The vast majority of results are below the new DRLs in force since 1 July 2019. This can be explained by two reasons whose influences cannot be separated: technological developments on the one hand, and the optimisation of protocols and awareness of good practices among users on the other. However, deviations from these DRLs are quite small, and there is no need to revise the DRL values in the near future. Moreover, more time is needed for experience feedback on the application of DRLs introduced on 1 July 2019 for new examinations, especially in interventional radiology.

IRSN proposals therefore focus primarily on adding new examination types or improving collection methods.

Changes to list of examinations

Mammography and breast tomosynthesis

For mammography, the dose assessments submitted are determined for an equivalent breast thickness of 45 mm during annual external quality control of medical devices as defined by ANSM. The values submitted are therefore not representative of the clinical practice of sites. Moreover, ANSM average glandular dose (AGD) measurement methods have recently changed, and now require the use of Polyethylene (PE) plates with the PMMA plates, so the 45 mm equivalent breast thickness no longer applies. They will enter into force from 22 January 2021 (35). It therefore seems necessary to revise the DRL for mammography. Furthermore, IRSN recommends adding breast tomosynthesis to the list of examinations covered by the DRL system. A survey could be performed to determine whether it would be possible to implement DRLs for mammography and breast tomosynthesis that are representative of clinical practice on sites.

Cone-beam computed tomography (CBCT)

Similarly, a survey on CBCT in dental radiology could be useful, especially for paediatrics, given the increasing use of this technique and the high doses sometimes delivered.

Using clinical indications in computed tomography

As illustrated with the chest CT scan in this report, defining DRLs by anatomical region for computed tomography leads to combining data that is very heterogeneous, because they present significantly varying clinical objectives. An SFPM working group recently studied doses delivered for different clinical indications in computed tomography and discovered significant differences depending on indications for some anatomical regions (skull, chest, abdomen-pelvis) (22). Computed tomography DRLs could be updated to take this into account. This is also being worked on at a European level with the EUCLID (23) project that IRSN is associated with.

Introduction of diagnostic performance assessment into the DRL process

Finally, as mentioned in the previous report, diagnostic performance assessment should be associated with the patient dose optimisation system in order to ensure that it does not impair examination quality. In particular, if local median values are lower than the regulatory achievable doses values recently introduced in the regulations, image quality, rather than dose, should be considered as a priority in the optimisation process.

SUMMARY and RECOMMENDATIONS

Analysis of the data collected for the 2016-2018 period, and more generally of DRL implementation since 2004, leads to the following observations:

- the DRL data collection and analysis system works well from the perspective of understanding practices and updating existing DRLs, except in paediatrics;
- there is a major lack of data in paediatrics;
- downward trends for DRL quantities justifies regularly reviewing regulations;
- for mammography, the DRL is not representative of clinical practice on sites. Regardless, it will no longer be able to be used from 22 January 2021 due to the updated quality control decision;
- defining computed tomography DRLs by anatomical region limits their applicability;
- the current DRL system does not prevent patient dose optimisation from impairing examination image quality.

Consequently, IRSN makes the following recommendations:

- the system for reviewing technical aspects of the regulations needs to be made more flexible so that it can respond better to changes in practices and technologies;
- some areas need to be reviewed: modification of DRL for mammography, addition of breast tomosynthesis and CBCT for dental radiology;
- plans need to be made for computed tomography DRLs to be defined by clinical indication;
- diagnostic performance of equipment needs to be associated with the dose optimisation approach;
- the effectiveness of measures taken recently to remedy the current lack of paediatric data needs to be assessed.

CONCLUSIONS

This sixth analysis report on French diagnostic reference level data comes against the backdrop of new regulations that came into force on 1 July 2019. Among other things, they take into account IRSN's recommendations in previous reports. They align with the recent changes in international recommendations, in accordance with the reinforced DRL requirements set out in Council Directive 2013/59/Euratom (16). This is therefore a transitionary report.

The results of this report confirm that these regulatory updates covering both organisational and technical aspects were justified. The next report should show how effective these adaptations have been, especially regarding the collection of paediatric data.

Analysis of data collected over the 2016-2018 period also shows a decrease in DRL quantities in all areas, which could offer justification for changing regulations. The vast majority of results are below the new DRLs in force since 1 July 2019. However, deviations from these new DRLs are quite small.

These results suggest that it would not be worthwhile recommending updates in the DRLs defined in ASN resolution2019-DC-0667 in the near future.

Moreover, IRSN recommends reviewing the digital mammography DRL in order to make it more relevant to clinical practice. IRSN also recommends adding breast tomosynthesis and CBCT in dental radiology to the list of examinations.

Furthermore, plans need to be made for computed tomography DRLs to be defined by clinical indication in the light of recent studies on the subject (22; 23).

Finally, work needs to be done on associating device diagnostic performance assessment with dose optimisation.

GLOSSARY

Abbreviations

AD	Achievable dose
AGD	Average glandular dose
ANSM	*Agence nationale de sécurité du médicament et des produits de santé* (French National Agency for Medicines and Health Products Safety (ANSM))
AP	Anterior posterior
ASN	*Autorité de sûreté nucléaire* (French Nuclear Safety Authority)
BMI	Body mass index
BW	Body weight
CBCT	Cone-beam computed tomography
CPD	Continuing professional development
$CTDI_{vol}$	Volume computed tomography dose index
DAP	Dose area product
DGOS	*Direction générale de l'offre de soins* (Directorate General for Healthcare Services)
DLP	Dose length product
DRL	Diagnostic reference level
DTPA	Diethylene triamine pentaacetic acid
EANM	European Association of Nuclear Medicine
EC	European Commission
ECD	Ethyl cysteine dimer
ESD	Entrance surface dose
FDD	Focus-to-detector distance
FDG	Fluorodeoxyglucose
FNMR	*Fédération Nationale des Médecins Radiologues* (French National Federation of Radiologists)
FSD	Focus-to-skin distance
GPMED	*Groupe permanent d'experts pour le domaine des expositions médicales et médico-légales des rayonnements ionisants (*Advisory committee for medical exposure)
HAS	*Haute autorité de santé* (French national health authority)
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
OPT	Orthopantomography

PA	Posterior anterior
PET	Positron emission tomography
SFIPP	*Société Francophone d'Imagerie Pédiatrique et Prenatale* (French-speaking Society for Paediatric and Prenatal Imaging)
SFMN	*Société française de médecine nucléaire et imagerie moléculaire* (French Society of Nuclear Medicine)
SFPM	*Société Française de Physique Médicale* (French Society of Medical Physics)
SFR	*Société Française de Radiologie* (French Society of Radiology)

ANNEXES

TYPE OF DATA TO BE REPORTED TO IRSN

DETAILED ANALYSES BY FIELD AND TYPE OF EXAMINATION

TYPE OF DATA TO BE REPORTED TO IRSN

The type of data to be reported to IRSN varies depending on the field. In general, records must be kept for patient groups. For mammography and orthopantomography, the data to be submitted are taken from external quality control reports.

Table 14: *List of data to be reported, according to field (excluding mammography and orthopantomography).*

Field	General data	Data to be recorded for each patient
Conventional radiology	Year Unit Examination Added filter Focus-to-detector distance (cm) Detector size (cm x cm)	Patient age (year) [*optional*] Patient weight (kg) Patient height (cm) High voltage (kV) Current-time product (mAs) [*optional*] Focus-to-skin distance (cm) *[optional]* DAP ($mGy.cm^2$; $cGy.cm^2$; $dGy.cm^2$; $Gy.cm^2$ or $\mu Gy.m^2$)
Computed tomography	Year Unit Examination Iterative reconstruction algorithm use (Y/N)	Patient age (year) *[optional]* Patient weight (kg) Patient height (cm) High voltage (kV) Pitch *[or increment + collimation]* $CTDI_{vol}$ (mGy) DLP (mGy.cm)
Nuclear medicine	Year Unit Examination (cardiology protocol) Radiopharamceutical	Patient weight (kg) Patient height (cm) Administered activity(ies) (MBq)

Table 15: *List of data to be reported for mammographies and orthopantomographies.*

Field	General data	Data to be collected from the external quality control report
Digital mammography	Year Unit Quality control date Quality control report	High voltage (kV) Current-time product (mAs) Anode/filter combination Half-value layer (mm Al) Focus-to-phantom distance (cm) Air KERMA (mGy) Average glandular dose (mGy)
Orthopantomography		High voltage (kV) DAP ($mGy.cm^2$)

DETAILED ANALYSES BY FIELD AND TYPE OF EXAMINATION

The statistical analyses of the results of dose assessments performed for 2016-2018 are given below for each type of examination, in the form of datasheets.

Content

The datasheets include:

- an initial section on the **analysis of 2016-2018 data** consisting of:
  - graphs showing the national distribution of reference doses (DAP in conventional radiology and in orthopantomography, AGD in mammography, $CTDI_{vol}$ and DLP in computed tomography, administered activity and activity per body weight in nuclear medicine);
  - tables summarising the statistical measures on these values;
- a second section on the **change since 2011** of statistical measures in the 75th and 50th percentiles, which serve as the basis for updating DRLs and ADs.

Analysis of 2016-2018 data

The data analysed are the median values per dose assessment (i.e. per unit) of the various reference dose values.

For example, the 75th percentile of the DAP is rigorously the "75th percentile of the distribution of dose assessment median DAPs". Similarly, the minimum and maximum DAP values are the minimum and maximum values of the assessment median DAPs, and not the minimum or maximum DAP values for an individual patient.

Graph key

- N: number of dose assessments used for the analysis;
- P75 (period): 75th percentile of the distribution of median values;
- P50 (period): 50th percentile of the distribution of median values;
- DRL (2019): diagnostic reference level (in force, as per ASN resolution 2019-DC-667);
- AD (2019): achievable dose (in force, as per ASN resolution 2019-DC-667).

The period selected was either 2016-2018, or 2018 alone when the volume of data received allowed for yearly analysis (DAP in conventional radiology, $CTDI_{vol}$ and DLP in computed tomography).

Clarifications regarding the tables

Number of units above the DRL:

- 2011 DRL (in force when data was collected): mean value of the dose above the 2011 DRL;
- 2019 DRL (in force since 1 July 2019) median value of the dose above the 2019 DRL;

Change since 2011

Graphs show the change in statistical measures (75th and 50th percentiles) calculated based on the median values of doses per unit since 2011. Since all the values published in the two previous reports (2011-2012 and 2013-2015) were based on means per unit, new values, based on medians per unit were calculated using patient doses. This calculation was not performed for data from 2004 to 2010, as only the means per unit were available in digital format.

To enable comparison between examinations despite higher diverging DRL orders of magnitude, a scale (to the nearest rounded figure for easier reading) common to each field was defined for the coordinate axis (dose value):

- radiography: range of 0.8 DRL (for example, for chest PA radiographs, the DRL of the DAP is 200 mGy.cm² and the ordinates axis therefore covers a range of 160 mGy.cm², from 100 to 260 mGy.cm²), except for thoracic spine lateral radiographs, with a range of 1 DRL.
- computed tomography: range of 0.8 DRL;
- nuclear medicine: range of 0.6 DRL.

Analysis of 2016-2018 data

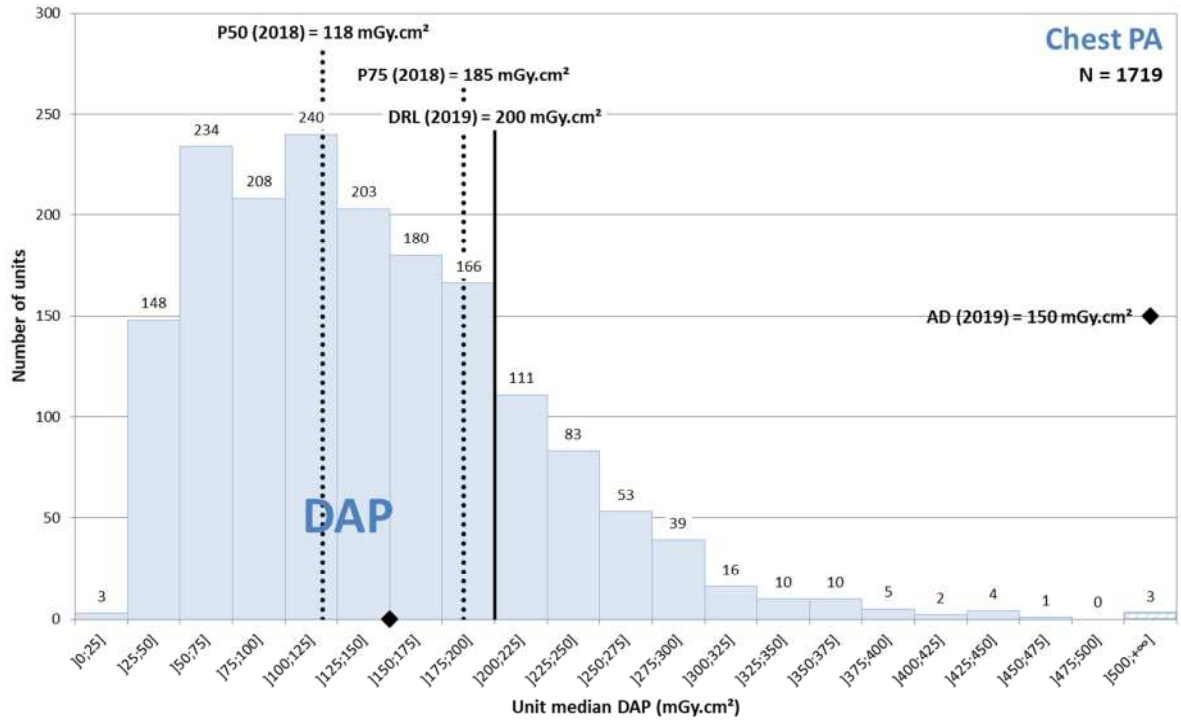


Figure 29: Distribution of unit median DAP from dose assessments performed for adult posterior anterior chest radiographs.

Table 16: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult posterior anterior chest radiographs.

Chest posterior anterior (adults)

DRL quantity	**DAP (mGy.cm²)**
DRL in force during data collection (2011 DRL)	250 (i.e. 25 cGy.cm²)
DRL in force (2019 DRL)	**200**
AD in force (2019 AD)	150

Period	**2016 - 2018**	**2018**
Number of units	1719	565

DRL quantity	**DAP (mGy.cm²)**	
75th percentile	**187**	**185**
50th percentile	130	118
Minimum - maximum values	16 - 673	16 - 544
Number of units above the 2011 DRL	176 (10%)	57 (10%)
Number of units above the 2019 DRL	337 (20%)	112 (20%)

Change since 2011

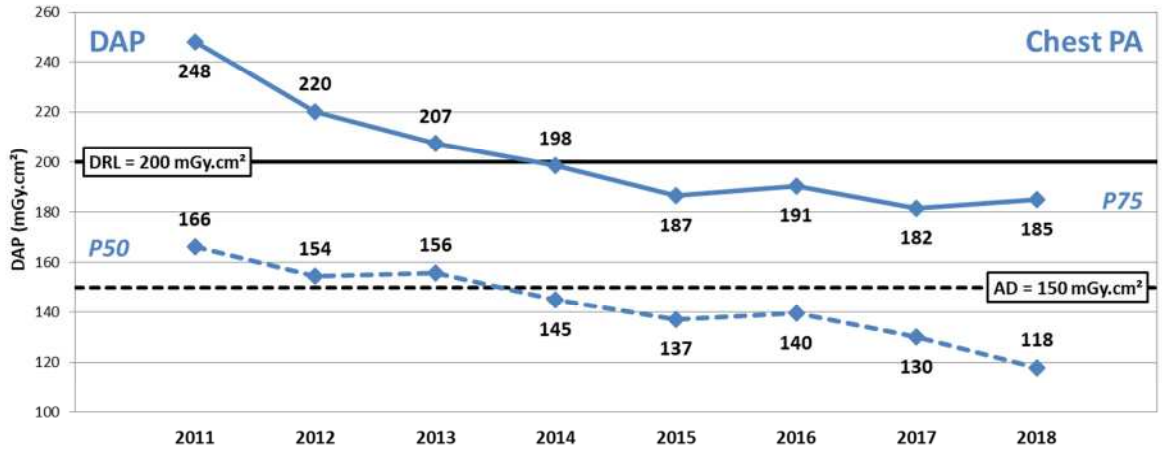


Figure 30: Change in the 75th and 50th percentiles of DAP for adult posterior anterior chest radiographs.

Analysis of 2016-2018 data

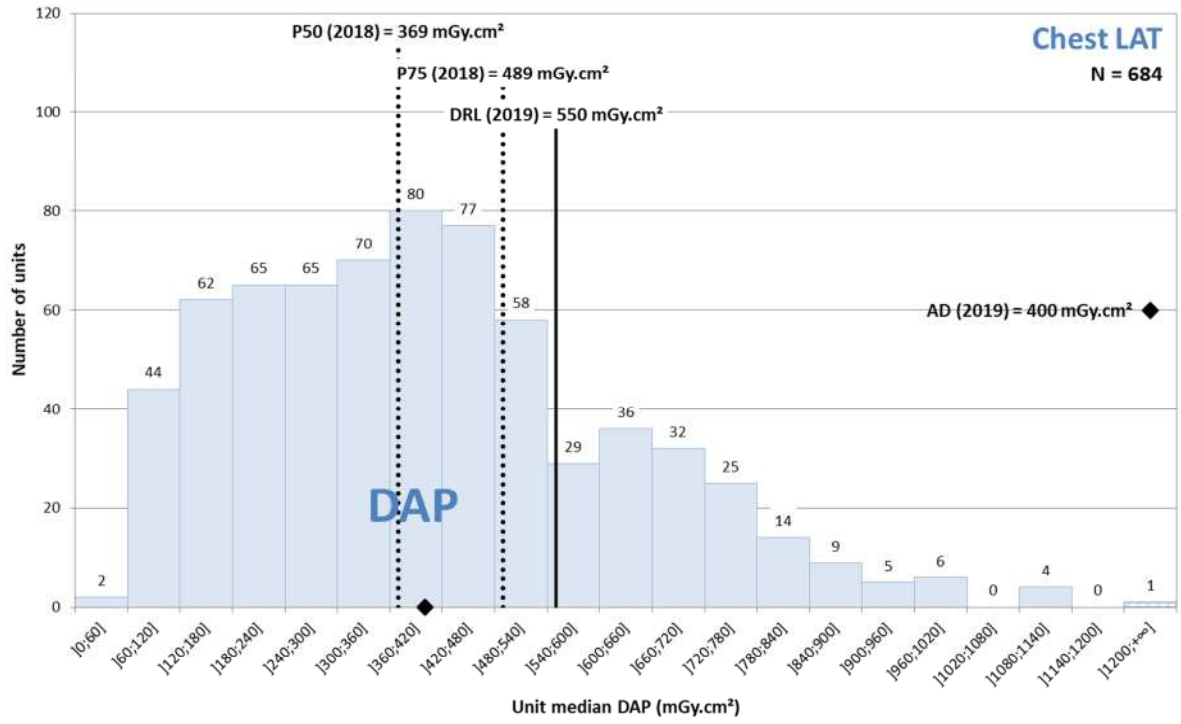


Figure 31: Distribution of unit median DAP from dose assessments performed for adult lateral chest radiographs.

Table 17: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult lateral chest radiographs.

Chest lateral (adults)

DRL quantity	**DAP (mGy.cm²)**
DRL in force during data collection (2011 DRL)	1000 (i.e. 100 cGy.cm²)
DRL in force (2019 DRL)	**550**
AD in force (2019 AD)	400

Period	**2016 - 2018**	**2018**
Number of units	684	234

DRL quantity	**DAP (mGy.cm²)**	
75th percentile	**525**	**489**
50th percentile	387	369
Minimum - maximum values	54 - 1600	54 - 1115
Number of units above the 2011 DRL	14 (2%)	3 (1%)
Number of units above the 2019 DRL	155 (23%)	44 (19%)

Change since 2011

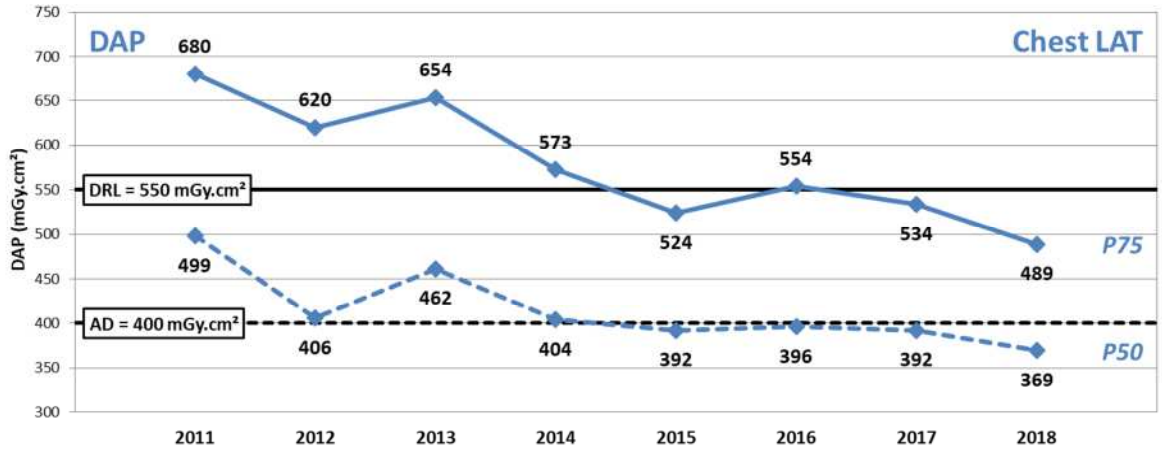


Figure 32: Change in the 75th and 50th percentiles of DAP for adult lateral chest radiographs.

Analysis of 2016-2018 data

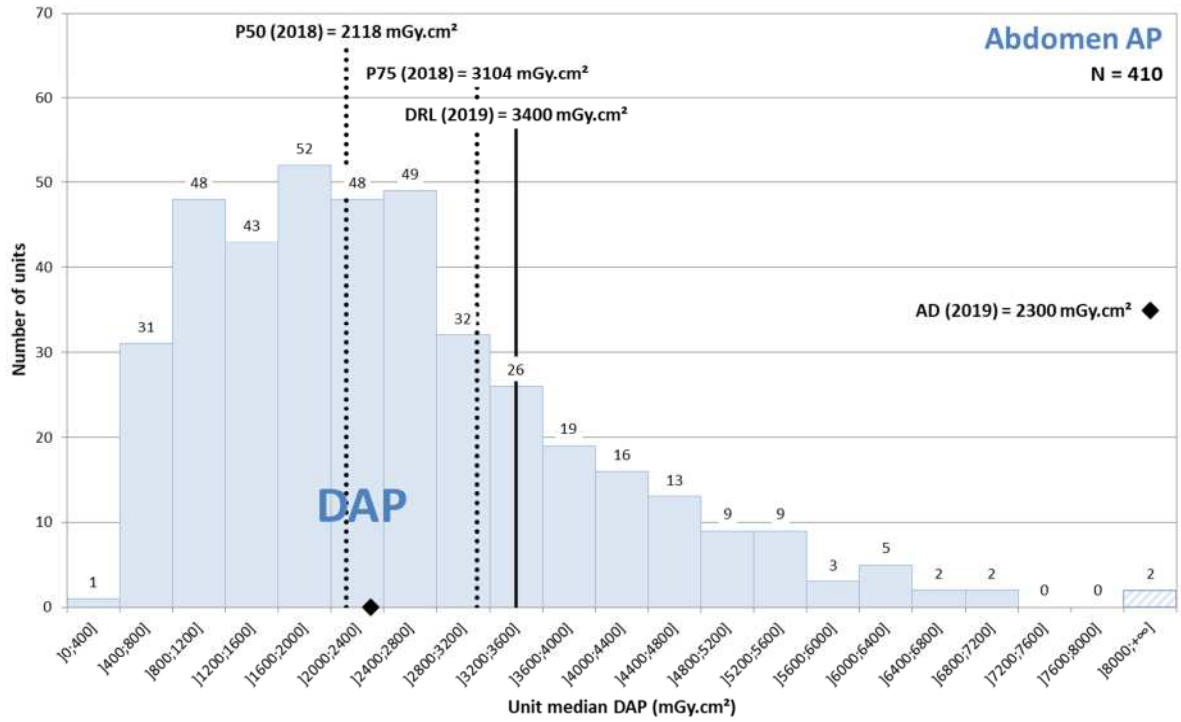


Figure 33: Distribution of unit median DAP from dose assessments performed for adult anterior posterior abdomen radiographs.

Tableau 18: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult anterior posterior abdomen radiographs.

Abdomen anterior posterior (adults)

DRL quantity	DAP (mGy.cm²)
DRL in force during data collection (2011 DRL)	7000 (i.e. 700 cGy.cm²)
DRL in force (2019 DRL)	**3400**
AD in force (2019 AD)	2300

Period	2016 - 2018	2018
Number of units	410	128

DRL quantity	DAP (mGy.cm²)	
75th percentile	**3244**	**3104**
50th percentile	2233	2118
Minimum - maximum values	285 - 9030	285 - 6740
Number of units above the 2011 DRL	4 (1%)	1 (1%)
Number of units above the 2019 DRL	91 (22%)	23 (18%)

Change since 2011

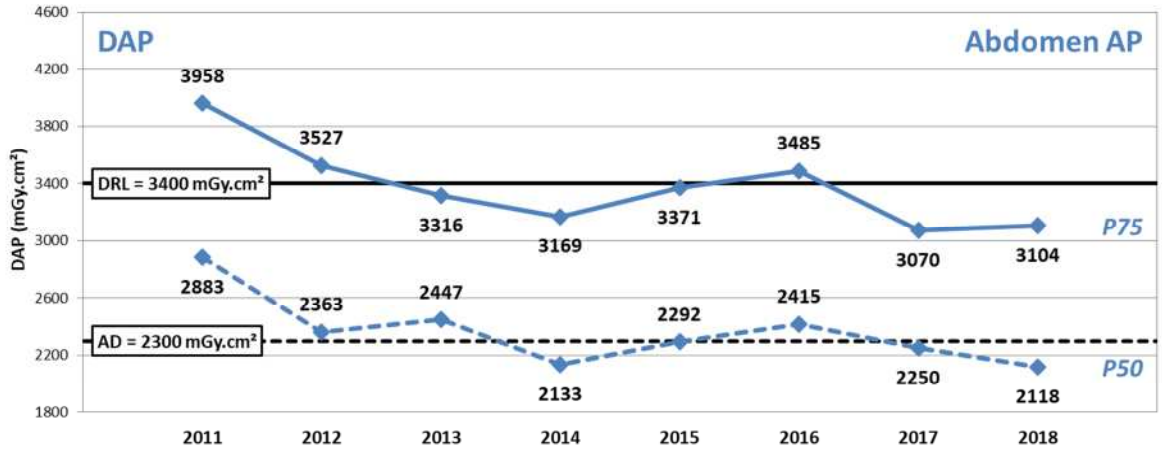


Figure 34: Change in the 75th and 50th percentiles of DAP for adult anterior posterior abdomen radiographs.

Analysis of 2016-2018 data

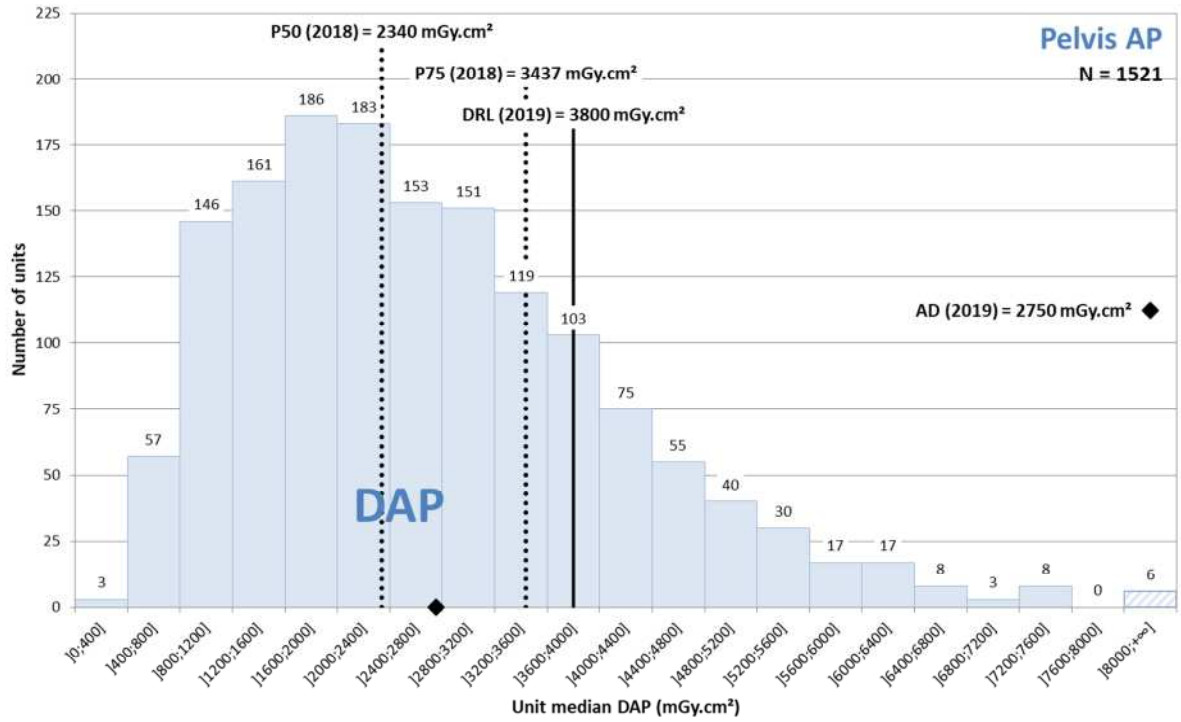


Figure 35: Distribution of unit median DAP from dose assessments performed for adult anterior posterior pelvis radiographs.

Table 19: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult anterior posterior pelvis radiographs.

Pelvis anterior posterior (adults)

DRL quantity	**DAP (mGy.cm²)**
DRL in force during data collection (2011 DRL)	7000 (i.e. 700 cGy.cm²)
DRL in force (2019 DRL)	**3800**
AD in force (2019 AD)	2750

Period	**2016 - 2018**	**2018**
Number of units	1521	497

DRL quantity	**DAP (mGy.cm²)**	
75th percentile	**3530**	**3437**
50th percentile	2470	2340
Minimum - maximum values	322 - 12184	421 - 10070
Number of units above the 2011 DRL	30 (2%)	10 (2%)
Number of units above the 2019 DRL	311 (20%)	97 (20%)

Change since 2011

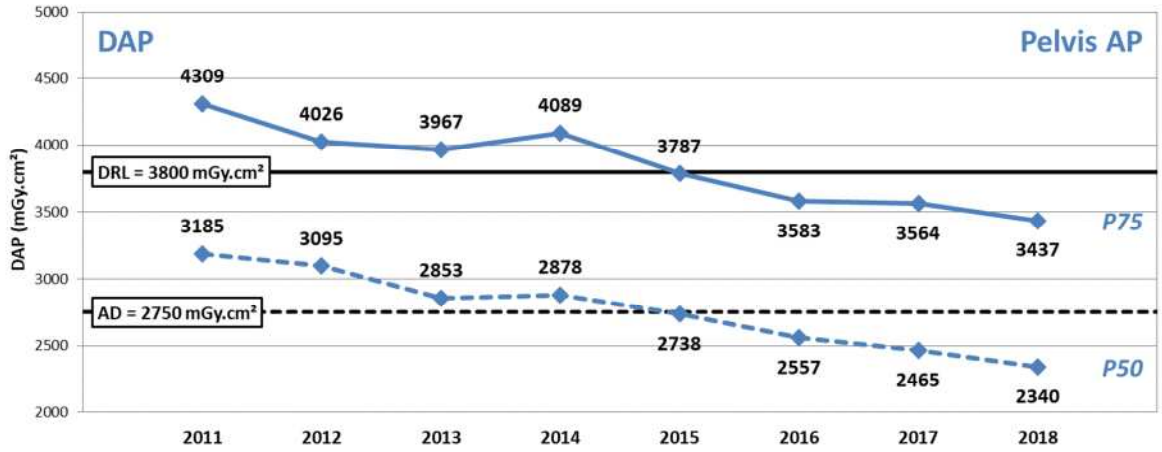


Figure 36: Change in the 75th and 50th percentiles of DAP for adult anterior posterior pelvis radiographs.

Analysis of 2016-2018 data

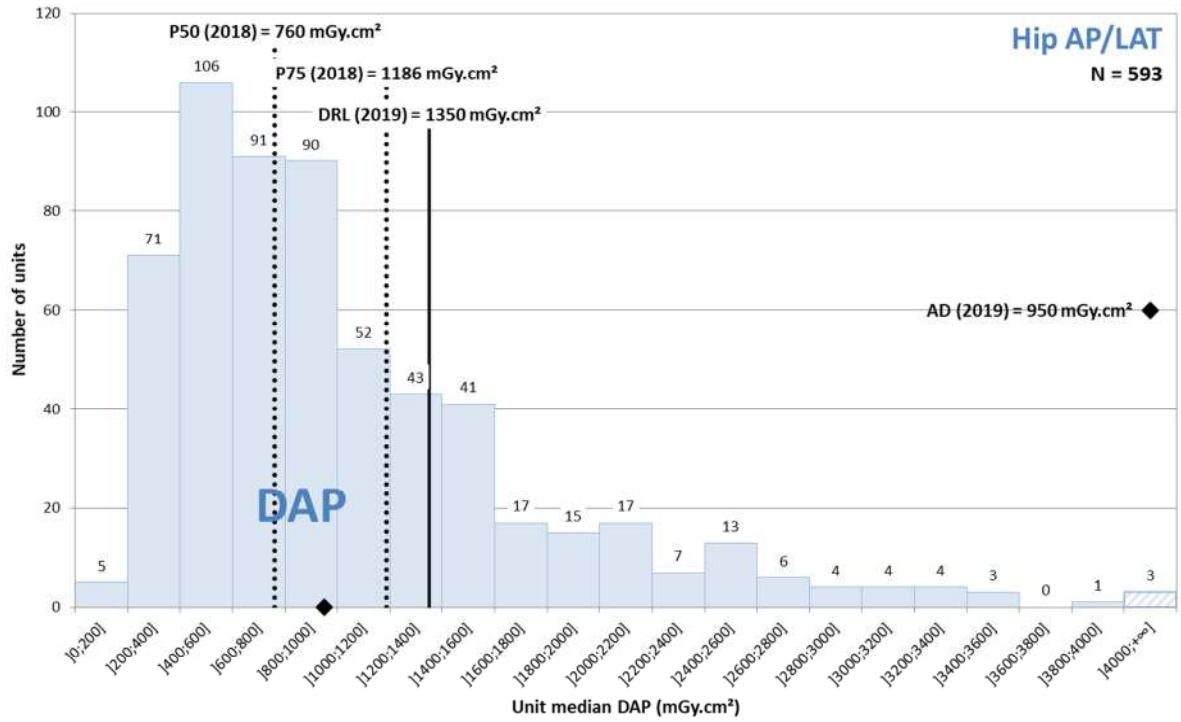


Figure 37: Distribution of unit median DAP from dose assessments performed for adult anterior posterior or lateral hip radiographs.

Table 20: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult anterior posterior or lateral hip radiographs.

Hip anterior posterior or lateral (adults)

DRL quantity	DAP (mGy.cm²)
DRL in force during data collection (2011 DRL)	3000 (i.e. 300 cGy.cm²)
DRL in force (2019 DRL)	**1350**
AD in force (2019 AD)	950

Period	2016 - 2018	2018
Number of units	593	217

DRL quantity	DAP (mGy.cm²)	
75th percentile	**1360**	**1186**
50th percentile	862	760
Minimum - maximum values	140 - 4432	156 - 4100
Number of units above the 2011 DRL	16 (3%)	7 (3%)
Number of units above the 2019 DRL	152 (26%)	49 (23%)

Change since 2011

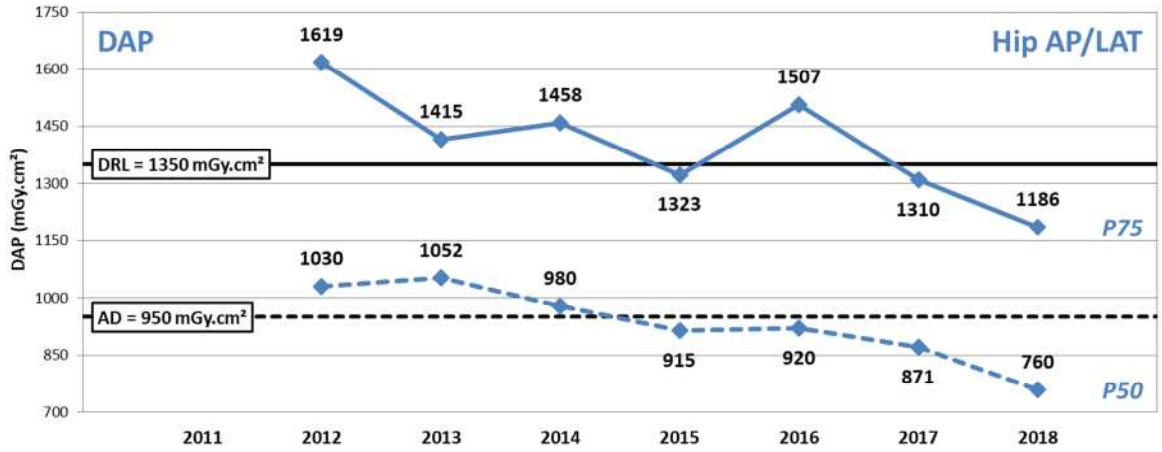


Figure 38: Change in the 75th and 50th percentiles of DAP for adult anterior posterior or lateral hip radiographs.

Anterior posterior or lateral hip radiographs were added to the list of examinations subject to DRLs by the Order of 24 October 2011. Therefore, data for this type of examination only started being collected in 2012.

Analysis of 2016-2018 data

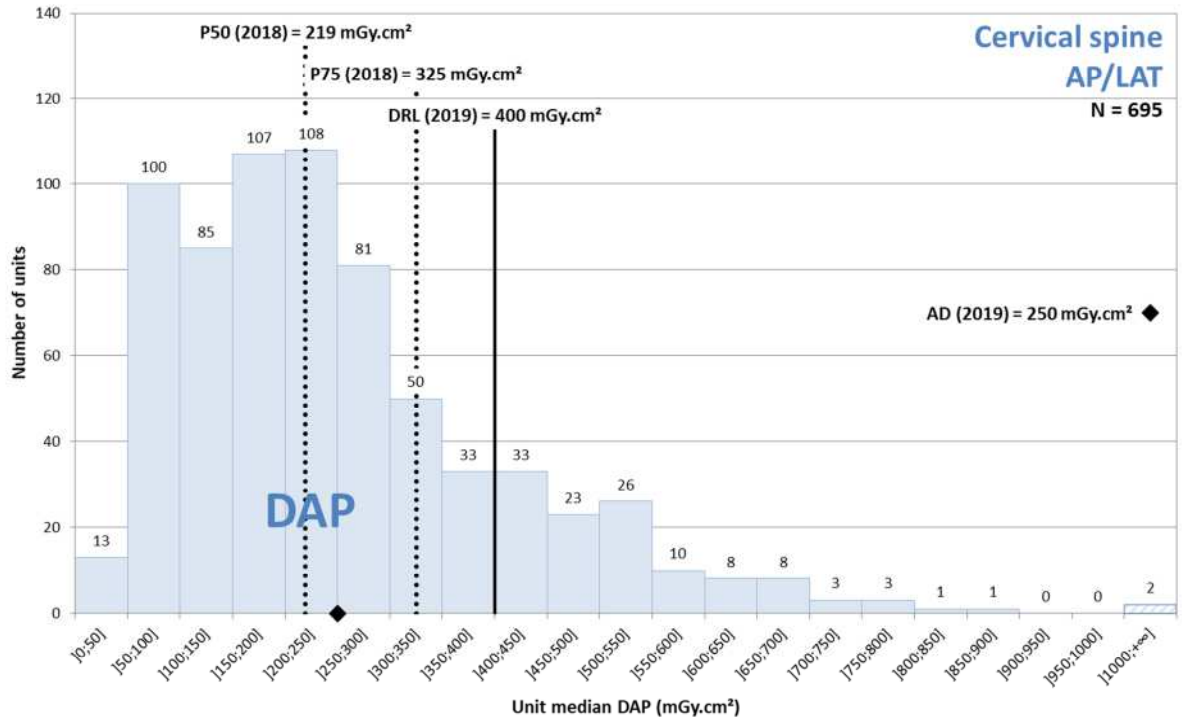


Figure 39: Distribution of unit median DAP from dose assessments performed for adult anterior posterior or lateral cervical spine radiographs.

Table 21: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult anterior posterior or lateral cervical spine radiographs.

Cervical spine anterior posterior or lateral (adults)

DRL quantity	DAP (mGy.cm²)
DRL in force during data collection (2011 DRL)	750 (i.e. 75 cGy.cm²)
DRL in force (2019 DRL)	**400**
AD in force (2019 AD)	250

Period	2016 - 2018	2018
Number of units	695	224

DRL quantity	DAP (mGy.cm²)	
75th percentile	**328**	**325**
50th percentile	224	219
Minimum - maximum values	30 - 1220	30 - 763
Number of units above the 2011 DRL	8 (1%)	1 (0%)
Number of units above the 2019 DRL	118 (17%)	35 (16%)

Change since 2011

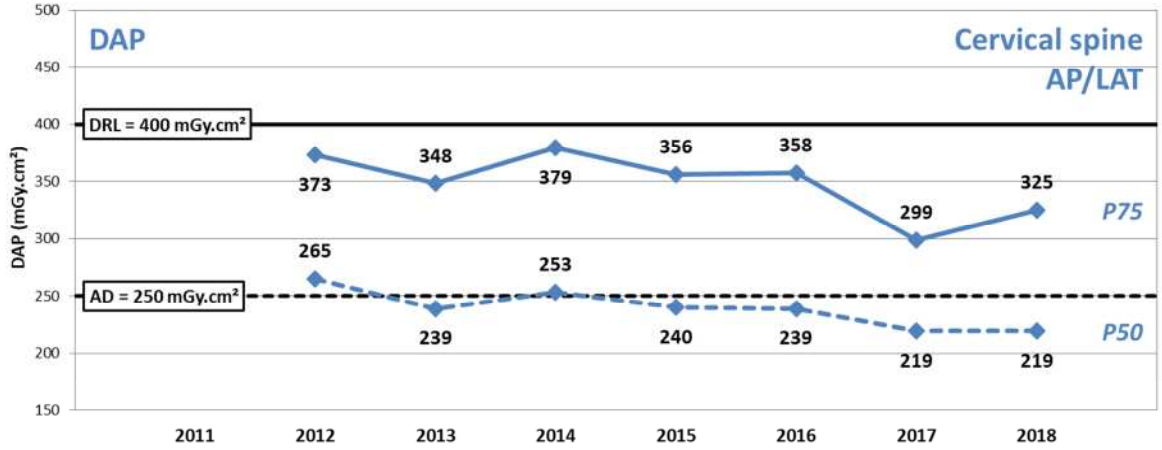


Figure 40: Change in the 75th and 50th percentiles of DAP for adult anterior posterior or lateral cervical spine radiographs.

Anterior posterior or lateral cervical spine radiographs were added to the list of examinations subject to DRLs by the Order of 24 October 2011. Therefore, data for this type of examination only started being collected in 2012.

Analysis of 2016-2018 data

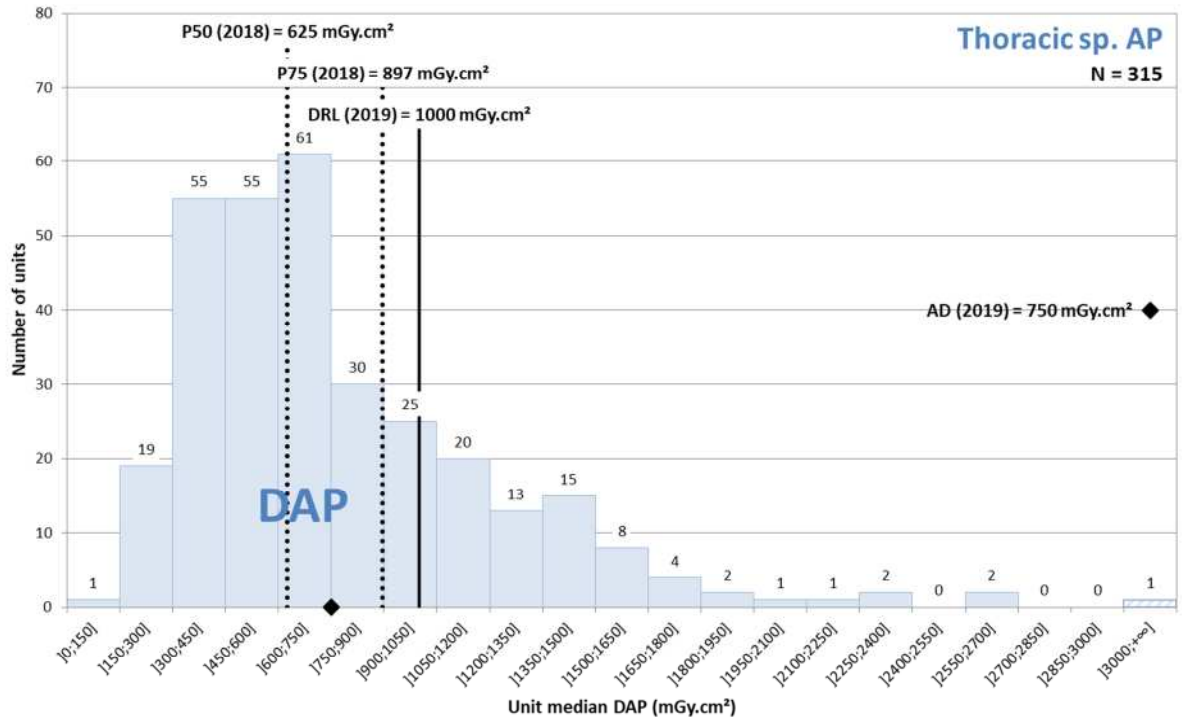


Figure 41: Distribution of unit median DAP from dose assessments performed for adult anterior posterior thoracic spine radiographs.

Table 22: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult anterior posterior thoracic spine radiographs.

Thoracic spine anterior posterior (adults)

DRL quantity	DAP (mGy.cm²)
DRL in force during data collection (2011 DRL)	1750 (i.e. 175 cGy.cm²)
DRL in force (2019 DRL)	**1000**
AD in force (2019 AD)	750

Period	2016 - 2018	2018
Number of units	315	82

DRL quantity	DAP (mGy.cm²)	
75th percentile	**978**	**897**
50th percentile	670	625
Minimum - maximum values	128 - 3505	280 - 2360
Number of units above the 2011 DRL	12 (4%)	2 (2%)
Number of units above the 2019 DRL	75 (24%)	15 (18%)

Change since 2011

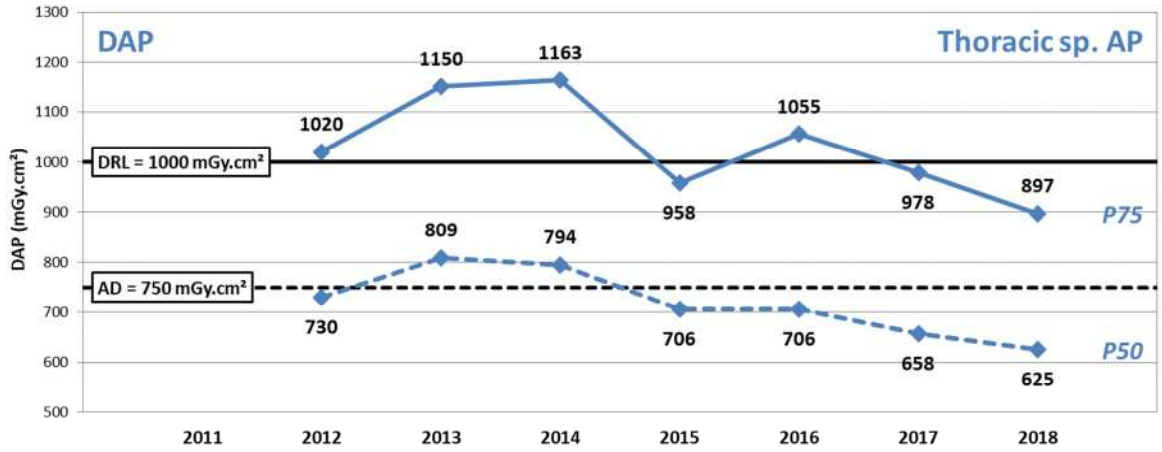


Figure 42: Change in the 75th and 50th percentiles of DAP for adult anterior posterior thoracic spine radiographs.

Anterior posterior thoracic spine radiographs were added to the list of examinations subject to DRLs by the Order of 24 October 2011. Therefore, data for this type of examination only started being collected in 2012.

Analysis of 2016-2018 data

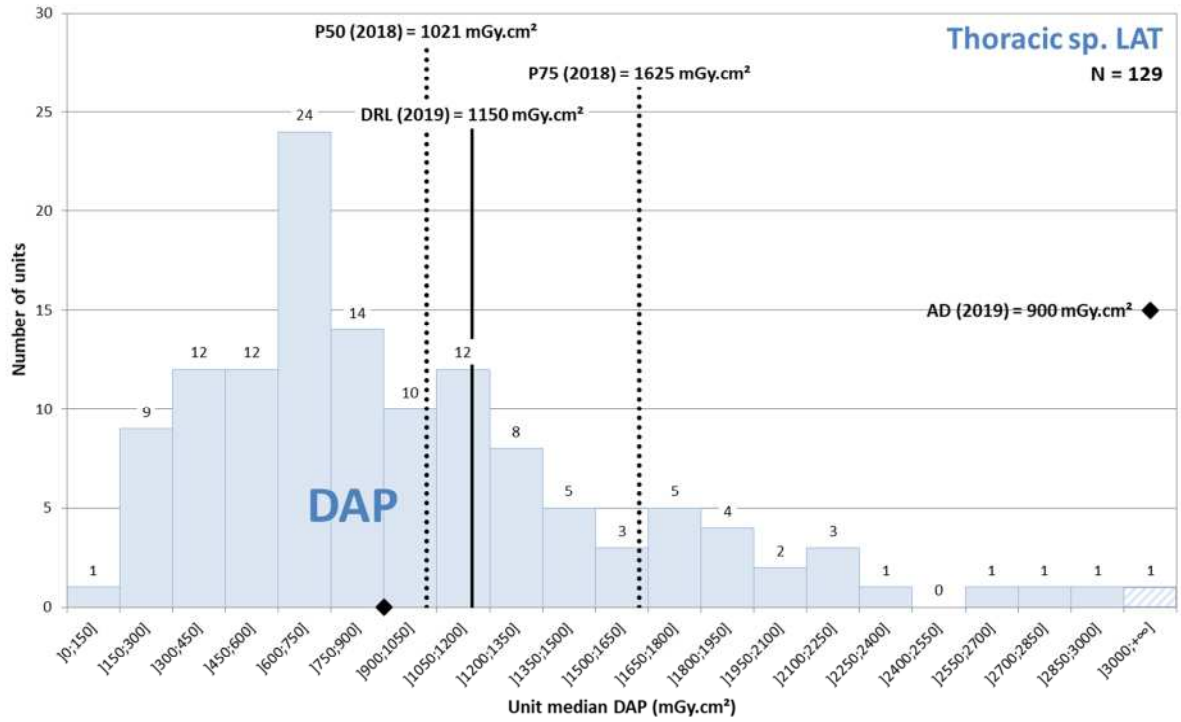


Figure 43: Distribution of unit median DAP from dose assessments performed for adult lateral thoracic spine radiographs.

Table 23: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult lateral thoracic spine radiographs.

Thoracic spine lateral (adults)

DRL quantity	DAP (mGy.cm²)
DRL in force during data collection (2011 DRL)	2750 (i.e. 275 cGy.cm²)
DRL in force (2019 DRL)	**1150**
AD in force (2019 AD)	900

Period	2016 - 2018	2018
Number of units	129	30

DRL quantity	DAP (mGy.cm²)	
75th percentile	**1275**	**1625**
50th percentile	811	1021
Minimum - maximum values	104 - 3190	180 - 3190
Number of units above the 2011 DRL	4 (3%)	1 (3%)
Number of units above the 2019 DRL	40 (31%)	14 (47%)

Change since 2011

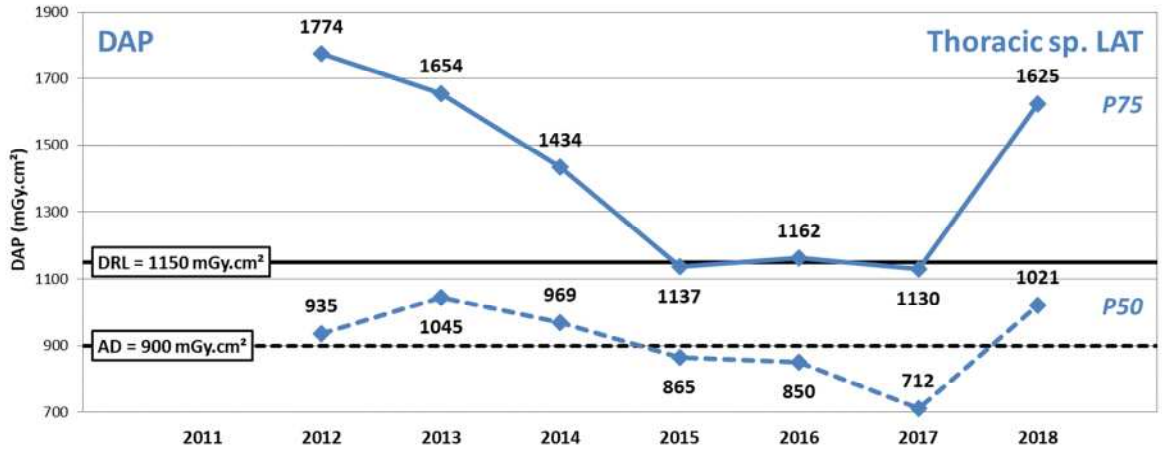


Figure 44: Change in the 75th and 50th percentiles of DAP for adult lateral thoracic spine radiographs.

Lateral thoracic spine radiographs were added to the list of examinations subject to DRLs by the Order of 24 October 2011. Therefore, data for this type of examination only started being collected in 2012.

Analysis of 2016-2018 data

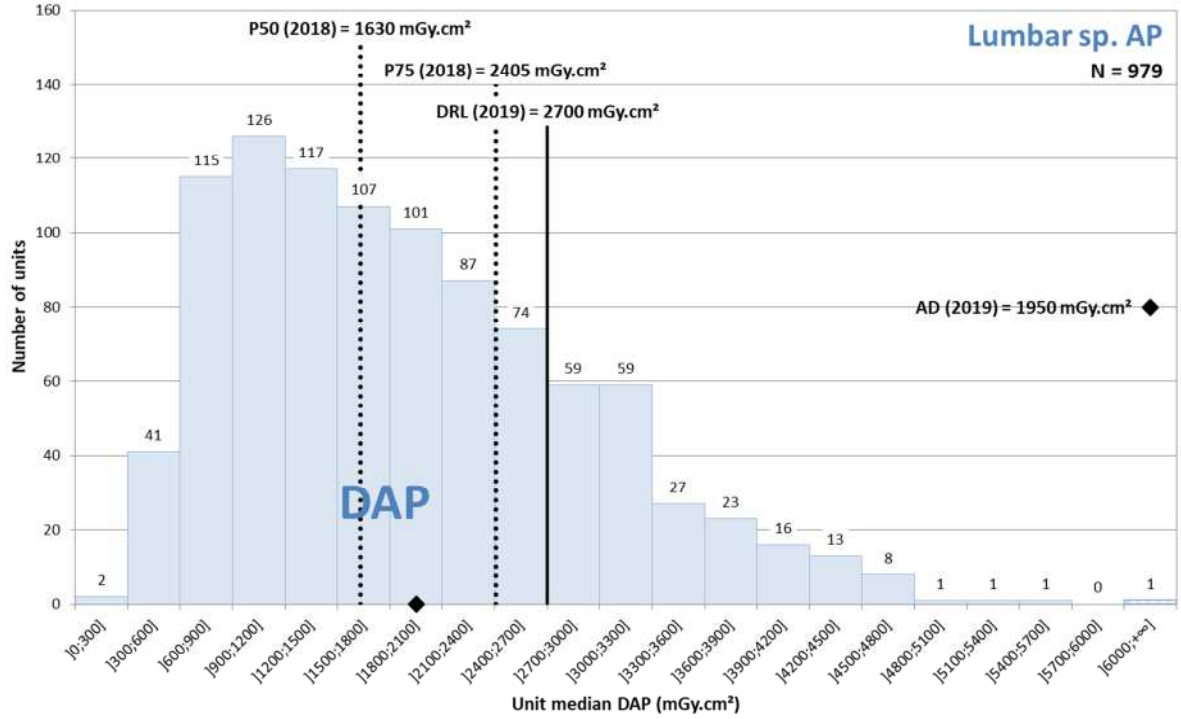


Figure 45: Distribution of unit median DAP from dose assessments performed for adult anterior posterior lumbar spine radiographs.

Table 24: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult anterior posterior lumbar spine radiographs.

Lumbar spine anterior posterior (adults)

DRL quantity	**DAP (mGy.cm²)**
DRL in force during data collection (2011 DRL)	4500 (i.e. 450 cGy.cm²)
DRL in force (2019 DRL)	**2700**
AD in force (2019 AD)	1950

Period	**2016 - 2018**	**2018**
Number of units	979	353

DRL quantity	**DAP (mGy.cm²)**	
75th percentile	**2580**	**2405**
50th percentile	1770	1630
Minimum - maximum values	223 - 6597	223 - 5590
Number of units above the 2011 DRL	18 (2%)	5 (1%)
Number of units above the 2019 DRL	209 (21%)	64 (18%)

Change since 2011

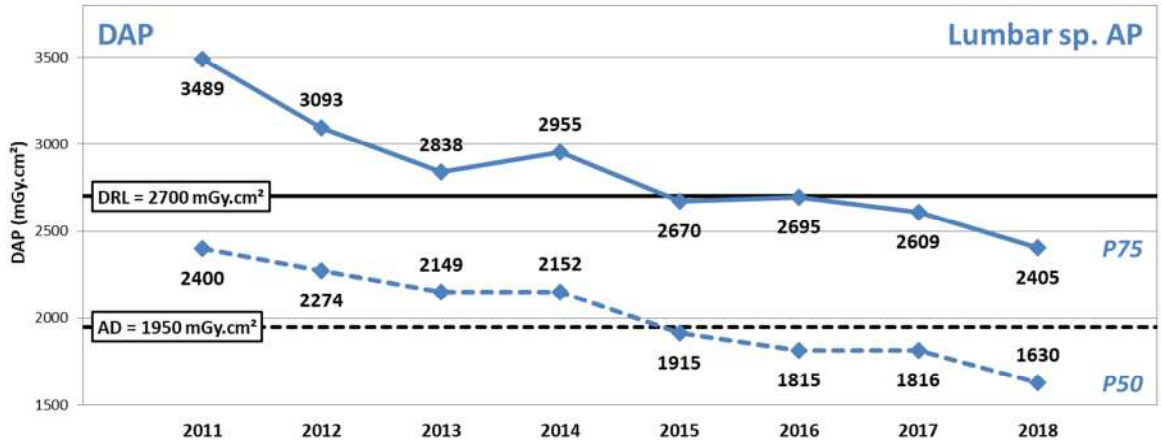


Figure 46: Change in the 75th and 50th percentiles of DAP for adult anterior posterior lumbar spine radiographs.

Analysis of 2016-2018 data

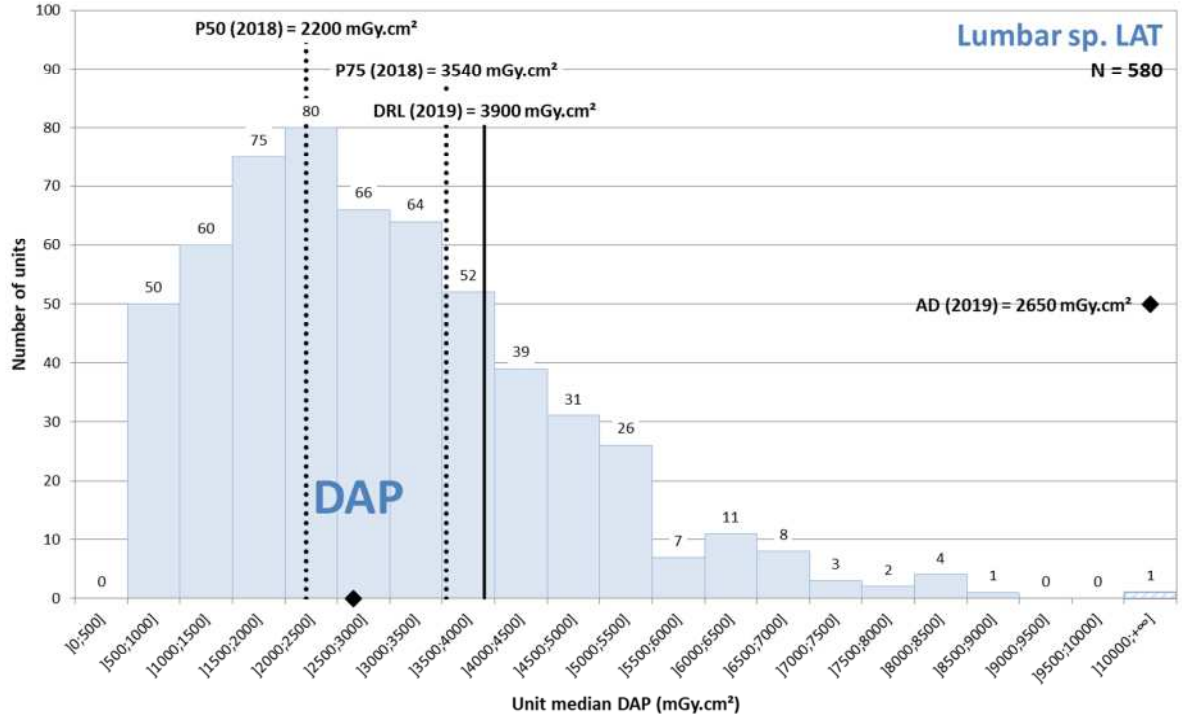


Figure 47: Distribution of unit median DAP from dose assessments performed for adult lateral lumbar spine radiographs.

Table 25: Statistical data associated with the distribution of unit median DAP from dose assessments performed for adult lateral lumbar spine radiographs.

Lumbar spine lateral (adults)

DRL quantity	DAP (mGy.cm²)	
DRL in force during data collection (2011 DRL)	8000 (i.e. 800 cGy.cm²)	
DRL in force (2019 DRL)	**3900**	
AD in force (2019 AD)	2650	
Period	**2016 - 2018**	**2018**
Number of units	580	201
DRL quantity	**DAP (mGy.cm²)**	
75th percentile	**3876**	**3540**
50th percentile	2699	2200
Minimum - maximum values	549 - 11820	702 - 11820
Number of units above the 2011 DRL	6 (1.0%)	3 (1.5%)
Number of units above the 2019 DRL	141 (24%)	38 (19%)

Change since 2011

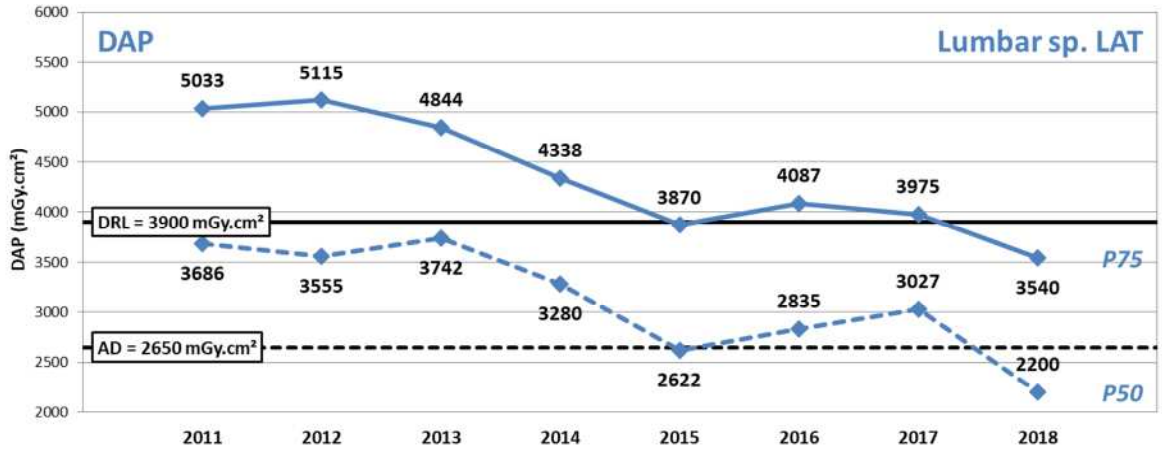


Figure 48: Change in the 75th and 50th percentiles of DAP for adult lateral lumbar spine radiographs.

Analysis of 2016-2018 data

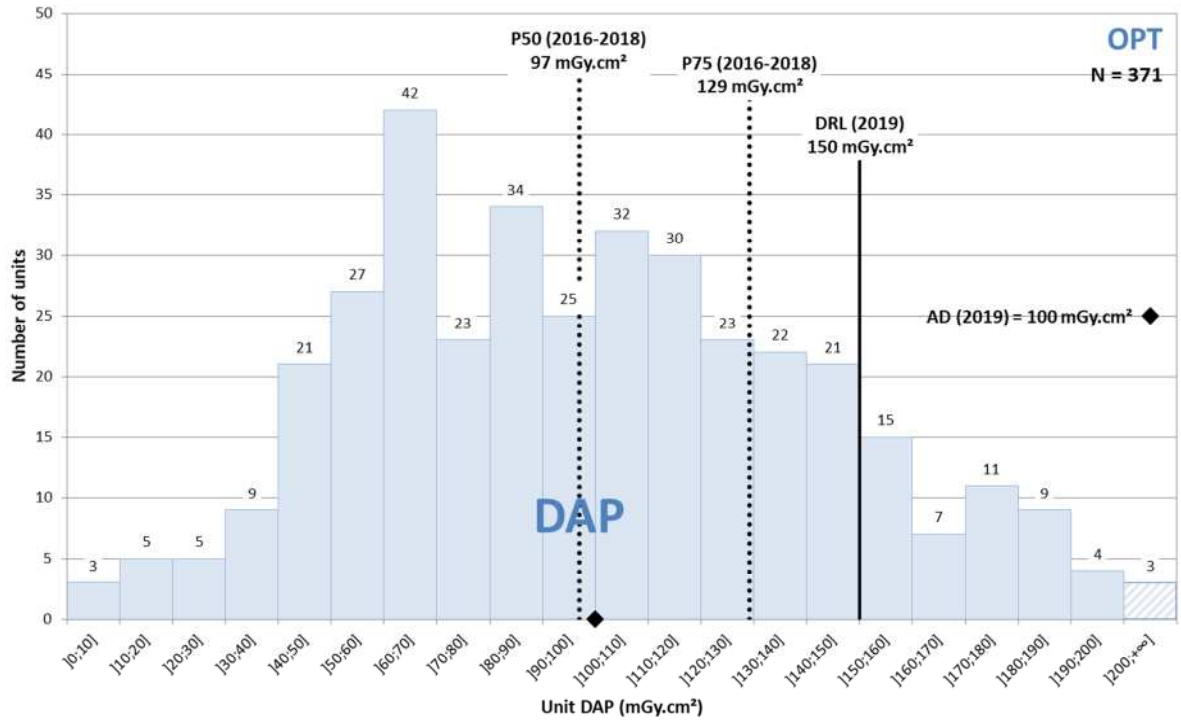


Figure 49: Distribution of DAP from dose assessments performed for orthopantomography.

Table 26: Statistical data associated with the distribution of DAP from dose assessments performed for orthopantomography.

Orthopantomography

DRL quantity	**DAP (mGy.cm²)**		
DRL in force during data collection (2011 DRL)	200 (i.e. 20 cGy.cm²)		
DRL in force (2019 DRL)	**150**		
AD in force (2019 AD)	100		
Period	**2016 - 2018**		
Type of institution	**All institutions**	**Dental practices**	**Other institutions**
Number of units	371	114	257
DRL quantity	**DAP (mGy.cm²)**		
75th percentile	**129**	**117**	**134**
50th percentile	97	87	102
Minimum - maximum values	7 - 239	28 - 188	7 - 239
Number of units above the 2011 DRL	3 (0.8%)	0	3 (1.2%)
Number of units above the 2019 DRL	49 (13%)	11 (10%)	38 (15%)

Change since 2011

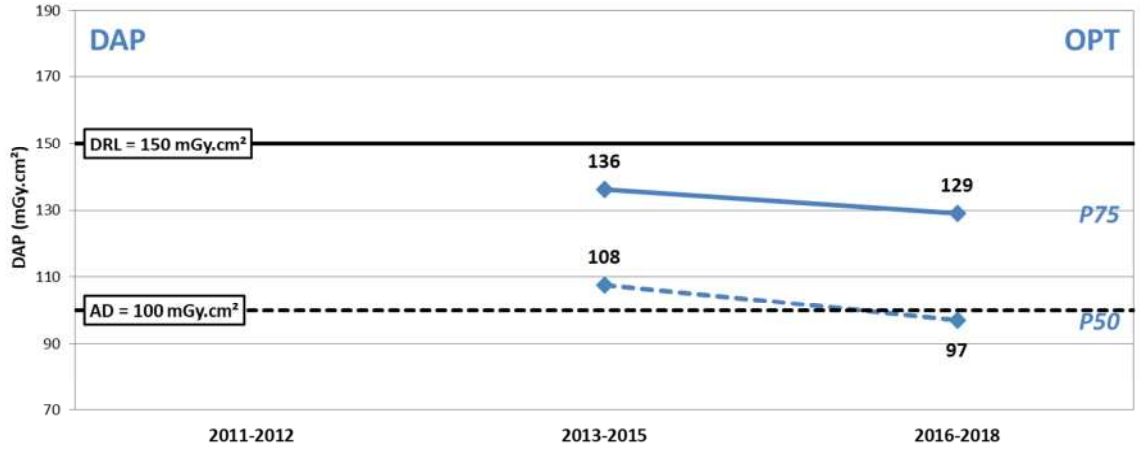


Figure 50: Change in the 75th and 50th percentiles of DAP for orthopantomography.

Orthopantomography was added to the list of examinations subject to DRLs by the Order of 24 October 2011. Therefore, data for this type of examination only started being collected in 2012. The number of dose assessments received in 2012 was considered insufficient for use.

Analysis of 2016-2018 data

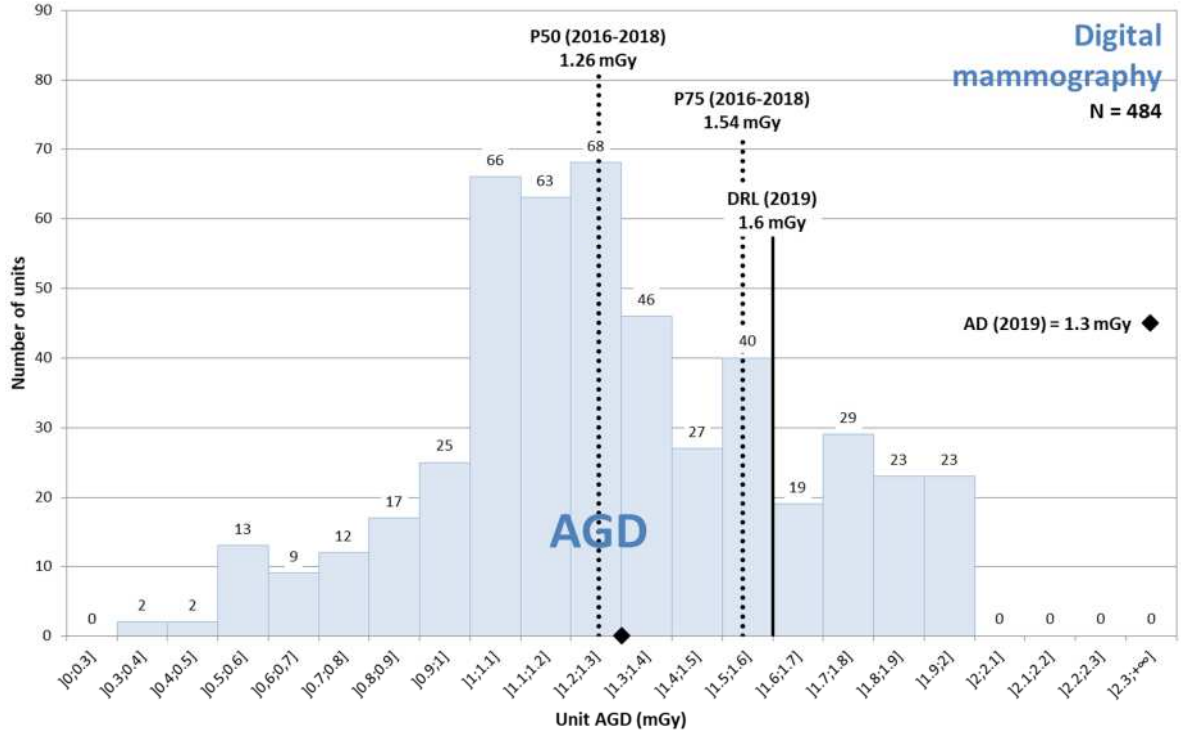


Figure 51: Total distribution of AGD from dose assessments performed for digital mammography.

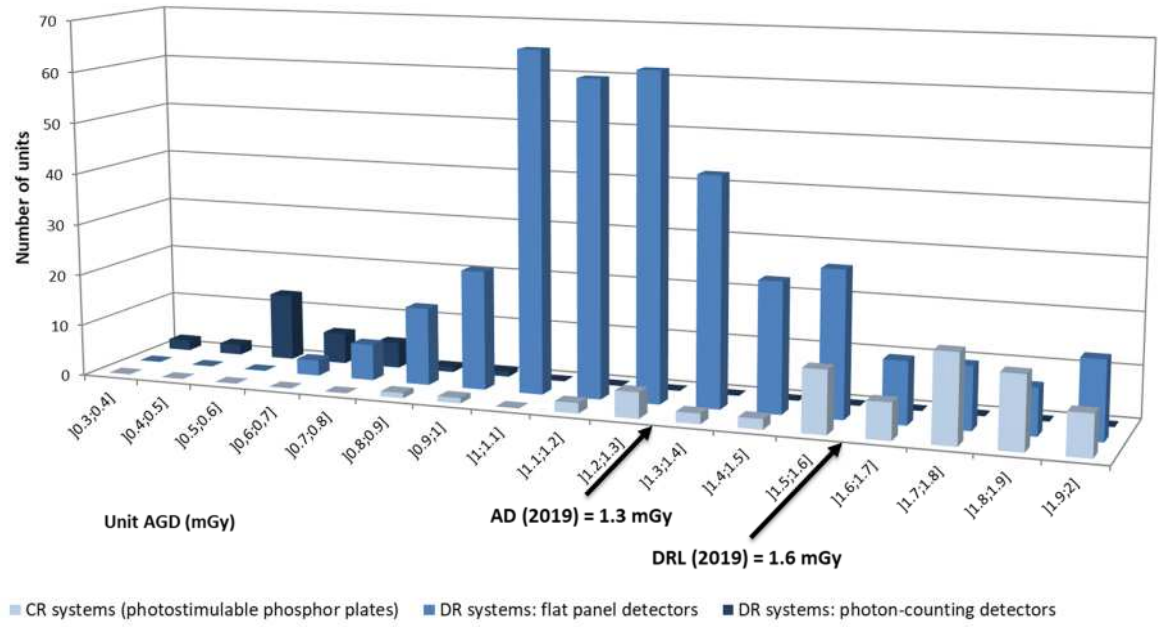


Figure 52: Distribution by type of detector of AGD from dose assessments performed for digital mammography.

Table 27: Statistical data associated with total distributions of AGD from dose assessments performed for digital mammography, by type of detector.

Digital mammography

DRL quantity	AGD (mGy)
DRL in force during data collection (2011 DRL)	1.8
DRL in force (2019 DRL)	**1.6**
AD in force (2019 AD)	1.3

Period	2016 - 2018			
Type of detector	All systems	CR systems	DR systems	
		Photostimulable phosphor plate	Flat panel detector	Photon-counting detector
Number of units	484	71	383	30

DRL quantity	AGD (mGy)			
75th percentile	**1.54**	**1.84**	**1.43**	**0.70**
50th percentile	1.26	1.74	1.22	0.58
Minimum - maximum values	0.39 - 2.00	0.84 - 2.00	0.61 - 2.00	0.39 - 0.98
Number of units above the 2011 DRL	46 (10%)	22 (31%)	24 (6%)	0
Number of units above the 2019 DRL	94 (19%)	46 (65%)	48 (13%)	0

Change since 2011

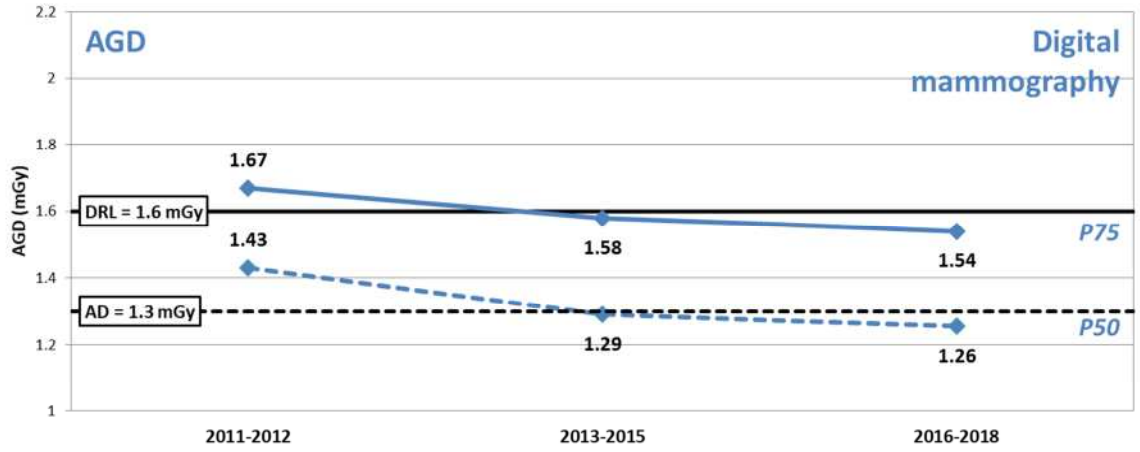


Figure 53: Change in the 75th and 50th percentiles of AGD for digital mammography.

Analysis of 2016-2018 data

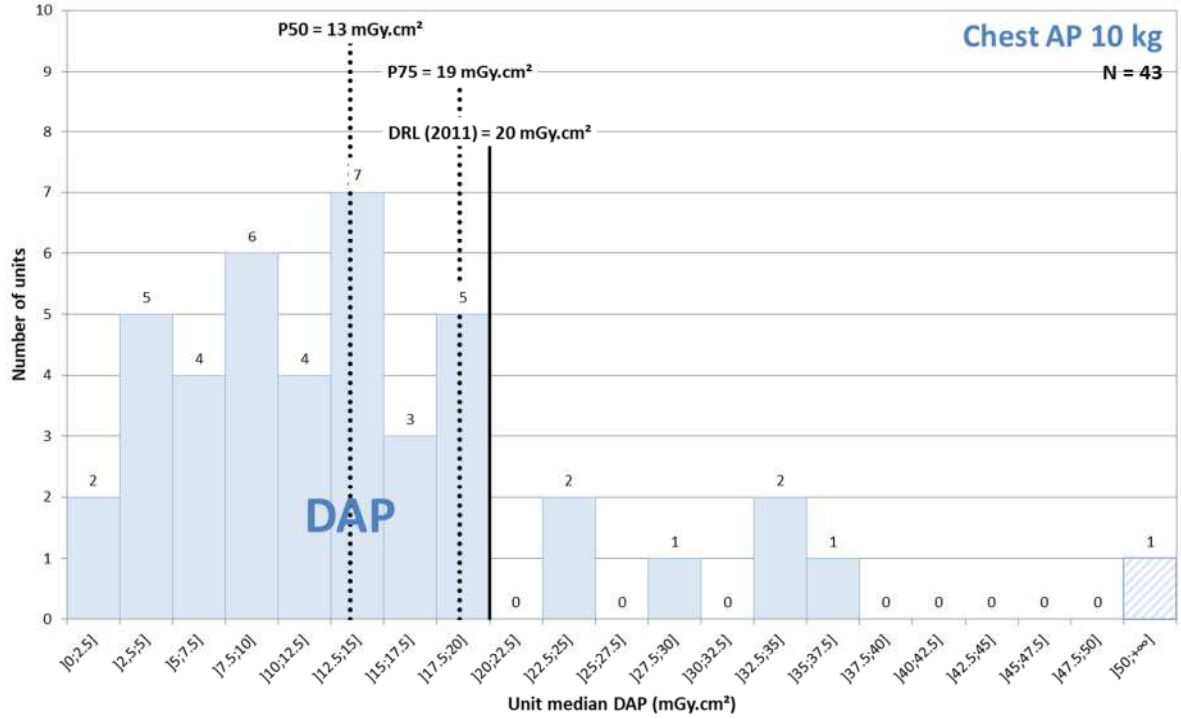


Figure 54: Distribution of unit median DAP from dose assessments performed for paediatric (10 kg) anterior posterior chest radiographs.

Table 28: Statistical data associated with the distribution of unit median DAP from dose assessments performed for paediatric (10 kg) anterior posterior chest radiographs.

Chest anterior posterior (children 10 kg)

DRL quantity	DAP (mGy.cm²)
DRL in force during data collection (2011 DRL)	20 (i.e. 2 cGy.cm²)
DRL in force (2019 DRL)	-
AD in force (2019 AD)	-

Period	2016 - 2018
Number of units	43

DRL quantity	DAP (mGy.cm²)
75th percentile	**19**
50th percentile	13
Minimum - maximum values	2 - 51
Number of units above the 2011 DRL	10 (23%)
Number of units above the 2019 DRL	-

Change since 2011

Due to the very low number of dose assessments received each year, it does not seem relevant to present a curve where variations are more related to the statistical inconsistency of data than the change in delivered doses over time.

Analysis of 2016-2018 data

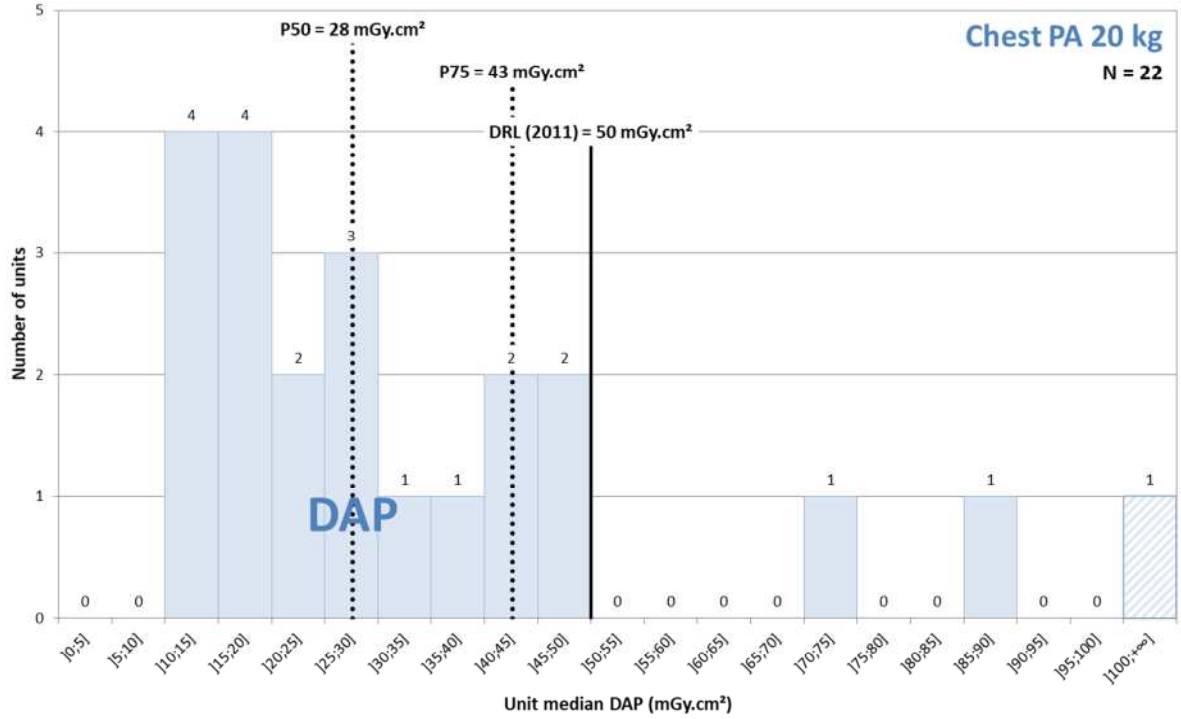


Figure 55: Distribution of unit median DAP from dose assessments performed for paediatric (20 kg) posterior anterior chest radiographs.

Table 29: Statistical data associated with the distribution of unit median DAP from dose assessments performed for paediatric (20 kg) posterior anterior chest radiographs.

Chest posterior anterior (children 20 kg)

DRL quantity	**DAP (mGy.cm²)**
DRL in force during data collection (2011 DRL)	50 (i.e. 5 cGy.cm²)
DRL in force (2019 DRL)	**-**
AD in force (2019 AD)	-

Period	**2016 - 2018**
Number of units	22

DRL quantity	**DAP (mGy.cm²)**
75th percentile	**43**
50th percentile	28
Minimum - maximum values	11 - 115
Number of units above the 2011 DRL	3 (14%)
Number of units above the 2019 DRL	-

Change since 2011

Due to the very low number of dose assessments received each year, it does not seem relevant to present a curve where variations are more related to the statistical inconsistency of data than the change in delivered doses over time.

Analysis of 2016-2018 data

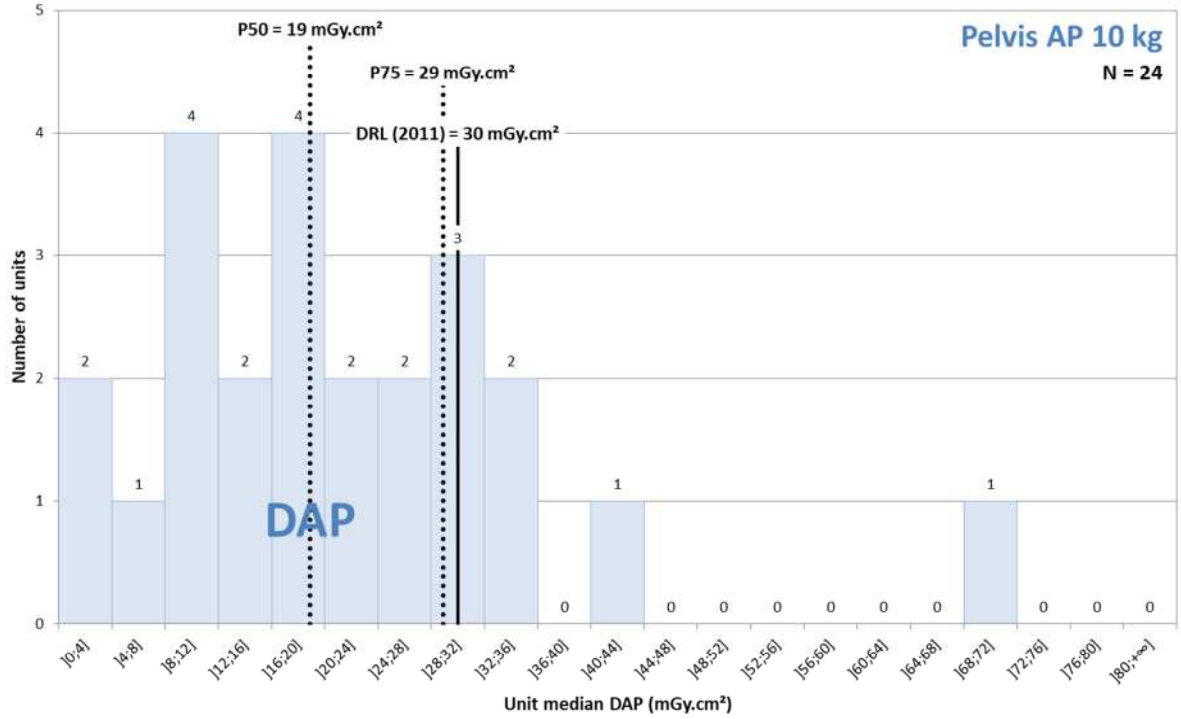


Figure 56: Distribution of unit median DAP from dose assessments performed for paediatric (10 kg) anterior posterior pelvis radiographs.

Table 30: Statistical data associated with the distribution of unit median DAP from dose assessments performed for paediatric (10kg) anterior posterior pelvis radiographs.

Pelvis anterior posterior (children 10 kg)

DRL quantity	**DAP (mGy.cm²)**
DRL in force during data collection (2011 DRL)	30 (i.e. 3 cGy.cm²)
DRL in force (2019 DRL)	**-**
AD in force (2019 AD)	-

Period	**2016 - 2018**
Number of units	24

DRL quantity	**DAP (mGy.cm²)**
75th percentile	**29**
50th percentile	19
Minimum - maximum values	2 - 70
Number of units above the 2011 DRL	5 (21%)
Number of units above the 2019 DRL	-

Change since 2011

Due to the very low number of dose assessments received each year, it does not seem relevant to present a curve where variations are more related to the statistical inconsistency of data than the change in delivered doses over time.

Analysis of 2016-2018 data

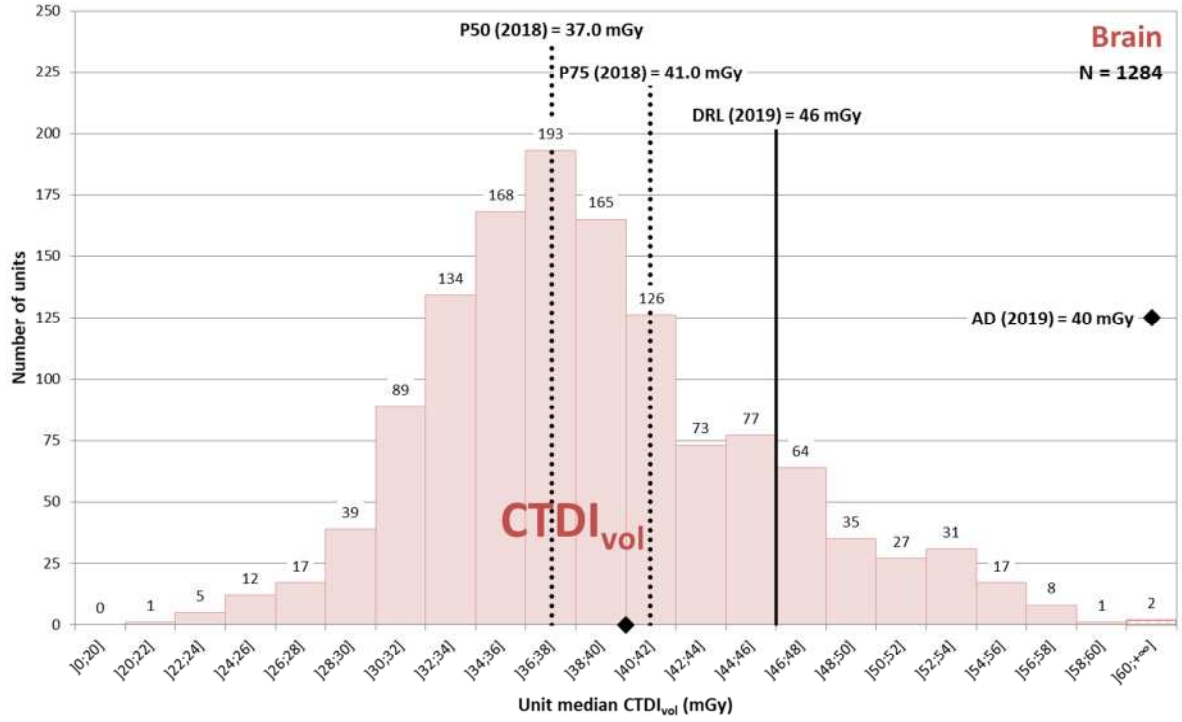


Figure 57: Distribution of unit median $CTDI_{vol}$ from dose assessments performed for adult brain CTacquisitions.

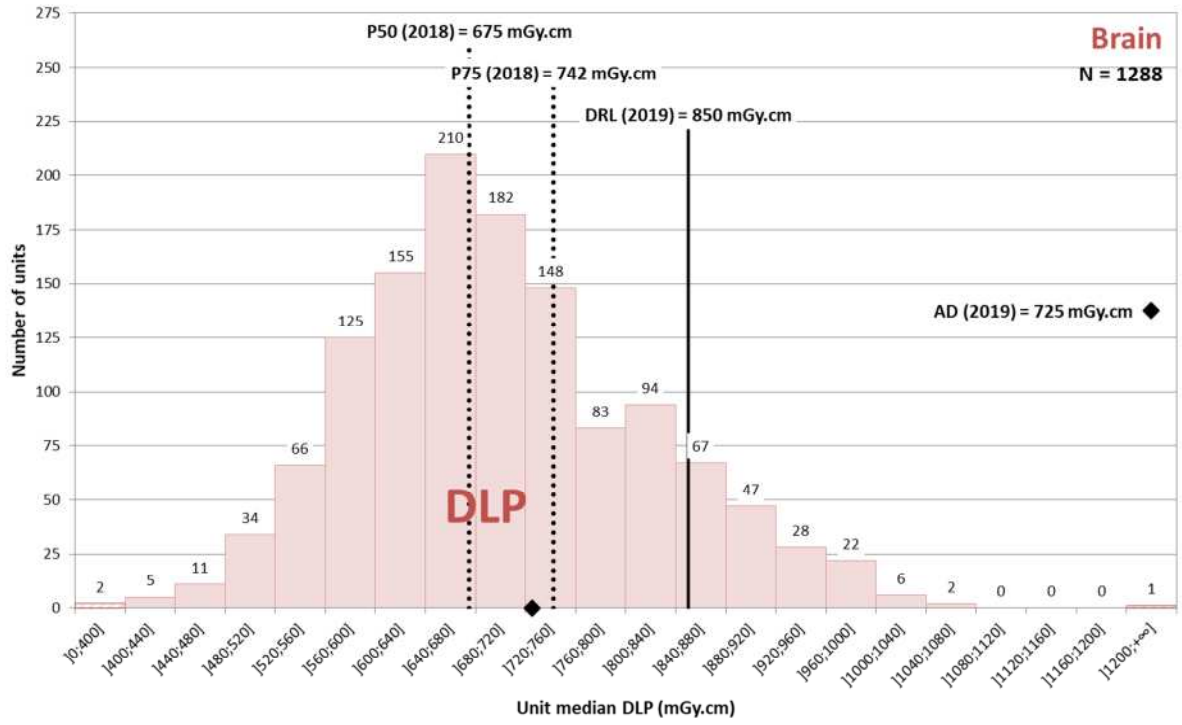


Figure 58: Distribution of unit median DLP from dose assessments performed for adult brain CT acquisitions.

Table 31: Statistical data associated with the distribution of unit median $CTDI_{vol}$ and DLP from dose assessments performed for adult brain CT acquisitions.

Brain CT (adults)

DRL quantity	$CTDI_{vol}$ (mGy)		DLP (mGy.cm)	
DRL in force during data collection (2011 DRL)	65		1050	
DRL in force (2019 DRL)	**46**		**850**	
AD in force (2019 AD)	40		725	
Period	**2016 - 2018**	**2018**	**2016 - 2018**	**2018**
Number of units	1284	422	1288	422
DRL quantity	**$CTDI_{vol}$ (mGy)**		**DLP (mGy.cm)**	
75th percentile	**42.2**	**41.0**	**771**	**742**
50th percentile	37.9	37.0	689	675
Minimum - maximum values	20.4 - 69.8	23.3 - 61.1	362 - 1261	413 - 1071
Number of units above the 2011 DRL	1 (0.1%)	0	3 (0.2%)	1 (0.2%)
Number of units above the 2019 DRL	185 (14%)	48 (11%)	154 (12%)	44 (10%)

Change since 2011

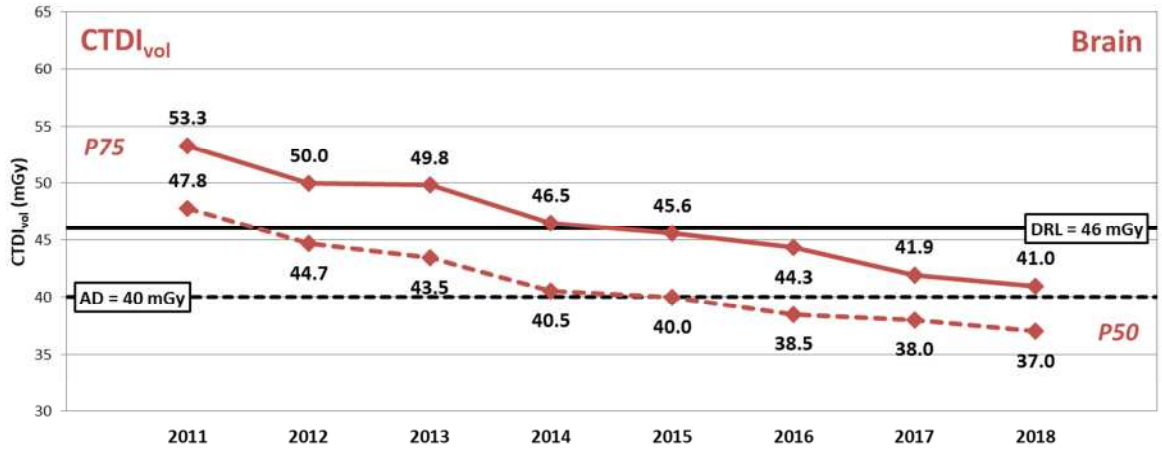


Figure 59: Change in the 75th and 50th percentiles of $CTDI_{vol}$ for adult brain CT acquisitions.

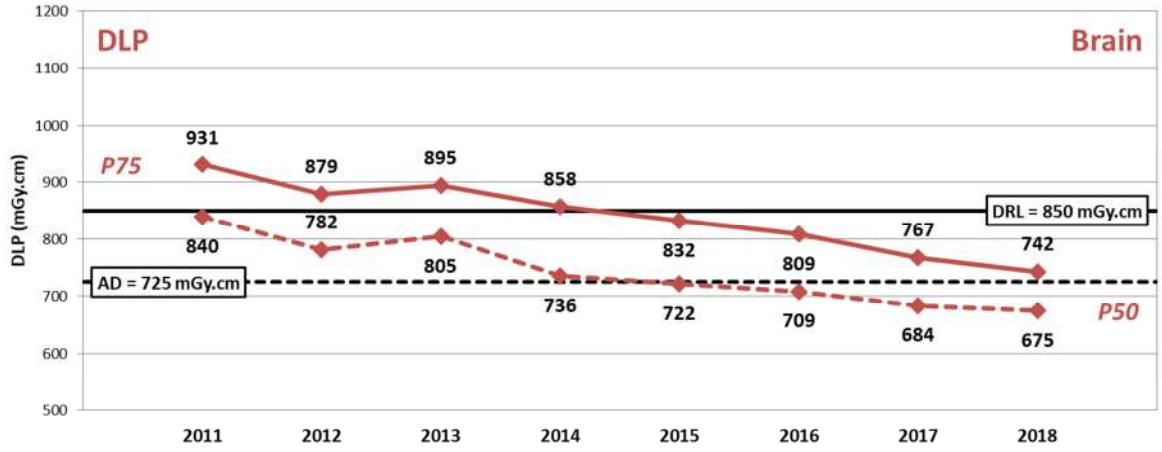


Figure 60: Change in the 75th and 50th percentiles of DLP for adult brain CT acquisitions.

Analysis of 2016-2018 data

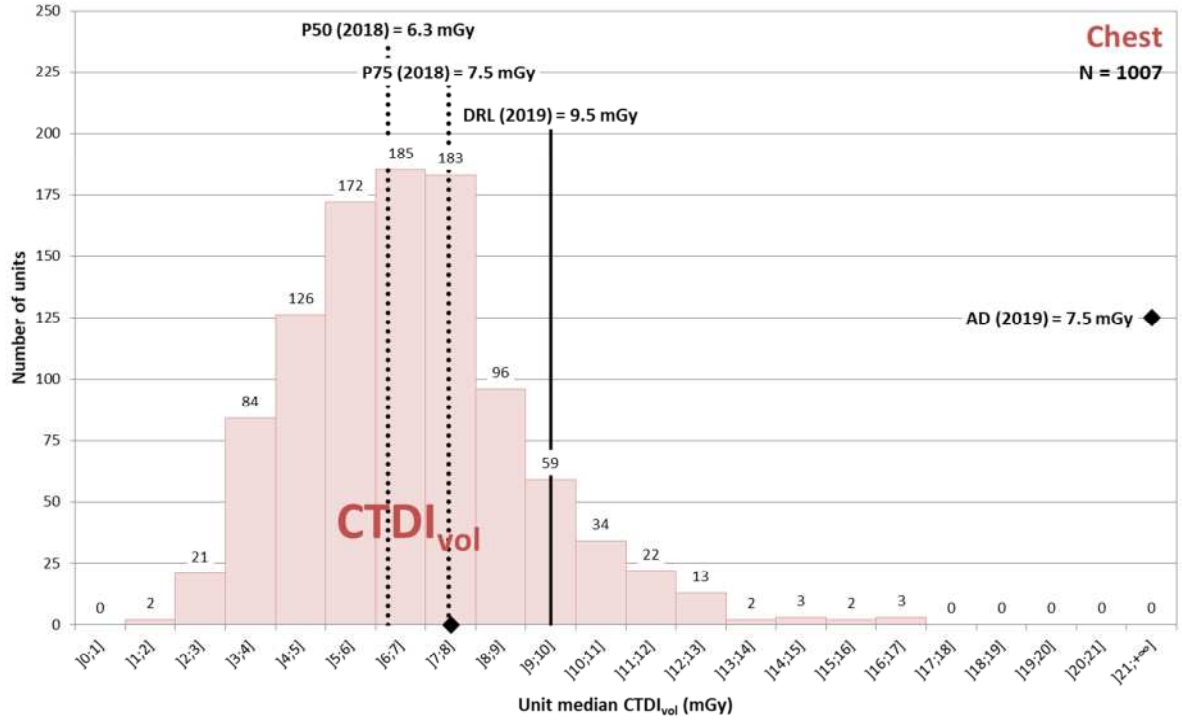


Figure 61: Distribution of unit median $CTDI_{vol}$ from dose assessments performed for adult chest CT acquisitions.

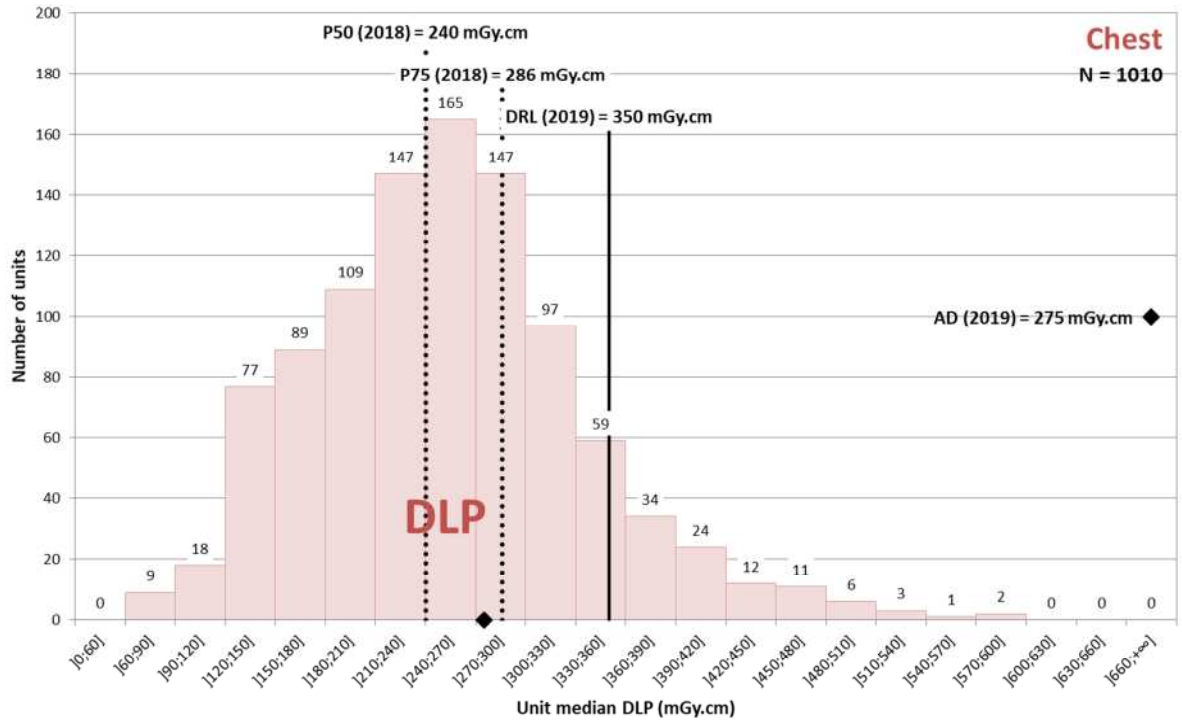


Figure 62: Distribution of unit median DLP from dose assessments performed for adult chest CT acquisitions.

Table 32: Statistical data associated with the distribution of unit median $CTDI_{vol}$ and DLP from dose assessments performed for adult chest CT acquisitions.

Chest CT (adults)

DRL quantity	$CTDI_{vol}$ (mGy)		DLP (mGy.cm)	
DRL in force during data collection (2011 DRL)	15		475	
DRL in force (2019 DRL)	**9.5**		**350**	
AD in force (2019 AD)	7.5		275	
Period	**2016 - 2018**	**2018**	**2016 - 2018**	**2018**
Number of units	1007	337	1010	337
DRL quantity	**$CTDI_{vol}$ (mGy)**		**DLP (mGy.cm)**	
75th percentile	**7.9**	**7.5**	**299**	**286**
50th percentile	6.6	6.3	252	240
Minimum - maximum values	1.7 - 17.0	1.8 - 17.0	62 - 589	71 - 589
Number of units above the 2011 DRL	3 (0.3%)	1 (0.3%)	11 (1.1%)	4 (1.2%)
Number of units above the 2019 DRL	99 (10%)	19 (6%)	105 (10%)	24 (7%)

Change since 2011

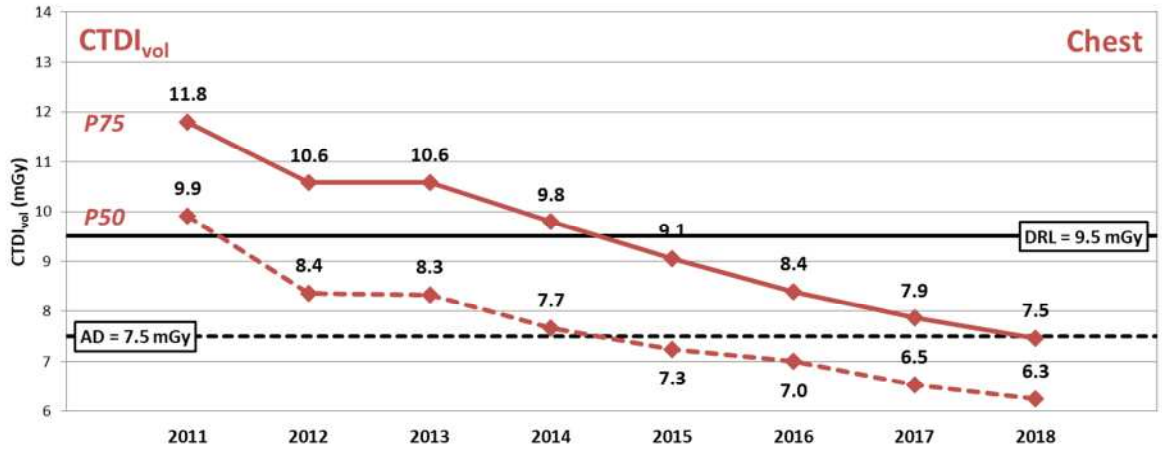


Figure 63: Change in the 75th and 50th percentiles of $CTDI_{vol}$ for adult chest CT acquisitions.

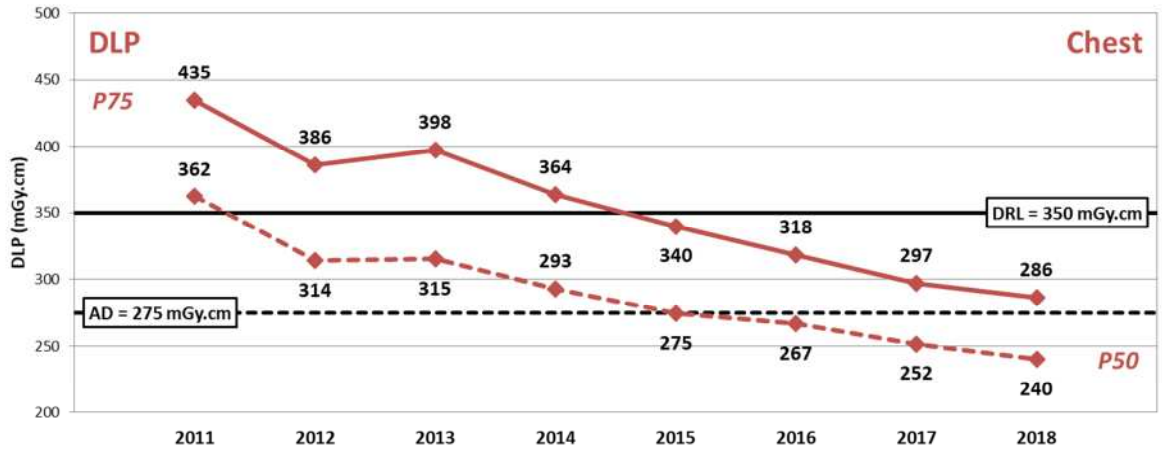


Figure 64: Change in the 75th and 50th percentiles of DLP for adult chest CT acquisitions.

Analysis of 2016-2018 data

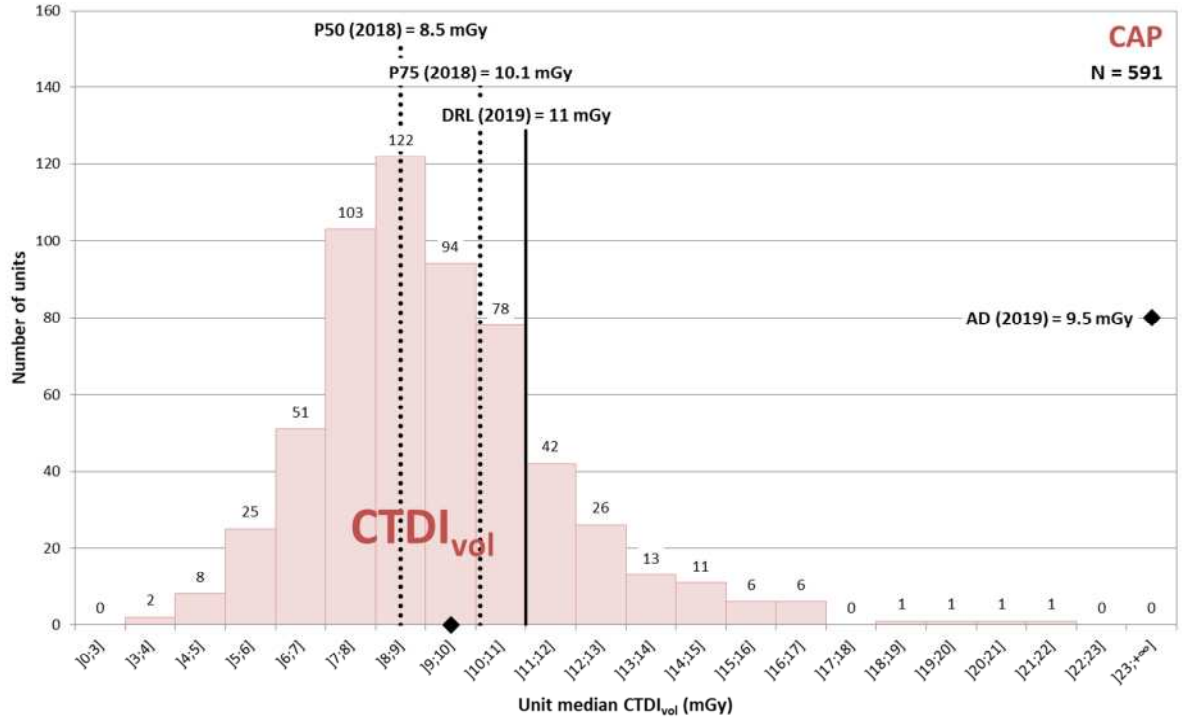


Figure 65: Distribution of unit median $CTDI_{vol}$ from dose assessments performed for adult chest-abdomen-pelvis (CAP) CT acquisitions.

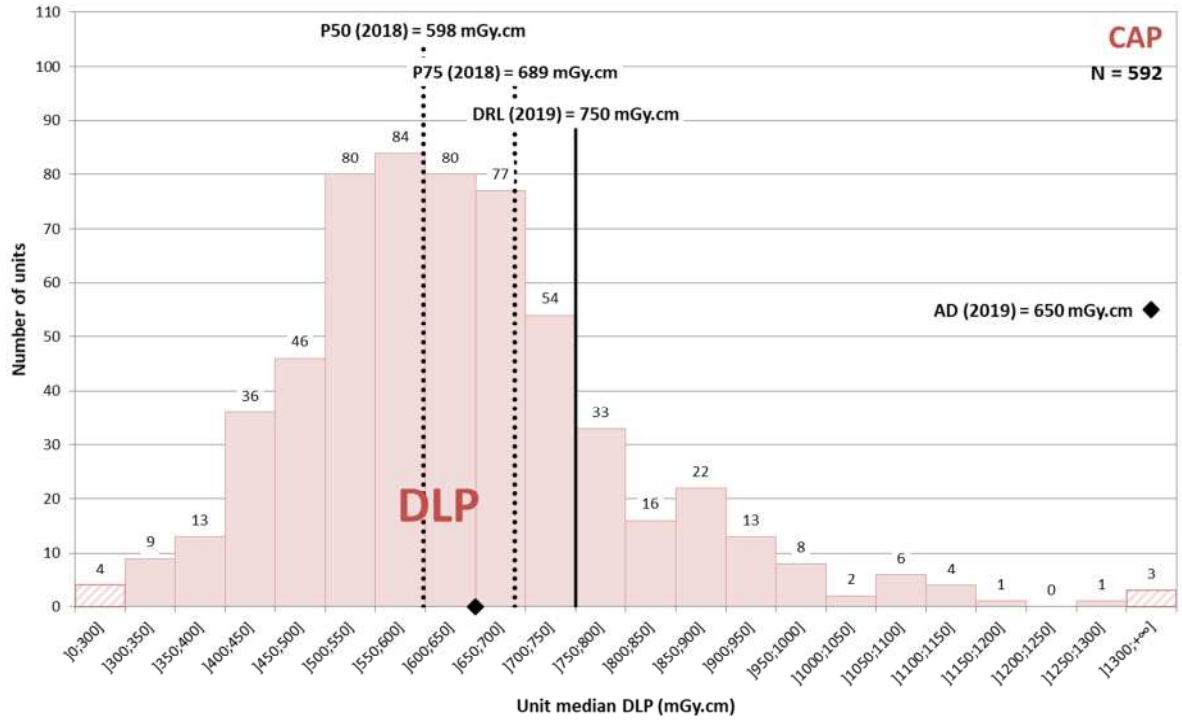


Figure 66: Distribution of unit median DLP from dose assessments performed for adult chest-abdomen-pelvis (CAP) CT acquisitions.

Table 33: Statistical data associated with the distribution of unit median $CTDI_{vol}$ and DLP from dose assessments performed for adult chest-abdomen-pelvis CT acquisitions.

Chest-abdomen-pelvis CT (adults)

DRL quantity	$CTDI_{vol}$ (mGy)		DLP (mGy.cm)	
DRL in force during data collection (2011 DRL)	20		1000	
DRL in force (2019 DRL)	**11**		**750**	
AD in force (2019 AD)	9.5		650	
Period	**2016 - 2018**	**2018**	**2016 - 2018**	**2018**
Number of units	591	207	592	207
DRL quantity	**$CTDI_{vol}$ (mGy)**		**DLP (mGy.cm)**	
75th percentile	**10.3**	**10.1**	**711**	**689**
50th percentile	8.9	8.5	613	598
Minimum - maximum values	3.4 - 21.0	3.5 - 20.7	223 - 1438	238 - 1416
Number of units above the 2011 DRL	1 (0.2%)	1 (0.5%)	22 (3.7%)	5 (2.4%)
Number of units above the 2019 DRL	108 (18%)	32 (15%)	109 (18%)	30 (14%)

Change since 2011

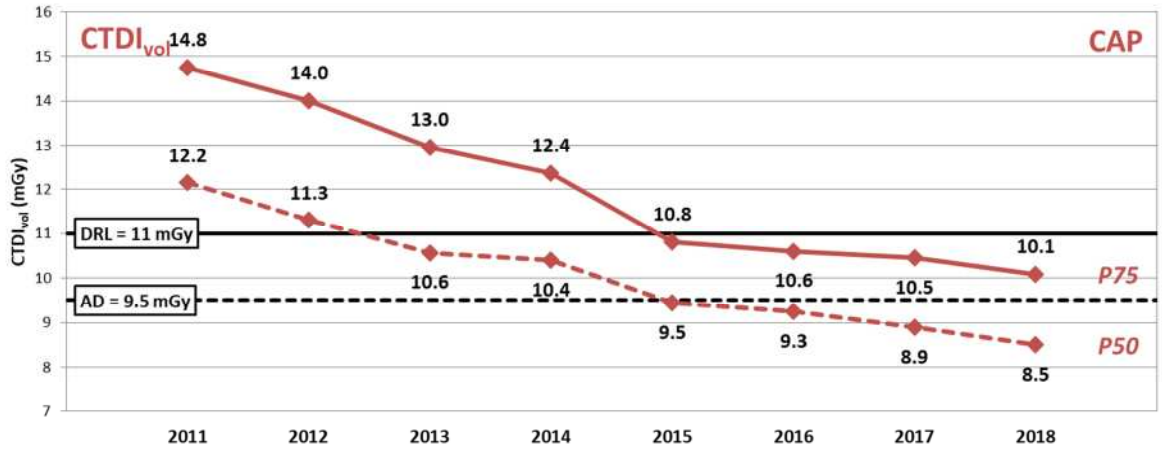


Figure 67: Change in the 75th and 50th percentiles of $CTDI_{vol}$ for adult chest-abdomen-pelvis CT acquisitions.

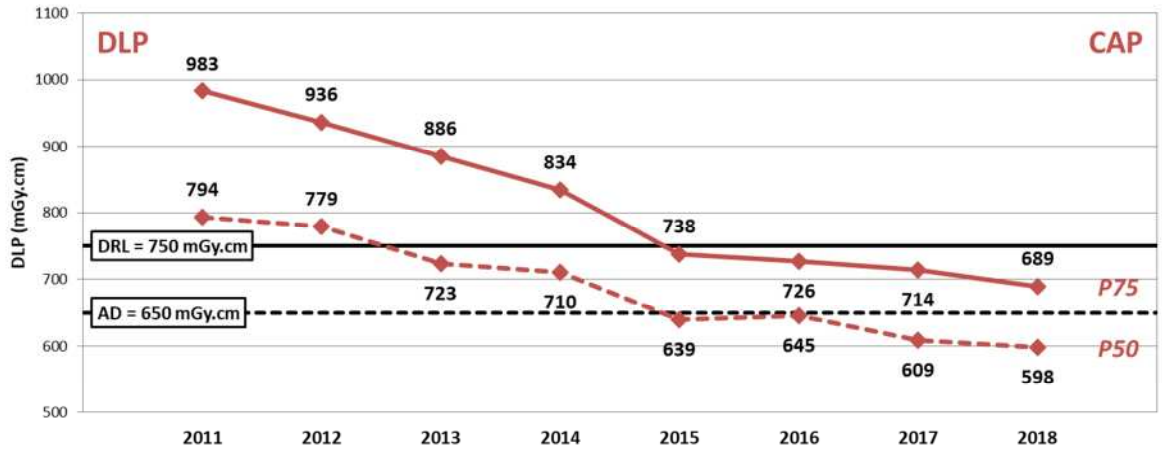


Figure 68: Change in the 75th and 50th percentiles of DLP for adult chest-abdomen-pelvis CT acquisitions.

Analysis of 2016-2018 data

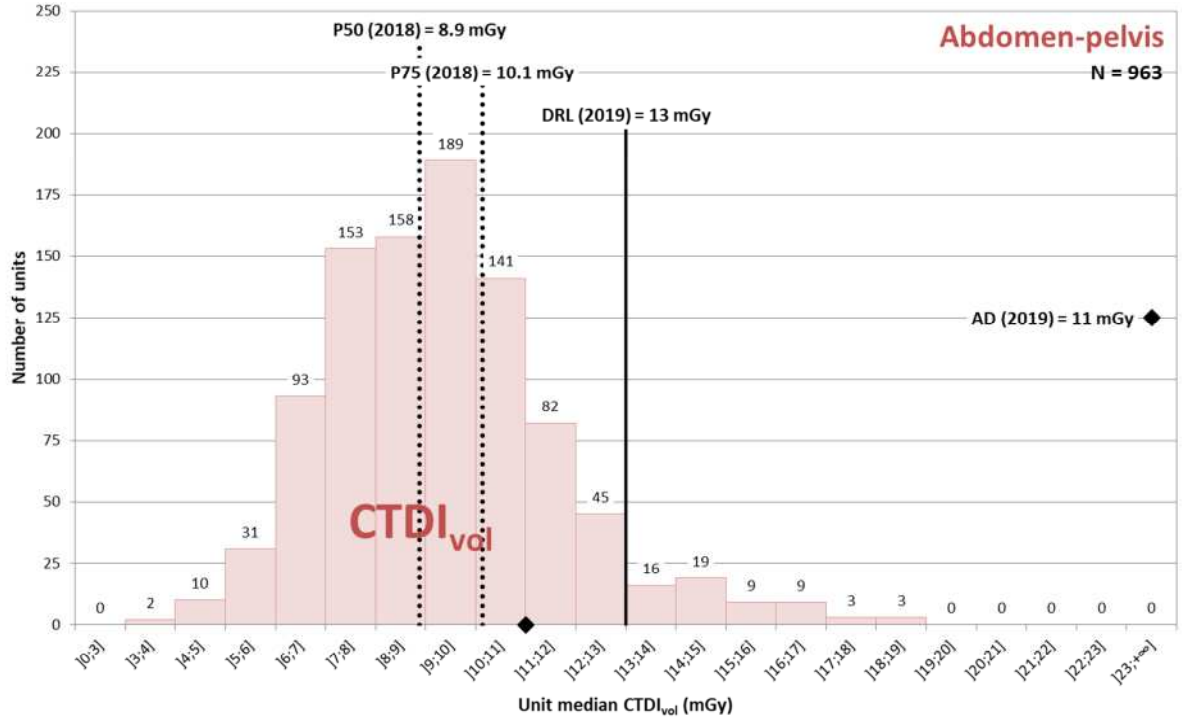


Figure 69: Distribution of unit median $CTDI_{vol}$ from dose assessments performed for adult abdomen-pelvis CT acquisitions.

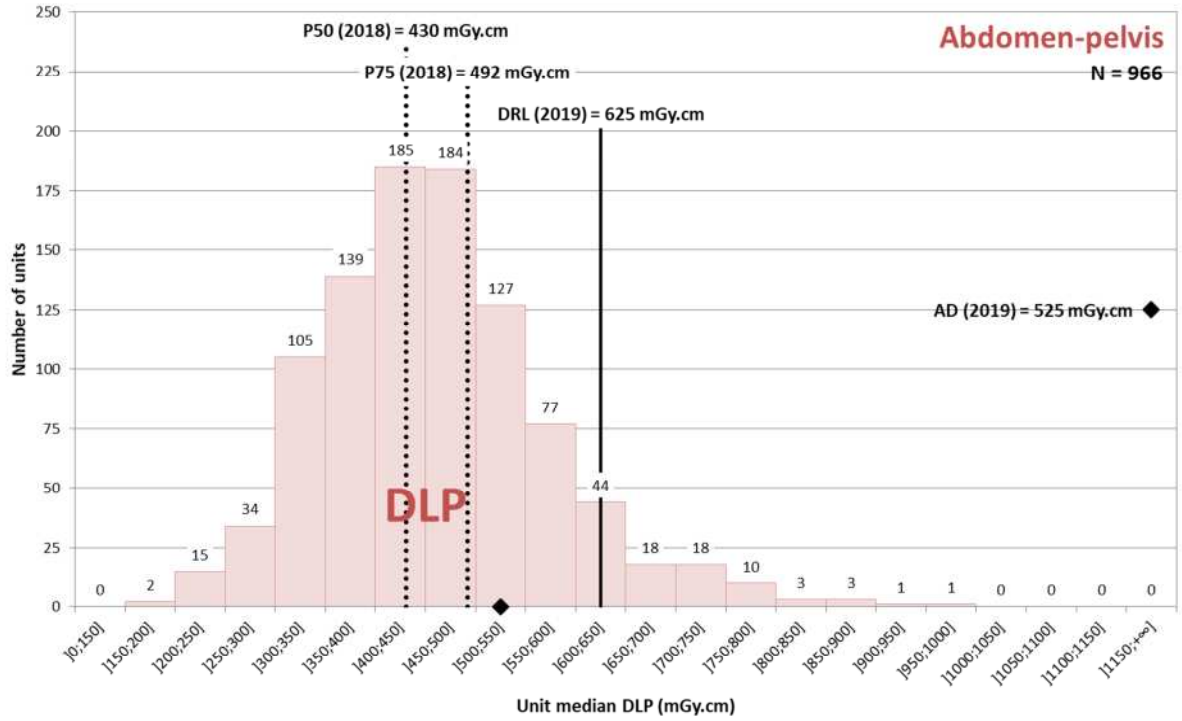


Figure 70: Distribution of unit median DLP from dose assessments performed for adult abdomen-pelvis CT acquisitions.

Table 34: Statistical data associated with the distribution of unit median $CTDI_{vol}$ and DLP from dose assessments performed for adult abdomen-pelvis CT acquisitions.

Abdomen-pelvis CT (adults)

DRL quantity	$CTDI_{vol}$ (mGy)		DLP (mGy.cm)	
DRL in force during data collection (2011 DRL)	17		800	
DRL in force (2019 DRL)	**13**		**625**	
AD in force (2019 AD)	11		525	
Period	**2016 - 2018**	**2018**	**2016 - 2018**	**2018**
Number of units	963	354	966	354
DRL quantity	**$CTDI_{vol}$ (mGy)**		**DLP (mGy.cm)**	
75th percentile	**10.5**	**10.1**	**524**	**492**
50th percentile	9.2	8.9	450	430
Minimum - maximum values	3.2 - 18.5	3.2 - 18.3	157 - 967	157 - 845
Number of units above the 2011 DRL	5 (0.5%)	1 (0.3%)	8 (0.8%)	1 (0.3%)
Number of units above the 2019 DRL	59 (6%)	11 (3%)	73 (8%)	13 (4%)

Change since 2011

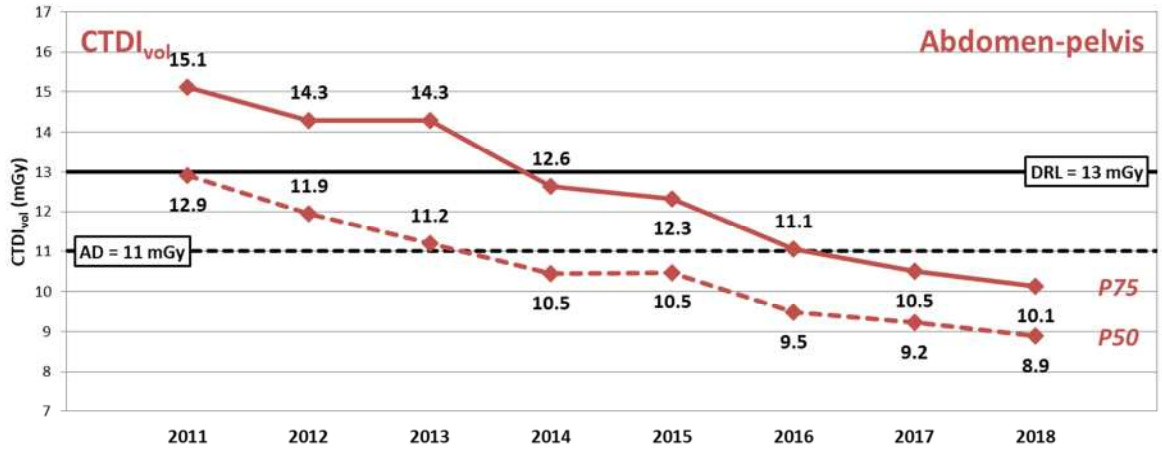


Figure 71: Change in the 75th and 50th percentiles of $CTDI_{vol}$ for adult abdomen-pelvis CT acquisitions.

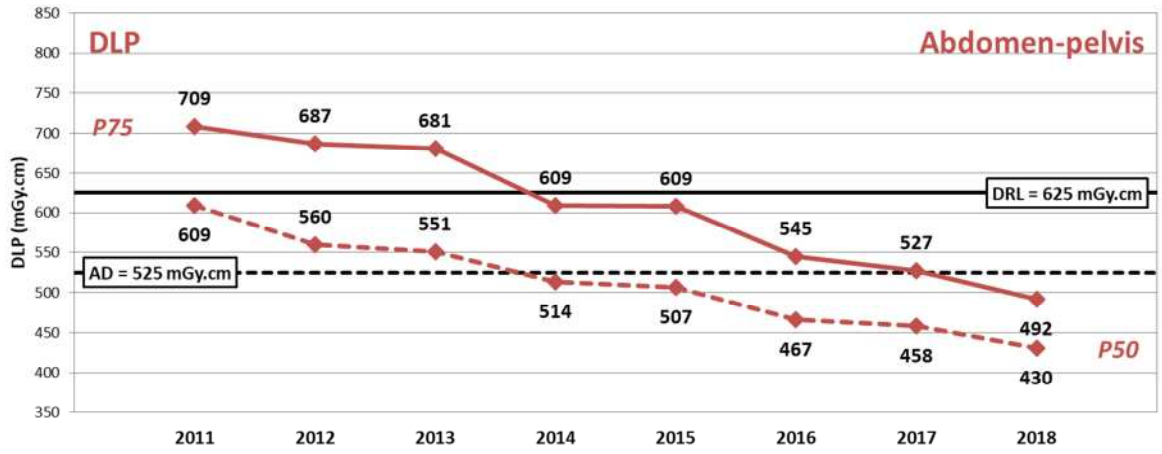


Figure 72: Change in the 75th and 50th percentiles of DLP for adult abdomen-pelvis CT acquisitions.

Analysis of 2016-2018 data

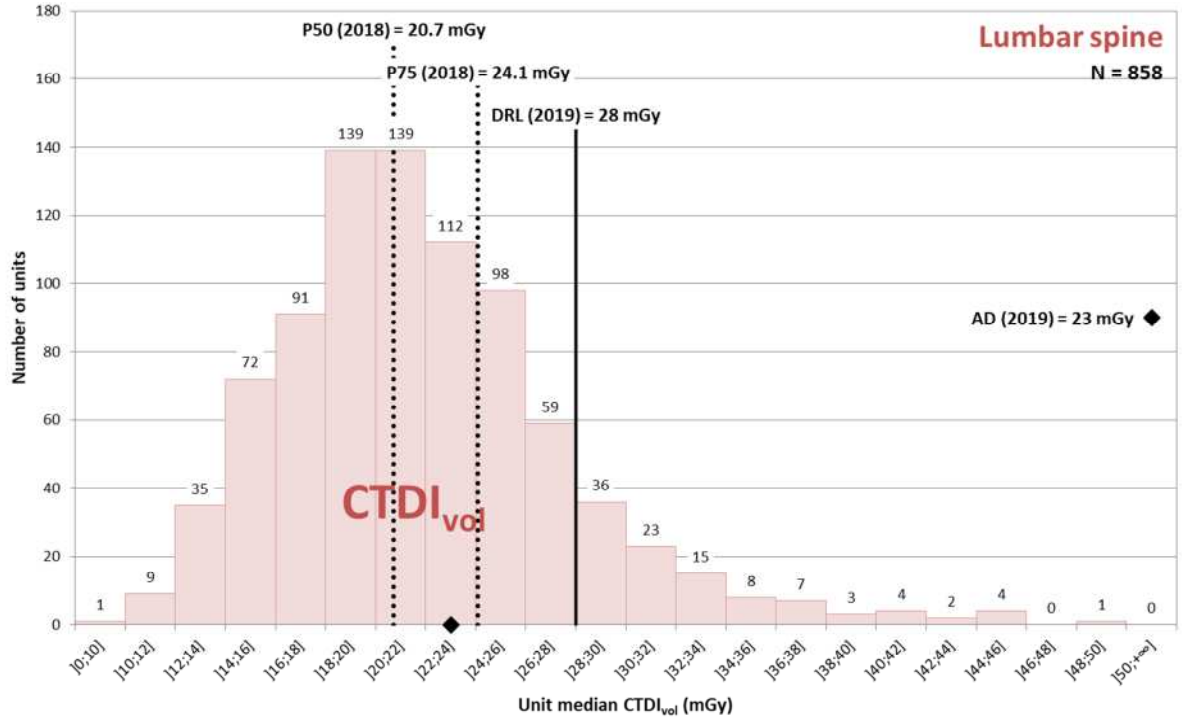


Figure 73: Distribution of unit median $CTDI_{vol}$ from dose assessments performed for adult lumbar spine CT acquisitions.

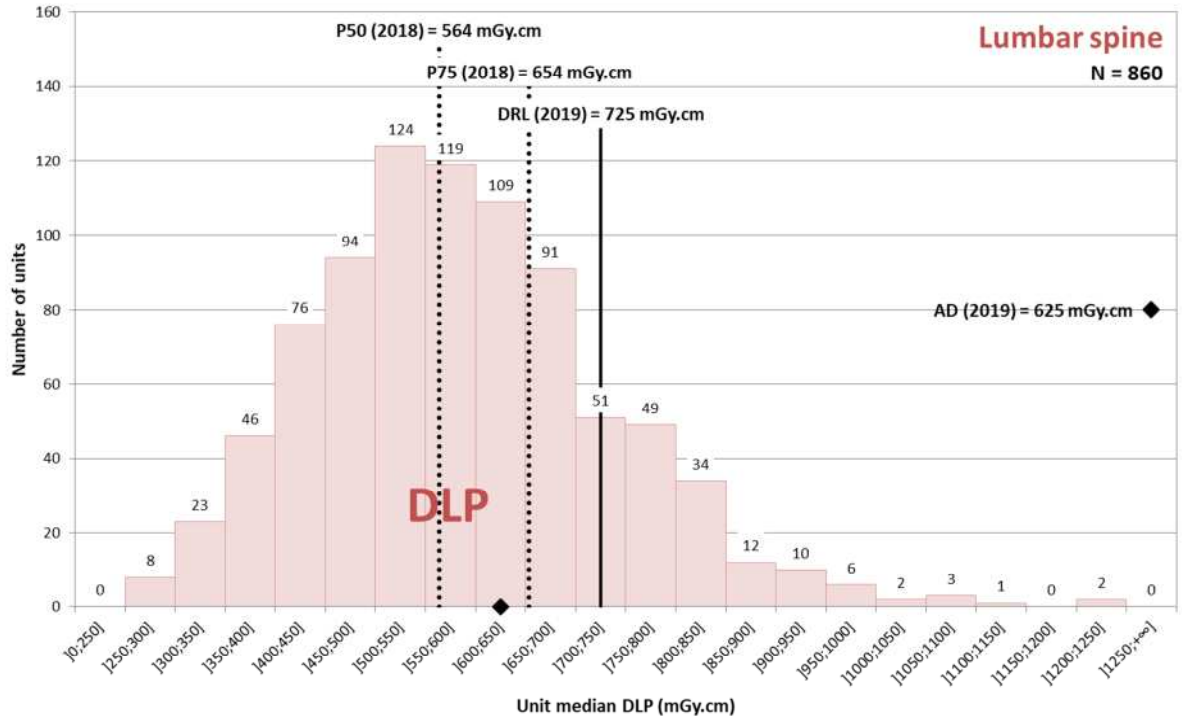


Figure 74: Distribution of unit median DLP from dose assessments performed for adult lumbar spine CT acquisitions.

Table 35: Statistical data associated with the distribution of unit median $CTDI_{vol}$ and DLP from dose assessments performed for adult lumbar spine CT acquisitions.

Lumbar spine CT (adults)

DRL quantity	$CTDI_{vol}$ (mGy)		DLP (mGy.cm)	
DRL in force during data collection (2011 DRL)	45		700	
DRL in force (2019 DRL)	**28**		**725**	
AD in force (2019 AD)	23		625	
Period	**2016 - 2018**	**2018**	**2016 - 2018**	**2018**
Number of units	858	298	860	298
DRL quantity	**$CTDI_{vol}$ (mGy)**		**DLP (mGy.cm)**	
75th percentile	**24.9**	**24.1**	**671**	**654**
50th percentile	21.1	20.7	573	564
Minimum - maximum values	9.8 - 48.1	10.9 - 48.1	256 - 1236	256 - 1202
Number of units above the 2011 DRL	0	0	226 (26%)	64 (22%)
Number of units above the 2019 DRL	103 (12%)	27 (9%)	141 (16%)	40 (13%)

Change since 2011

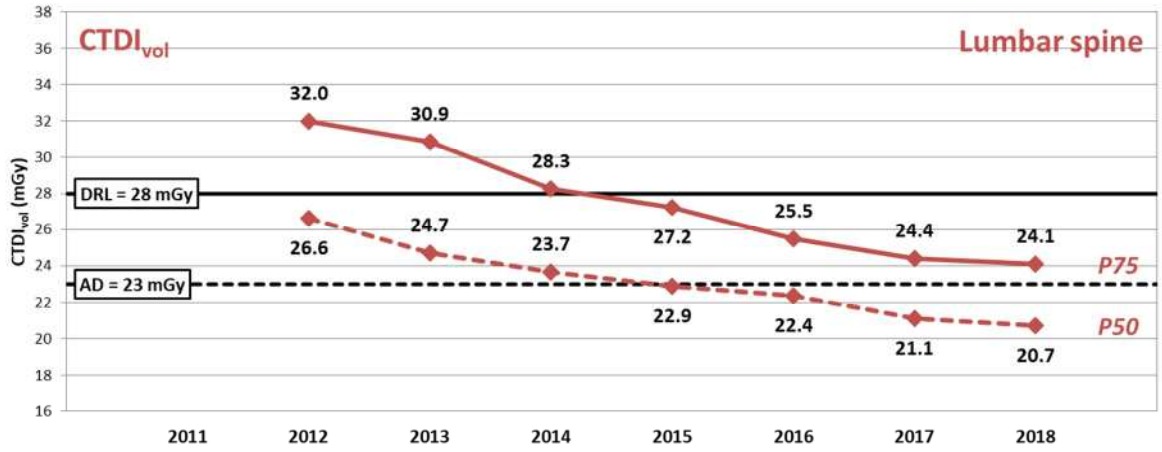


Figure 75: Change in the 75th and 50th percentiles of $CTDI_{vol}$ for adult lumbar spine CT acquisitions.

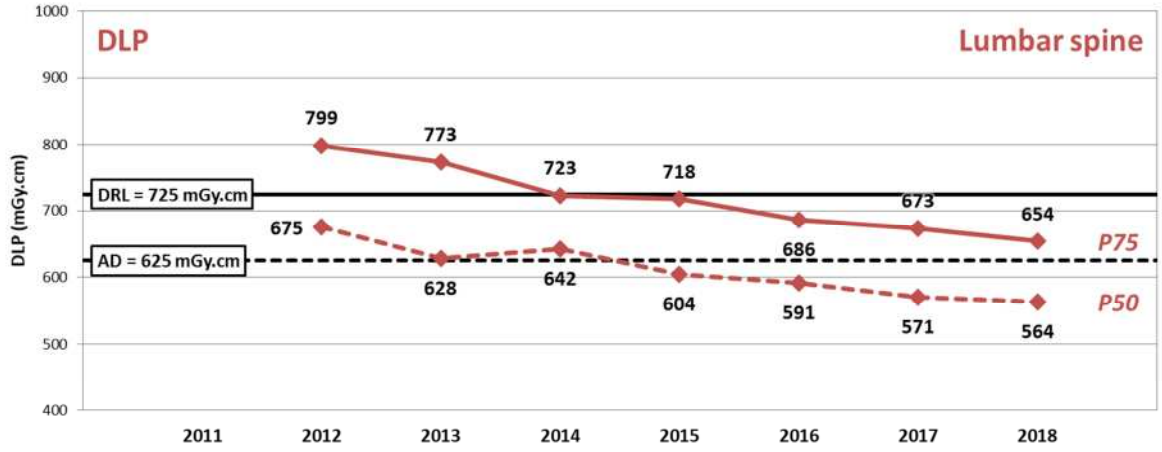


Figure 76: Change in the 75th and 50th percentiles of DLP for adult lumbar spine CT acquisitions.

Lumbar spine CT scans were added to the list of examinations subject to DRLs by the Order of 24 October 2011. Therefore, data for this type of examination only started being collected in 2012.

Analysis of 2016-2018 data

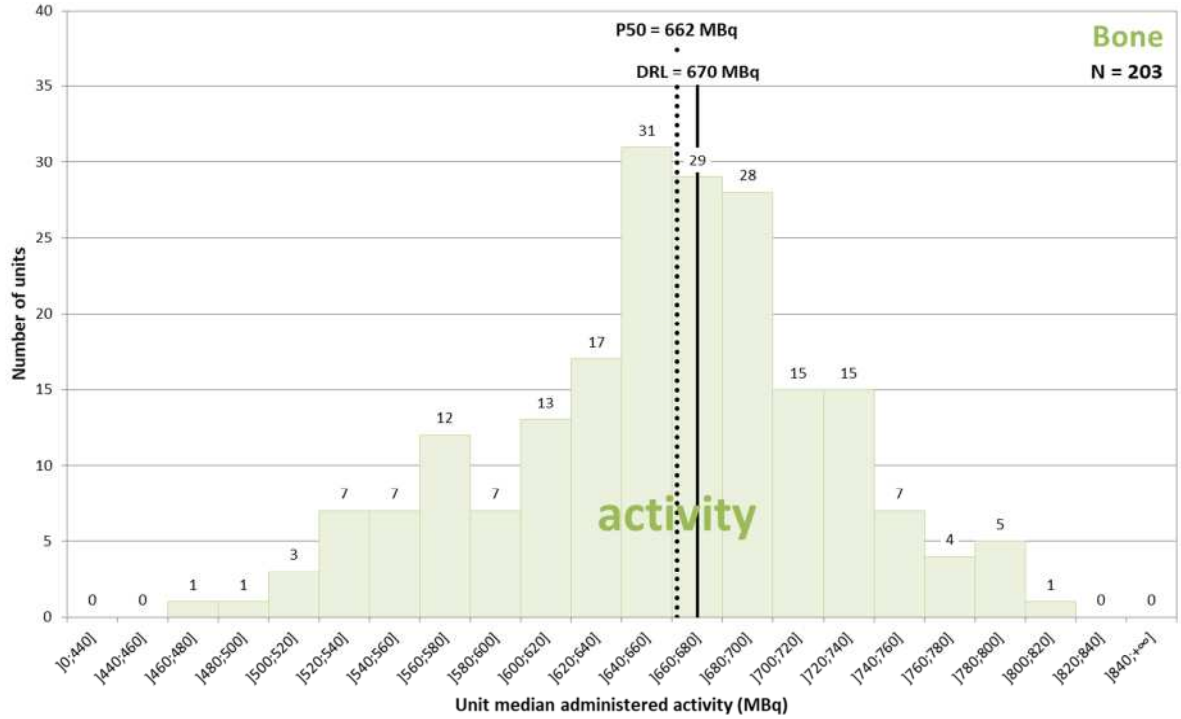


Figure 77: Distribution of unit median administered activities from dose assessments performed for adult bone scans.

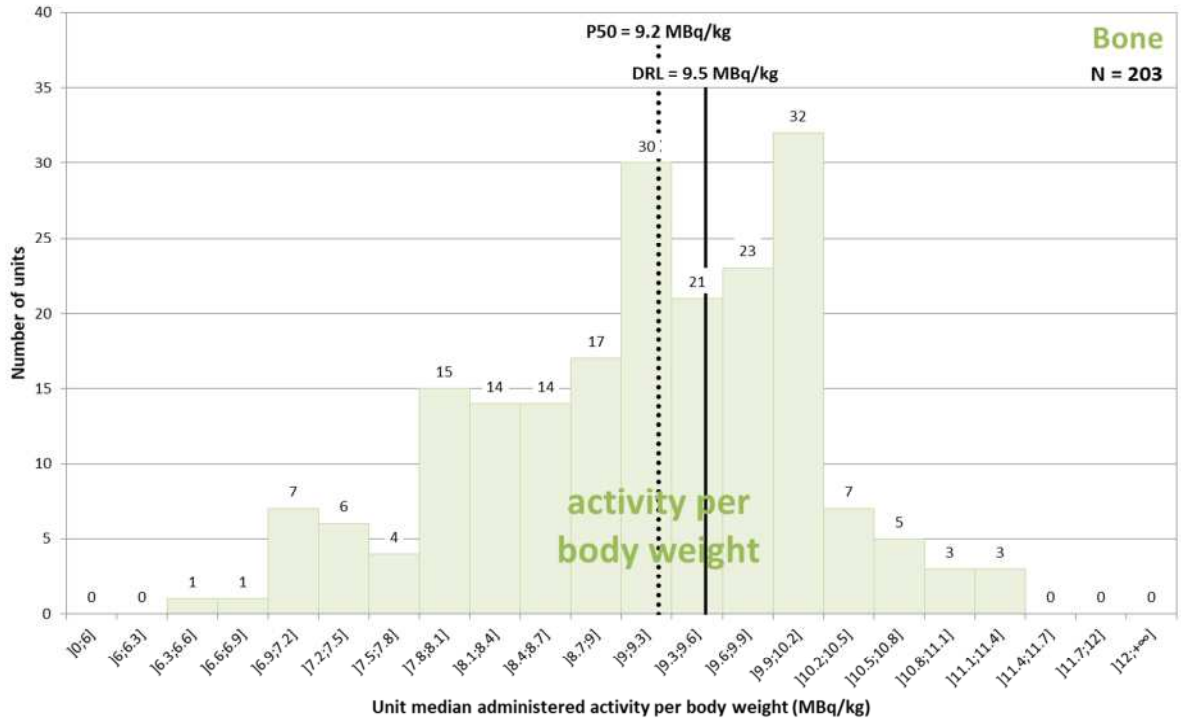


Figure 78: Distribution of unit median administered activities per body weight from dose assessments performed for adult bone scans.

Table 36: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult bone scans.

Bone scan (adults)

Radiopharmaceutical(s)	^{99m}Tc-HDP, ^{99m}Tc-DPD	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	700	-
DRL in force (2019 DRL)	670	9.5
Period	**2016 - 2018**	
Number of units	203	203
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**662**	**9.2**
Minimum - maximum values	469 - 808	6.3 - 11.2
Number of units above the 2011 DRL	49 (24%)	-
Number of units above the 2019 DRL	85 (42%)	78 (38%)

Change since 2011

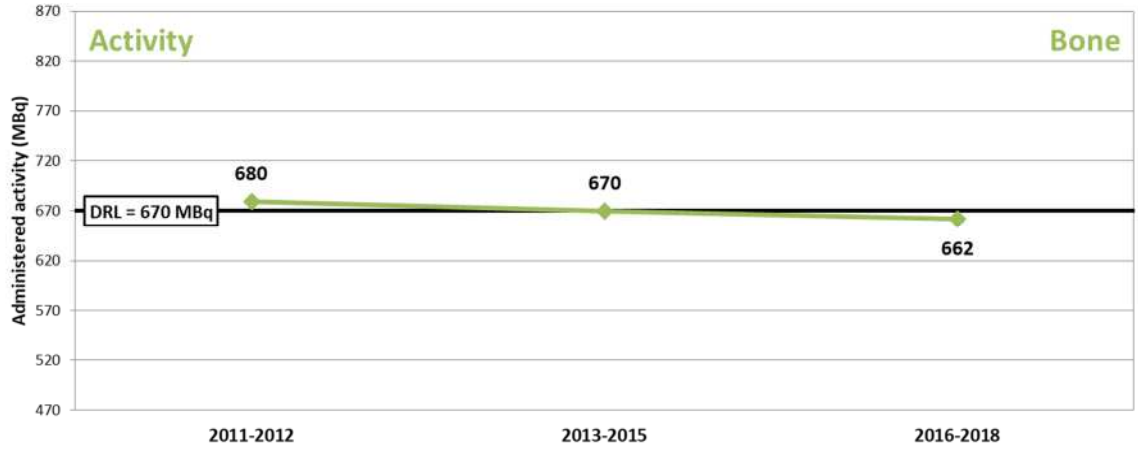


Figure 79: Change in the 50th percentile of administered activity for adult bone scans.

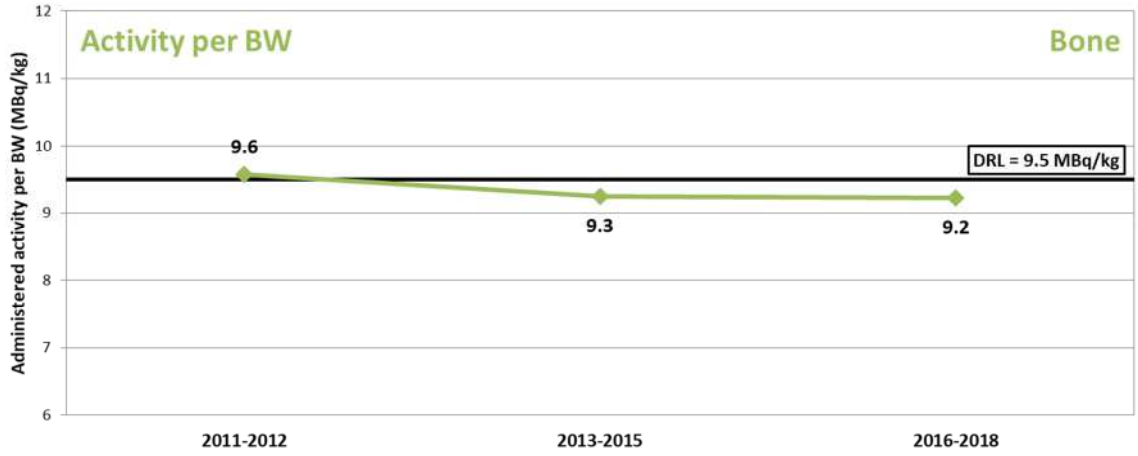


Figure 80: Change in the 50th percentile of administered activity per body weight for adult bone scans.

Analysis of 2016-2018 data

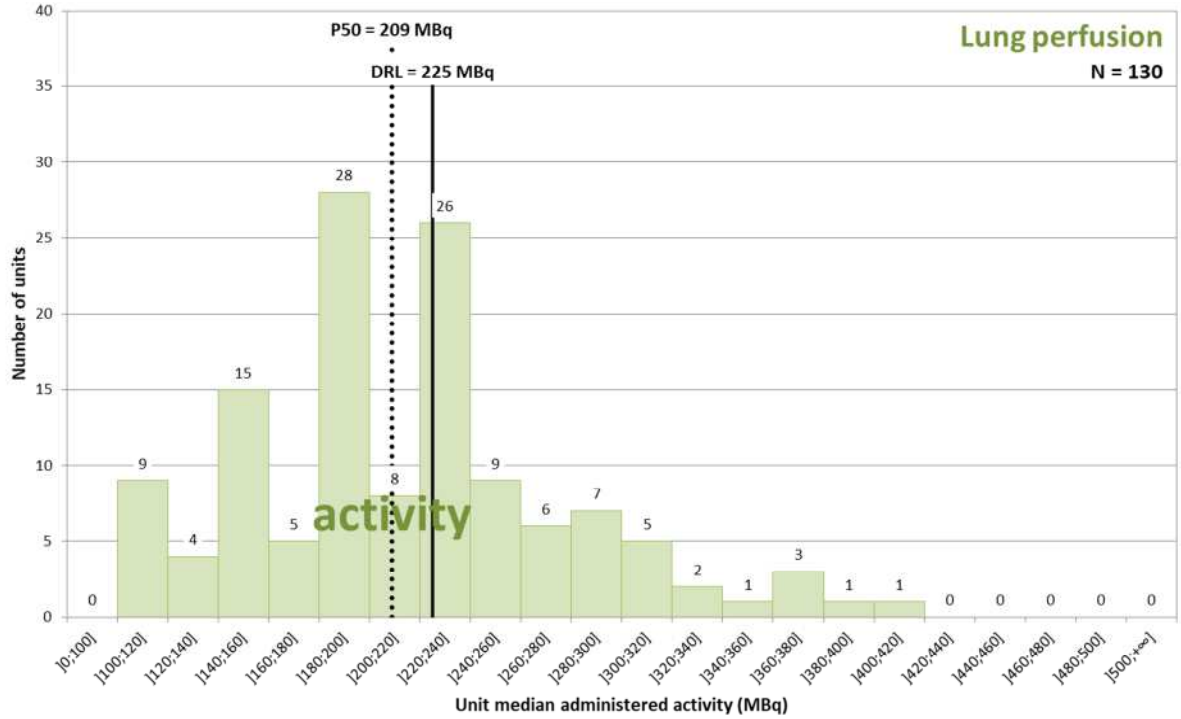


Figure 81: Distribution of unit median administered activities from dose assessments performed for adult perfusion lung scans.

Table 37: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult perfusion lung scans.

Lung perfusion scan (adults)

Radiopharmaceutical(s)	^{99m}Tc-macroaggregated human albumin, ^{99m}Tc-microspheres
DRL quantity	**Administered activity (MBq)**
DRL in force during data collection (2011 DRL)	240
DRL in force (2019 DRL)	225

Period	**2016 - 2018**
Number of units	130

DRL quantity	**Administered activity (MBq)**
50th percentile	**209**
Minimum - maximum values	107 - 404
Number of units above the 2011 DRL	38 (29%)
Number of units above the 2019 DRL	59 (45%)

Change since 2011

Figure 82: Change in the 50th percentile of administered activity for adult perfusion lung scans.

Analysis of 2016-2018 data

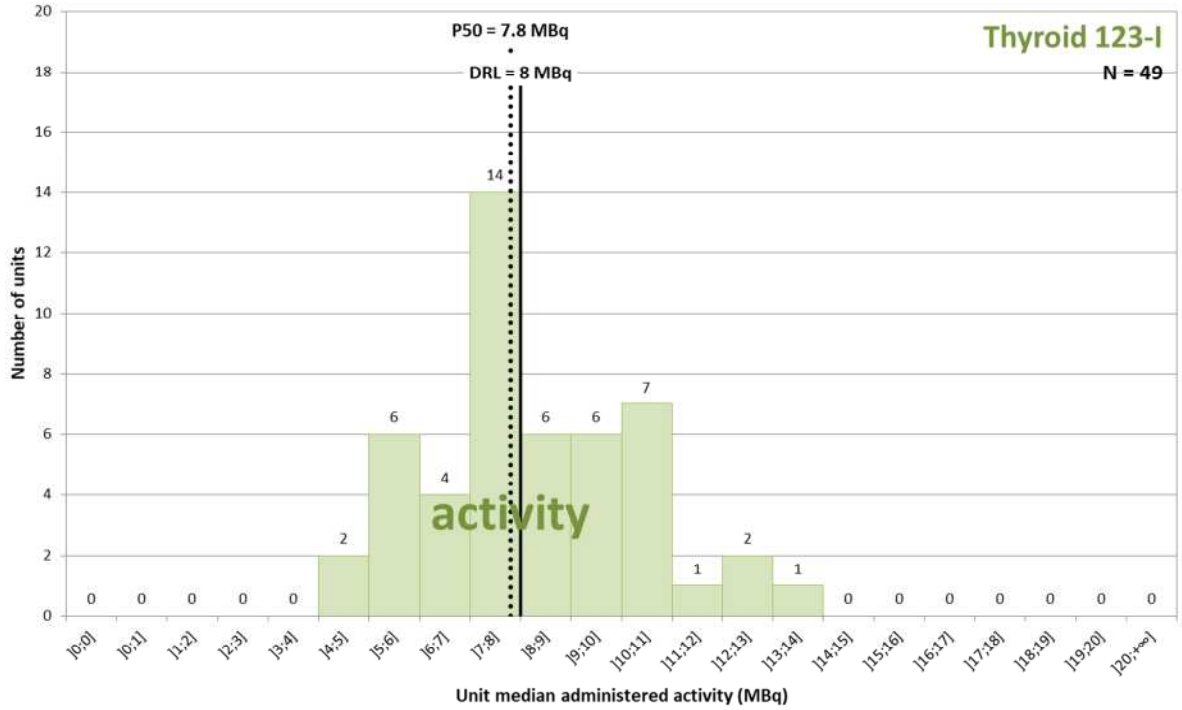


Figure 83: Distribution of unit median administered activities from dose assessments performed for adult thyroid scans with iodine-123.

Table 38: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult thyroid scans with iodine-123.

Thyroid scan (adults)

Radiopharmaceutical(s)	^{123}I (sodium iodide)
DRL quantity	**Administered activity (MBq)**
DRL in force during data collection (2011 DRL)	10
DRL in force (2019 DRL)	8

Period	**2016 - 2018**
Number of units	49

DRL quantity	**Administered activity (MBq)**
50th percentile	**7.8**
Minimum – maximum values	4.7 – 13.3
Number of units above the 2011 DRL	12 (24%)
Number of units above the 2019 DRL	23 (47%)

Change since 2011

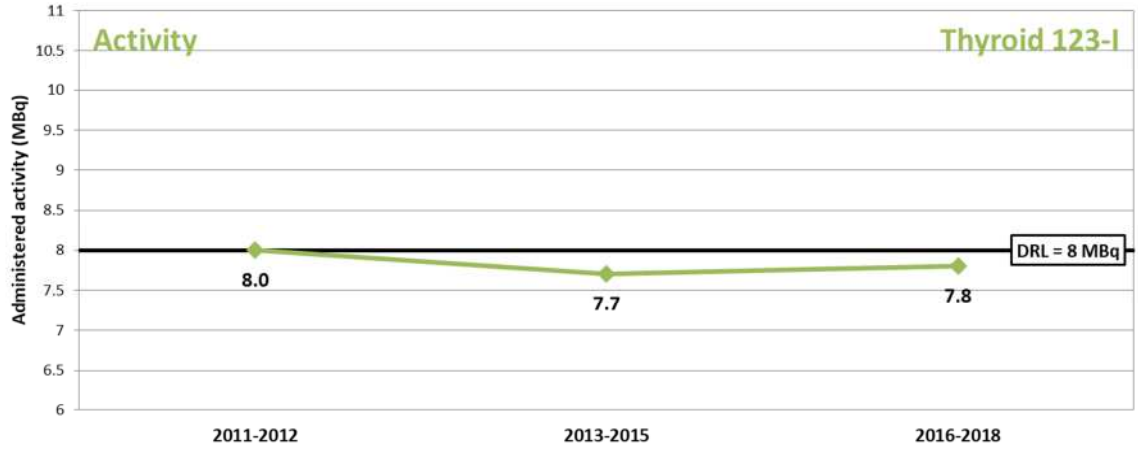


Figure 84: Change in the 50th percentile of administered activity for adult thyroid scans with iodine-123.

Analysis of 2016-2018 data

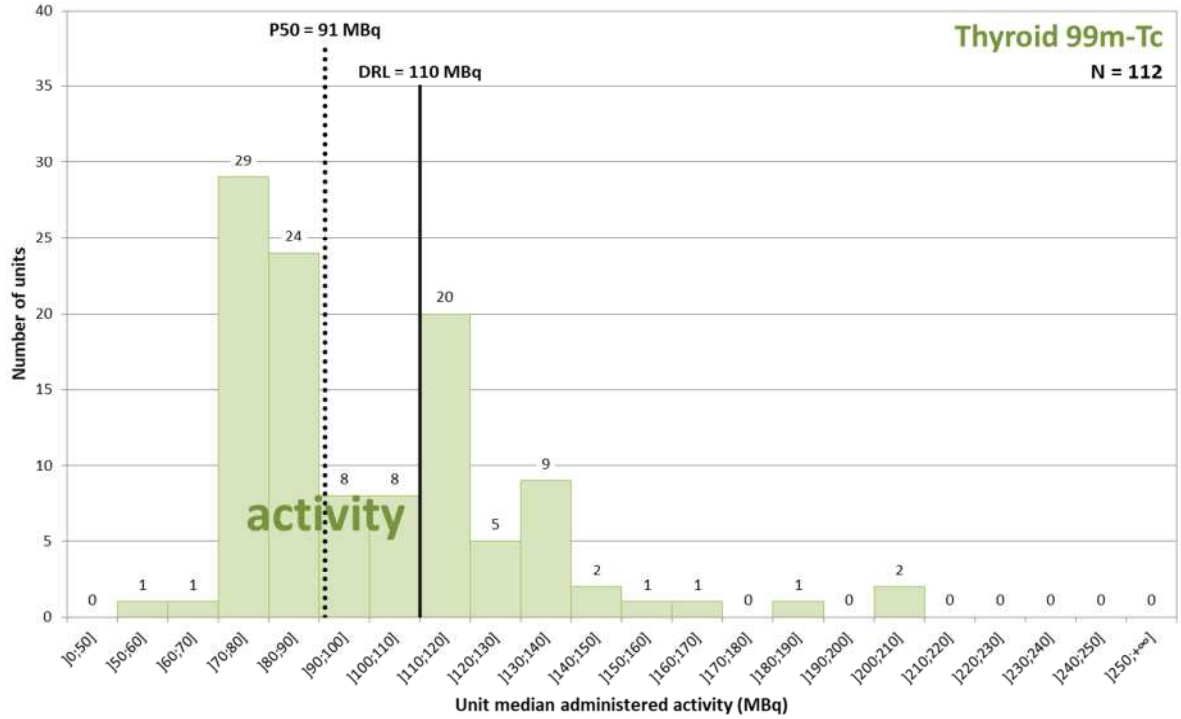


Figure 85: Distribution of unit median administered activities from dose assessments performed for adult thyroid scans with technetium-99m.

Table 39: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult thyroid scans with technetium-99m.

Thyroid scan (adults)

Radiopharmaceutical(s)	^{99m}Tc (sodium pertechnetate)
DRL quantity	**Administered activity (MBq)**
DRL in force during data collection (2011 DRL)	80
DRL in force (2019 DRL)	110

Period	**2016 - 2018**
Number of units	112

DRL quantity	**Administered activity (MBq)**
50th percentile	**91**
Minimum - maximum values	54 - 202
Number of units above the 2011 DRL	81 (72%)
Number of units above the 2019 DRL	41 (37%)

Change since 2011

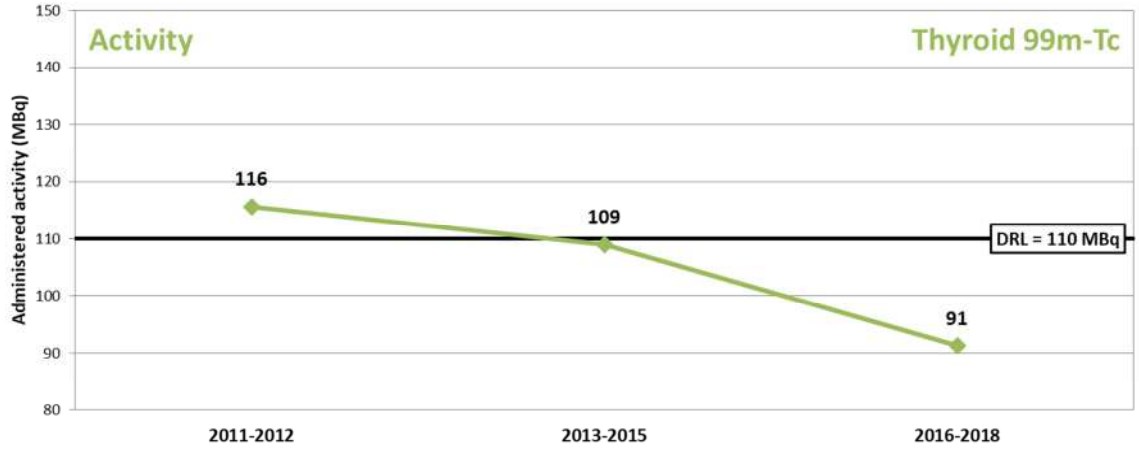


Figure 86: Change in the 50th percentile of administered activity for adult thyroid scans with technetium-99.

Analysis of 2016-2018 data

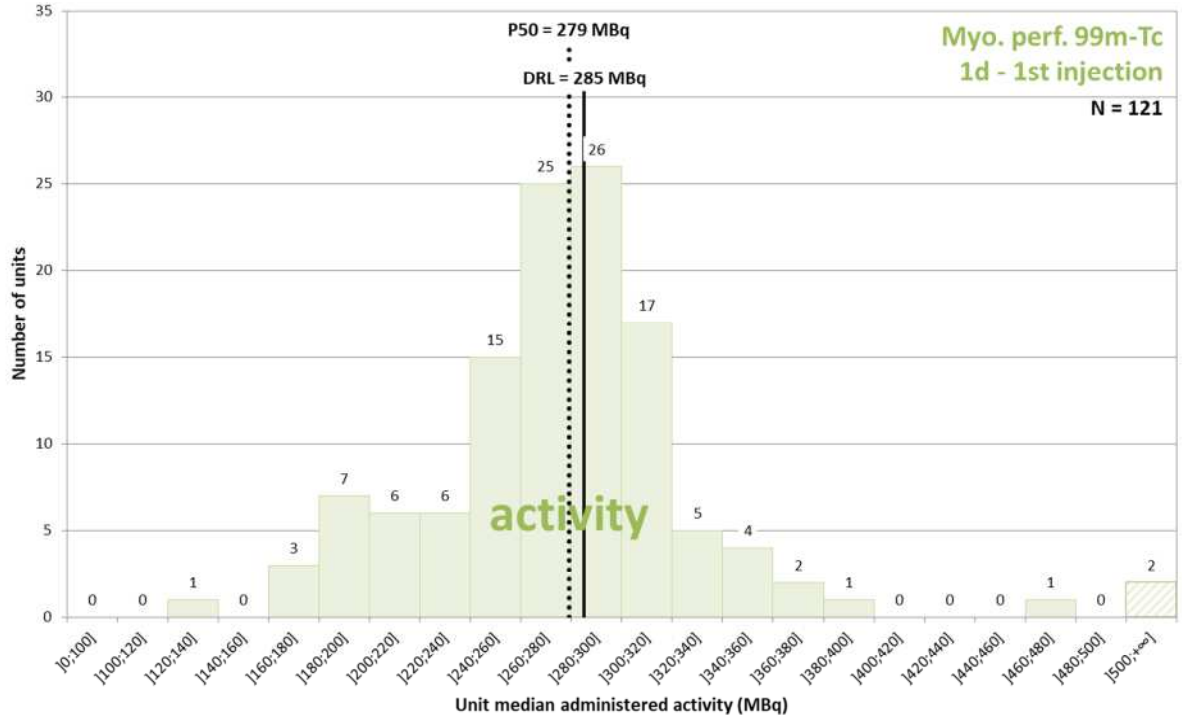


*Figure 87: Distribution of unit median administered activities for the **first injection** from dose assessments performed for **1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

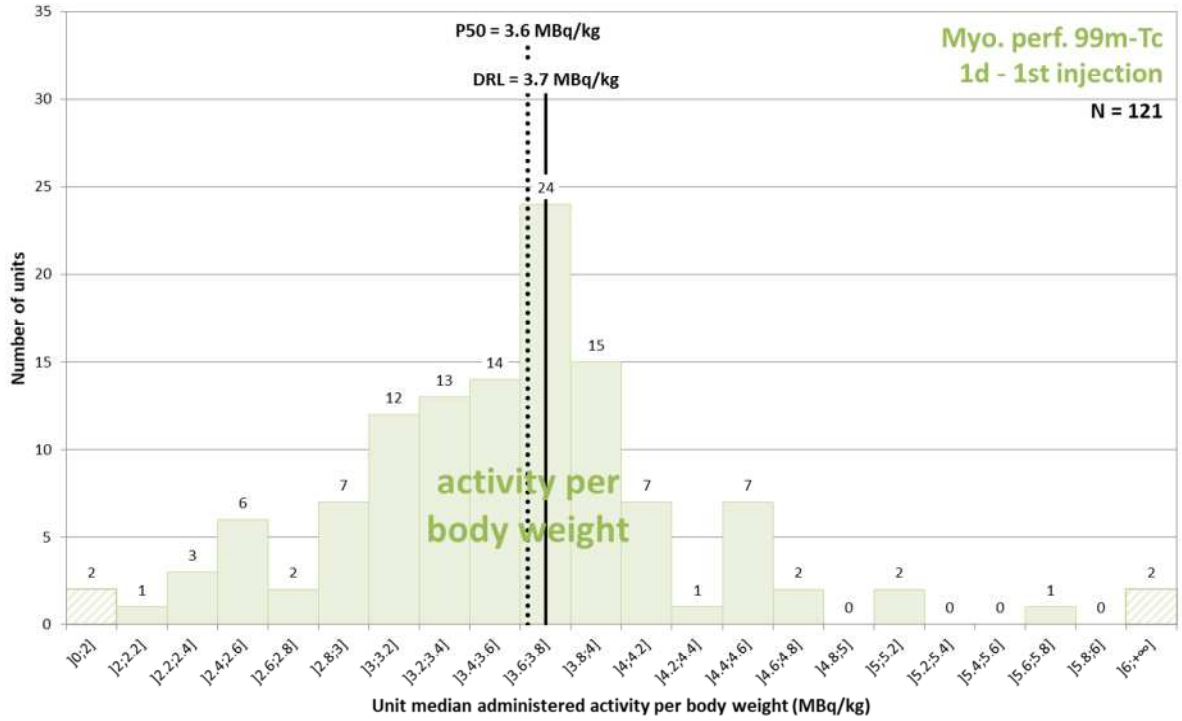


*Figure 88: Distribution of unit median administered activities per body weight for the **first injection** from dose assessments performed for **1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

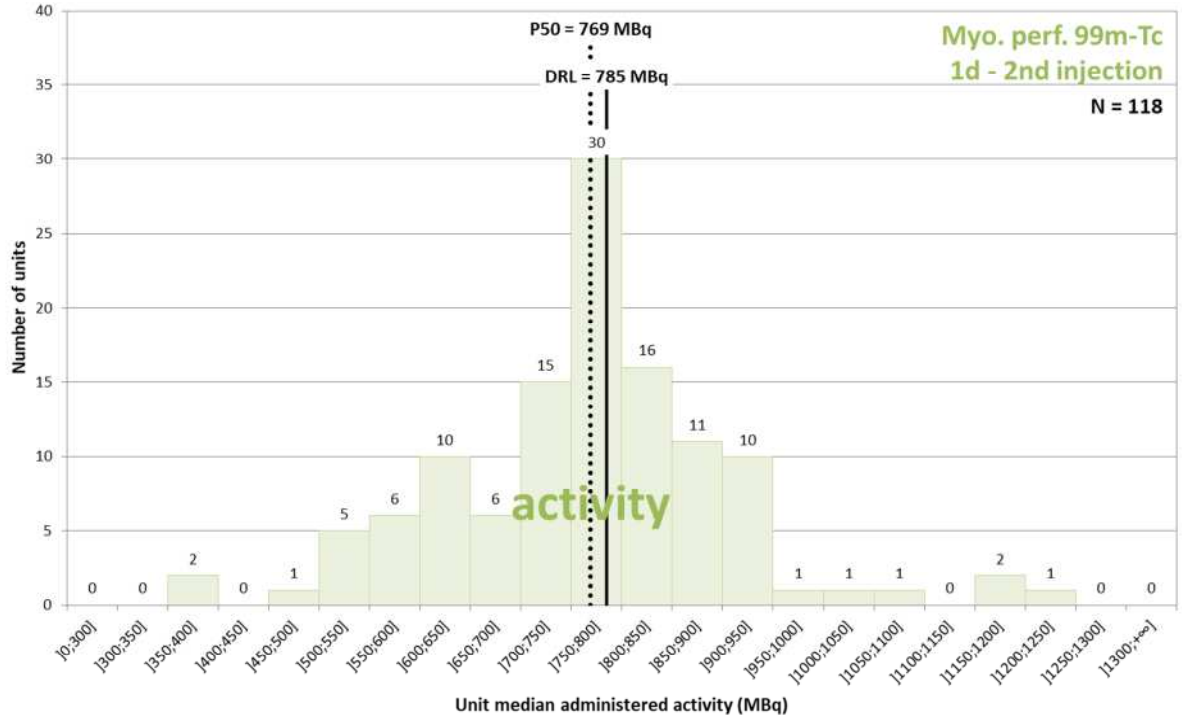


*Figure 89: Distribution of unit median administered activities for the **second injection** from dose assessments performed for **1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

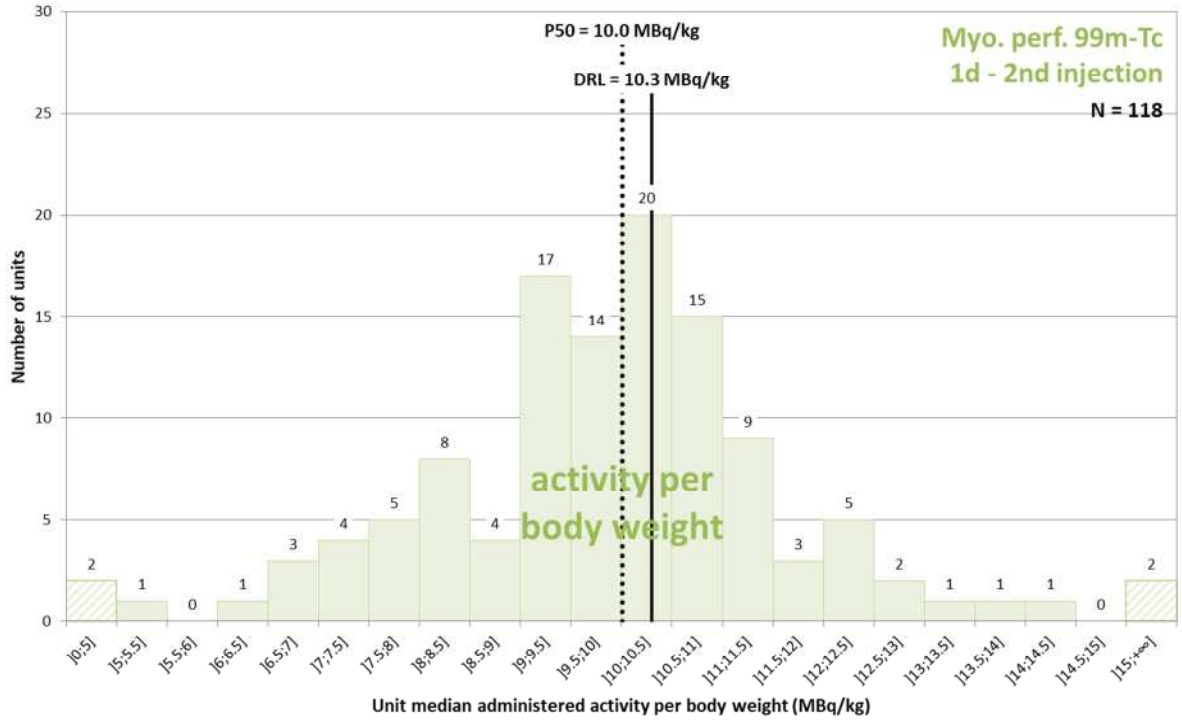


*Figure 90: Distribution of unit median administered activities per body weight for the **second injection** from dose assessments performed for **1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

*Table 40: Statistical data associated with the distribution of unit median administered activities for the **first injection** from dose assessments performed for **1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

Myocardial perfusion SPECT scan with stress test (dynamic or pharmacological)

Radiopharmaceutical(s)	^{99m}Tc-MIBI, ^{99m}Tc-tetrofosmin	
Protocol and injection	1-day protocol: first injection	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	300	-
DRL in force (2019 DRL)	285	3.7
Period	**2016 - 2018**	
Number of units	121	121
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**279**	**3.6**
Minimum - maximum values	126 - 509	1.5 - 6.2
Number of units above the 2011 DRL	32 (26%)	-
Number of units above the 2019 DRL	52 (43%)	46 (38%)

*Table 41: Statistical data associated with the distribution of unit median administered activities for the **second injection** from dose assessments performed for **1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

Myocardial perfusion SPECT scan with stress test (dynamic or pharmacological)

Radiopharmaceutical(s)	^{99m}Tc-MIBI, ^{99m}Tc-tetrofosmin	
Protocol and injection	1-day protocol: second injection	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	800	-
DRL in force (2019 DRL)	785	10.3
Period	**2016 - 2018**	
Number of units	118	118
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**769**	**10.0**
Minimum - maximum values	368 - 1223	4.4 - 15.4
Number of units above the 2011 DRL	42 (36%)	-
Number of units above the 2019 DRL	48 (41%)	47 (40%)

Change since 2011

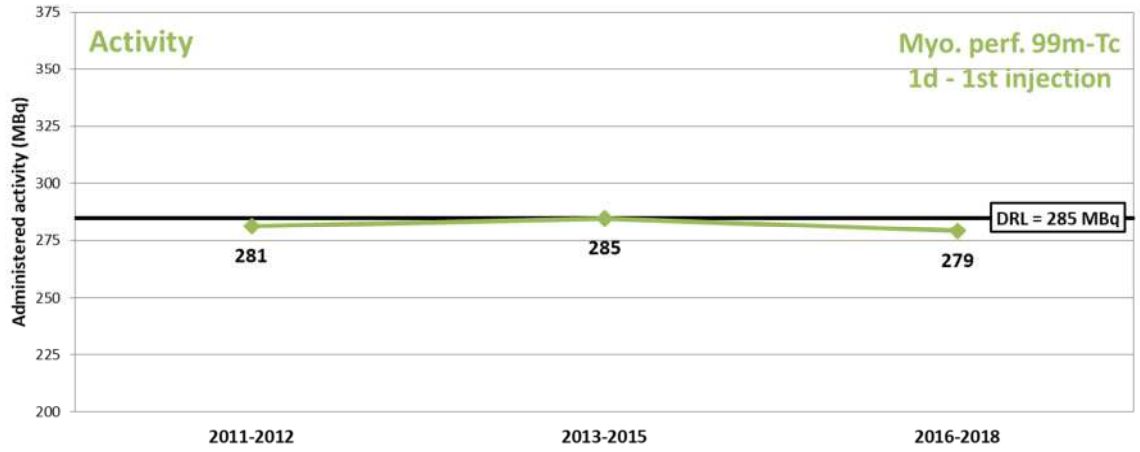


*Figure 91: Change in the 50th percentile of the activity administered for the **first injection for 1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

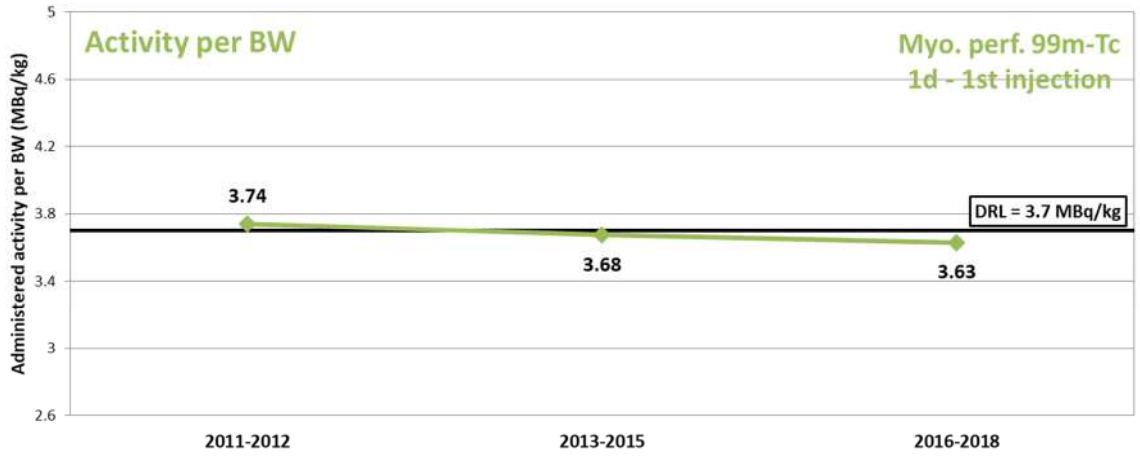


*Figure 92: Change in the 50th percentile of the activity per body weight administered for the **first injection for 1-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

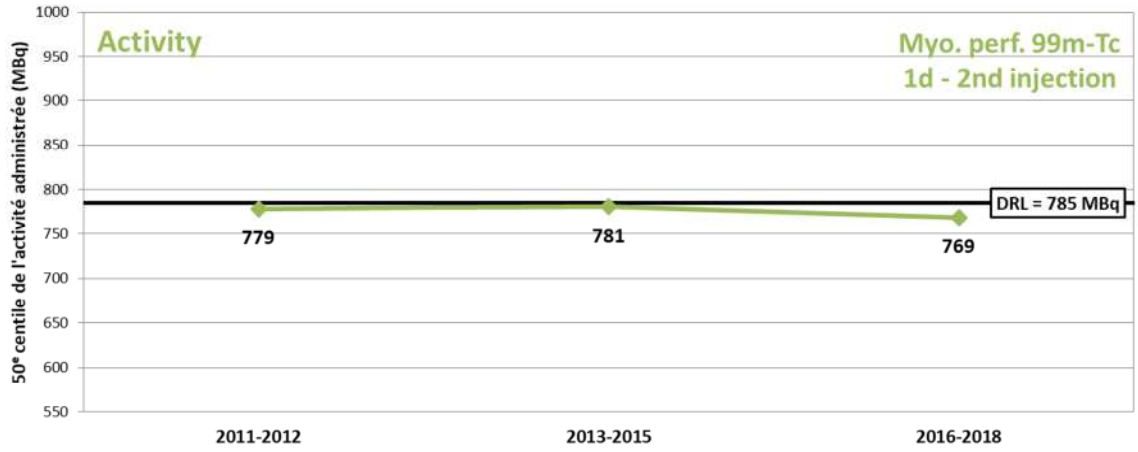


Figure 93: Change in the 50th percentile of the activity administered for the ***second injection for 1-day protocol*** *myocardial perfusion SPECT scans with technetium-99m.*

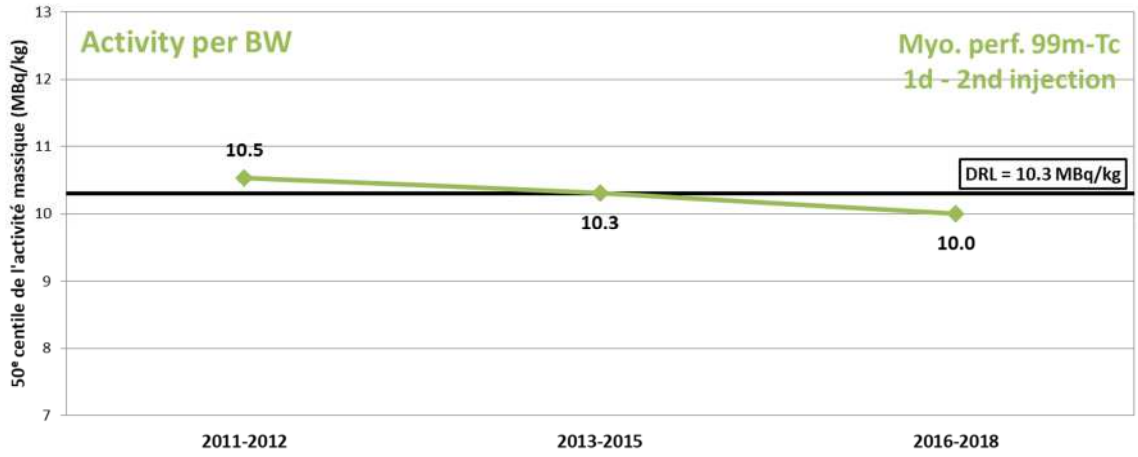


Figure 94: Change in the 50th percentile of the activity per body weight administered for the ***second injection for 1-day protocol*** *myocardial perfusion SPECT scans with technetium-99m.*

Analysis of 2016-2018 data

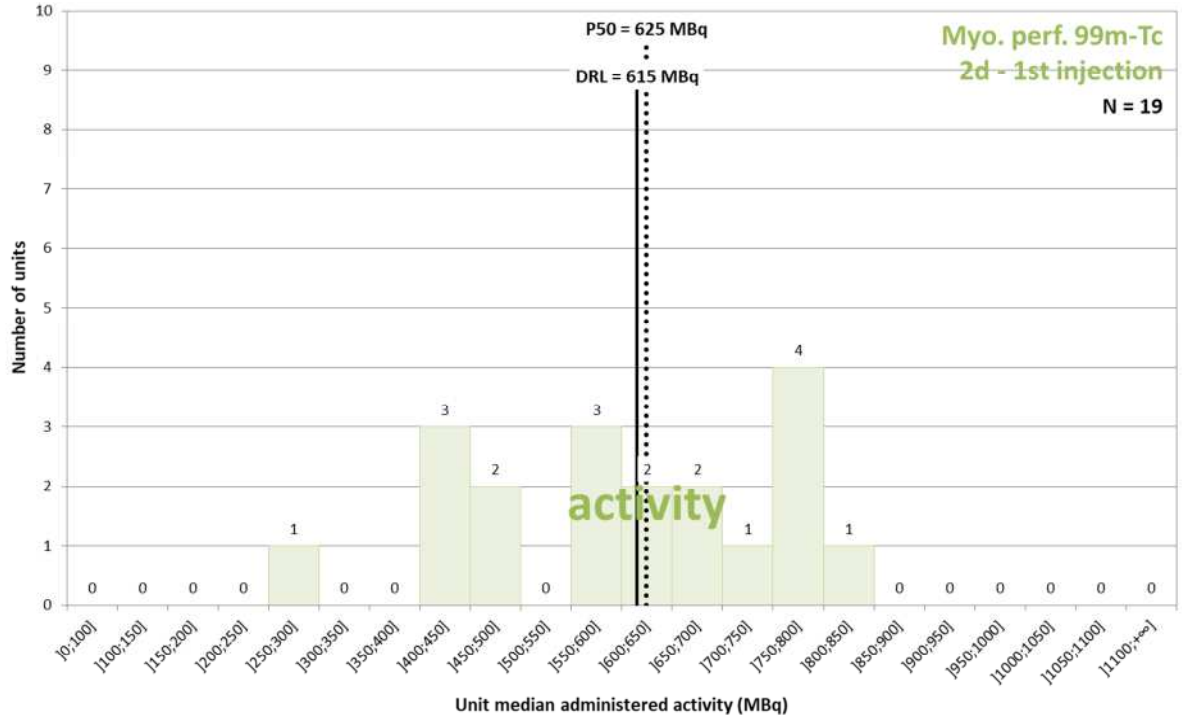


*Figure 95: Distribution of unit median administered activities for the **first injection** from dose assessments performed for **2-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

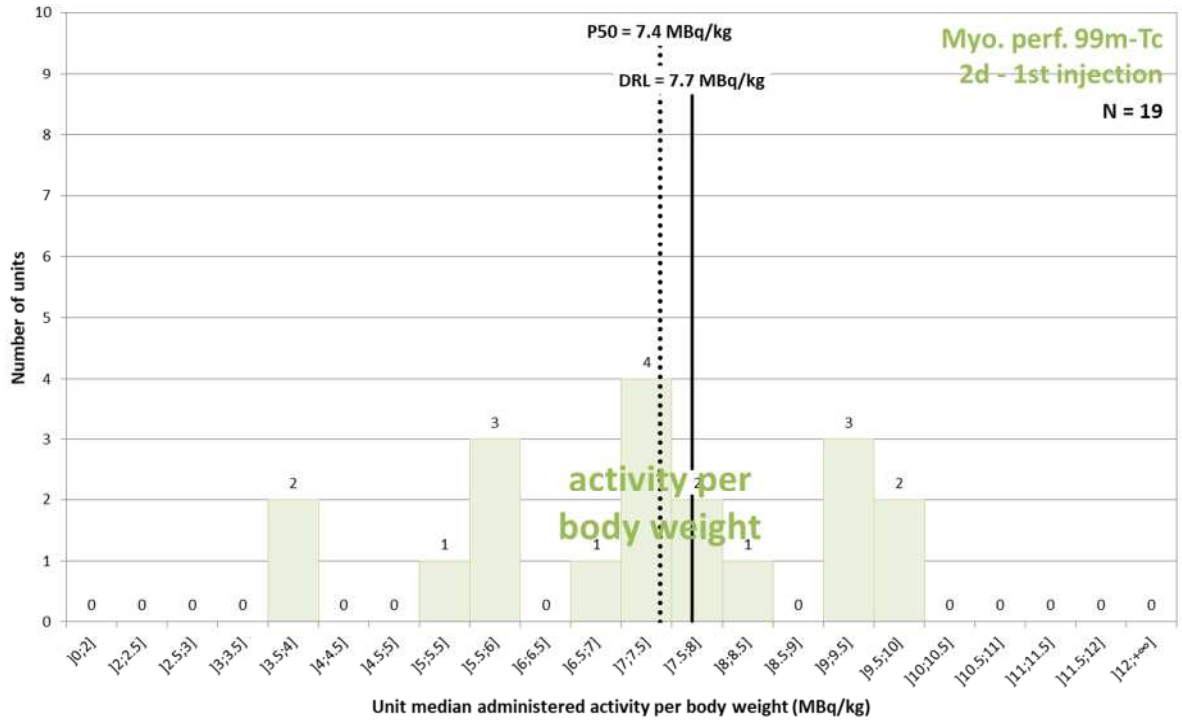


*Figure 96: Distribution of unit median administered activities per body weight for the **first injection** from dose assessments performed for **2-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

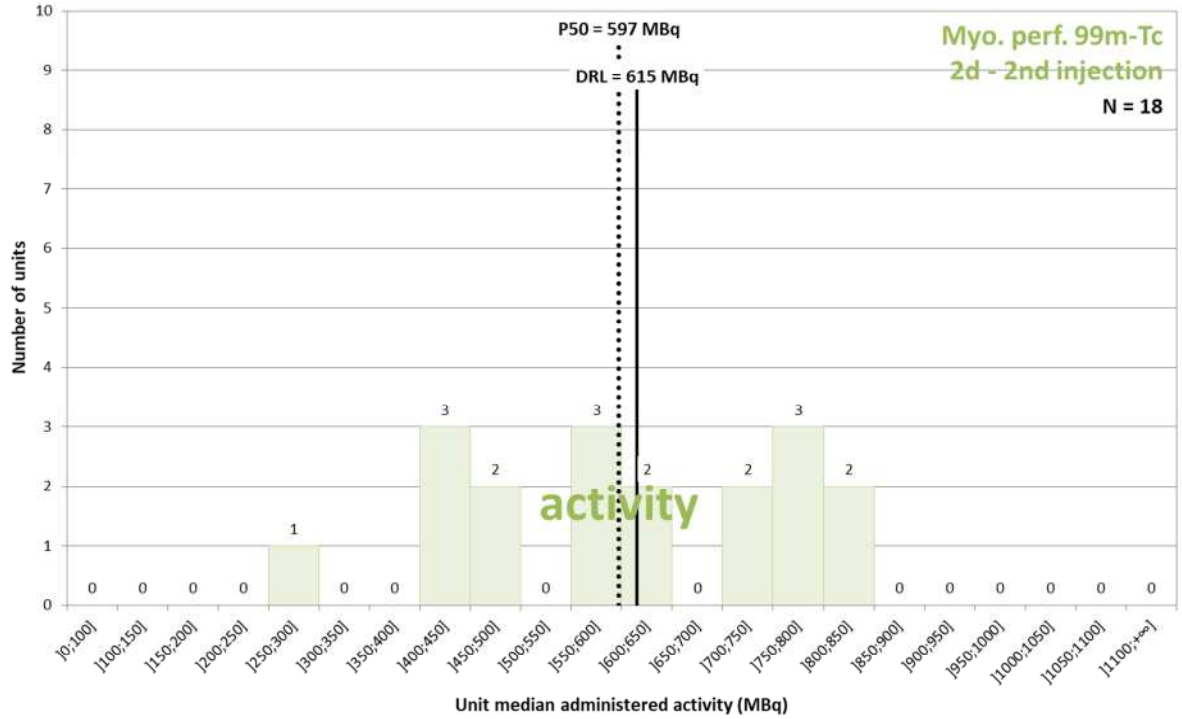


*Figure 97: Distribution of unit median administered activities for the **second injection** from dose assessments performed for **2-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

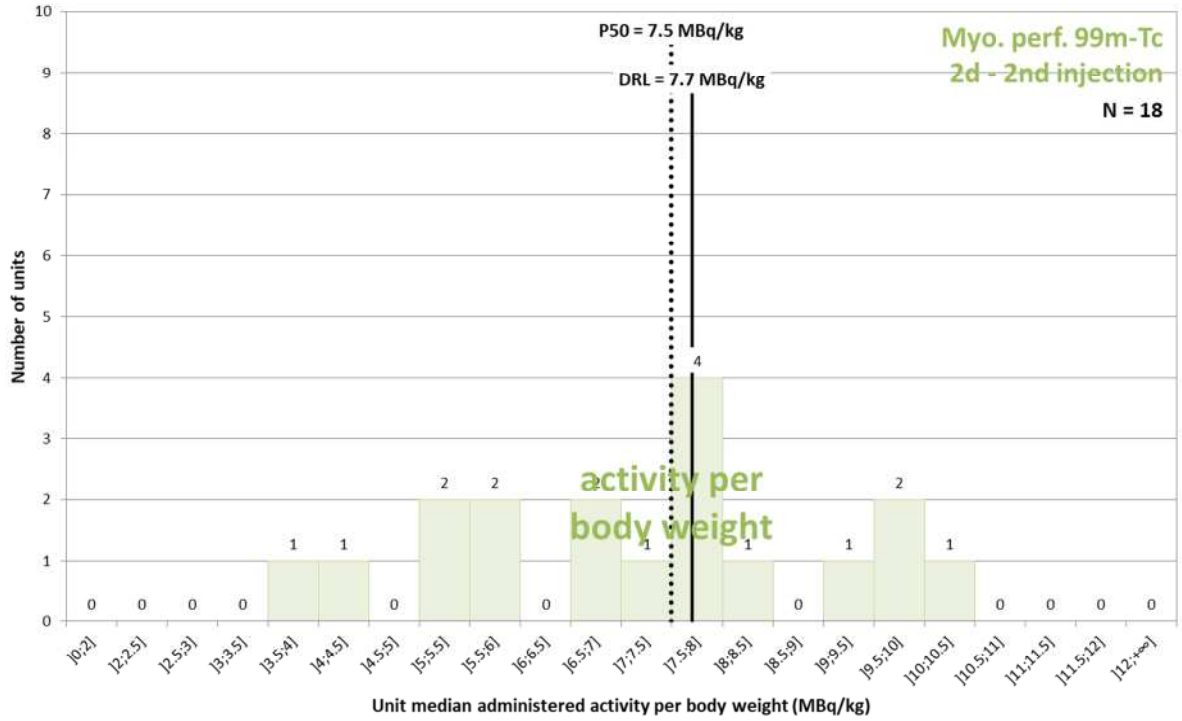


*Figure 98: Distribution of unit median administered activities per body weight for the **second injection** from dose assessments performed for **2-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

*Table 42: Statistical data associated with the distribution of unit median administered activities for the **first injection** from dose assessments performed for **2-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

Myocardial perfusion SPECT scan with stress test (dynamic or pharmacological)

Radiopharmaceutical(s)	^{99m}Tc-MIBI, ^{99m}Tc-tetrofosmin	
Protocol and injection	2-day protocol: first injection	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	850	-
DRL in force (2019 DRL)	615	7.7

Period	**2016 - 2018**	
Number of units	19	19

DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**625**	**7.4**
Minimum - maximum values	290 - 802	3.9 - 9.9
Number of units above the 2011 DRL	0	-
Number of units above the 2019 DRL	10 (53%)	8 (42%)

*Table 43: Statistical data associated with the distribution of unit median administered activities for the **second injection** from dose assessments performed for **2-day protocol** myocardial perfusion SPECT scans with technetium-99m.*

Myocardial perfusion SPECT scan with stress test (dynamic or pharmacological)

Radiopharmaceutical(s)	^{99m}Tc-MIBI, ^{99m}Tc-tetrofosmin	
Protocol and injection	2-day protocol: second injection	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	850	-
DRL in force (2019 DRL)	615	7.7

Period	**2016 - 2018**	
Number of units	18	18

DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**597**	**7.5**
Minimum - maximum values	289 - 811	3.9 - 10.2
Number of units above the 2011 DRL	0	-
Number of units above the 2019 DRL	9 (50%)	8 (44%)

Change since 2011

Due to the very low number of dose assessments received each year for 2-day protocol myocardial perfusion SPECT scans with technetium-99m, it does not seem relevant to present curves where variations are more related to the statistical inconsistency of data than the change in administered activity over time.

Analysis of 2016-2018 data

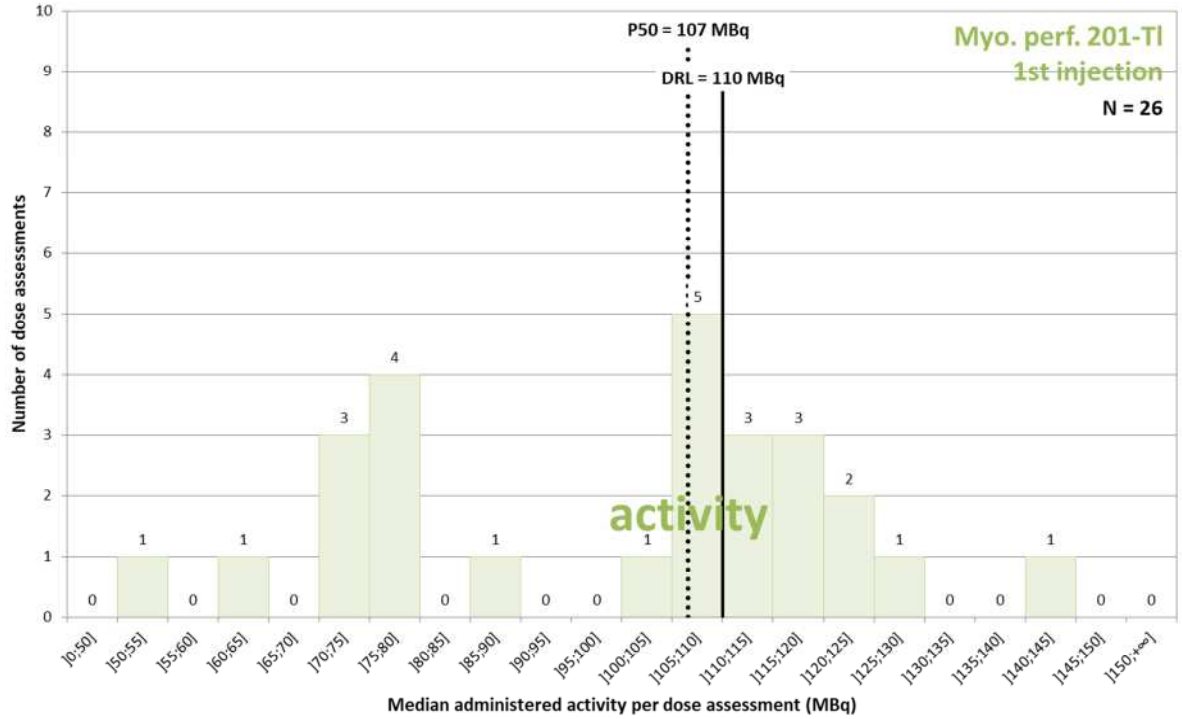


*Figure 99: Distribution of unit median administered activities for the **first injection** from dose assessments performed for myocardial perfusion SPECT scans with thallium-201.*

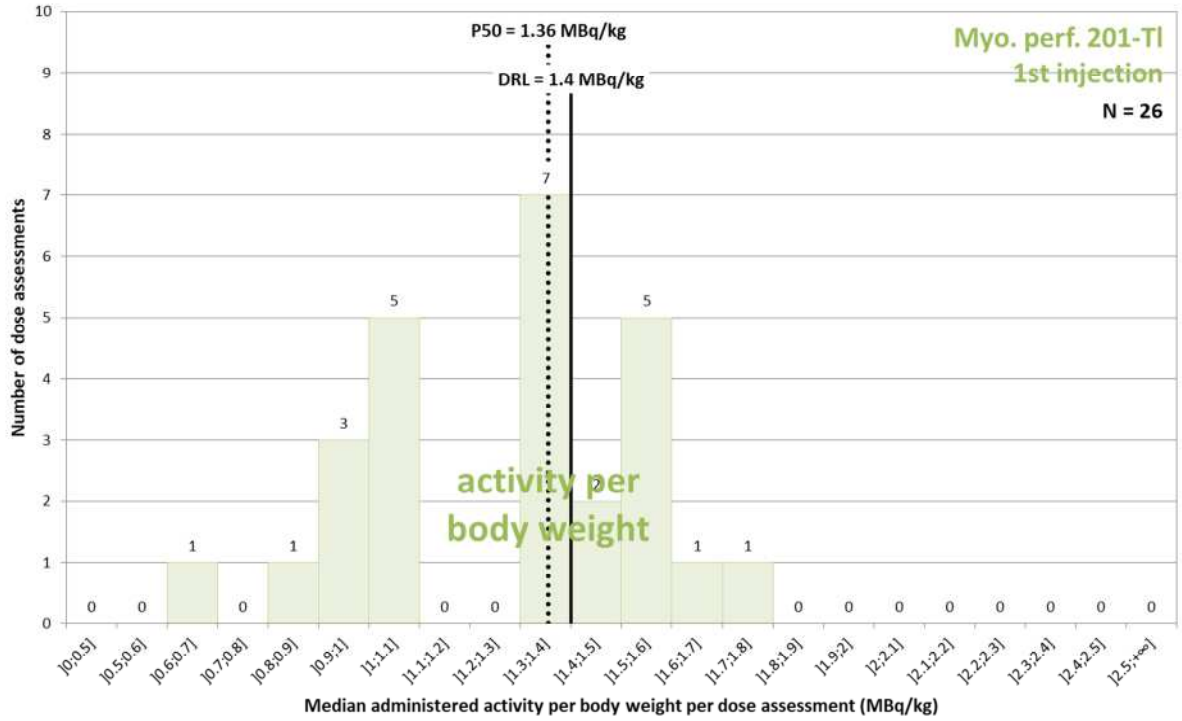


*Figure 100: Distribution of unit median administered activities per body weight for the **first injection** from dose assessments performed for myocardial perfusion SPECT scans with thallium-201.*

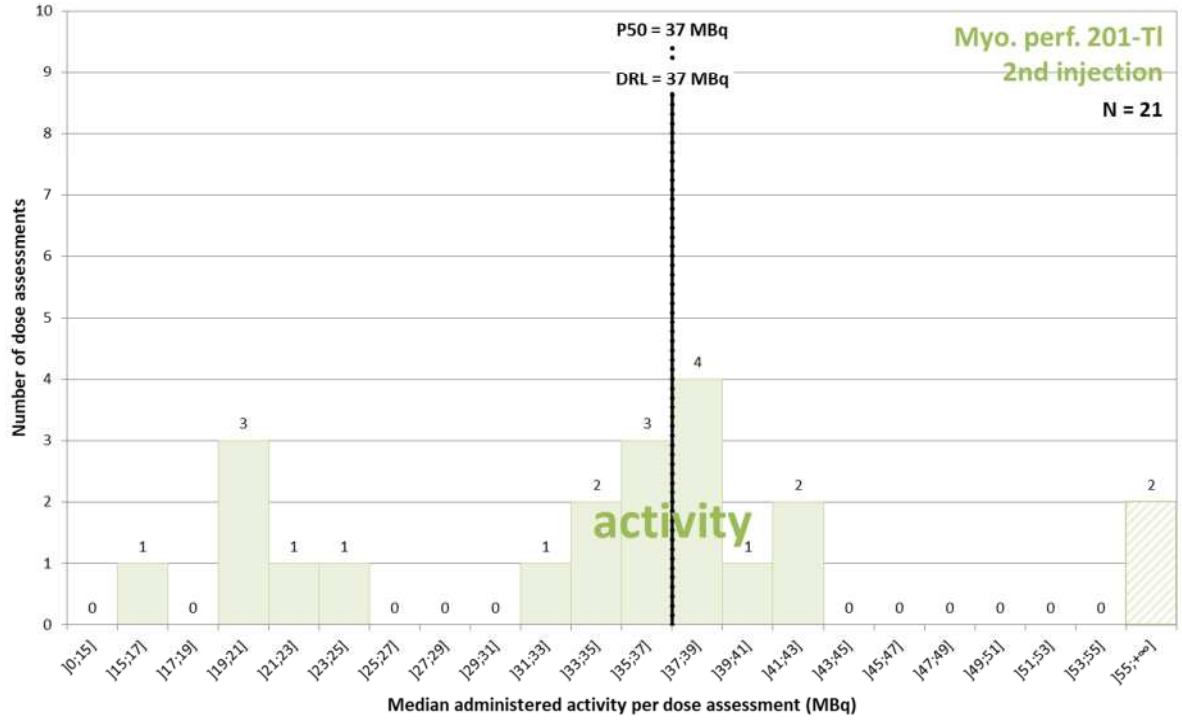


*Figure 101: Distribution of unit median administered activities for the **second injection** from dose assessments performed for myocardial perfusion SPECT scans with thallium-201.*

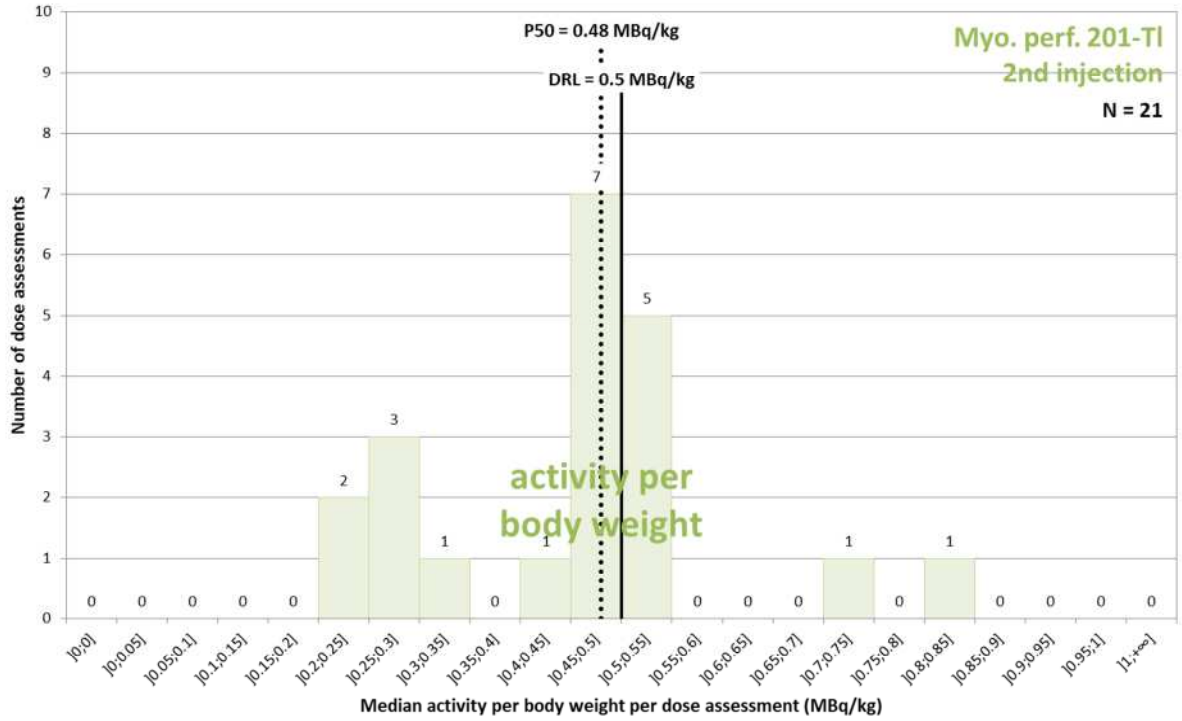


*Figure 102: Distribution of unit median administered activities per body weight for the **second injection** from dose assessments performed for myocardial perfusion SPECT scans with thallium-201.*

*Table 44: Statistical data associated with the distribution of unit median administered activities for the **first injection** from dose assessments performed for myocardial perfusion SPECT scans with thallium-201.*

Myocardial perfusion SPECT scan with stress test (dynamic or pharmacological)

Radiopharmaceutical(s)	^{201}Tl (chloride)	
Protocol and injection	All protocols: first injection	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	110	-
DRL in force (2019 DRL)	110	1.4
Period	**2016 - 2018**	
Number of units	26	26
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**107**	**1.36**
Minimum - maximum values	52 - 143	0.7 - 1.8
Number of units above the 2011 DRL	11 (42%)	-
Number of units above the 2019 DRL	10 (38%)	9 (35%)

*Table 45: Statistical data associated with the distribution of unit median administered activities for the **second injection** from dose assessments performed for myocardial perfusion SPECT scans with thallium-201.*

Myocardial perfusion SPECT scan with stress test (dynamic or pharmacological)

Radiopharmaceutical(s)	^{201}Tl (chloride)	
Protocol and injection	All protocols: second injection	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	40	-
DRL in force (2019 DRL)	37	0.5
Period	**2016 - 2018**	
Number of units	21	21
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**37**	**0.48**
Minimum - maximum values	16 - 61	0.2 - 0.8
Number of units above the 2011 DRL	5 (24%)	-
Number of units above the 2019 DRL	9 (43%)	3 (14%)

Change since 2011

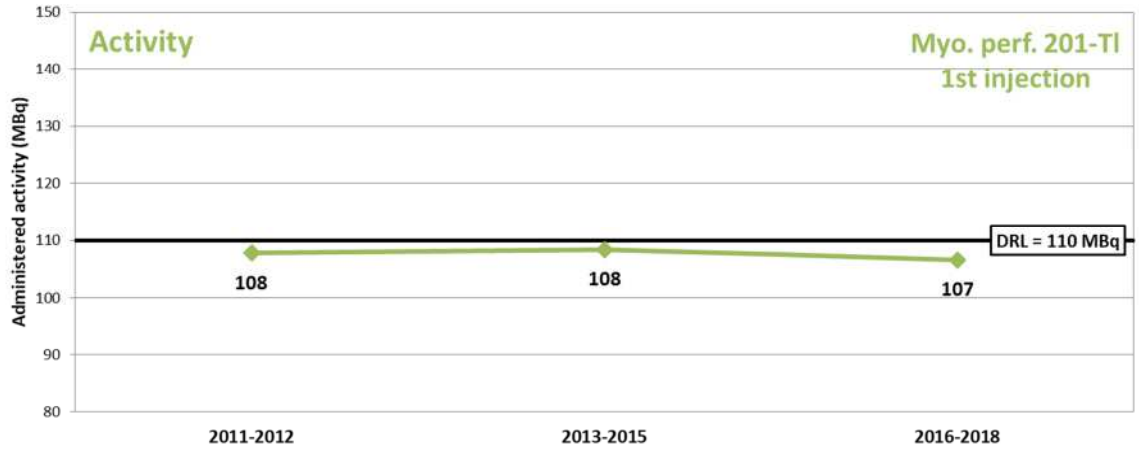


*Figure 103: Change in the 50th percentile of the administered activity for the **first injection** for myocardial perfusion SPECT scans with thallium-201.*

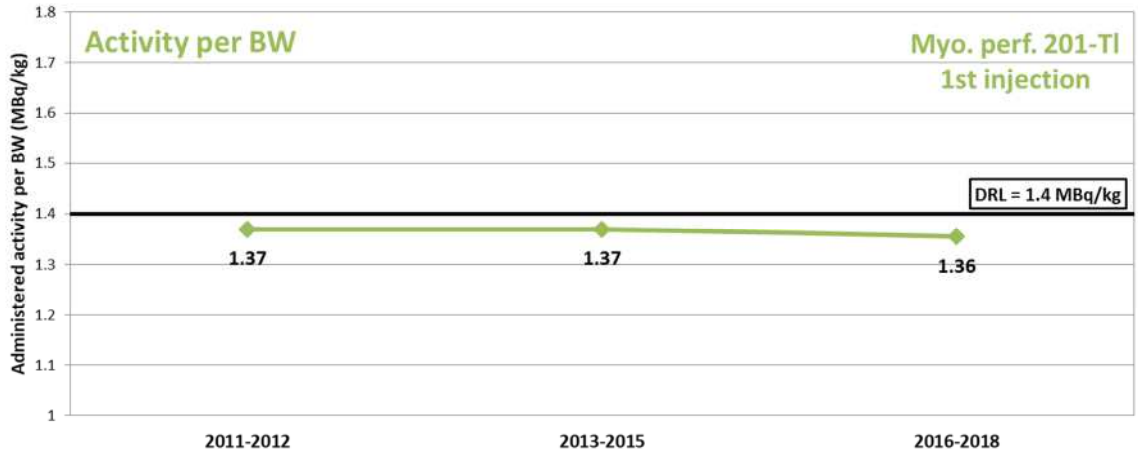


*Figure 104: Change in the 50th percentile of the administered activity per body weight for the **first injection** for myocardial perfusion SPECT scans with thallium-201.*

Due to the very low number of dose assessments received each year for the second injection for myocardial perfusion SPECT scans with thallium-201, it does not seem relevant to present curves where variations are more related to the statistical inconsistency of data than the change in administered activity over time.

Analysis of 2016-2018 data

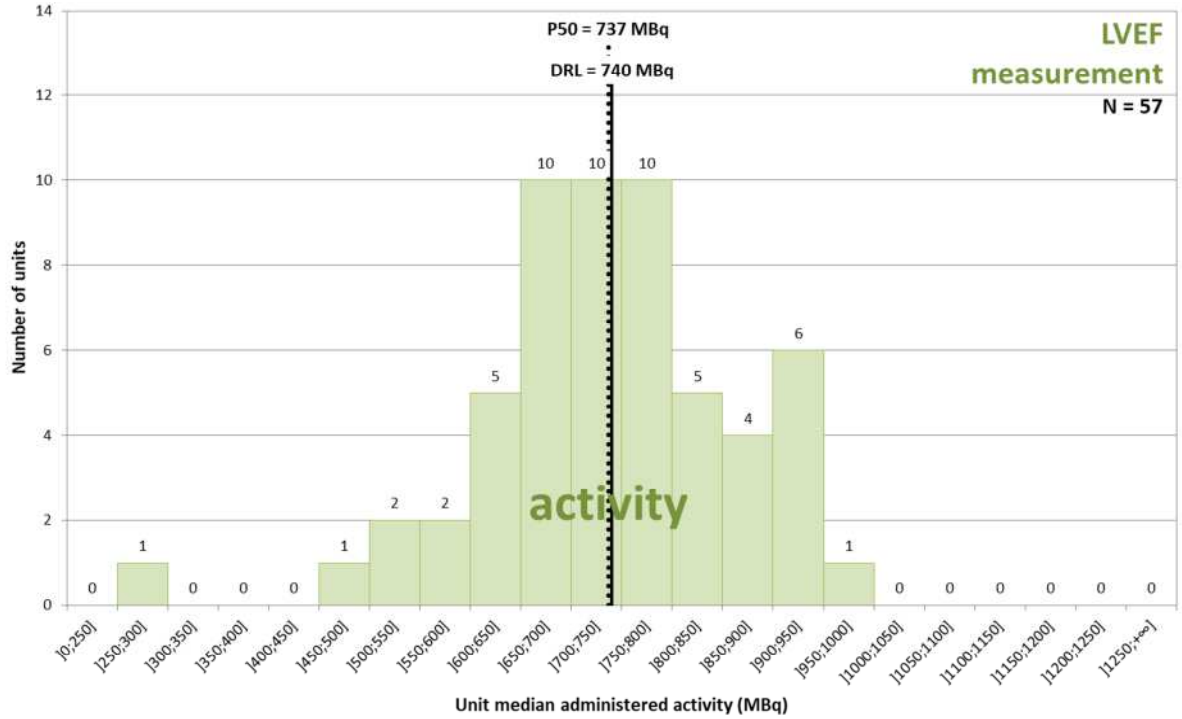


Figure 105: Distribution of unit median administered activities from dose assessments performed for equilibrium radionuclide ventriculographies (left ventricular ejection fraction measurement) in adults.

Table 46: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for equilibrium radionuclide ventriculographies (left ventricular ejection fraction measurement) in adults.

Equilibrium radionuclide ventriculography for left ventricular ejection fraction measurement (adults)

Radiopharmaceutical(s)	^{99m}Tc-human serum albumin, ^{99m}Tc-red blood cells
DRL quantity	**Administered activity (MBq)**
DRL in force during data collection (2011 DRL)	850
DRL in force (2019 DRL)	740

Period	**2016 - 2018**
Number of units	57

DRL quantity	**Administered activity (MBq)**
50th percentile	**737**
Minimum - maximum values	299 - 992
Number of units above the 2011 DRL	9 (16%)
Number of units above the 2019 DRL	27 (47%)

Change since 2011

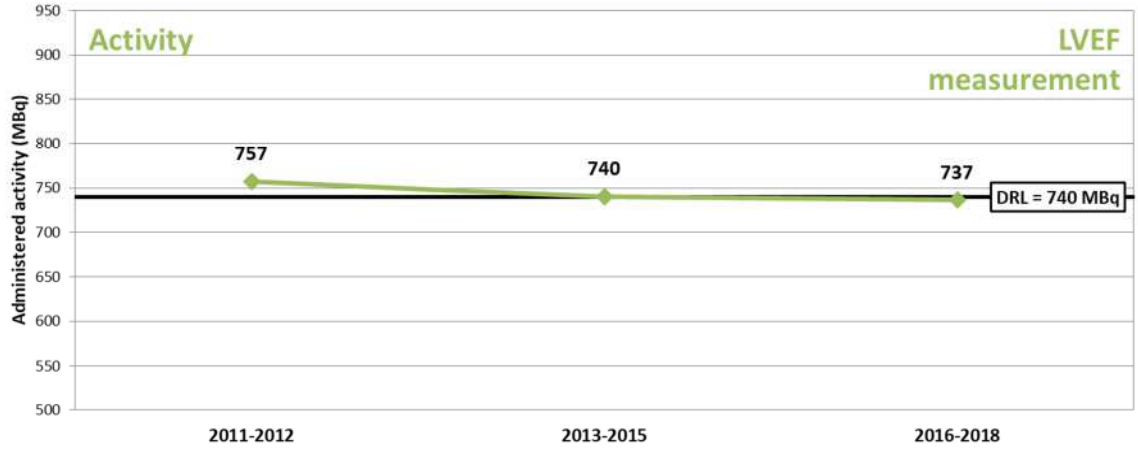


Figure 106: Change in the 50th percentile of the administered activity for equilibrium radionuclide ventriculographies (left ventricular ejection fraction measurement) in adults.

Analysis of 2016-2018 data

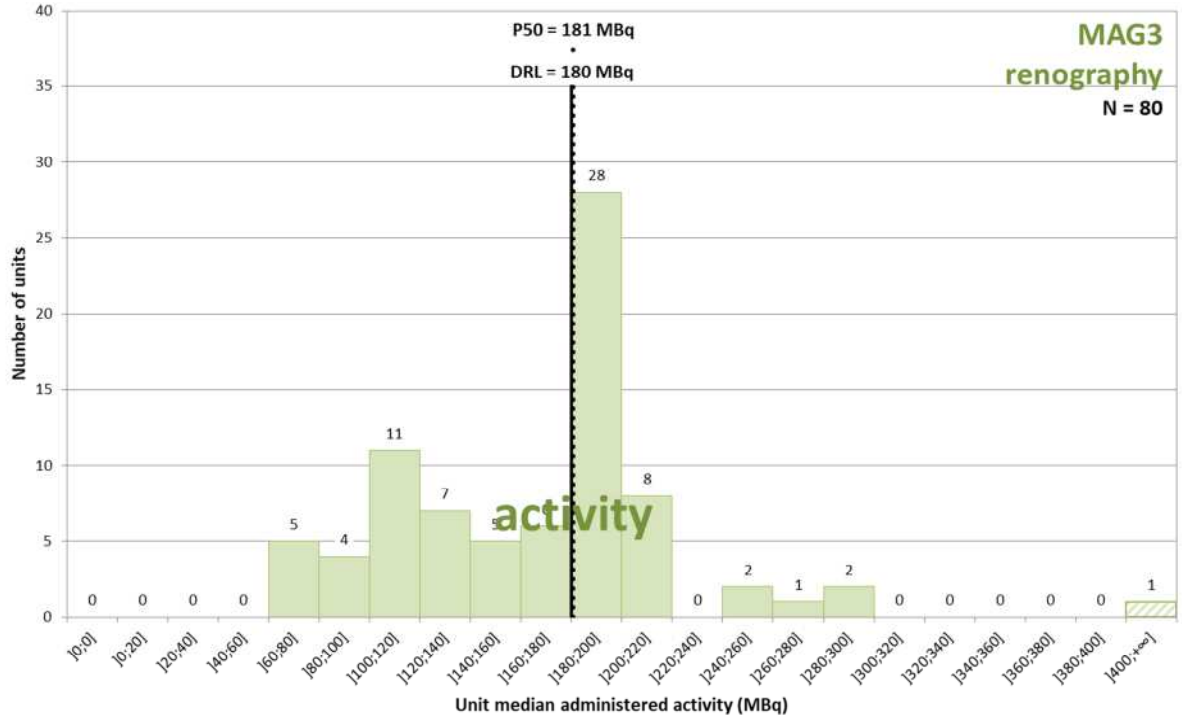


Figure 107: Distribution of unit median administered activities from dose assessments performed for adult dynamic renal scans with ^{99m}Tc-MAG3 (MAG3 renography).

The distribution of dose assessments for adult dynamic renal scans with ^{99m}Tc-DTPA is not shown due to the lack of data received (N = 8).

Table 47: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult dynamic renal scans with ^{99m}Tc-MAG3 (MAG3 renography).

Renal dynamic scans (adults)

Radiopharmaceutical(s)	^{99m}Tc-MAG3
DRL quantity	**Administered activity (MBq)**
DRL in force during data collection (2011 DRL)	200
DRL in force (2019 DRL)	180

Period	**2016 - 2018**
Number of units	80

DRL quantity	**Administered activity (MBq)**
50th percentile	**181**
Minimum - maximum values	68 - 410
Number of units above the 2011 DRL	16 (20%)
Number of units above the 2019 DRL	42 (53%)

Change since 2011

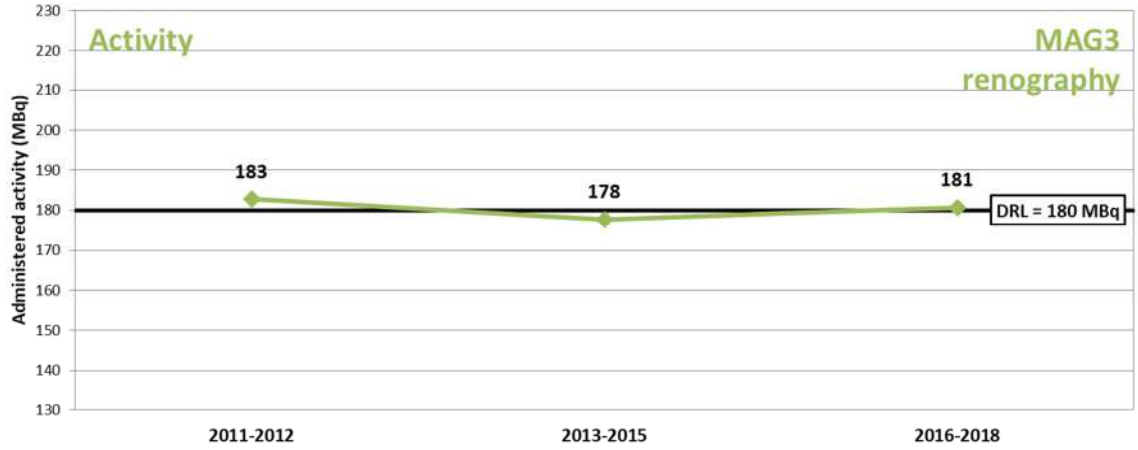


Figure 108: Change in the 50th percentile of administered activity for adult dynamic renal scans with ^{99m}Tc-MAG3.

The change in the 50th percentile of the administered activity for adult dynamic renal scans with ^{99m}Tc-DTPA is not shown due to the lack of data received.

Analysis of 2016-2018 data

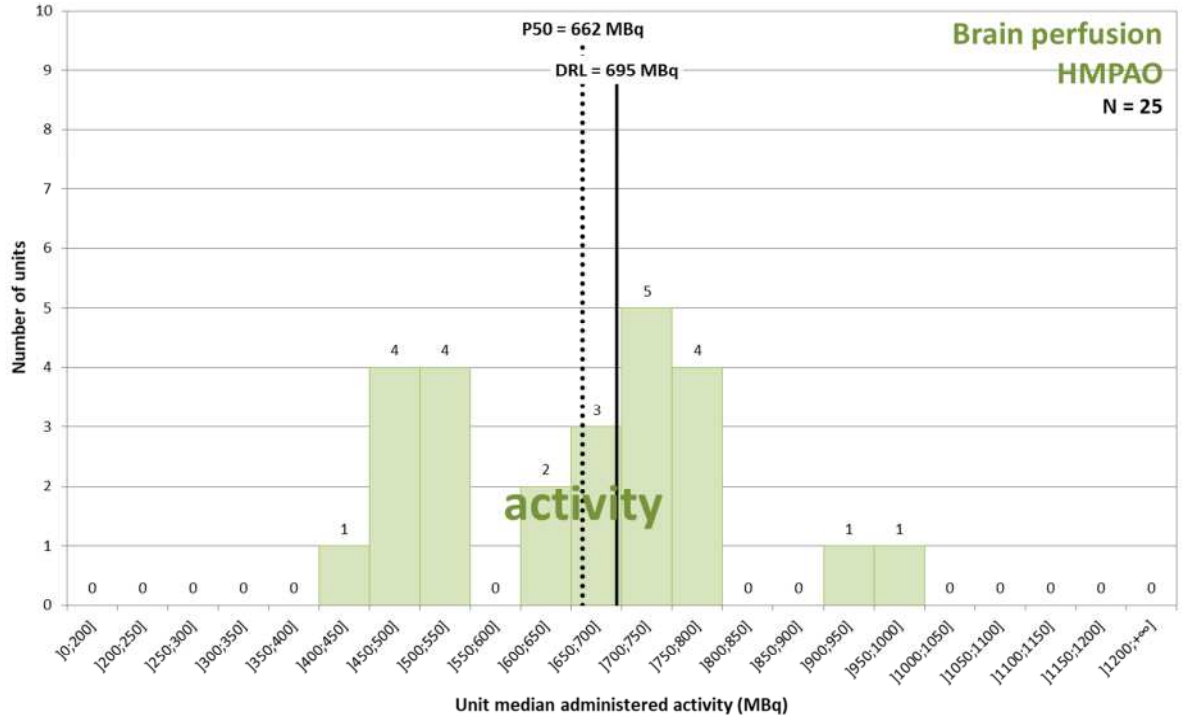


Figure 109: Distribution of unit median administered activities from dose assessments performed for adult brain perfusion SPECT scans with ^{99m}Tc-HMPAO.

The distribution of dose assessments for adult brain perfusion SPECT scans with ^{99m}Tc-ECD is not shown due to the lack of data received (N = 3).

Table 48: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult brain perfusion SPECT scans with ^{99m}Tc-HMPAO.

Brain perfusion SPECT scans (adults)

Radiopharmaceutical(s)	^{99m}Tc-HMPAO
DRL quantity	**Administered activity (MBq)**
DRL in force during data collection (2011 DRL)	500
DRL in force (2019 DRL)	695

Period	**2016 - 2018**
Number of units	25

DRL quantity	**Administered activity (MBq)**
50th percentile	**662**
Minimum - maximum values	442 - 980
Number of units above the 2011 DRL	20 (80%)
Number of units above the 2019 DRL	11 (44%)

Change since 2011

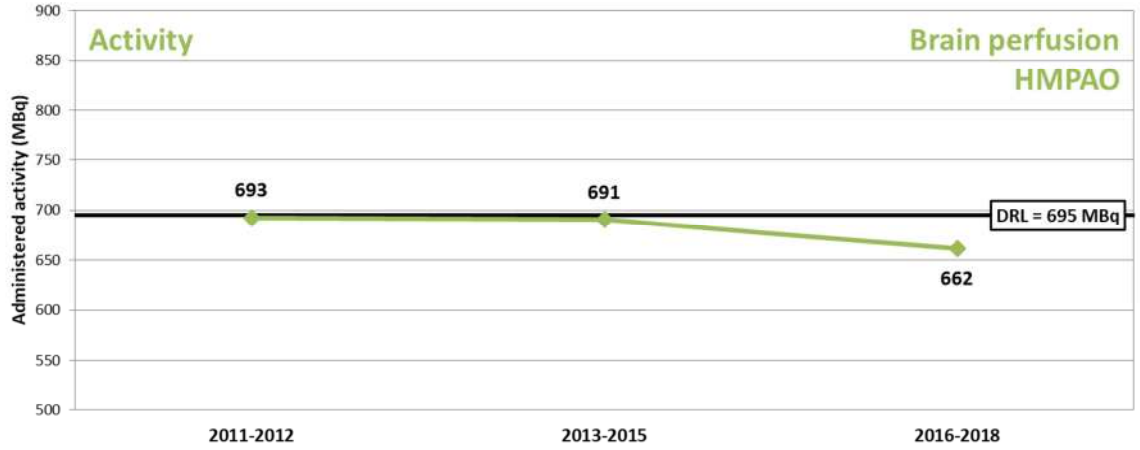


Figure 110: Change in the 50th percentile of administered activity for adult brain perfusion SPECT scans with ^{99m}Tc-HMPAO.

The change in the 50th percentile of the administered activity for adult brain perfusion SPECT scans with ^{99m}Tc-ECD is not shown due to the lack of data received.

Analysis of 2016-2018 data

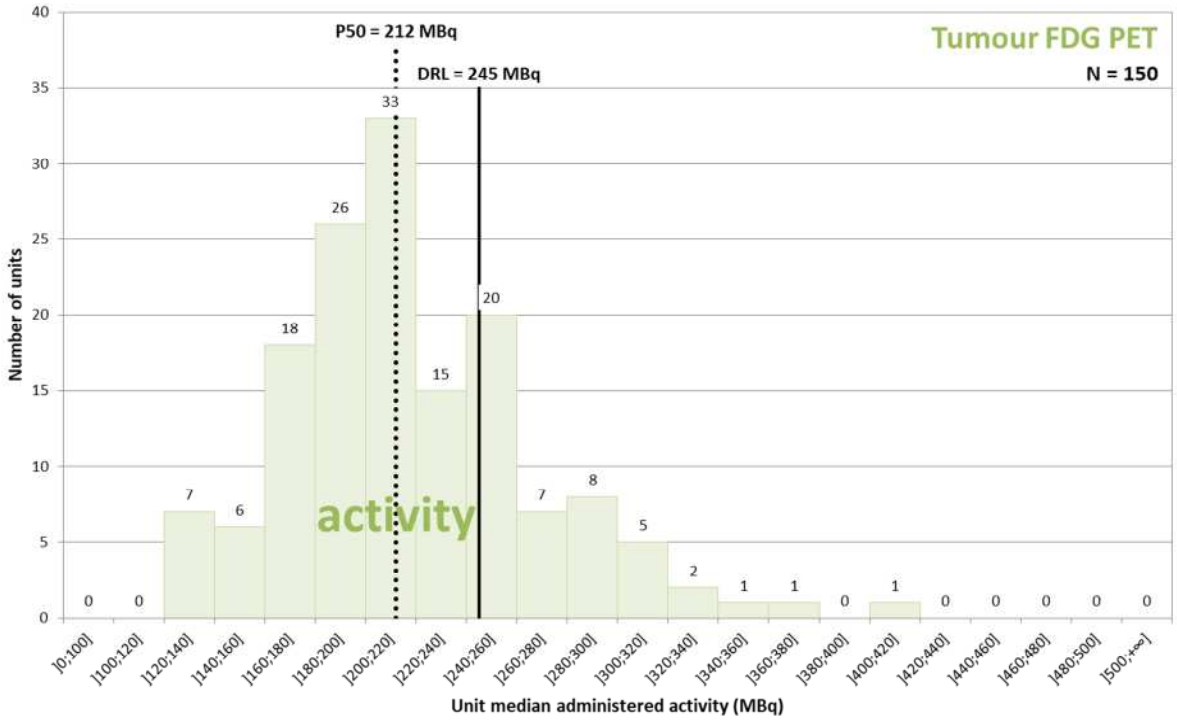


Figure 111: Distribution of unit median administered activities from dose assessments performed for adult positron emission tomography scans with ^{18}F-fluorodeoxyglucose.

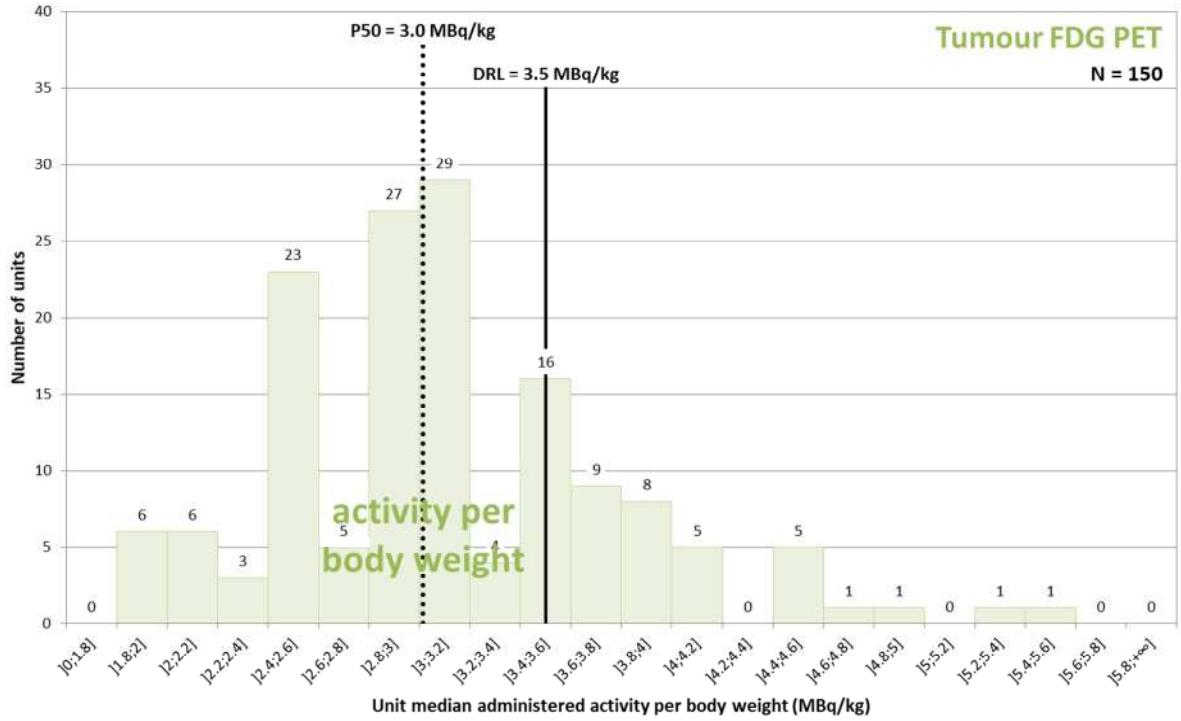


Figure 112: Distribution of unit median administered activities per body weight from dose assessments performed for adult positron emission tomography scans with ^{18}F-fluorodeoxyglucose.

Table 49: Statistical data associated with the distribution of unit median administered activities from dose assessments performed for adult positron emission tomography scans with ^{18}F-fluorodeoxyglucose.

Tumour PET scans (adults)

Radiopharmaceutical(s)	^{18}F-FDG	
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
DRL in force during data collection (2011 DRL)	350	-
DRL in force (2019 DRL)	245	3.5
Period	**2016 - 2018**	
Number of units	150	150
DRL quantity	**Administered activity (MBq)**	**Administered activity per body weight (MBq/kg)**
50th percentile	**212**	**3.0**
Minimum - maximum values	129 - 401	2.0 - 5.6
Number of units above the 2011 DRL	2 (1%)	-
Number of units above the 2019 DRL	39 (26%)	37 (25%)

Change since 2011

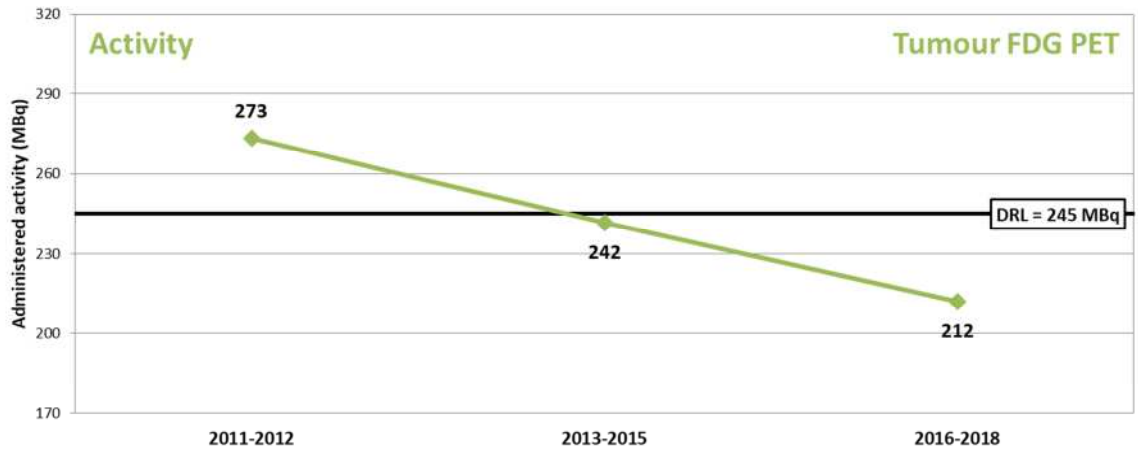


Figure 113: Change in the 50th percentile of administered activity for adult positron emission tomography scans with ^{18}F-fluorodeoxyglucose.

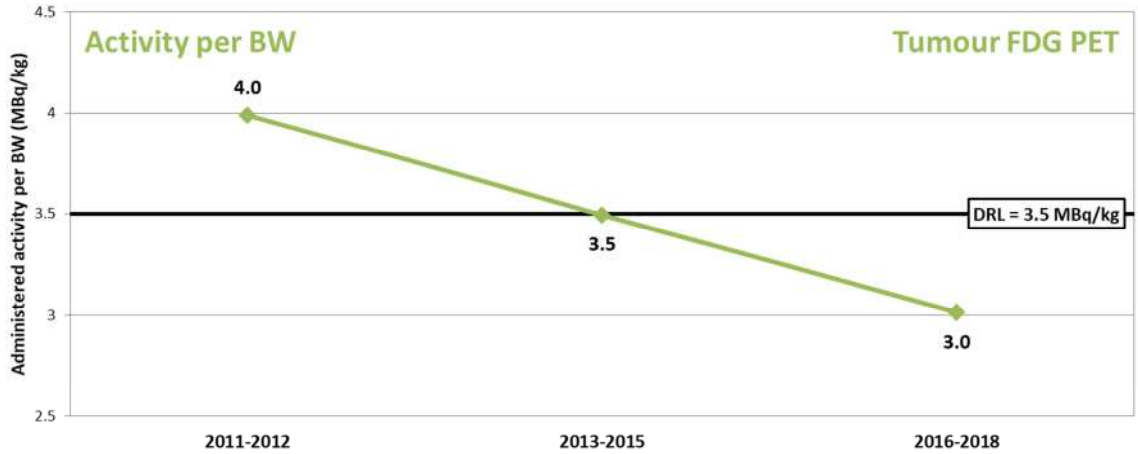


Figure 114: Change in the 50th percentile of administered activity per body weight for adult positron emission tomography scans with ^{18}F-fluorodeoxyglucose.

REFERENCE DOCUMENTS

(1) *Arrêté du 12 février 2004 relatif aux niveaux de référence diagnostiques en radiologie et en médecine nucléaire*. Journal officiel de la République Française du 16 mars 2004.

(2) ICRP, 1996. *Radiological protection and safety in medicine. ICRP Publication 135*. Ann ICRP 26(2).

(3) European Commission, 1999. *Radiation Protection No. 109. European Guidance on diagnostic reference levels (DRLs) for medical exposures*.

(4) *Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, repealing Directive 84/466/Euratom*. Official Journal of the European Union of 9 July 1997.

(5) *Arrêté du 24 octobre 2011 relatif aux niveaux de référence diagnostiques en radiologie et en médecine nucléaire*. Journal officiel de la République Française du 14 janvier 2012.

(6) IRSN, 2012. *Analyse des données relatives à la mise à jour des niveaux de référence diagnostiques en radiologie et en médecine nucléaire. Bilan 2009-2010. Rapport PRP-HOM/2012-12*.

(7) IRSN, 2014. *Analyse des données relatives à la mise à jour des niveaux de référence diagnostiques en radiologie et en médecine nucléaire. Bilan 2011-2012. Rapport PRP-HOM/2014-9*.

(8) IRSN, 2016. *Analyse des données relatives à la mise à jour des niveaux de référence diagnostiques en radiologie et en médecine nucléaire. Bilan 2013-2015. Rapport PRP-HOM-2016-00006*.

(9) Autorité de sûreté nucléaire, 2015. *Rapport du groupe de travail issu du GPMED. Recommandations du groupe de travail sur les niveaux de référence diagnostiques en imagerie médicale*.

(10) Autorité de sûreté nucléaire, 2015. *Avis du GPMED sur les niveaux de référence diagnostiques en imagerie*.

(11) European Society of Radiology, 2015. *PiDRL Project*. http://www.eurosafeimaging.org/pidrl/

(12) European Commission, 2018. *Radiation Protection No. 185. European Guidelines on Diagnostic Reference Levels Paediatric Imaging Radiation Protection*.

(13) ICRP, 2017. *Diagnostic reference levels in medical imaging. ICRP Publication 135*. Ann. ICRP 46 (1).

(14) *Décision n°2019-DC-0667 de l'Autorité de sûreté nucléaire du 18 avril 2019 relative aux modalités d'évaluation des doses de rayonnements ionisants délivrées aux patients lors d'un acte de radiologie, de pratiques interventionnelles radioguidées ou de médecine nucléaire et à la mise à jour des niveaux de référence diagnostiques associés*. Bulletin officiel de l'ASN du 29 avril 2019.

(15) *Arrêté du 23 mai 2019 portant homologation de la décision n° 2019-DC-0667 de l'Autorité de sûreté nucléaire du 18 avril 2019 relative aux modalités d'évaluation des doses de rayonnements ionisants délivrées aux patients lors d'un acte de radiologie, de pratiques interventionnelles radioguidées ou de médecine nucléaire et à la mise à jour des niveaux de référence diagnostiques associés*. Journal officiel de la République Française du 30 mai 2019.

(16) *Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom*. Official Journal of the European Union of 17 January 2014.

(17) *Décret n° 2018-434 du 4 juin 2018 portant diverses dispositions en matière nucléaire*. Journal officiel de la République Française du 5 juin 2018.

(18) NCRP, 2012. *NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States*.

(19) HERCA, 2012. *HERCA-DAP display proposal Approved on the occasion of the 10th HERCA Meeting, 31 October 2012*.

(20) J. Greffier et al., 2019. *Patient dose reference levels in surgery: a multicenter study*. European Radiology 29 pp. 674–681.

(21) Jean-Louis Georges et al., 2017. *Radiation doses to patients in interventional coronary procedures—estimation of updated national reference levels by dose audit*. Radiation Protection Dosimetry 175(1) pp. 17–25.

(22) Geryes et al., 2019. *Patient dose evaluation in computed tomography: A French national study based on clinical indications*. Physica Medica 61 pp. 18–27.

(23) European Society of Radiology, 2017. EUCLID http://www.eurosafeimaging.org/euclid

(24) Celier et al., 2020. *Multicentre survey on patient dose in paediatric imaging and proposal for updated diagnostic reference levels for France. Part 2: plain radiography and diagnostic fluoroscopy*. European Radiology 30 pp. 1182–1190.

(25) Celier et al., 2020. *Multicentre survey on patient dose in paediatric imaging and proposal for updated diagnostic reference levels for France. Part 1: computed tomography*. European Radiology 30 pp. 1156–1165.

(26) Celier et al., 2017. *Mise à jour des NRD en pédiatrie : enquête SFMN-SFPM-IRSN sur les pratiques en médecine nucléaire*. Médecine Nucléaire 41(3) p. 170.

(27) *Décision du 30 janvier 2006 fixant les modalités du contrôle de qualité des installations de mammographie numérique, modifiée par la décision du 22 novembre 2010 et celle du 23 novembre 2012*, fixant les modalités du contrôle de qualité des installations de mammographie numérique. Journal officiel de la République Française du 11 mars 2006.

(28) *Décision du 8 décembre 2008 fixant les modalités du contrôle de qualité des installations de radiologie dentaire*. Journal officiel de la République Française du 26 décembre 2008.

(29) Järvinen H et al., 2017. *Patient dose monitoring and the use of diagnostic reference levels for the optimization of protection in medical imaging: current status and challenges worldwide*. J Med Imaging (Bellingham) 4(3): 031214.

(30) IRSN, 2014. *Exposition de la population française aux rayonnements ionisants liée aux actes de diagnostic médical en 2012 ; Rapport PRP-HOM N°2014-6*.

(31) IRSN, 2018. *Exposition des enfants aux rayonnements ionisants due aux actes d'imagerie médicale diagnostique réalisés en France en 2015. Étude ExPRI pédiatrique 2015. Rapport n° PSE-SANTE/SER/2018-00004*.

(32) ANSM, 2019. *Contrôle de qualité des dispositifs médicaux exposant les personnes aux rayonnements ionisants - bilan d'activité 2018*.

(33) INCa, 2014. *Performance de la mammographie dans le dépistage organisé des cancers du sein - Synthèse de l'enquête*.

(34) INCa, 2017. *Performance de la mammographie dans le dépistage organisé des cancers du sein. Résultats 2013-2014. Recensement des équipements de mammographie dans le dépisatage organisé des cancers. Résultats 2017. Rapports d'enquêtes*.

(35) ANSM, 2020. Decision of 15 January 2020 establishing the quality control procedures for digital mammography units.

(36) IRSN, 2018. *Parc de scanners et recommandations relatives à la radioprotection en imagerie médicale. Rapport n° PSE-SANTE/SER/2018-00002*.

(37) Cour des comptes, 2016. *L'imagerie médicale*.

(38) ASN, 2019. *Médecine nucléaire en France état du parc, des moyens humains et des activités en 2017*.

(39) Groupe de travail "Chirurgie endocrinienne Médecine Nucléaire Endocrinologie" (CEMEN) Société Française de Médecine Nucléaire et d'Imagerie Moléculaire (SFMN), 2006. *Guide pour la rédaction de protocole pour la scintigraphie thyroïdienne diagnostique. Version : 10*.

(40) Société Française de Biophysique et de Médecine Nucléaire (SFBMN), 2014. *Guide pour la rédaction de protocoles pour la scintigraphie pulmonaire dans le diagnostic d'embolie pulmonaire. Version: 1.0*.

(41) Hyafil, F. et al., 2019. *EANM procedural guidelines for myocardial perfusion scintigraphy using cardiac-centered gamma cameras*. European Journal of Hybrid Imaging 3, 11.

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