Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

Diagnostic Reference Levels

Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation

December 2023

Safer Better Care

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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1. Introduction

Medical exposure to ionising radiation is the largest contributor of artificial ionising radiation exposure to Irish people.[1] To ensure that individuals are protected when undergoing medical exposures, the core components of radiation protection principles — justification* and optimisation† — must be used.[2] An essential part of ensuring medical exposures are optimised is the establishment, use and regular review of diagnostic reference levels (DRLs) for medical radiological procedures.[2,3,4]

What are DRLs?

DRLs are dose levels set to aid optimisation of diagnostic and interventional medical exposures. They provide a standard for comparison to help ensure the radiation protection of patients undergoing these types of medical radiological procedures.

The concept of using DRLs for medical radiological procedures was adopted by the European Directive 97/43/Euratom in 1997.[5] DRLs are dose levels that are not expected to be exceeded for standard diagnostic and interventional radiological procedures when good practice regarding diagnostic and technical performance is applied.[2,3] Where a DRL is exceeded on a consistent basis, a review must be carried out to determine the cause and corrective actions must be taken without undue delay.[6]

Why should DRLS be used for medical radiological procedures?

DRLs help to ensure that the radiation dose received by patients for a specific type of medical radiological procedure is optimised.

2. Purpose of this document

In 2018, European legislation on the regulation of medical exposures to ionising radiation was transposed into Irish law. The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (and associated amendments), referred to in this document as the regulations, designate the Health Information and Quality Authority (HIQA) as the competent authority for the establishment and review of national DRLs.[6,7,8]

* Justification is the process of weighing up the potential benefit of a medical exposure against the detriment for that individual.
† Optimisation is the process by which doses that are as low as reasonably achievable (ALARA).

What does this mean for HIQA?

HIQA, as the competent authority, must establish national DRLs. Under the regulations HIQA must publish:

- national DRLs
- the details of any regular reviews carried out of these national DRLs
- guidance in relation to the establishment, review and use of diagnostic reference levels for use by undertakings, practitioners, medical physics experts, and persons delegated the practical aspects of medical radiological procedures.[6]

The purpose of this guidance is to fulfil HIQA's obligation under the regulations to publish national DRLs, including details of the review of these national DRLs and guidance on the establishment, review and use of DRLs. Similarly, undertakings must ensure that local facility DRLs are established, regularly reviewed and used, having regard to national DRLs. The regulations also require the undertaking to make this guidance document available to practitioners, medical physics experts and persons delegated the practical aspects of medical radiological procedures.[6]

What does this mean for undertakings?

Undertakings must ensure that this guidance document is made available to practitioners, medical physics experts and persons delegated the practical aspects of medical radiological procedures. Undertakings must also establish local facility DRLs, ensure that these are regularly reviewed and used by persons conducting medical radiological procedures.

3. Introduction to DRLs

The Basic Safety Standards define DRLs as:

> dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment.[2]

This means that a DRL is a dose level that is set for typical diagnostic and interventional radiological procedures. For setting DRLs, a standard sized patient is considered to be 55 to 85 kg.[9]

It is important to note that DRLs are not dose limits or dose constraints. They should only be used as an indicator of a dose level that, if exceeded, should lead to a review of the medical radiological procedure to ensure that optimisation was adequate.[2,3,4,5,6] The use of DRLs is an important way of ensuring that medical exposures are optimised and helps to ensure that the 'as low as reasonably achievable' (ALARA) principle[‡] is used to deliver maximum diagnostic yield at the lowest radiation dose necessary.[3]

The assessment and evaluation of patient doses for medical radiological procedures is a requirement under the regulations and undertakings can partly achieve this through the establishment of local facility DRLs.[6] Once established, local facility DRLs should be compared with national DRL values. If local facility DRLs consistently exceed or are substantially lower than national DRL values, an investigation must be conducted to ensure optimal practices and intended outcomes are delivered.[3, 4] An assessment of clinical image quality should be included as part of any local review of dose levels to ensure the intended benefit from the medical exposure is still achieved. Objective measures for the assessment of image quality must be used where available. Where issues are identified, an investigation or risk assessment must be undertaken to identify possible causes. Corrective actions to mitigate the risks to patients should be implemented.[3, 4, 10, 11]

Clinical audits and DRLs

The process for reviewing patient doses, comparing to national DRLs, identifying issues, taking corrective actions as necessary and repeating this cycle regularly is consistent with established clinical audit models.[10,12, 14]

[‡] The ALARA principle is a key principle of optimisation, where all doses due to medical exposure should be kept as low as reasonably achievable, consistent with obtaining the intended outcomes of the exposure.

The process for reviewing patient doses and DRLs is consistent with established clinical audit models.[10, 12, 14] The establishment and ongoing review of DRLs should be embedded into an undertaking's clinical audit schedule. Any clinical audit model for the review of DRLs should be multidisciplinary and adhere to local and national clinical audit procedures, where available.

4. National DRLs

4.1 Background

National DRLs established by the competent authority represent common national diagnostic and interventional radiological procedures and or the clinical task for which medical exposures are performed. When developing national DRLs, priority is given to medical exposures with the highest frequency and or that result in the highest patient radiation dose and for which the assessment of DRL quantities is practicable.[3]

In 2013, the Health Service Executive (HSE) Medical Exposure Radiation Unit (MERU) published national DRLs for a range of standard medical radiological procedures.[13] These national DRLs were updated in 2017 following the publication of HSE MERU's *Patient Radiation Protection Manual 2017* [14] and *National Survey on Population Dose from Computed Tomography 2017*.[15]

The *National Survey on Population Dose from Computed Tomography* also introduced the concept of defining medical radiological procedures by clinical task or based on clinical indications (Clinical DRLs).[15] Traditional DRLs built for specific anatomical locations may have different clinical indications, use different protocols and subsequently deliver different exposure levels. The use of clinical DRLs has been acknowledged as more appropriate in CT and interventional radiology [17]

4.2 Establishment and review of National DRLs by HIQA

In February 2020, HIQA adopted national DRLs following consultation with its expert advisory group (EAG), which includes representation from relevant professional bodies. These national DRLs were developed based on the categories, procedures and or clinical tasks included in:

- the existing national DRLs established by HSE MERU[14, 15]
- Public Health England's DRL guidance[16]
- EUCLID ongoing research and DRL review[17]
- European guidelines on paediatric DRLs[4]
- the Administration of Radioactive Substances Advisory Committee (ARSAC) guidance[18]
- other published international literature.[19, 20]

In July 2021, these national DRLs were updated following HIQA's national review of DRLs in general radiography, mammography and dual-energy X-ray absorptiometry (DXA) scanning. [21] In October of 2022 and November 2023 these were again updated following a national review of fluoroscopic and fluoroscopically guided interventions and nuclear medicine procedures respectively.[22, 23]

As the organisation responsible for the establishment, review and publication of national DRLs, HIQA carry out a cyclical thematic request for dose information to update national DRL values. Undertakings will also be required to contribute to these national reviews by submitting further radiation dose data when requested by HIQA under Regulation 18(2).

The information that may be required by HIQA to complete national DRL reviews includes:

- median dose quantity values, where available, for diagnostic and interventional medical radiological procedures or clinical tasks published by HIQA (National DRLs)
- median dose quantity values for diagnostic and interventional medical radiological procedures or clinical tasks which deliver high radiation doses (not included in national DRLs)
- frequency per annum of these medical radiological procedures
- equipment details (manufacturer, model, detector types and software available).

Undertakings should note that this list is not exhaustive and may be subject to change.

The collected data will be collated and used to establish a national 75th percentile DRL value. For mammography screening, the 95th percentile may also be considered as a standard metric due to more defined and extensive quality assurance programmes.

What is a percentile?

A percentile is the value below which a percentage of data falls. For example, a value is the 75th percentile where 75% of the data is below that value.

HIQA's ongoing DRL review process will create an opportunity to identify and address any gaps in current DRL data available, particularly in differentiation of medical radiological equipment types, software available and new or evolving radiological procedures.

What is a national DRL value?

A national DRL value is a dose level which is set at the 75th percentile of the distribution of the medians obtained from national surveys or other means.

The national DRLs adopted and established by HIQA, including further information on DRL categories, quantities, symbols and units, can be found in Appendix 2.

5. Local facility DRLs

5.1 Establishing local facility DRLs

Does the use of local facility DRLs apply to all healthcare providers?

Yes, local facility DRLs must be established, used and regularly reviewed for all diagnostic and appropriate interventional medical radiological procedures or clinical tasks.

All undertakings have a requirement under the regulations to establish local facility DRLs, irrespective of size and complexity. Local facility DRLs should be established for procedures or clinical tasks quoted by national DRLs (when these procedures are undertaken locally). However, some procedures or clinical tasks may not be included in the national DRLs as they may be unique to a facility, hospital or medical speciality and expertise. Where this is the case, particularly when these procedures involve high patient doses, local facility DRLs for such procedures or clinical tasks should be established by the undertaking.

What does this mean for undertakings?

Undertakings must ensure that local facility DRLs are established, regularly reviewed and used, taking corrective action where necessary

The process for establishing local facility DRLs is detailed in Table 1. Establishing local facility DRLs is the first step in the cyclical DRL process or audit cycle. A typical value should be used for setting an individual undertaking's local DRLs. A typical value is defined as the median value of the distribution of DRL quantities for medical radiological procedures.[3]

What value should be used when establishing facility DRLs?

A **median value** should be used when setting an individual undertaking's facility DRLs and should generally be used for all undertakings.

(To find the median, the data should be arranged in order from least to greatest. If there is an even number of items in the distribution of the dose quantities collected, then the median is found by taking the mean (average) of the two middlemost quantities collected. If there are an odd number of items the median is the middlemost quantity)

Dose management systems, where available, can be used to contribute to the establishment and review of local facility DRLs. However, its application may not be practicable in all installations, for example, dental surgeries, due to cost. It should be noted that there is no regulatory requirement for undertakings to acquire or use such software however the availability and use of such systems demonstrates an example of proactive dose monitoring and prospective optimisation.

Retrospective analysis of radiology information systems (RIS) and hospital information systems (HIS) may allow access to dose data on large numbers of patients to facilitate the establishment of local facility DRLs.

Manual recording of patient doses may also be used by undertakings to contribute to the establishment of local facility DRLs. Undertakings must consider the resources available and establish appropriate dose data collection methods to enable the establishment and review of local facility DRLs.

For establishment of adult nuclear medicine local facility DRLs, a median value should be set using the methodology outlined in Table 1. Noting the differences between nuclear medicine and other modalities, undertakings establishing local facility DRLs may find that administered dose may only differ slightly between patients. Facilities should clearly indicate in their DRL procedures, policies and guidance how local facility DRLs for nuclear medicine procedures are established.

Ideally the administered activity should be based on weight for all nuclear medicine procedures. However, it is noted that the use of weight-based administered activity is not yet common practice in Ireland for most adult nuclear medicine procedures. As a result, local facility DRLs can be established using the methodology as described in Table 1.

Based on the results of the nuclear medicine DRL survey, and in line with current practice in Ireland, the recommended weight-based administered activities provided by the EANM paediatric dosage card and the ARSAC guidance are considered as the paediatric nuclear medicine national DRLs for the purposes of optimisation of paediatric nuclear medicine procedures in Ireland.[23] These references include information on the scaling of adult administered activity for children and young persons and also provide information on recommended minimum administered activity.

However, please note that DRLs do not apply to individual patients and the administered activities must be considered in line with intended clinical outcomes under the clinical responsibility of a practitioner for each individual patient.

When establishing intra-oral dental DRLs, dosimetric measurements made by a medical physicist are favoured over patient studies. To establish intra-oral dental

DRLs, measurements of incident air kerma (Ka, i) can be made at standard settings with a suitable calibrated detector placed at the end of the spacer cone of the X-ray set.

What is a DRL quantity?

A DRL quantity is a commonly used and easily measured or determined metric (for example, dose length product (DLP) in computed tomography (CT)) which indicates the amount of ionising radiation used to perform the medical radiological procedure.[3]

Recommended dose quantities for the establishment of local DRLs can be found in Appendix 2.

Table 1. How to establish local facility DRLs

How to establish local DRLs	
Step 1	**Create a list of medical radiological procedures to be included** The list of medical radiological procedures should consist of procedures or clinical tasks: ▪ that national DRL values exist for ▪ that are commonly carried out or associated with high patient doses. This may result in some procedures or clinical tasks included in local facility DRLs that are not included in the national DRLs.
Step 2	**Establish what needs to be recorded** This should include the dose quantities used to measure that amount of dose used to carry out the procedure and or clinical task for which a DRL is being established. Calibration of all dosimeters used for patient dosimetry should be performed regularly and verified periodically by a medical physicist[3] to ensure accuracy, consistency and reproducibility of results. Further information on what dose quantities to use is included in Appendix 2.

Step 3[§]	**Sample methodology and sample sizes** **Adult DRLs** 1. If available, electronic dose management systems can be used to establish local DRLs. These can generate descriptive statistics (and median dose values) using all procedures within a given time period (No patient weight standardisation or manual data manipulation is necessary). 2. If dose management systems are not available, select in excess of 50 representative data points (patients) using RIS or HIS for each local facility DRL. Where larger numbers of patients (>50) are included in the survey, it is recommended that that any dose outliers should be removed from the data. However, it should be noted that dose outliers should only have a minimal effect on the median of the distribution. (No patient weight standardisation is necessary)[3] 3. If neither 1 nor 2 are possible, manually select 20 representative patients (preferably 30 for diagnostic imaging, fluoroscopy or CT and 50 patients for mammography). Ensure patients are weight-standardised (70 ± 15kg). **Paediatric DRLs** 1. For paediatric DRLs, patients should be grouped by weight for body examination and age groups for head examinations and each group should include a minimum of 10 patients. 2. For nuclear medicine procedures, please refer to recommended weight-based administered activities provided by the EANM paediatric dosage card and the ARSAC guidance document.[23]
Step 4	**Establish local facility DRL** Establish a median dose for each dose quantity for each procedure or clinical task (local facility DRL) chosen in step 1.

5.2 Using local facility DRLs

The first step in using local facility DRLs is comparison with the national DRL value. If this does not exist for a particular procedure or clinical task, similar internationally established DRL values or peer reviewed literature can be consulted.

If local facility DRLs exceed or are substantially lower than DRL values, an investigation must be conducted to ensure optimal practices and intended outcomes

[§] If annual procedure numbers are insufficient to establish a local facility DRL, data from multiple years can be used, provided equipment and imaging protocols used to conduct medical exposures are the same.

are delivered. Under the regulations, undertakings are required to retain records of DRL reviews and any corrective actions carried out for a period of five years and make these records available to HIQA on request. Failure to do so is an offence under the regulations.

All individuals who carry out medical radiological procedures should be familiar with the important role of DRLs in optimisation of medical radiological procedures for the protection and safety of patients. The concept and proper use of DRLs should be included in the education and training programmes of practitioners (including dentists), medical physics experts, individuals that conduct medical exposures and others as appropriate, who are involved in medical exposure to ionising radiation.[6]

Local facility DRLs should be made available to appropriate staff but should not be used for individual patients or as trigger (alert or alarm) level for individual patients as some radiation doses may be justified given their size or the complexity of the procedure.[3] It is important to note that DRLs should be used as a supplement to professional judgement to aid in the optimisation of medical exposures to ionising radiation.[3,4,9,10] The priority for any diagnostic and or interventional medical radiological procedure is to obtain the required medical information while using the lowest dose achievable.[2,5,11]

DRLs are not dose limits

DRLs are not individual dose limits for patients or procedures. They should be used as a supplement to professional judgement to aid in the optimisation of medical exposures to ionising radiation.

Local facility DRLs must be established and used, and their adherence regularly reviewed, for different pieces of medical radiological equipment, procedures and clinical tasks.[3] This will allow more in-depth analysis of patient dose (for the same procedure/clinical task) in order to evaluate:

- specific equipment (for example, comparing the dose routinely given by two different dental X-ray sets)
- devices utilised to capture the image (for example, computed radiography compared to direct digital radiography or flat panel detector fluoroscopy compared to image intensifier fluoroscopy)
- use of available software (for example, iterative reconstruction compared to filtered back projection).

5.3 Reviewing local facility DRLs

The development of DRLs is a cyclical process and local facility DRLs must be regularly reviewed by the undertaking.[6] Generally, local facility medical DRLs should

be reviewed annually and local facility dental DRLs should be reviewed every two years. DRLs should also be reviewed when new technologies are introduced or a medical radiological procedure is changed to ensure that there is adequate optimisation of medical radiological procedures to protect patients. [3, 4]

How often should facility DRLs be reviewed?

Facility DRLs should be annually reviewed or after the introduction of new equipment, software or techniques.

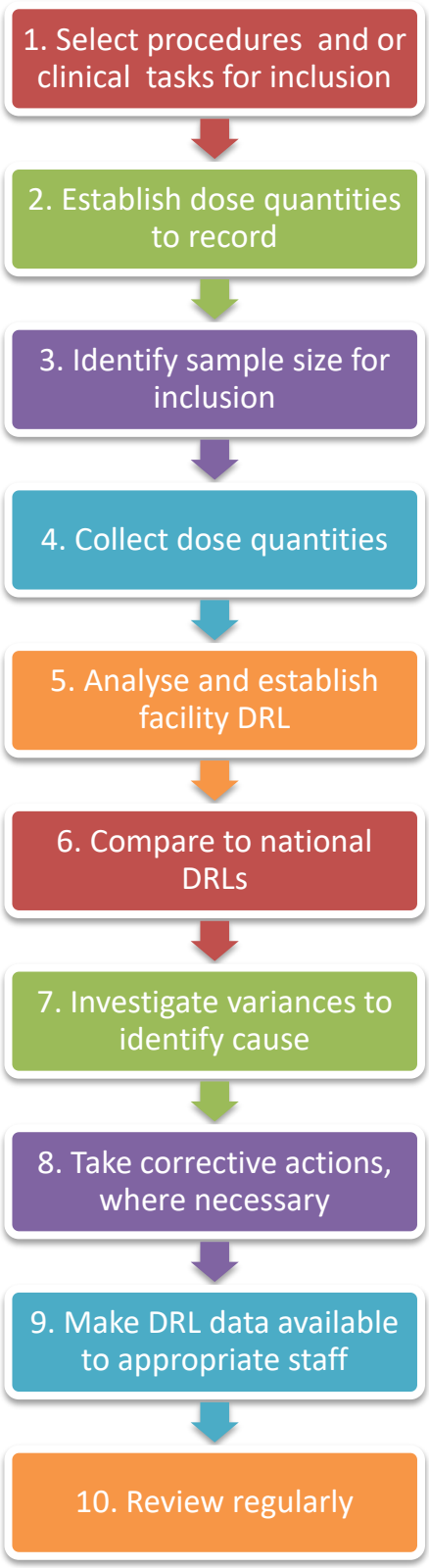
DRL values are not static. The DRL process does not stop after one review but should be subject to regular review and incorporated into an undertaking's quality assurance programme.

Under the regulations, undertakings are required to retain records of such DRL reviews and any corrective actions carried out for a period of five years and make these records available to HIQA on request.[6]

What records should be kept?

Under the regulations, undertakings are required to retain records of DRL reviews and any corrective actions carried out for a period of five years and make these records available to HIQA on request.

Figure 1. DRL process



5.4 Corrective actions

When is a DRL value considered to be 'consistently exceeded'?

A DRL value is considered to be 'consistently exceeded' when the median dose quantity is greater than the established DRL value.

When a DRL value is identified as being consistently exceeded, an investigation of equipment and practices must be conducted immediately to ensure optimisation of safety and protection of patients. When the investigation determines the reason that the DRL is consistently exceeded, corrective actions must be taken without undue delay.

The undertaking must ensure that this review is appropriate and investigates the reasons the DRL was consistently exceeded. An appropriate review should involve:

- a multidisciplinary team with appropriate expertise and experience
- a designated individual of suitable seniority identified as having responsibility on the undertakings behalf for implementing the corrective actions identified.

Furthermore, review should identify:

- the precise cause
- the corrective actions to be taken, which should be outlined as SMART objectives (specific, measurable, achievable, realistic and timely).

This investigation into the cause should, at a minimum, examine:

- the measurement methodology used to assess the DRL quantities
- the characteristics and performance of medical radiological equipment
- the case-mix included in the sample size
- the technical parameters used in the medical radiological procedure
- the technique(s) used in the medical radiological procedure
- medical radiological procedure protocols and adherence to the use of these protocols.

Table 2. Examples of possible causes of why a DRL is consistently exceeded (assuming appropriate measurement methodology)

Possible causes for consistently exceeding a DRL
A protocol is not adapted to account for paediatric patient characteristics
Unsatisfactory equipment performance
Incorrect technical parameters selected

For example, when the cause is related to unsatisfactory equipment performance, a review should be conducted by a medical physics expert in conjunction with the equipment manufacturer. The equipment manufacturer should consider their regulatory requirements to report such issues to the Health Products Regulatory Authority (HPRA). If it is determined that the equipment is old or substandard, the corrective action may require the replacement or upgrading of the equipment. If the cause is not related to age or substandard equipment, then the quality assurance programmes for the equipment should be reviewed. Where performance testing indicates that the equipment is functioning adequately, the criteria used to determine what adequate performance is may need to be reviewed and updated. Where this change to the performance criteria for the equipment indicates an issue, steps must be taken without undue delay to improve equipment which is inadequate or defective.

Furthermore, where the cause is related to the practical aspects of carrying out the medical radiological procedure, a review of the protocols for the medical radiological procedure and adherence to these protocols should be conducted and staff competence and training should be considered. The corrective actions taken in such cases may include:

- the revision and adjustment of the protocol
- additional training of staff and reassessment of competencies
- increasing awareness around the use and adherence to these protocols.

6. Conclusion

National DRL values are set for common procedures and clinical tasks undertaken in Ireland. These allow undertakings to compare local facility DRLs, representative of patient dose, to a national standard. Where local facility DRLs are deemed too high or low, an immediate investigation into the cause is required. Corrective actions identified must be recorded. An undertaking must ensure that practitioners (including dentists), medical physics experts and individuals that conduct medical exposures are informed of national DRLs and local facility DRLs must be established to facilitate patient dose optimisation.

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Appendix 1: Glossary of terms

Air kerma — the kinetic energy released per unit mass of air; measured in Gray (Gy).

Clinical audit — a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.

Computed radiography (CR) — a digital image acquisition and processing system for radiography that uses computers and laser technology.

Diagnostic reference levels — dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment.

Direct digital radiography — a digital image acquisition and processing system for radiography that captures data and immediately transfers it to a computer system.

Dose constraint — a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation.

Dose limit — the value of the effective dose (where applicable) or the equivalent dose in a specified period which shall not be exceeded for an individual.

Dual-energy X-ray absorptiometry (DXA or DEXA) — a type of medical exposure typically used to assess bone density in service users where low bone density or osteoporosis is suspected.

Filtered back projection — means an analytic reconstruction algorithm which applies a filter to remove blurring.

Flat panel detector — a class of solid-state X-ray digital radiography used in both radiography and fluoroscopy (as an alternative to X-ray image intensifiers in fluoroscopy equipment).

Gray (Gy) — a unit of measurement for absorbed dose. It is equivalent to one joule of energy absorbed per kilogram of material.

Image intensifier — a device to facilitate visual real-time imaging.

Interventional radiology — the use of X-ray imaging techniques to facilitate the use of devices in the body for diagnostic or treatment purposes.

Ionising radiation — energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3×10^{15} hertz or more) capable of producing ions directly or indirectly.

Iterative reconstruction — the use of iterative algorithms to reconstruct 2D and 3D images in certain imaging techniques.

Mammography — the specialised area of radiology involved in the imaging of breast tissue.

Mean glandular dose —the absorbed dose of radiation to the breast in mammography.

Median — is the middle number in a sorted list of numbers.

Medical exposure — exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research.

Medical radiological — pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes.

Medical radiological procedure — any procedure giving rise to medical exposure.

MERU — the HSE Medical Exposure Radiation Unit audited radiation practice in medical radiological installations in Ireland on behalf of the Department of Health prior to the commencement of European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

Patient entrance reference point — the position at which the cumulative air kerma for interventional X-ray equipment is measured in order to reasonably represent the air kerma incident on the patient's skin surface.

Quality assurance — all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance.

Quality control — the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring,

evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

Undertaking — a person or body who has a legal responsibility for carrying out, or engaging others to carry out, a medical radiological procedure, or the practical aspects of a medical radiological procedure, as defined by the regulations.

Appendix 2: National DRLs

Table 3. National DRL category, quantity, symbol and units

DRL Category	DRL Quantity	DRL Quantity Symbol	Other Common Symbols	DRL Quantity Unit
Dental radiography	Incident air kerma	Ka,i	IAK	mGy
	Air kerma-area product (Panoramic)	PKA	KAP, DAP	Gy.cm²
Radiography	Air kerma-area product	PKA	KAP, DAP	Gy.cm²
Mammography	Entrance-surface air kerma,	Ka,e,	ESAK, ESD	mGy
	Incident air kerma OR	Ka,i,	IAK	mGy
	Mean glandular dose	DG	MGD, AGD	mGy
Diagnostic fluoroscopy	Air kerma-area product	PKA	KAP, DAP	Gy.cm²
	Incident air kerma at the patient entrance reference point	± Ka,r	CAK	mGy
	Fluoroscopy time	FT		s
Interventional radiology	Air kerma-area product	PKA	KAP, DAP	Gy.cm²
	Incident air kerma at the patient entrance reference point	Ka,r	CAK	mGy
	Number of images (in cine or digital subtraction angiography runs)	n		
Computed tomography	Computed tomography dose index (volume)	CTDI vol		mGy

DRL Category	DRL Quantity	DRL Quantity Symbol	Other Common Symbols	DRL Quantity Unit
	Dose–length product	DLP		mGy.cm
Nuclear medicine	Administered activity/Activity per body weight			MBq or MBq/kg

Table 4. National adult dental DRLs [16]

Procedure / Clinical task	DRL Quantity	DRL
Intra oral	Ka,i	1.2 mGy
Panoramic	PKA	81 mGy.cm²
Lateral cephalometric radiograph	PKA	35 mGy.cm²
Dental CBCT (prior to placement of a maxillary molar implant)	PKA	265 mGy.cm²

Table 5. National adult general radiography DRLs [21]

Procedure / Clinical task	DRL Quantity	DRL
Chest PA	PKA	0.12 Gy.cm²
Chest AP	PKA	0.13 Gy.cm²
Portable Chest AP	PKA	0.16 Gy.cm²
Abdomen AP	PKA	1.7 Gy.cm²
Pelvis AP	PKA	1.91 Gy.cm²
Cervical spine AP	PKA	0.16 Gy.cm²
Cervical spine LAT	PKA	0.19 Gy.cm²
Thoracic spine AP	PKA	0.76 Gy.cm²
Thoracic spine LAT	PKA	1.8 Gy.cm²
Lumbar spine AP	PKA	1.6 Gy.cm²
Lumbar spine LAT	PKA	2.24 Gy.cm²
Extremities (Foot/ankle/wrist/hand)	PKA	0.06 Gy.cm²

Table 6. National mammography DRLs [21]

Procedure / Clinical task	DRL Quantity	DRL
Single mediolateral oblique (MLO) view	DG	2.2 mGy
Single craniocaudal (CC) view	DG	2.2mGy
Breast Tomosynthesis – MLO view	DG	2.8 mGy
Breast Tomosynthesis – CC view	DG	2.8 mGy

Table 7. National adult fluoroscopy DRLs [22]

Procedure / Clinical task	DRL Quantity	DRL
Central line/central venous catheter (CVC) insertion excluding peripherally inserted central venous catheter (PICC)	PKA	1 Gy.cm²
Lumbar puncture under fluoroscopy	PKA	3.1 Gy.cm²
Peripherally inserted central venous catheter (PICC)	PKA	0.8 Gy.cm²
Barium (or water soluble) enema	PKA	10.5 Gy.cm²
Barium (or water soluble) meal + swallow	PKA	10.6 Gy.cm²
Barium (or water soluble) swallow	PKA	5.8 Gy.cm²
Barium swallow (video)/speech and language therapy (SLT) investigation	PKA	2.4 Gy.cm²
Endoscopic retrograde cholangiopancreatography (ERCP)	PKA	3 Gy.cm²
Nephrostomy - bilateral	PKA	5.6 Gy.cm²
Nephrostomy - unilateral	PKA	2.9 Gy.cm²
Nephrostography - unilateral	PKA	1.9 Gy.cm²
Nephrostography + Ureteric stent insertion - unilateral	PKA	4.5 Gy.cm²
Hysterosalpingography (HSG)	PKA	1.4 Gy.cm²

Arthrography - extremity injection	PKA	0.2 Gy.cm²
Arthrography - pelvic injection	PKA	0.3 Gy.cm²
Arthrography - spinal injection	PKA	1 Gy.cm²
Intramedullary (IM) nail - femur	PKA	1.9 Gy.cm²
Orthopaedic – extremity excluding Intramedullary (IM) nail	PKA	0.1 Gy.cm²
Orthopaedic - pelvis	PKA	1.9 Gy.cm²
Orthopaedic - spinal	PKA	1.2 Gy.cm²

Table 8. National interventional radiology DRLs [22]

Procedure / Clinical task	DRL Quantity	DRL
Aortic endovascular aneurysm repair (EVAR)	PKA	103 Gy.cm²
Inferior vena cava (IVC) filter insertion/retrieval	PKA	11.3 Gy.cm²
Transcatheter arterial chemoembolisation (TACE)	PKA	127 Gy.cm²
Percutaneous transhepatic biliary drainage	PKA	11.5 Gy.cm²

Table 9. National interventional cardiology DRLs [22]

Procedure / Clinical task	DRL Quantity	DRL
Angiography coronary arteries	PKA	26 Gy.cm²
Angiography coronary arteries (CA) + Grafts	PKA	39.2 Gy.cm²
Angiography coronary arteries (CA) + percutaneous coronary intervention (PCI) - single vessel	PKA	50.2 Gy.cm²
Angiography coronary arteries (CA) + percutaneous coronary intervention (PCI) - multi vessel	PKA	68.3 Gy.cm²
Percutaneous coronary intervention (PCI) - multiple vessels	PKA	96.5 Gy.cm²
Percutaneous coronary intervention (PCI) -single vessel	PKA	51.9 Gy.cm²
Implantable cardioverter defibrillator (ICD) insertion - dual chamber	PKA	6.3 Gy.cm²
Implantable cardioverter defibrillator (ICD) insertion - single chamber	PKA	1.3 Gy.cm²
Pacemaker insertion - dual chamber	PKA	4 Gy.cm²
Pacemaker insertion - single chamber	PKA	3.3 Gy.cm²
Right heart study	PKA	4.2 Gy.cm²
Transcatheter aortic valve implantation (TAVI)	PKA	89.7 Gy.cm²
Cardiac ablation +/- electrophysiological (EP) study - atrial flutter	PKA	6.7 Gy.cm²

Cardiac ablation +/- electrophysiological (EP) study - atrial fibrillations	PKA	7 Gy.cm²
Cardiac ablation +/- electrophysiological (EP) study- Premature ventricular contractions (PVC)	PKA	7 Gy.cm²

Table 10. National adult computed tomography (CT) DRLs [15,16]

Procedure / Clinical task	DRL Quantity	DRL
Brain (routine imaging/head trauma/ haemorrhagic assessment)	DLP	908 mGy.cm
Brain acute stroke (all phases/series)	DLP	970 mGy.cm
Sinuses/chronic sinusitis	DLP	184 mGy.cm
C spine/trauma — detection or exclusion of a fracture	DLP	473 mGy.cm
Thorax	DLP	310 mGy.cm
Thorax Hi resolution/interstitial lung disease	DLP	337 mGy.cm
Thorax CTPA/detection or exclusion of pulmonary embolus	DLP	346 mGy.cm
Thorax/pulmonary metastases	DLP	258 mGy.cm
Abdomen and pelvis	DLP	556 mGy.cm
Abdomen liver /abdominal metastases in colorectal cancer	DLP	554 mGy.cm
Abdomen/appendicitis-detection or exclusion	DLP	486 mGy.cm
KUB-urogram (All phases/series)	DLP	1150 mGy.cm
KUB/exclusion or detection of a urinary calculus	DLP	263 mGy.cm
Thorax, abdomen and pelvis (TAP)	DLP	770 mGy.cm
Thorax, abdomen and pelvis (TAP)/oncological follow up	DLP	635 mGy.cm
Virtual colonoscopy (All phases/series)/polyps, tumour	DLP	950 mGy.cm

Procedure / Clinical task	DRL Quantity	DRL
Coronary CT angiography prospective, no padding*	DLP	170 mGy.cm
Coronary CT angiography prospective, with padding	DLP	280 mGy.cm
Retrospective with gating	DLP	380 mGy.cm

*Padding refers to predefined scanning area of every R-R interval.

Table 11. National adult nuclear medicine DRLs [23]

Radionuclide	Pharmaceutical	Procedure / Clinical Task	Route of Administration	Type of Imaging	DRL Quantity	DRL
Planar and SPECT imaging						
^{99m}Tc	Sestamibi (MIBI)	Parathyroid imaging (washout method)	IV	Planar and SPECT combined	Administered activity	740 MBq
^{99m}Tc	Pertechnetate	Thyroid imaging/ uptake	IV	Planar	Administered activity	100 MBq
^{99m}Tc	DTPA	Renal imaging	IV	Planar	Administered activity	300 MBq
^{99m}Tc	MAG3	Renal imaging	IV	Planar and SPECT combined	Administered activity	105 MBq
^{99m}Tc	DMSA	Renal imaging	IV	Planar	Administered activity	84 MBq

^{99m}Tc	Colloid/ Nanocolloid	Sentinel node (Breast) study – same day	Interstitial	Planar	Administered activity	23 MBq
^{123}I	Ioflupane	Brain imaging (Brain Dopaminergic System Imaging and or DAT scan)	IV	SPECT	Administered activity	183 MBq
^{99m}Tc	Phosphonates and phosphates	Bone imaging scan	IV	Planar	Administered activity	613 MBq
^{99m}Tc	Phosphonates and phosphates	Bone imaging scan	IV	SPECT	Administered activity	680 MBq
^{99m}Tc	Phosphonates and phosphates	Triple phase bone imaging scan	IV	Planar and SPECT combined	Administered activity	658 MBq
PET-CT						
^{18}F	FDG	Whole body tumour imaging	IV	PET	Administered activity	368 MBq

Table 12. National adult nuclear medicine CT component of hybrid imaging DRLs [23]

Procedure / Clinical task	DRL Quantity	DRL
CT hybrid imaging for SPECT		
Ankles and Feet – Orthopaedic or infection – Attenuation correction/localisation	DLP	131 mGy.cm
	$CTDI_{vol}$	6.35 mGy
Pelvis (to include hips) – Orthopaedic or infection and possible bone metastasis –Attenuation correction/localisation	DLP	171 mGy.cm
	$CTDI_{vol}$	4.85 mGy
Lumbar spine – Orthopaedic or infection and possible bone metastasis –Attenuation correction/localisation	DLP	160 mGy.cm
	$CTDI_{vol}$	4.15 mGy
Neck – Parathyroid imaging – Attenuation correction/localisation	DLP	124 mGy.cm
	$CTDI_{vol}$	5.46 mGy
MIBG and Octreotide – Oncology imaging – Attenuation correction/localisation	DLP	151 mGy.cm
	$CTDI_{vol}$	3.38 mGy
CT hybrid imaging for PET		
Whole body (vertex to toes) – Attenuation correction/localisation	DLP	665 mGy.cm
	$CTDI_{vol}$	5.7 mGy
Whole body (eyes to thighs) – Attenuation correction/localisation	DLP	559 mGy.cm
	$CTDI_{vol}$	5.7 mGy

Table 13. National paediatric nuclear medicine DRLs [23]

Procedure / Clinical task	DRL Quantity	DRL
Paediatric nuclear medicine procedures	Activity per body weight (MBq/kg)	EANM paediatric dosage card and or ARSAC guidance

Table 14. National adult DXA DRLs [21]

Procedure / Clinical task	DRL Quantity	DRL
Lumbar Spine/Bone Density Analysis (BDA)	PKA	20 mGy.cm²
Single Hip/ BDA	PKA	15 mGy.cm²
Distal forearm/ BDA	PKA	7 mGy.cm²
Lumbar spine/Vertebral Fracture analysis (VFA)	PKA	71 mGy.cm²

Table 15. National paediatric CT DRLs [4,15]

Procedure / Clinical task	DRL Quantity	DRL
Head (0 - < 3 months)	DLP	239 mGy.cm
Head (3 months - 1 year)	DLP	376 mGy.cm
Head (1 - 6 years)	DLP	536 mGy.cm
Head (> 6 years)	DLP	742 mGy.cm
Thorax (<5 kg)	DLP	35 mGy.cm
Thorax (5<15 kg)	DLP	81 mGy.cm
Thorax (15<30 kg)	DLP	99 mGy.cm
Thorax (30<50 kg)	DLP	166 mGy.cm
Thorax (50<80 kg)	DLP	131 mGy.cm
Abdomen (<5 kg)	DLP	45 mGy.cm
Abdomen (5<15 kg)	DLP	120 mGy.cm
Abdomen (15<30 kg)	DLP	168 mGy.cm
Abdomen (30<50 kg)	DLP	210 mGy.cm
Abdomen (50<80 kg)	DLP	397 mGy.cm

Table 16. National paediatric radiography and fluoroscopy DRLs [21, 22]

Procedure / Clinical task	DRL Quantity	DRL
Thorax AP/PA (<5 kg)	PKA	9 mGy.cm²
Thorax AP/PA (5-<15 kg)	PKA	17 mGy.cm²
Thorax AP/PA (15-<30 kg)	PKA	22 mGy.cm²
Thorax AP/PA (30-<50 kg)	PKA	50 mGy.cm²
Thorax AP/PA (50-80 kg)	PKA	70 mGy.cm²
Abdomen AP (<5 kg)	PKA	13 mGy.cm²
Abdomen AP (5-<15 kg)	PKA	63 mGy.cm²
Abdomen AP (15-<30 kg)	PKA	100 mGy.cm²
Abdomen AP (30-<50 kg)	PKA	286 mGy.cm²
Abdomen AP (50-80 kg)	PKA	457 mGy.cm²
Pelvis AP (<5 kg)	PKA	27 mGy.cm²
Pelvis AP (5-<15 kg)	PKA	39 mGy.cm²
Pelvis AP (15-<30 kg)	PKA	111 mGy.cm²
Pelvis AP (30-<50 kg)	PKA	412 mGy.cm²
Pelvis AP (50-80 kg)	PKA	800 mGy.cm²
Cervical Spine AP (15-<30 kg)	PKA	28 mGy.cm²
Cervical Spine AP (30-<50 kg)	PKA	59 mGy.cm²
Cervical Spine AP (50-80 kg)	PKA	96 mGy.cm²
Cervical Spine LAT (15-<30 kg)	PKA	41 mGy.cm²
Cervical Spine LAT (30-<50 kg)	PKA	54 mGy.cm²
Cervical Spine LAT (50-80 kg)	PKA	68 mGy.cm²
Thoracic Spine AP (30-<50 kg)	PKA	244 mGy.cm²

Thoracic Spine AP (50-80 kg)	PKA	306 mGy.cm²
Thoracic Spine LAT (30-<50 kg)	PKA	566 mGy.cm²
Thoracic Spine LAT (50-80 kg)	PKA	551 mGy.cm²
Lumbar Spine AP (15-<30 kg)	PKA	124 mGy.cm²
Lumbar Spine AP (30-<50 kg)	PKA	262 mGy.cm²
Lumbar Spine AP (50-80 kg)	PKA	445 mGy.cm²
Lumbar Spine LAT (15-<30 kg)	PKA	125 mGy.cm²
Lumbar Spine LAT (30-<50 kg)	PKA	628 mGy.cm²
Lumbar Spine LAT (50-80 kg)	PKA	850 mGy.cm²
Scoliosis AP (30-<50 kg)	PKA	980 mGy.cm²
Scoliosis AP (50-80 kg)	PKA	1630 mGy.cm²
Scoliosis LAT (30-<50 kg)	PKA	1869 mGy.cm²
Scoliosis LAT (50-80 kg)	PKA	1840 mGy.cm²
Paediatric gastro-intestinal (GI) tract - upper GI investigations (5-<15 kg)	PKA	177.4 mGy.cm²
Micturating or voiding cystourethrography (MCU/VCU) (5-<15 kg)	PKA	207 mGy.cm²

Revision History

Publication date	Title /version	Summary of changes
February 2020	Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation, version 1	First publication
March 2021	Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation, version 1.1	Section 4.2, Mammography 95th percentile dose added as a complementary metric Section 5.1, Footnote added to address low annual procedure numbers in the establishment of local facility DRLs Section 5.4, Addition of regulatory requirements of equipment manufacturers to report issues to the Health Products Regulatory Authority (HPRA)
July 2021	Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation, version 1.2	Section 4.2, Update to include general radiography, mammography and DXA national DRL survey Appendix 2, Update tables 5, 6 and 13. Addition of table 12
October 2022	Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation, version 1.3	Section 4.2, Update to include fluoroscopy and fluoroscopically guided interventions (FGI) national DRL survey Appendix 2, Update tables 7, 8, 9 and 14.
November 2023	Guidance on the establishment, use and review	Cover updated.

	of diagnostic reference levels for medical exposure to ionising radiation, version 1.4	Table 1, updated with information about paediatric nuclear medicine procedures. Section 4.2, Update to nuclear medicine procedures national DRL survey Section 5.1, Update to the methodology for establishing local facility DRLs for nuclear medicine. Appendix 2, Update Table 11 and addition of new Tables to incorporate CT hybrid imaging national DRLs and paediatric DRLs for nuclear medicine
December 2023	Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation, version 1.5	Update formatting and typographical error

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