New ICRP Recommendations on Assessment and Use of Diagnostic Reference Levels in Medical Imaging

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Content

• Introduction
• Diagnostic Reference Levels (DRLs): concept and practical use
• New ICRP recommendations
• Practical implementation
Framework of radiological protection

- Justification
- Optimisation
- Dose limitation for staff and population (no for medical exposures)
Why optimisation of exposure in medical imaging?

• Radiological practice shows wide variation in patient doses from hospital to hospital, both for simple and complex examinations.

UK patient dose distributions (mean dose of x-ray room) (HPE Reports, UK)
The basic aim of the optimisation of protection is to maximise the net benefit

- optimisation does not necessarily mean the reduction of doses to the patient
- it means minimum dose compatible with image quality necessary to obtain the diagnostic information

Optimisation is usually applied at two levels:

1. the design, appropriate selection, and construction of equipment and installations
2. the day-to-day methods of working (procedures)
Objective of establishing and, after, using DRLs is the promotion of the exposure control to avoid unnecessary exposure to patients.

Evaluation of DRLs is included in a more general program of quality assurance → contextual analysis of different factors:

- Exposure
- Image Quality
- Equipment quality
- Procedure and Protocols quality
Main aim of the DRL: to cut high doses

- DRL are set at the 75th percentile of the dose distribution from a survey conducted across a broad user base using a specified dose measurement protocol and phantom.
- Hospitals/clinics in the upper band are invited to investigate and implement corrective actions
Expected impact on radiological practice

Fig. 4. The use of a reference levels in existing situation and the evolution of the distribution of individual doses with time as a result of the optimisation process.
Diagnostic reference levels were first mentioned by the International Commission on Radiological Protection (ICRP) in 1990 and subsequently recommended in more details in 1996.

DRL introduced as **Dose Constraints**:

ICRP 1996 (par. 180)

“..Considerations should be given to the use of dose constraints, or investigation levels, selected by appropriate bodies or regulatory agency, for application in some common diagnostic procedures...”
History of DRL concept

ICRP 73 (1996) - *Radiological Protection and Safety in Medicine*

- Introduced the term “diagnostic reference level”
- Explained its place in the broader ICRP concept of reference levels
- Expanded the ICRP Publication 60 recommendation

ICRP 73 (1996)

“.. Dose limits/constraints are not applicable. To use diagnostic reference levels. A DRL is not a limit and do not apply to a single patient... It is a form of investigation level to identify unusually high levels, which calls for local review if consistently exceeded”
History of DRL concept

QA PROGRAMS

– QC
– PATIENT DOSE ASSESMENT

ICRP-103 (2007):

Diagnostic reference level. Used in medical imaging with ionizing radiation to indicate whether, in routine conditions, the patient dose or administered activity from a specified procedure is unusually high or low for that procedure.
Present status of the use of DRLs

- After 20 years of use of DRLs, still a lack of knowledge on the concept in the medical community
- Sometimes DRLs are used as limits and applied to individual patients
- The name “diagnostic reference levels” may be confusing (in the past) when applied to interventional procedures
- Need to improve the use of DRLs
New ICRP 135 (2017)

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7. **APPLICATION OF DRLS IN CLINICAL PRACTICE**
8. **SUMMARY OF MAIN POINT**
• **Diagnostic reference level (DRL)** is the Commission’s term for a form of investigation level used for optimisation of protection in the medical exposure of patients.
Common facts

- DRLs are **not dose limits**
- The DRL has been shown to be an **effective tool for identification** of examinations for which optimisation of protection should be undertaken.
- All individuals who have a role in subjecting a patient to a medical exposure should be familiar with the DRL process as a tool for optimisation of protection.
- Application of DRLs is **not sufficient** for optimisation.
- The diagnostic quality of image(s) must be evaluated.
The DRL process has been popularized in Europe and applied with good results.

In the United Kingdom, DRLs have been redefined every 5 years since the mid-1980s, reducing doses up to 50%. (of course, technology advancement has also played a role)
New definitions

More coherent terminology:

• ‘DRL quantity’ : a commonly and easily measured or determined radiation metric that assesses the amount of ionising radiation used to perform a medical imaging task

• ‘DRL value’ : an arbitrary notional value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of the DRL quantity
How to define the DRLs

• The Commission considers use of the **median of the national distribution** of a DRL quantity to be a useful additional tool for improving optimisation.

• In previous recommendation DRL derived from national distribution of the **mean values**.
Radiation metrics

• The radiation metric used as a DRL quantity should be easily measured or available
  – Air kerma-area product ($P_{KA}$)
  – Entrance-surface air kerma ($K_a,e$)
  – Entrance-surface air kerma ($K_a,e$) or Mean glandular dose ($D_G$) in mammography
  – Volume computed tomography (CT) dose index (CTDIvol) and Dose–length product (DLP) for CT
  – Administered activity, or preferably administered activity per body weight
Radiation metrics: effective dose

- Effective dose is not appropriate as a DRL quantity.
- Effective dose is not a measurable quantity and does not assess the amount of ionising radiation used to perform a medical imaging task.
- Its use could introduce extraneous factors (stochastic risk in the average population) that are not needed and not pertinent for the purpose of DRLs.
How to use the DRL

• **Median values** of distributions of DRL quantities at a facility should be compared with (national/regional) DRL values

• Values of DRL quantities for individual patients should not be compared with DRL, because DRL is intended for groups of patients (standard patients, equipment and procedure)

• The DRL process should be part of the quality assurance (QA)

• Repeat surveys following any optimisation, and periodically
How to assess DRLs

• National legislation should identify organisations responsible to assess DRLs

• 1st step: to identify:
  – examination/procedures with highest frequencies and/or doses
  – DRL quantities
  – the hospitals/clinics sample (20-30 facilities can be sufficient in a large country)

• 2nd step: to conduct the national survey
  – At least 20 patients/room (30 for fluoroscopy and CT, 50 for mammography) of standardised size
  – Hospitals with HIS/PACS can easily provide more data
How to assess DRLs (cont.)

- **Accuracy** of doses provided/transferred from radiological equipment should be assured.
- **Median value** from each x-ray installation and procedure should be assessed.
- **National DRLs** should be set as the 75th percentile of the median values in the sample of installations.
- **Local DRLs** (< national DRL value) may be used as additional tools for optimisation.
- **National DRL** should be revised every 3-5 years or after substantial technology changes.
How to assess DRLs (cont.)

- Measures on patients or phantoms?

<table>
<thead>
<tr>
<th>Examination</th>
<th>DRL recommended</th>
<th>Method of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammography</td>
<td>Yes</td>
<td>Patient survey to set DRL and phantom measurements as standard dose comparator</td>
</tr>
<tr>
<td>Intra-oral dental radiography</td>
<td>Yes</td>
<td>Output measurement on standard settings</td>
</tr>
<tr>
<td>Panoramic dental radiography</td>
<td>Yes</td>
<td>Measurement of air kerma-area product on standard settings</td>
</tr>
<tr>
<td>CT</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Radiography of the trunk</td>
<td>Yes</td>
<td>Patient survey preferred</td>
</tr>
<tr>
<td>Skull radiography</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Paediatric radiology</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Paediatric CT</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Extremity radiography</td>
<td>Yes (lower priority)</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Mobile radiography</td>
<td>Yes (lower priority)</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Neonatal radiography</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Paediatric mobile radiography</td>
<td>Yes (for dedicated children’s hospitals)</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Barium studies</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Interventional radiology and cardiology</td>
<td>Yes</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Other fluoroscopy</td>
<td>Possibly, depending on level of use</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Nuclear medicine – adult</td>
<td>Yes</td>
<td>Based on administered activity or, preferably, activity per body weight</td>
</tr>
<tr>
<td>Nuclear medicine – paediatric</td>
<td>Yes</td>
<td>Based on administered activity with adjustments for the size or weight of the child</td>
</tr>
<tr>
<td>Bone densitometry</td>
<td>Yes (lower priority)</td>
<td>Patient survey</td>
</tr>
</tbody>
</table>

DRL, diagnostic reference level; CT, computed tomography.
Distribution of DRL quantities (automatic electronic collection of data)

• Large numbers of patients can be included from an electronic data collection system (dose tracking systems)

• The distribution should be reviewed to identify outliers (large patients, incorrect procedure name, ..)

• These outliers can be easily identified and removed.

• In any case they have minimal impact of the median value
Why the 75% percentile?

- Typical distributions from multiple facilities are approximately log-normal, with few facilities with uncommonly high values.
- The 75th percentile usually lies well below the high tail of the distribution → useful marker for identification of high dose facilities.
- It is reasonable to set the DRL value at the 75th percentile of the distribution, and the ICRP now recommends this practice.
DRLs purpose

- To identify facilities where investigation of practices is advisable because protection is not optimised (i.e. local median value > national DRL value).
- But, facilities with local median values < national DRL value can improve practice to take the optimisation process further forward.
- So, DRLs provide additional benchmark against which such healthcare facilities can evaluate their performance.
Application of the DRLs in clinical practice

• When the median facility value of a DRL quantity is very much lower than the DRL, image quality (or diagnostic information) should be examined as a priority.

The DRL process does not stop after a single assessment. Repeat surveys are required following any optimisation, and the whole process should be repeated after an appropriate time interval.
DRLs in conventional radiography and mammography

- DRLs are widely applied.
- For mammography, the DRL quantity can be:
  - Entrance surface air kerma
  - Or, mean glandular dose (less dependent from kV, filtration and anode-filter combination)
  - In Europe, a set of DRLs function of breast thickness has been recommended
  - Screening or clinical mammography: same DRLs
  - Mammo tomosynthesis should have proper DRL
DRLs in interventional procedures

- DRLs are challenging to implement for interventional procedures because patient doses depend on a wide variety of factors in addition to patient size.
- Complexity is a determinant of patient dose:
  - A multiplying factor for the DRL may be appropriate for more complex cases of a procedure
  - An alternative method requires both a regional or national data set comprising dosimetric data for every case of a procedure from a large number of facilities, and a local data set of the dosimetric data for every case of the same procedure performed at the local facility.
Complexity index method

Clinical and Technical Determinants of the Complexity of Percutaneous Transluminal Coronary Angioplasty Procedures: Analysis in Relation to Radiation Exposure Parameters

Guglielmo Bernardi, Renato Padovani, Giorgio Morocutti, Eliseo Vaño, Maria Rosa Malisan, Massimo Rinnuncini, Leonardo Spedicato, and Paolo M. Fioretti

Conference on Physics in Medicine: From Diagnosis to Treatment, Riyadh, 7-9 Nov 2017

Approx.

Medium = 1.5 x simple

Complex = 2.0 x simple
Complexity index method

- A complexity index is used to normalise DRL
- e.g. Complexity factors for percutaneous coronary interventions (PTCA): number of vessels treated, number of lesions, number of vessels with severe tortuosity, number of bifurcation stents have been identified that allow these procedures to be classified as simple, medium, or complex

(Ryan et al., 1988; Bernardi et al., 2000; Balter et al., 2008; IAEA, 2009).
Data set method

• An ”Advisory Data Set (ADS)” comprises every case performed in the sample of installations (do not require information on the single procedure)
• It provides a distribution of the DRL quantity
• A “Facility Data Set (FDS)” comprises every case and its distribution is compared with the national ADS:
  — i.e. the local median value is compared with the 75th percentile of the benchmark data, and an investigation is performed if the local median exceeds the 75th percentile
  — An investigation may also be desirable if the local median is below the 10th percentile (IAEA, 2009) or the 25th percentile (NCRP, 2010) of the ADS.
How to use DRLs in IR

• If the values of DRL quantities for patients are higher than expected, the investigation should start with evaluation of
  1. equipment and equipment set-up
  2. procedure protocols
  3. operator technique (more difficult)
• Frequently more quantities are used to provide a set of DRL values for each procedure type:
  – *\(K_{a,r}\) and \(PKA\)* as estimators of the risk of radiation-related tissue effects and stochastic effects, respectively
  – *Cumulative fluoroscopy time*, as an indicator of procedure complexity and/or operator experience
  – *The number of acquired cine or DSA images* as indicator of some aspects of procedure protocol
Example: multiple DRL values in IR

A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures

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### TABLE III. Reference (guidance) levels for simple, medium and complex PCI procedures expressed in term of fluoroscopy time and $P_{KA}$.

<table>
<thead>
<tr>
<th>Complexity group</th>
<th>Reference (guidance) levels</th>
<th>Fluoroscopy time (min)</th>
<th>No. images</th>
<th>$P_{KA}$ (Gy cm$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple CI=1</td>
<td></td>
<td>15</td>
<td>1500</td>
<td>100</td>
</tr>
<tr>
<td>Medium CI=2</td>
<td></td>
<td>22</td>
<td>1700</td>
<td>125</td>
</tr>
<tr>
<td>Complex CI&gt;2</td>
<td></td>
<td>32</td>
<td>2300</td>
<td>200</td>
</tr>
</tbody>
</table>

$^{a}$CI=complexity index.

### TABLE V. Suggested guidance levels (75th percentile).

<table>
<thead>
<tr>
<th>Procedure</th>
<th>$P_{KA}$ (KAP) (Gy cm$^2$)</th>
<th>Fluoroscopy time (min)</th>
<th>No. of images</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>50</td>
<td>9</td>
<td>1000</td>
</tr>
<tr>
<td>(PCI)—moderate complexity</td>
<td>125</td>
<td>22</td>
<td>1700</td>
</tr>
</tbody>
</table>
Computed Tomography

- CT utilises CTDIvol and DLP as DRL quantities. The number of scan sequences in the examination may also be helpful.
- Size-specific dose estimates (SSDE) (AAPM, 2011) may be used as an additional step for optimisation.
- The DLP value used is the cumulative DLP for the entire examination.
- DLP values for individual scan sequences can also be useful, in addition to the cumulative DLP.
Cone Beam CT

• Cone-beam CT used in dental, IR and radiotherapy
  – Important in IR: 16% of total $P_{KA}$ in paediatric cardiology

• DRL quantities: $P_{KA}$, $K_{a,r}$, $CTD_{vol}$, and DLP, depending on availability

• Little experience on DRL setting:
  – Dental (UK,2010): 250 mGycm$^2$
Nuclear medicine

• DRL values should be established in terms of the administered activity or, preferably, activity per body weight

• Weight-based administered activities may not be appropriate for examinations where the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid scans).
Hybrid systems

• Hybrid systems: use different DRL quantities for each modality independently
e.g. activity for radiopharmaceutical and CT DRL quantities for the CT component
• Wide variations between PET-CT systems: four-fold variations in CTDIvol

• CT patient dose depends on the purpose of the CT examination
  – It is preferable to perform a diagnostic CT alone for limited portions of the body
  – For the rest of the body, a low-dose CT is sufficient for attenuation correction and anatomic localisation

• CT DRL values of 8 mGy (CTDIvol) and 750 mGycm (DLP) have been proposed for whole-body PET-CT (Etard et al., 2012)
Paediatrics

• Establishing DRL values for children is more challenging than for adults, due to the broad range of sizes of paediatric patients

• Patient age categories have been used (not a good indicator)

• Weight categories are preferred, and should be used whenever possible:
  – <5 kg, 5-<15 kg, 15-<30 kg, 30-<50 kg, and 50-< 80 kg.
  – Or, ages of 0, 1, 5, 10, and 15 years (when weight not available or for head examinations)
Paediatrics

• General paucity of dosimetric data for patients in paediatric imaging

• DRL quantity can be presented as a function of patient weight instead of presentation in weight bands (little experience)

DRL quantity–weight curves for computed tomography (CT) of the chest (Jarvinen et al., 2015)
Paediatrics CT

- For CT: CTDIvol and DLP, based on calibration with a 32cm diameter phantom for body examinations and a 16cm diameter phantom for head examinations
- SSDE may be used in addition to the recommended DRL quantities as an additional source of information for optimisation
Application of the DRLs in clinical practice

• Each x-ray/nuclear medicine unit should be surveyed at intervals of about 3 years, and when substantial changes in technology or software have been introduced
  – more frequent (annual) for CT, interventional and hybrid systems.
  – more frequent if an automatic collection of data is available
Application of the DRLs in clinical practice

• Account must always be taken of the image quality and diagnostic information required for the medical imaging task.

• The highest priority for any diagnostic imaging examination is achieving image quality sufficient for the clinical purpose.

• The median (the 50th percentile) of the national DRL distribution can be accomplished with radiological practice that optimises dose management with respect to clinical image quality goals. (Achievable values)

• These median values provide additional information that can assist in optimising image quality and patient dose.
Example: Acceptable and achievable levels for digital mammography screening (EUREF)

<table>
<thead>
<tr>
<th>Thickness of PMMA [cm]</th>
<th>Equivalent breast thickness [cm]</th>
<th>Maximum average glandular dose to equivalent breasts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>acceptable level [mGy]</td>
</tr>
<tr>
<td>2.0</td>
<td>2.1</td>
<td>&lt; 0.8</td>
</tr>
<tr>
<td>3.0</td>
<td>3.2</td>
<td>&lt; 1.3</td>
</tr>
<tr>
<td>4.0</td>
<td>4.5</td>
<td>&lt; 2.0</td>
</tr>
<tr>
<td>4.5</td>
<td>5.3</td>
<td>&lt; 2.5</td>
</tr>
<tr>
<td>5.0</td>
<td>6.0</td>
<td>&lt; 3.3</td>
</tr>
<tr>
<td>6.0</td>
<td>7.5</td>
<td>&lt; 5.0</td>
</tr>
<tr>
<td>7.0</td>
<td>9.0</td>
<td>&lt; 7.3</td>
</tr>
</tbody>
</table>
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