

# DIAGNOSTIC REFERENCE LEVELS: CONCEPT, MISCONCEPTIONS AND CURRENT TRENDS-A REVIEW

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PJR January - March 2018; 28(1): 45-49

## ABSTRACT

The concept of diagnostic reference level has been in existence for almost three decades. It has also found its place in regulatory systems for nearly 20 years. Currently, national bodies are expected to establish their diagnostic reference level values. There is also provision for local and regional diagnostic reference levels. Also, almost all regulatory systems include the use of diagnostic reference levels for patient protection as an optimization tool. Despite the foregoing, there is still a lack of knowledge of the concept within the medical community. This prompted the International Commission on Radiological Protection (ICRP) to review its current document on diagnostic reference level with a view to come up with a new one consistent with current technology and practice. This paper seeks to review the concept, misconceptions and current trends in diagnostic reference level with special focus on some revised section in the new (ICRP) document.

## Introduction

It is normal for a patient undergoing a radiologic examination involving the use of ionising radiation to expect that the radiation dose received in different hospitals for the same procedure will be within a narrow range. However, several empirical surveys show that this is not always the case.<sup>1,2,3</sup> Dose variations by a factor of 20 or more have been reported for radiographic examinations in the early and late 1980's both in the United Kingdom and European Union. Diagnostic reference levels (DRLs) have proved useful as a tool in support of dose audit and practice review for promoting improvements in patient protection.<sup>3</sup> The application of DRLs in the UK since 1989 within a coherent framework has led to increase awareness of dose and helped to reduce unnecessary x-ray exposure. DRLs were first implemented in relation to conventional radiography in the 1980's and subsequently developed for other imaging modalities in the 1990.<sup>4</sup>

DRLs as defined by the current International Basic

Safety Standard (BSS), General Safety Requirements GSR Part 3 is a level used in medical imaging to indicate whether in routine conditions the doses to patients or the amount of radiopharmaceutical administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.<sup>5</sup> While DRLs are a useful tool, they are but only one step in the overall optimization process.<sup>6</sup> Several misconceptions have trailed the use of Diagnostic Reference Levels within the medical imaging community especially in developing countries. This review is intended to explore the concept, misconceptions and current trends in diagnostic reference levels.

### CONCEPT OF DIAGNOSTIC REFERENCE LEVELS

The International Commission on Radiological Protection (ICRP), whose recommendations form the basis of radiation safety standards worldwide, introduced the concept of DRLs in 1990 and further developed

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Submitted 2 October 2017, Accepted 5 December 2017

the concept with the guidelines in publications 73 and 105 and ICRP supporting guidance 2: specifically the ICRP defines a DRL as “a form of investigation level, apply to an easily measured quantity, usually the absorbed dose in air or equivalent material at the surface of a simple standard phantom or representative patient”.<sup>7</sup>

DRLs are not dose limits. Whereas dose limits are dose values that are not to be exceeded, DRLs can be exceeded if clinical need demands.<sup>8</sup> Dose limits do not apply to exposure of patients (Medical exposures) because this may compromise patient care. However, dose limits are applicable to occupational exposures. DRLs are used as a trigger level to identify those facilities with unusually high doses in a specified radiologic procedure, for which optimization actions are needed. In contrast to occupational dose limits, DRLs should not apply to individual patients, because one patient’s body mass and habitus may require higher dose than those of a standard patient.<sup>4</sup>

Type of procedure	Dose quantity and units
Radiography (including dental radiography)	Incident air kerma $K_i$ (in air, without backscatter) or entrance surface air kerma (or dose) $K_e$ (in air with backscatter), in mGy, for a given radiographic projection; air kerma (or dose)-area product in mGy.cm <sup>2</sup>
Mammography	Incident air kerma ( $K_i$ ), in mGy; mean glandular dose (DG), in mGy
Complex procedures including fluoroscopy guided procedures	Air kerma (or dose)-area product (PKA), in Gy.cm <sup>2</sup> cumulative air kerma at the reference point ( $K_{a,r}$ ) in Gy
CT	CT air kerma (or dose) index in mGy; CT air kerma (or dose) length product, in mGy.cm
Diagnostic nuclear medicine	Administered activity (A), in MBq

**Table 1:** Currently accepted reference dose quantities according to the International Commission on Radiation measurements and Units (ICRU) excerpted from Vassileva and Rehani<sup>4</sup> presented on Table 1

Standardization of radiation dose and reduction of variations in dose without compromising the clinical purpose of such examination or procedure makes the need for DRLs imperative. Examination-specific or procedure-specific DRLs for various patient groups can provide stimulus for monitoring practice to promote improvement in patient protection. It is also a useful

tool to promote dose audit.<sup>3,4</sup>

It is recommended that DRLs be set for representative examination or procedures performed in the local area, country or region where they are applied. DRLs reflect the typical practice in a country or region.<sup>7,9,10</sup> Due to variations in equipment and procedure protocols between different facilities in countries or regions, it is a good practice to establish national or regional DRLs. The government has a responsibility to ensure that DRLs are established for the country.<sup>5</sup> However, the processes and steps towards establishing DRLs are likely to involve many players including the imaging facilities, the health authorities, the professional bodies and the regulatory body.<sup>6</sup>

Two approaches are adopted for patient dose measurements and setting of diagnostic reference levels from radiologic procedures; patient-based dosimetry and phantom-based dosimetry.<sup>11,12</sup> The advantage of the use of a phantom is that only one or two exposures would be needed for each examination type and each radiology facility; the disadvantage is that it does not represent a real clinical situation, and the same standard phantom shall be required for consistency. If patient dose measurement is used, patient sample should be selected to match the mean body indexes (e.g patient weight and height or body mass index [weight in kg /weight<sup>2</sup> m]) to the predefined “standard- sized” patient. It is expected that patient sample should be large enough to ensure that the mean values represent the typical practice in the facility - e.g at least 20 patients within a predefined range of body mass indexes. Separate diagnostic reference levels for paediatric and adult patients should be established distinguished by age body size and weight.<sup>12</sup>

#### Establishment of DRLs involves four steps:

**First**, the most commonly performed routine diagnostic examinations are identified and lexicons defined; for each type of examination, reference dose quantities are accepted and identified and measuring method is standardised.

**Second**, in each imaging facility, dose measurements are performed following standardised method; mean dose from patient sample or phantom measurement is estimated for each examination and set as a typical dose, usually by medical physicists.

**Third**, typical doses from all or representative sample

of facilities in the country or region are centrally analyzed; diagnostic reference levels should be based on doses measured in various types of hospitals, clinics, and practices representing the typical practice in the country or region.

Finally, for diagnostic radiology, national and regional diagnostic reference levels are usually set at 75% percentile of the distribution of typical doses for the sample.

#### **Certain essential facts to note about diagnostic reference levels are;**

- (i) They are not dose limits;
- (ii) They do not represent a border between good and poor medical practice;
- (iii) They facilitate investigation or are action levels to identify facilities with unusually high or low doses (outliers) where optimization actions need to be applied;
- (iv) Diagnostic reference levels should be considered together with image quality;
- (v) They apply to radiologic including nuclear medicine diagnostic procedures.
- (vi) DRLs are specified for standard-sized patient or standard phantom; they are given in easily and reproducibly measured dose metrics;
- (vii) They should not be set in effective dose; and they are dynamic values that should be reviewed periodically especially as practice and technology changes.

#### **MISCONCEPTIONS ABOUT DIAGNOSTIC REFERENCE LEVEL**

The concept of diagnostic reference level has been trailed by several misconceptions in practice. This is more of a concern in developing countries where diagnostic reference levels have not yet been established. This paper is intended to correct some of these misconceptions.

There is a tendency to assume that being below DRL means adequate optimization, DRLs provide good tools in previous years when the spread of doses were by far large order of magnitude and the shape of the dose distribution curve was right-skewed asymmetric.<sup>13</sup> However, the trend has changed over time with improvements in technology and practice. In the words of Professor Medan Rehani of the global outreach for radiation protection, "There is no problem

with DRLs but stopping at DRLs and using DRLs in ways it was not supposed to be used creates problems".

There are a number of problems with the way DRLs are used as outlined in a recent commentary.<sup>13</sup>

There has been a tendency to use diagnostic reference levels as de facto dose limits that should not be exceeded which becomes detrimental to patients of higher body build who actually need doses higher than the DRL to get adequate image quality.

Despite nearly 30 years of its existence DRLs for adult patients have been confined to representative standard size patients whereas most patients encountered in daily practice are not standard sized DRLs were developed for a defined technology and it was envisaged that they would be updated with technology changes. This has not been done in most countries with some few exceptions. Other areas also include;

Use of DRLs for individual patients

Use of effective dose for DRL

#### **CURRENT TRENDS IN DIAGNOSTIC REFERENCE LEVELS**

Over the past few decades there have been growing concerns about radiation protection in medicine worldwide with particular emphasis on radiation protection of patients.<sup>14</sup> This is due to increase in technological advances as well as increasing population exposure leading to growing concerns about the need for adequate radiation protection. Therefore, much emphasis is laid on the need to establish diagnostic reference level and to update existing ones consistent with current practice and technology.<sup>3,15</sup> To that effect some time last year in 2016 the ICRP has reviewed its document on DRLs.<sup>16</sup> The document was in the public domain for a period of three months for consultations. The period for consultation is over and the committee has submitted their final draft to the main commission awaiting publication.<sup>16</sup> Some useful excerpts extracted from a presentation by the immediate past chair of the ICRP Committee 3 at the recently concluded European Congress for Radiology (ECR 2017) are presented below for the benefit of the radiology community especially those of us from the developing countries.

## Recommendations or Main points from the ICRP's DRL document

- 1) A DRL value is considered to be exceeded when the local median value of the appropriate DRL quantity for a representative sample of patients within an agreed weight range is greater than the local, national or regional DRL value. Here consistently means 'in a majority of cases' and not 'over a period of time'
- 2) DRL value shall not be used for individual patients or as a trigger level for individual patients or individual examinations
- 3) All individuals who have a role in subjecting patients to a medical imaging procedure should be familiar with DRLs as a tool for optimization of protection (should be introduced for training programs for radiation protection)
- 4) Comparison of local practices to DRL values is not sufficient, by itself, for optimization of protection. Action is required to identify and address any deficiencies. The highest priority for any diagnostic imaging examination is achieving image quality (diagnostic information) sufficient for the clinical purpose.
- 5) The concept and proper use of DRLs should be included in the education and training programmes of the health professionals involved in medical imaging with ionising radiation (also as part of patient info)
- 6) Quantities used for DRLs should assess the amount of ionising radiation applied to perform a particular medical imaging task, and should be easily measured or determined. DRL quantities assess the amount of ionising radiation used for a medical exposure not absorbed dose to a patient or organ.
- 7) Compliance with DRLs does not indicate that the procedure is performed at an optimized level with regard to the amount of radiation used. The Commission recognizes that additional improvement can be obtained by using the median value (50th percentile of the distribution used to set the national DRL value)
- 8) The commission recommends setting local and national DRL values based on surveys of the DRL quantities for procedures performed on appropriate sample of patients. The use of phantoms is not sufficient in most cases.
- 9) Calibration of all dosimeters should be performed regularly and should be traceable to a primary or secondary standard laboratory.
- 10) The accuracy of DRL quantity data produced by and transferred from x-ray systems should be periodically verified by a medical physicist.
- 11) DRL values are dependent on the state of practice and available technology (including post-processing software) at a particular point in time.
- 12) For interventional procedures, complexity of the procedure may be considered in setting DRLs and a multiplying factor for the DRL value maybe appropriate for more complex cases of a procedure.
- 13) National and regional DRL values should be raised at regular intervals (3-5 years) or more frequently when substantial changes in technology, new imaging protocols or post-processing of image become available.
- 14) If a local or national DRL value for any procedure is exceeded, an investigation should be carried out without undue delay, and appropriate corrective actions should be taken.
- 15) Corrective action? (Optimization of protection) should include a review of equipment of equipment performance, the settings used, and the examination protocols. The factors most likely to be involved are survey methodology, equipment performance, procedure protocol, operator skill and, for interventional techniques, procedure complexity.

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