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REVIEW ARTICLE

The application of diagnostic reference levels: General principles and an Irish perspective

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Abstract The principles of justification and optimisation, and the establishment and use of diagnostic reference levels (DRLs) are core tenets of the European Medical Exposures Directive [Council Directive 97/43], and ensuing legislation across Europe. This is the third in a series of three review articles: the previous two discussed the principles of justification and optimisation, the current review covers the concept of DRLs.

In this paper, a brief synopsis of the history of DRLs is presented, and their possible applications are outlined. Approaches and progress with DRLs in a number of European countries, as derived from published literature, are summarised and a comparison of the approaches highlights some practical issues in using DRLs. Irish data are then considered in the context of literature ensuing from SI478 of 2002, and relating to the establishment of national diagnostic reference levels.

The reviewed literature supports the opinion that national DRLs are preferable to those drawn from pan-European dose data.

The principle of dose limits

The third principle of the radiation protection structure recommended by the ICRP is that of application of dose constraints. This principle requires that the combined effect of all relevant exposures to any individual should be constrained either by a dose limit, or to some control of risk.[1] These concepts of dose limits and control of risk were introduced because of substantial biological and epidemiological evidence for radiation-induced effects in man.[2] Deterministic effects are those which occur above a certain threshold dose value, and include most types of direct tissue damage.[1] Stochastic effects are those that occur without a dose threshold, but increase in probability with increasing dose. They include all late-expressing health effects of radiation such as cancer induction and heritable disease, but exclude late tissue reaction as a consequence of direct irradiation.[1] The ICRP publishes dose limits for the general public and for occupationally exposed workers

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that remove the possibility of deterministic effects, and hold the risk of stochastic effects to an acceptable level.[3] Dose limits for the new ICRP recommendations are not publicly available at the time of writing, although pre-release information advises that the organ and effective dose limits in ICRP 60[3] will be retained, with the exception that when it becomes available, imminent new data may lead to reconsideration and lowering of the dose limit for the eye.[4]

All this said, dose limits do not apply to patients undergoing medical exposure, since the exposure must be justified by a net benefit to the patient, and hence clinical necessity supersedes dose limitation. However, exposures must be optimised by maximising radiation protection to achieve the best balance between necessary radiation dose and diagnostic outcome.[1] Since optimisation is defined partially in terms of the ALARA principle,[1,3,5–7] optimisation research must establish what is a feasible low dose, and what measures are reasonable in achieving it. The idea of an unnecessarily high dose, or what dose constitutes an acceptable minimum for a particular procedure, would have been difficult to theorise before the early 1980s.[8] However, the late 1980s and early 1990s witnessed publication of a plethora of dose measurement studies internationally, conducted by both individual research teams and professional authorities.[9]

Patient dose monitoring

A dose measurement protocol was published in 1992 by the United Kingdom's National Radiological Protection Board.[10] The range of dose values recorded for specific adult X-ray examinations during compilation of the protocol showed upwards of fourfold variation between the maximum and minimum level in different hospitals.[10] This degree of variation, and greater, was replicated in many similar studies, and from then on ongoing dose measurement appeared widely established as part of a quality audit cycle in many imaging departments. Terminologies varied, as did methods of measuring dose. Consideration of the various methodologies and terminologies led the ICRP, in 1996, to recommend the adoption of diagnostic reference levels (DRLs) for medical radiological examinations.[6]

Diagnostic reference levels

DRLs are not dose limits, and have no relationship with numerical dose limits or dose constraints.[6] In explaining their first recommendation on DRLs, the ICRP indicated that they are:

- an easily measured dose quantity, such as absorbed dose in air, or entrance surface dose for a tissue-equivalent phantom or representative patient;
- an investigation level, which, if exceeded, should lead to a review of procedures and equipment in order to evaluate whether the approaches to optimisation are adequate, and to indicate when consideration of dose reducing measures should be made;
- intended for use as a simple test for identifying situations where the levels of patient dose are unusually high;
- supplementary to professional judgement;
- not intended to be used in a precise manner, but related only to common types of diagnostic examination and to broadly defined types of equipment.[6]

The European Medical Exposures Directive required member states to promote the establishment and use of DRLs,[5] [Article 4.2.a], and presented a succinct definition of what constitutes a DRL, as follows:

DRLs are: ''*dose levels in medical radio-diagnostic practices … for typical examinations for groups of standard sized patients or standard phantoms for broadly defined types of equipment. These levels are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied*''[2] [page 2].

The ICRP had proposed that DRLs be initially drawn from a percentile point in the patient dose distribution for a particular examination, and be reviewed at intervals as more optimised techniques are developed.[6] Arising from pan-European cooperation between various professional groups and authorities associated with diagnostic imaging, European DRLs were established for a range of radiological examinations.[11,12] These followed the ICRP guidance, and expressed the DRL as the dose quantity found at the 75th centile of the mean dose distribution for each type of radiograph. Whilst the establishment of a DRL at the 75th centile provides a benchmark for objective assessment of application of the ALARA principle, achievement of the DRL does not guarantee good practice.[13] Indeed, DRLs were not originally proposed as a guide to optimisation, but rather as a mechanism for identifying outdated and/or poor techniques.[14]

Uses of DRLs

In order to use DRLs effectively therefore, it is important to have a clear understanding of exactly how they can be applied. To this end, the ICRP presented a review document with additional guidance on DRLs in 2002.[9] Simultaneously with any other application, the primary and overriding purpose of a DRL is ''*to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task*''.[9] This can be achieved by comparing dose values from clinical practice with the DRL, and consequently triggering appropriate investigation when the DRL is exceeded in normal practice.[9] The DRL hence makes a fundamental contribution to the optimisation process, allowing analysis of the potential for dose reduction, and initiation of action that will progress towards lower dose levels. As a consequence, DRLs can be used to:

- reduce the number of high or low dose values in a regional, national, or local dose distribution;
- promote a narrower range of dose values that represent good practice for a particular examination;
- promote progression towards an optimum range of dose values for a particular examination.[9]

These dynamic progressions towards generally lowered dose distributions were anticipated in the ICRP guidance