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Diagnostic Reference Levels in Medical Imaging

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[Guest?] Editorial

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To be completed.

The average editorial occupies about 1½ page.

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AUTHOR (S)

Diagnostic reference levels in medical imaging

ICRP Publication 1XX

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Abstract-The International Commission on Radiological Protection (ICRP) first introduced the term 'diagnostic reference level' (DRL) in *Publication 73* (1996). The concept was subsequently developed further, and practical guidance was provided in 2001. DRLs have been proven to be an effective tool that aids in optimisation of protection in the medical exposure of patients for diagnostic and interventional procedures. However, with time it has become evident that additional advice is needed. There are issues related to definitions of the terms used in previous guidance, determination of the values for DRLs, the appropriate interval for re-evaluating and updating these values, appropriate use of DRLs in clinical practice, methods for practical application of this tool, and application of the DRL concept to newer imaging technologies. This report is intended as a further source of information and guidance on these issues. Some terminology has been clarified. In addition, the report recommends quantities for use as DRLs for various imaging modalities, and provides information on use of DRLs for interventional procedures and in paediatric imaging. It suggests modifications in the conduct of DRL surveys that take advantage of automated reporting of radiation dose related quantities, and points out the importance of including information on DRLs in training programmes for health care workers. The target audience for this report is national, regional and local authorities, professional societies, facilities where ionising radiation is used for medical purposes, and responsible staff within these facilities. A full set of the Commission's recommendations is provided.

Keywords: Diagnostic reference levels, patient doses, optimisation.

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PREFACE

The measurement of quantities related to patient dose for optimisation of protection in medical imaging with ionising radiation began more than half a century ago. Beginning in the 1950s, national surveys of such quantities for diagnostic x-ray examinations were performed in the United States and the United Kingdom. In the 1970s, the Nationwide Evaluation of X-Ray Trends (NEXT) surveys began in the United States and in the 1980s the National Radiation Protection Board (NRPB, now Public Health England) surveys in the United Kingdom measured entrance surface exposure either free-in-air or incident on the patient. The results of these and similar surveys were the basis for recommendations for radiographic technique and for levels of the quantities surveyed. These were first developed in the United States, then in the United Kingdom, and subsequently in Europe. These recommendations were referred to variously as exposure guides, guideline doses, guidance levels (by the International Atomic Energy Agency), reference doses and, from 1996, as diagnostic reference levels (DRLs) in the publications of the International Commission on Radiological Protection (ICRP). The European Commission included DRLs in a Directive on medical exposures in 1997. In 2001, ICRP published a Supporting Guidance expanding the use of DRLs to interventional radiology and giving further advice on flexibility in their selection and implementation. The present report is the result of the work of a Working Party of ICRP Committee 3, which was created during the annual meeting held in Bethesda, Maryland, USA, on 22-28 October 2011. Digital techniques and interventional procedures, and new combined imaging techniques such as positron emission tomography-computed tomography (PET-CT) require new and updated advice. Committee 3 realised that the proper use of DRLs was still rather poor within the medical community. The target group for this report is medical physicists, radiologists, nuclear medicine specialists, radiographers, industry, health and regulatory authorities.

The membership of the Working Party was as follows:

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D.L. Miller	M.M. Rehani	

The corresponding members were:

S. Mattsson	P. Ortiz López	R. Padovani
A. Rogers	M. Rosenstein	

The membership of Committee 3 during the period of preparation of this report was:

(*2009-2013*)

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EXECUTIVE SUMMARY

1. Introduction

(a) The Commission first introduced the term 'diagnostic reference level' (DRL) in *Publication 73* (ICRP, 1996). The concept was subsequently developed further, and practical advice was provided in ICRP (2001). This development and the 2001 advice are summarised in Annex A.

(b) As the Commission stated in *Publication 103*, in medical exposures the principle of optimisation of protection is implemented through the use of DRLs (ICRP, 2007). DRLs have proven to be an effective tool that aids in optimisation of protection in the medical exposure of patients for diagnostic and interventional procedures. DRLs are not intended for use in radiation therapy.

(c) With time, it has become evident that additional advice is needed. There are issues related to definitions of some of the terms used in previous guidance, determination of the values for DRLs, the appropriate interval for re-evaluating and updating these values, appropriate use of DRLs in clinical practice, methods for practical application of this tool, and application of the concept to certain newer imaging technologies [e.g. dual-energy computed tomography (CT), positron emission tomography (PET)/CT, single photon emission CT (SPECT)/CT, cone-beam CT, digital radiography, tomosynthesis].

(d) This report is intended as a further source of information and guidance on these issues. Some terminology has been clarified. In addition, the report recommends radiation dose quantities for use as DRLs for various imaging modalities, provides information on use of DRLs for interventional procedures and in paediatric imaging, points out common errors in the determination and application of DRLs, suggests modifications in DRL surveys that take advantage of automated reporting of radiation dose related quantities, and points out the importance of including information on DRLs in training programmes for health workers and in information for patients.

(e) The target audience for this report is national, regional and local authorities, professional societies, facilities where ionising radiation is used for medical exposures, and responsible staff within these facilities.

(f) A full set of the Commission's recommendations is provided as the last chapter (Chapter 8) of this report. In addition, each chapter is preceded by a set of Main Points that summarise the principal concepts in that chapter. A limited summary of the most important points and recommendations is presented below for the convenience of the reader.

2. Diagnostic reference levels

(g) The principles of justification and optimisation of protection are key and complementary radiological safety tenets. Diagnostic reference level (DRL) is the Commission's term for a tool used to aid in optimisation of protection in the medical exposure

of patients for diagnostic and interventional procedures. A DRL value is a selected level of a radiation dose quantity (a "DRL quantity") for broadly defined types of equipment for typical examinations for groups of standard-sized patients or, in certain specific circumstances, a standard phantom. DRLs do not apply to individual patients. They are derived from an arbitrary threshold in a distribution of values obtained locally and collected nationally or regionally. A DRL is a supplement to professional judgement and does not provide a dividing line between good and bad medical practice. All individuals who have a role in subjecting a patient to a medical exposure should be familiar with DRLs as a tool for optimisation of protection.

(h) The application of DRLs is not sufficient, by itself, for optimisation of protection. Optimisation is generally concerned with maintaining the quality of the diagnostic information provided by the examination commensurate with the medical purpose while, at the same time, seeking to reduce patient exposures to radiation to a level as low as reasonably achievable. Image quality or, more generally, the diagnostic information provided by the examination (including the effects of post-processing), must also be evaluated. Methods to achieve optimisation that encompass both DRLs and image quality evaluation should be implemented. In some cases, optimisation may result in an increase in dose.

(i) Compliance with DRLs does not, by itself, indicate that the procedure is performed at an optimised level with regard to the amount of radiation used. Therefore, the Commission recognises that additional improvement can often be obtained by using the median value (the 50th percentile) of the distribution of values of dose-related quantities used to set the national or regional DRL value, rather than the 75th percentile commonly used for the DRL value. The median value of the distribution also provides guidance on when investigation of image quality should be considered as a priority.

3. DRL quantities and values

(j) Radiation metrics used for DRLs should be appropriate to the imaging modality being evaluated, should assess the amount of ionising radiation applied to perform a medical imaging task, and should be easily measured or determined. When two imaging modalities are used for the same procedure (e.g. PET/CT, SPECT/CT), it is appropriate to set and present DRLs for both modalities independently.

(k) The numerical value of the DRL should be tied to defined clinical and technical requirements for the selected medical imaging task. The Commission recommends setting DRLs based on surveys of the DRL quantities for procedures performed on an appropriate sample of patients. The use of phantoms is not sufficient in most cases, as when phantoms are used, the effects of operator performance are not taken into account. The numerical values of DRLs are advisory. However, an authorised body may require implementation of the DRL concept.

(l) DRL values are not static. As optimisation continues or hardware and software improve, DRLs should be updated on a regular basis. When new imaging techniques are introduced, an effort should be made to measure DRL quantities and set DRLs as soon as is practicable.

(m) For interventional procedures, complexity of the procedure may be considered in setting DRLs and a multiplying factor for the DRL value (e.g. 2 or 3) may be appropriate for more complex cases of a procedure.

4. Local, national and regional DRLs

(n) Organisations responsible for different components of the tasks of collating data on DRL quantities and setting DRLs should be identified in each country or region. The process to set and update DRLs should be both flexible and dynamic. Flexibility is necessary for procedures where few data are available (e.g. interventional procedures in paediatric patients), or where data are available from only one or a few centres. A dynamic process is necessary to allow initial DRLs to be derived from these data while waiting for a wider survey to be conducted.

(o) Data for determining national DRL values are obtained from surveys. Values of DRL quantities from patient examinations are collected from at several different health facilities. The 75th percentile value of the distribution of median values (the 50th percentile) of a DRL quantity at healthcare facilities throughout a country is used as the 'national DRL'.

(p) When national DRL values exist for many or most countries within a region (e.g. the European Union), regional DRL values may be determined by using the median value of the available national DRL values.

(q) National and regional DRLs should be revised at regular intervals of 3-5 years, or more frequently when substantial changes in technology, new imaging protocols or improved post-processing of images become available.

(r) Since national DRLs require large surveys, which can require substantial effort to perform and analyse, they are not always as responsive to changes in technology. Where it is apparent that further optimisation is being achieved locally, 'Local DRLs' based on surveys within that limited area might be introduced to further assist the optimisation process. One example of their use is to account for the substantial dose reduction that could be achieved through the introduction of digital radiography detectors into dental radiography. Another example is the introduction of new methods for post-processing of images.

5. Using DRLs for optimisation of protection

(s) Median values of the DRL quantity for medical imaging procedures for a specific x-ray room or for a radiology department or other facility should be compared with DRL values to identify whether the data for the location are substantially higher or lower than might be anticipated.

(t) A DRL is considered to be exceeded when the median value of the DRL quantity for a representative sample of standard-sized patients at a facility is greater than the local or national DRL value.

(u) If a DRL value for any procedure is exceeded, an investigation should be undertaken without undue delay to determine possible reasons, and a corrective action plan should be implemented and documented.

(v) DRLs are not intended to be used for individual patients or as trigger (alert or alarm) levels for individual patients or individual examinations. Also, DRL values are not limits.

6. Considerations for paediatric examinations

(w) The amount of administered radiation for examinations of children can vary tremendously due to the great variation in patient size and weight. This variation in patient radiation dose is appropriate. Variation in patient radiation dose is not appropriate if it is due to failure to adapt the imaging protocol to account for paediatric diseases and paediatric patient sizes.

(x) Appropriate weight bands (generally with 10 kg intervals) are recommended for establishing paediatric DRLs and should be promoted for paediatrics.

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GLOSSARY

Air kerma-area product (P_{KA})

The integral of the air-kerma free-in-air (i.e. in the absence of backscatter) over the area of the x-ray beam in a plane perpendicular to the beam axis. In many medical publications, the acronym used for this quantity is KAP. The older terminology is dose-area product (DAP).

Air kerma at the patient entrance reference point (Ka,r)

The air kerma at a point in space located at a fixed distance from the focal spot (see patient entrance reference point) expressed in gray. The International Electrotechnical Commission (IEC, 2010) refers to this quantity as reference air kerma. The U.S. Food and Drug Administration calls it cumulative air kerma. The International Commission on Radiation Units and Measurements (ICRU) has not defined a symbol for this quantity — Ka,r is the notation introduced by the National Council on Radiation Protection and Measurements (NCRP) in Report No. 168 (NCRP, 2010). In many medical publications, the acronym used for this quantity is CAK. This quantity is referred to in older medical publications as cumulative dose, and has also been called reference air kerma and reference point air kerma.

Computed tomography dose index (volume) ($CTDI_{vol}$)

The weighted CTDI, $CTDI_w$, normalised by the helical pitch. The weighted $CTDI_w$ is an estimate of the average dose over a single slice in a CT dosimetry phantom. See ICRU Report 87 (2012).

Constancy testing

A form of quality control (QC) testing that evaluates the current state of equipment performance and image quality at regular intervals in time.

Cumulative air kerma

See Air kerma at the patient entrance reference point.

Deterministic effect

See Tissue reaction.

Detriment

The total harm to health experienced by an exposed group and its descendants as a result of the group's exposure to a radiation source. Detriment is a multidimensional concept. Its principal components are the stochastic quantities: probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe heritable effects, and potential years of life lost if the harm occurs.

Diagnostic reference level (DRL)

A diagnostic reference level is a tool used to aid in optimisation of protection in the medical exposure of patients for diagnostic and interventional procedures. It is used in medical imaging with ionising radiation to indicate whether, in routine conditions, the patient dose or administered activity (amount of radioactive material) from a specified procedure is unusually high or low for that procedure. Also see DRL quantity.

Dose (ionising radiation)

A general term used when the context is not specific to a particular dosimetric quantity related to the exposure of an individual to ionising radiation. When the context is specific, the name or symbol for the dosimetric quantity is used.

Dose length product (DLP)

A parameter used as a surrogate measure for energy imparted to the patient in a CT scan of length L. By convention, the DLP is reported in the units of mGy cm. See ICRU Report 87 (2012) for more details.

DRL quantity

A commonly and easily measured or determined radiation dose quantity or metric (e.g. Ka,e, Ka,i, $CTDI_{vol}$, DLP, P_{KA}, Ka,r, D_G) that assesses the amount of ionising radiation used to perform a medical imaging task. The quantity or quantities selected are those that are readily available for each type of medical imaging modality and medical imaging task. Suitable quantities for medical imaging modalities and tasks are identified in this publication. With the single exception of mean breast glandular dose (D_G) for mammography, these quantities are not the tissue or organ doses received by the patient or quantities derived from such doses, which cannot be measured or easily determined.

DRL value

A selected numerical value of a DRL quantity, set at the 75th percentile of the medians of DRL quantity distributions observed at multiple facilities or in some specific cases, the 75th percentile of the DRL quantity distributions observed at one or more local healthcare facilities. Regional DRL values can also be based on the median values of the available national DRLs.

Entrance-surface air kerma (Ka,e)

Air kerma on the central x-ray beam axis at the point where the x-ray beam enters the patient or phantom (includes backscattered radiation). In many medical publications, the acronym used for this quantity is ESAK.

Incident air kerma (Ka,i)

Air kerma from the incident beam on the central x-ray beam axis at the focal-spot-to-surface distance (does not include backscattered radiation). In many medical publications, the acronym used for this quantity is IAK.

Kerma, (K)

The quotient of the sum of the kinetic energies, dE_{tr}, of all charged particles liberated by uncharged particles in a mass dm of material, and the mass dm of that material.

$$K = \frac{dE_{tr}}{dm}$$

The unit for kerma is joule per kilogramme (J kg^{-1}). This unit's special name is gray (Gy) (ICRP, 2007). "Kerma" is an acronym for kinetic energy released in a mass.

Local diagnostic reference level

A DRL set in a particular healthcare facility or several local healthcare facilities for defined clinical imaging tasks. Also see "DRL value".

Mean glandular dose (D_G)

In mammography, D_G is the mean absorbed dose in the glandular tissue of the breast, where glandular tissue is the radiosensitive tissue of the breast. D_G is calculated from either the Ka,i or the Ka,e used for the specific mammography examination. The conversion from Ka,i to D_G is a function of beam quality [i.e. half value layer (HVL)], anode material, filtration, breast thickness and breast composition. The conversion from Ka,e to D_G is a function of all these factors as well as adjustment for the backscatter factor from breast tissue. D_G is also called average glandular dose (AGD).

Medical exposure

Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly, while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

National diagnostic reference levels

DRLs set in a country based on data from a representative sample of healthcare facilities in that country. Also see "DRL value".

Notification Value

A component of the National Electrical Manufacturers Association (NEMA) Computed Tomography (CT) Dose Check standard (XR 25) (NEMA, 2010). CT scanners that are compliant with this standard will notify the operator prior to starting a scan whenever the estimated dose index is above a facility-defined value for volume CT dose index ($CTDI_{vol}$) or dose-length product (DLP) for a specific scan protocol (i.e. either metric may be chosen by the facility). If the Notification Value is exceeded, a

warning is displayed on the operator's console that prompts the radiographer to review the scan settings before proceeding with the examination, and either verify that they are correct or change them.

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. For isocentric fluoroscopes (C-arms), the patient entrance reference point is defined (IEC, 2010) as lying on the central axis of the x-ray beam, 15 cm on the x-ray tube side of isocentre.

Peak skin dose ($D_{skin,max}$)

The maximum absorbed dose to the most heavily irradiated localised region of skin (i.e. the localised region of skin that lies within the primary x-ray beam for the longest period of time during a fluoroscopically guided procedure). The notation recommended by ICRU for the mean absorbed dose in a localised region of skin is $D_{skin,local}$ (ICRU, 2005). The notation used by NCRP for the maximum absorbed dose to the most heavily irradiated localised region of skin is $D_{skin,max}$ (NCRP, 2010). Peak skin dose is measured in units of Gy (NCRP, 2010).

Radiation detriment

See detriment

Reference phantom

Computational anthropomorphic phantom based on medical tomographic images where the anatomy is described by small three-dimensional volume elements (voxels) that specify the density and the atomic composition of the various organs and tissues of the human body. ICRP phantoms are available for adult male and female human bodies.

Reference value

The value of a parameter recommended by the Commission for use in a biokinetic model in the absence of more specific information, i.e. the exact value used to calculate the dose coefficients presented in ICRP reports. Reference values may be specified to a greater degree of precision than that which would be chosen to reflect the uncertainty with which an experimental value is known, in order to avoid the accumulation of rounding errors in a calculation.

Reference level

In emergency or existing controllable exposure situations, this represents the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration. For medical exposures, the term "diagnostic

reference levels" should be used to avoid confusion with the term "reference level" used by the Commission for other exposures.

Region
: A group of countries, usually defined by geographical proximity and/or cultural similarities, that agree to link together and pool resources for purposes of patient dosimetry.

Regional diagnostic reference levels
: DRLs set in a region, based on either a representative sample of healthcare facilities or on national DRL values.

Size-specific dose estimate (SSDE)
: A patient dose estimate for CT scans that takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or on patient images. The American Association of Physicists in Medicine (AAPM) Report 204 bases SSDE values on the $CTDI_{vol}$ reported on CT scanners, but future modifications may include SSDE correction factors based on other pertinent phantom measurements (AAPM, 2011).

Stochastic effects of radiation
: Malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without a threshold.

Tissue reaction
: Injury in populations of cells, characterised by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Tissue reactions were previously called deterministic effects. In some cases, tissue reactions are modifiable by post-irradiation procedures including healthcare and biological response modifiers.

Voxel phantom
: See reference phantom.

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1. INTRODUCTION

- **Diagnostic reference level (DRL) is the Commission's term for a tool used for optimisation of protection in the medical exposure of patients undergoing radiological imaging (including interventional procedures). DRLs are not intended for use in radiation therapy.**
- **DRLs have been shown to be an effective tool for identification of examinations using ionising radiation 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 DRLs as a tool for optimisation of protection.**
- **Application of DRLs is not sufficient for optimisation of protection. The diagnostic quality of the corresponding image(s) must also be evaluated.**
- **The Commission considers use of the median of the distribution of a DRL quantity observed in a survey of departments to be a useful additional tool for improving optimisation and for identifying situations where investigation of image quality should be a priority.**
- **The radiation metric quantity used for a DRL should be easily measured, such as air kerma-area product (P_{KA}) and entrance surface air kerma (Ka,e) for diagnostic radiology, volume computed tomography (CT) dose index ($CTDI_{vol}$) and dose-length product (DLP) for CT, and administered activity for diagnostic nuclear medicine.**
- **Effective dose is not an appropriate quantity for use as a DRL. Effective dose is not a measurable quantity and is not a good indicator of the amount of ionising radiation used to perform a medical imaging task. Its use could introduce extraneous factors not needed and not pertinent for the purpose of DRLs.**
- **DRL values should not be used as dose limits. Dose limits do not apply to medical exposures of patients.**
- **Median values of distributions of DRL quantities obtained from groups of patients should be compared with DRL values. Values DRL quantities for individual patients should not be compared with DRL values, because DRLs are intended for optimisation of protection for groups of patients, not individual patients.**

1.1. Introduction

(1) This report provides guidance for the practical use of diagnostic reference levels (DRLs) for specific imaging modalities, reviews methods for determining DRL values,

provides advice on periodic revision of DRL values, and recommends DRL quantities for specific imaging modalities. Compilations of DRL values are available from many sources (Hesse et al., 2005; Hart et al 2009, 2012; Miller et al., 2009, 2012b; NCRP, 2012; Padovani et al., 2008; Samara et al., 2012; ICRP, 2007c; Foley et al., 2012; Lassmann et al., 2007; Lassmann and Treves, 2014; Botros et al., 2009; Etard et al., 2012; ARSAC, 2014; Sánchez et al., 2014). This report discusses issues to be considered when setting and using DRLs as opposed to providing lists of DRL values. It provides the Commission's recommendations for conducting surveys, determining DRL values, and applying the DRL process in clinical facilities.

(2) This report uses symbols for DRL quantities defined by the International Commission on Radiation Units and Measurements (ICRU). For the convenience of the reader, Table 2.2 provides the names, ICRU symbols, and common symbols for the quantities.

1.2. Historical perspective on terminology

(3) In its 1990 recommendations (ICRP, 1991), the Commission describes reference levels (when used for applications other than medical exposures of patients), as values of measured quantities above which some specified action or decision should be taken. These include recording levels, above which a result should be recorded, lower values being ignored; investigation levels, above which the cause or the implications of the result should be examined; and intervention levels, above which some remedial action should be considered. 'Diagnostic reference level' was introduced in ICRP (1996) as the term for a form of investigation level used to identify situations where optimisation of protection may be required in the medical exposure of patients.

(4) In its 2007 recommendations (ICRP, 2007a), the Commission uses the terms 'dose constraint' in the context of planned exposure situations and 'reference level' for existing and emergency exposure situations. Thus, the term 'reference level' should not be used in the context of medical imaging. Although the medical exposure of patients is a planned situation, the use of 'dose constraints' is not applicable (ICRP, 2007a).

1.3. History

(5) Wall and Shrimpton (1998) have reviewed the use of measurements of quantities related to patient dose for optimisation of protection. Beginning in the 1950s, national surveys of such quantities for diagnostic x-ray examinations were performed in the United States (U.S.) and the United Kingdom (U.K.) (Wall and Shrimpton, 1998). In the 1970s, the Nationwide Evaluation of X-Ray Trends (NEXT) surveys began in the U.S. (FDA, 1984), and in the 1980s the National Radiation Protection Board [NRPB, now Public Health England (PHE)] surveys in the U.K. measured entrance surface exposure either free-in-air or incident on the patient (Shrimpton et al., 1986). The results of these and similar surveys were the basis for recommendations for radiographic technique and for levels of the quantities surveyed.

These were first developed in the U.S. (CRCPD/CDRH, 1992; Jensen and Butler, 1978; Wall and Shrimpton, 1998), then in the U.K. (NRPB/RCR, 1990), and subsequently in Europe (EC, 1996a, 1996b, 1999; Neofotistou et al., 2003; Padovani et al., 2008). These recommendations were referred to variously as exposure guides, guideline doses, guidance levels (IAEA, 1996), reference doses and, in *Publication 73* (ICRP, 1996), as DRLs.

(6) In 2001, the Commission published Supporting Guidance 2 (ICRP, 2001), which was subsequently made available for free download from the Commission's website (www.icrp.org) (ICRP, 2003). A summary of the Commission's guidance on DRLs from *Publications 60* and *73*, and Supporting Guidance 2 was included in *Publication 105* (ICRP, 2007b).

(7) In Europe, DRLs were formally introduced in Council Directive 97/43/EURATOM (EC, 1997), and Member States of the European Union were obligated to promote the establishment and the use of DRLs as a strategy for optimisation. This obligation was reiterated in the European Commission (EC, 2013), with a requirement for the establishment, regular review and use of DRLs. The 2013 Council Directive also states that appropriate local reviews are undertaken whenever DRLs are consistently exceeded, and that appropriate corrective action is taken without undue delay. Several research programmes were launched by EC, beginning in 1990, to collect data on patient doses and image quality, produce guidance on image quality criteria for adult, paediatric radiology and CT and promote the use of DRLs (EC, 1996a,b, 1999a,b). During the years 1995-2005, additional programmes (SENTINEL, DIMOND) on digital and interventional radiology established initial DRL values for newer imaging modalities.

1.4. Effectiveness of DRLs

(8) DRLs are an effective tool for optimisation of protection in the medical exposure of patients. The U.S. Breast Exposure: Nationwide Trends (BENT) mammographic quality assurance (QA) programme was an early demonstration of the effectiveness of this approach (Jensen and Butler, 1978). An initial survey used phantoms to collect data on entrance exposures from facilities in 19 states. On the basis of these data, trained surveyors visited facilities with unnecessarily high or low values. These surveyors made recommendations for improving aspects of the facilities' imaging programmes. At one-year follow-up, there was a substantial decrease in the mean entrance exposure and a decrease in the standard deviation of the distribution of entrance exposures, with improved image quality.

(9) In the U.K., where data have been collected approximately every 5 years since the mid-1980s, DRLs determined from the results of the 2005 survey were 16% lower than those in the 2000 survey, and approximately half of those in a mid-1980s survey (Hart et al., 2009, 2012). The value of this tool was recognised in the EC's 1997 Medical Exposure Directive (EC, 1997).

1.5. Issues with the current use of DRLs

(10) There are several issues with the application of the DRL process in current practice: misuse of DRLs for individual patients (or individual examinations) instead of groups of patients or a series of examinations, misuse of DRL values as a limit for individual patients or individual examinations, using phantoms or inappropriate measures of radiation output to set DRL values, establishing DRL values when there are differences in technology among imaging systems and differences in necessary image quality for different clinical indications for the same examination, and characterising image quality.

(11) With time, it has become evident that additional guidance is needed pertaining to the proper clinical implementation of DRLs. Clarification is needed for definitions of some of the terms used in previous guidance, determination of the values for DRLs, the appropriate interval for re-evaluating and updating these values, appropriate use of DRLs in clinical practice, methods for practical application of this tool, and application of the concept to certain newer imaging technologies [e.g. dual-energy CT, positron emission tomography (PET)/CT, single-photon emission CT (SPECT)/CT, digital radiography, and tomosynthesis].

1.5.1. DRLs are not intended for individual patients

(12) The appropriate and optimised dose for an individual depends on the patient's size and the purpose of the medical imaging task. Once protocols for "standard patients" are optimised, the equipment's automatic control mechanisms should be able to scale technique factors appropriately for smaller or larger patients. For nuclear medicine, the administered activity is weight-based.

(13) In 2010, the National Electrical Manufacturers Association (NEMA) published the Computed Tomography Dose Check standard (XR 25) (NEMA, 2010), and manufacturers of CT scanners began to implement this feature on their products. CT scanners that are compliant with this standard will notify and alert the operator prior to starting a scan whenever the estimated quantity [either volume CT dose index ($CTDI_{vol}$) or dose-length product (DLP)] is above one or more of two defined values. One of these, the "Notification Value", is a value for a specific scan protocol. The CT Dose Check standard does not provide specific numerical values for the Notification Value. While the American Association of Physicists in Medicine (AAPM, 2011) has suggested numerical values for the Notification Value, some facilities have elected to use DRLs instead. This use is not appropriate, as DRLs are intended for optimisation of protection for *groups* of patients, not *individual* patients.

1.5.2. DRLs are not dose limits

(14) The Commission's principle of *application of dose limits* states that "the total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission" (ICRP, 2007a,b). It is important to note that this principle explicitly excludes medical exposure of patients. Dose limits do not apply to medical exposures, defined by the Commission as "the exposure of persons as part of their diagnosis or treatment (or exposure

of a patient's embryo/fetus or breast-feeding infant) and their comforters and carers (caregivers) (other than occupational)" (ICRP, 2007b).

(15) As the Commission has stated, "Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good" (ICRP 2007b). It is therefore clear that DRL values are not intended as dose limits, and should not be used as such.

1.5.3. DRLs should be based on clinical practice

(16) For x-ray imaging, values for DRLs should in general be determined using data on values of DRL quantities derived from patient examinations. Phantoms were often used in the past. The Commission now recommends setting DRL values based on surveys of patient examinations, because the numerical value of the DRL should be tied to defined clinical and technical requirements for the medical imaging task. The data gathered from patient examinations provide a perspective on the distribution of these data that cannot be observed using simple phantoms.

(17) This report discusses when the use of phantoms or patient surveys is more appropriate, and the limitations imposed by using phantoms instead of patient surveys. It describes appropriate methods for determining DRL values, based on the particular imaging modality and other concerns. It discusses setting DRL values when there is a limited sample of data.

(18) The Commission has previously recommended that the quantity used for a DRL 'should be easily measured, such as absorbed dose in air or tissue-equivalent material at the surface of a simple standard phantom or representative patient for diagnostic radiology, and administered activity for diagnostic nuclear medicine." (ICRP, 2001). DRL quantities should assess the amount of ionising radiation used to perform a medical imaging task. The quantity or quantities selected are those that are readily available for each type of medical imaging modality and medical imaging task.

(19) The quantity effective dose, used for other purposes in the ICRP system of radiological protection, has been suggested for use as a DRL. It is not suitable for this purpose because it does not assess the amount of ionising radiation used to perform a medical imaging task and introduces extraneous factors not needed and not pertinent for the purpose of DRLs. Also, effective dose is not readily available. Therefore, it should not be used as a quantity for DRLs.

1.5.4. Technology and clinical indication affect DRL values

(20) DRL values are dependent on the state of practice and the available technology at a particular point in time. Technological advances may allow adequate image quality at values of the DRL quantity lower than an arbitrary percentile of the survey distribution. An example is the introduction of iterative reconstruction for CT. These reconstruction algorithms permit CT acquisitions at lower patient doses; in this case, DRL values based on

CT performed with filtered back projection algorithms are not appropriate guides to indicate if values of the DRL quantity are unusually high when iterative reconstruction is used.

(21) The Commission, in *Publication 73*, stated: "In principle, it might be possible to choose a lower reference below which the doses would be too low to provide a sufficiently good image quality. However, such reference levels are very difficult to set, because factors other than dose also influence image quality" (ICRP, 1996). This difficulty is compounded when, for example, some newer CT scanners use iterative reconstruction, but the DRL values are based on surveys conducted primarily on older CT units. In this case, a value intended to indicate possible image quality issues for CT scanners that employ filtered back projection would be inappropriate for CT scanners that employ iterative reconstruction.

(22) In some cases, different clinical indications for an examination may require different image qualities, and therefore different amounts of radiation. For example, a CT of the abdomen done to exclude renal calculi will require a lower value of the DRL quantity than a CT of the abdomen done to characterise a tumour. Therefore, the DRL values for these indications should ideally be different. The same is true for certain screening examinations, such as low-dose CT for lung cancer screening.

(23) An area of particular concern is optimisation of follow-up examinations. Such examination protocols frequently do not require the same diagnostic information, and hence the same amount of radiation to a patient, as is necessary in an initial examination intended to establish a diagnosis. Follow-up examinations should be suitably optimised to their purpose, and will thereby result in both radiation and time saving.

(24) For interventional procedures, the amount of radiation applied to the patient depends largely on the type of procedure and on procedure complexity. Procedure complexity may vary for different clinical indications for the same procedure. For example, a nephrostomy done for ureteric obstruction, where the renal collecting system is dilated, requires less radiation to the patient than the same procedure done for a ureteric leak or for access for stone removal, a more complex and difficult procedure because the collecting system is not dilated (Miller et al., 2003).

1.5.5. Image quality must not be neglected

(25) "Image quality" can apply to a single image [e.g. for a posteroanterior (PA) chest radiograph], but the term may not be relevant with respect to single images when multiple images are obtained and used for guidance or diagnosis, as in the case of fluoroscopy, cineradiography, digital subtraction angiography and rotational angiography. In these modalities, a single image may demonstrate poor image quality, but evaluation of several images, with the use of recursive filtering, may be adequate in terms of information content.

(26) Criteria for characterising image quality have been defined and agreed upon for certain specific adult and paediatric radiographs and for CT (EC, 1996a,b, 1999a), but similar criteria are lacking for other imaging modalities.

(27) In this report, the Commission emphasises the importance of the link between the amount of radiation applied to the patient and image quality. Application of DRLs is not sufficient for optimisation of protection. Image quality must be evaluated as well. For medical exposures, the optimisation of radiological protection is best described as management of the radiation dose to the patient to be commensurate with the medical purpose (ICRP, 2007b). If radiation dose is decreased to a level that results in image quality or diagnostic information inadequate for the medical purpose, either by reducing dose or dose rate excessively or by failing to obtain a sufficient number of images, optimisation has not been achieved.

1.6. Rationale for this report

(28) The Commission's most recently published guidance on DRLs is now nearly a decade old (ICRP, 2007b). There are a number of areas where the Commission believes that it would be useful to provide additional guidance on the application of DRLs and the development of DRL values, clarification of previous recommendations, and recommendations for newer technologies.

(29) Several terms used in earlier ICRP reports were not defined clearly. This report clarifies and defines some of these terms, such as local, national, and regional DRLs. There has been some confusion regarding the proper use of local DRLs in certain situations. In this report, the Commission provides recommendations on adapting local DRLs in facilities where different types or levels of technology are used. Examples include newer CT scanners with iterative dose reduction algorithms, interventional fluoroscopy systems with advanced dose reduction software, and dental radiography with digital radiography detectors.

(30) The majority of published DRL values are based on "standard" adults. In this report, the Commission provides recommendations for establishing DRL values and the use of DRLs for paediatric patients (Chapter 6).

(31) This report discusses the use of DRLs in nuclear medicine, where DRLs have been assessed in a different way than in x-ray imaging (Chapter 5). In nuclear medicine, administered radioactivity, absolute or weight adjusted, is used as the DRL quantity, and DRL values have usually represented typical or optimised values rather than investigation levels. Some imaging modalities use more than one method for irradiating the patient during a single examination (e.g. PET/CT, SPECT/CT). In this report, the Commission provides recommendations for applying the DRL process to optimisation of radiological protection for these modalities.

(32) The Commission has not previously given advice on appropriate intervals for periodic revision of DRL values. In Europe, the new directive on Basic Safety Standards requires periodic revision of DRL values (EC, 2013). In this report, the Commission suggests criteria for the timing of these revisions.

(33) DRL values are useful as investigation levels for optimisation of protection in the medical exposure of patients, but they do not provide guidance on what is achievable with optimum performance. In 1999, NRPB (1999) introduced a proposed new tool, 'achievable dose' (AD), for this purpose. AD is a level of a DRL quantity "achievable by standard techniques and technologies in widespread use, without compromising adequate image quality" (NRPB, 1999). The NRPB introduced this concept to further improve efforts to maximise the difference between benefit and risk in diagnostic procedures, without compromising the clinical purpose of the examination. The NRPB proposed values for AD that were based on the mean values observed for a selected sample of departments that met EC recommendations on technique (NRPB, 1999).

(34) In 2012, the U.S. National Council on Radiation Protection and Measurements (NCRP) discussed the concept of AD further, and proposed that AD values be set at the median value (the 50th percentile) of the distribution of a DRL quantity observed in a survey of departments (NCRP, 2012). The Commission considers that this approach may be useful (i.e. use of the median of the distribution of a DRL quantity observed in a survey of departments) as an additonal tool for improving optimisation.

(35) The use of the median of the distribution of a DRL quantity observed in a survey of healthcare facilities may have an additional role. A certain degree of patient dose reduction can be achieved without affecting image quality adversely. However, patient dose must not be reduced so much that the images become non-diagnostic. The Commission (ICRP, 1996) has previously noted that, in principle, there could be an additional value specified that would serve as a simple test to identify situations where levels of patient dose are low and investigation of image quality should be the first priority (i.e. below which there might be insufficient radiation dose to achieve a suitable medical image). The Commission has not previously specified such a value, either as an absolute value or as a percentile of the distribution of data used to determine the DRL. The Commission now suggests that the median value of the distribution of a DRL quantity observed in a survey of healthcare facilities could be used for this purpose.

(36) The Commission has noted that, in principle, DRLs could be used for dose management in interventional fluoroscopy with regard to stochastic effects (ICRP, 2007b). DRLs are challenging to implement because of the very wide distribution in the amount of radiation applied to patients, even for instances of the same procedure performed at the same facility (ICRP, 2007b; Vañó and Gonzalez, 2001). Most published DRL values for these procedures are based on the 75th percentile of collected data for DRL quantities, in the same fashion as DRL values for standardised radiographic examinations (Miller et al., 2009, 2012b; Hart et al., 2009, 2012; Neofotistou et al., 2003; Padovani et al., 2008). The Commission has previously suggested one possible approach, incorporating the complexity of the interventional procedure, thereby adjusting the DRL value for different patient anatomy, lesion characteristics, and disease severity. Complexity has been quantified for percutaneous coronary interventions (PCI) (Bernardi et al., 2000). The International Atomic Energy Agency (IAEA) explored the feasibility of establishing DRL values for certain cardiology

interventions using procedure complexity to normalise the amount of radiation applied (Balter et al., 2008; IAEA, 2009).

(37) Assessing procedure complexity requires substantial clinical data, but these data are often not available. NCRP has recommended a different approach, applicable to stochastic effects, that uses data on appropriate DRL quantities from all cases of a specific interventional procedure, rather than a sample of cases (Balter et al., 2011; Miller et al., 2012b; NCRP, 2010). In this report, the Commission discusses the advantages and disadvantages of these different approaches to establishing DRL values for interventional fluoroscopy, and provides recommendations on quantities (Chapter 4).

(38) DRLs are not applicable to management of the risk of tissue reactions (i.e. radiation-induced skin injuries). The Commission has described other methods for managing this risk (ICRP, 2013).

1.7. Target Audience

(39) DRLs are an effective tool for optimisation of protection in medical imaging. In different countries, different individuals may be responsible for implementing optimisation of radiological protection in medical facilities. The individual with primary responsibility may be a medical physicist, a physician, a radiographer, or an administrator. However, all individuals who have a role in subjecting a patient to a medical exposure should be familiar with DRLs as a tool for optimisation of protection.

(40) The target audience for this report is national, regional and local authorities and the clinical community: professional societies, facilities where ionising radiation is used for medical exposures, and responsible staff within these facilities. In particular, professional medical societies of radiologists, cardiologists, and other practitioners who use radiation should promote QA and quality improvement programmes that include evaluation of the amount of radiation applied using the DRL process.

1.8. Summary

(41) DRLs have proven to be a useful and valuable tool for optimisation of radiological protection in medical exposures of patients. In this report, the Commission refines its existing recommendations on using DRLs and determining DRL values and provides additional recommendations that address areas of confusion and misuse. These recommendations should help clarify the appropriate use of DRLs, and provide guidance on the application of this tool to a wide variety of imaging modalities and clinical situations. This should help prevent the inappropriate use of DRLs, such as treating a DRL value as a limit, applying DRL values to individual patients, or using quantities that are not easily and directly measureable.

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2. CONSIDERATIONS IN CONDUCTING SURVEYS TO ESTABLISH DRLS

- **Where appropriate or required, national or state legislation should clearly identify organisations having responsibility for different components of the tasks of collating data on DRL quantities and setting DRLs.**
- **The first step in setting DRLs is to identify the examinations/procedures for which DRLs should be established. They should represent the common examinations performed in the region, with priority given to those that are performed with the highest frequency or that result in the highest patient radiation dose. They should also be ones for which assessment of DRL quantities is practicable.**
- **The primary variables that are recorded should be quantities that can be readily assessed, preferably from a direct measurement for the examination (e.g. P_{KA}, Ka,e, DLP, $CTDI_{vol}$, administered activity), and that indicate the amount of radiation or administered activity applied.**
- **The survey will normally comprise larger or medium-size facilities that have a sufficient workload to ensure that data for a representative selection of patients can be obtained. A survey for a particular examination in a facility would normally involve the collection of data on the DRL quantity for at least 20 patients, preferably 30 for diagnostic fluoroscopy examinations and 50 patients for mammography. The sample should also cover the range of healthcare providers.**
- **A survey of a random selection of a small proportion of all the imaging facilities can provide a good starting point. Results from 20-30 facilities are likely to be sufficient in the first instance. In a small country with fewer than 50 facilities, a survey of 30% to 50% of them may suffice.**
- **Hospital and Radiology Information Systems can provide data for large numbers of patients. Wherever possible, utilisation of electronic transfer of these data is recommended.**
- **There should be some standardisation of weight for patients included in surveys.**
- **Calibrations of all dosimeters, P_{KA} meters, etc., used for patient dosimetry should be performed regularly and should be traceable to a primary or secondary standard laboratory. The accuracy of DRL quantity data produced by and transferred from x-ray systems should be periodically verified by a medical physicist.**
- **The Commission now recommends that the median value (not the mean value) for the DRL quantity from each of the facilities in the survey should be used. National DRLs should be set as the 75th percentile of median values obtained in a sample of representative centres.**

- **When national DRL values exist for many or most countries within a region, regional DRL values may be determined by using the median value of the available national DRL values.**
- **National and regional DRLs should be revised at regular intervals (3-5 years) or when substantial changes in technology, new imaging protocols or post-processing of images become available.**
- **Assessment of clinical image quality should be performed as part of the optimisation process. Objective measures should be used where these are available.**
- **The median (the 50th percentile) of the distribution used to set the national DRL may also be used as an additonal tool for optimisation.**

2.1. Introduction

(42) This chapter deals with the development of a DRL programme and establishment of DRL values for diagnostic procedures – diagnostic radiography and fluoroscopy, mammography, dentistry and nuclear medicine. Digital radiography, CT, nuclear medicine, and multimodality procedures are also dealt with in Chapter 5, and specific considerations for paediatric examiantions are dealt with in Chapter 6, but general principles that apply to all diagnostic examinations are discussed here. DRLs were originally developed with the underlying assumption that they are for a "standard" examination, where the value of the DRL quantity for a specific examination performed on a specific radiographic unit will vary only as function of body part thickness (or some other measure of body mass). Interventional procedures are by their nature non-standard and are dealt with separately in Chapter 4.

(43) DRLs are a form of investigation level used to aid in optimisation of protection in the medical exposure of patients for diagnostic and interventional procedures. A DRL is defined for types of equipment for typical examinations of groups of standard-sized patients or, in certain specific circumstances, a standard phantom. It is derived from an arbitrary threshold in a distribution and is not a scientific definition. DRLs are supplements to a professional judgement, and do not provide a dividing line between good and bad medicine.

(44) DRLs utilise 'DRL quantities' – commonly and easily measured or determined quantities or metrics (e.g. Ka,e, Ka,i, $CTDI_{vol}$, DLP, P_{KA}, Ka,r, D_G) that assess the amount of ionising radiation used to perform a medical imaging task. These quantities indicate the amount of radiation or administered activity applied, and not the actual absorbed doses in tissues and organs of the patient.

(45) The quantities selected are those that are readily available for each type of medical imaging modality and medical imaging task. DRLs are utilised to evaluate whether, in routine conditions, the median value of a DRL quantity obtained for a representative group of standard-sized patients from a specified procedure is unusually high or low for that procedure.

(46) DRLs should be representative of procedures performed in the local area, country or region where they are applied. In some countries, hospitals or health authorities may set their own local DRLs. These will ideally be based on national values, but can be adjusted to apply to local practices to encourage further optimisation. They can also be used to set lower values for new technologies that allow lower dose levels to be achieved. Where no national or regional DRLs are available, DRLs can be set based on local dosimetry or practice data.

(47) A 'DRL value' is a selected numerical value of a DRL quantity, set at the 75th percentile of the medians of DRL quantity distributions observed at healthcare facilities in a nation or region. DRL values are not static. As optimisation continues or hardware and software improve, DRLs should be updated on a regular basis. When new imaging techniques are introduced, an effort should be made to measure appropriate DRL quantities and set DRL values as soon as is practicable. Software tools for collection and management of dose-related data may simplify the process of establishing and updating DRL values.

(48) In nuclear medicine, the DRL represents what is regarded as the acceptable level of radioactivity to administer for an examination of an average patient. The practices involved in the use of DRLs in nuclear medicine are different from those in diagnostic radiology, although they serve a similar purpose, to assist in establishing agreed requirements for good practice. DRLs for nuclear medicine and hybrid imaging procedures are discussed in more detail in Chapter 5.

(49) Median values of DRL quantities for diagnostic procedures for a specific x-ray room or for a radiology department or other section of a healthcare facility can be compared with DRL values to identify whether the median values in the room, department or facility are higher or lower than might be anticipated. Comparison of data from local practice to the DRL value is the first step in the optimisation of protection, and can indicate whether an investigation of practices should be performed.

(50) If the median value of a DRL quantity for a particular type of examination in a particular healthcare facility exceeds the relevant DRL value (or is less than some specified percentile), an internal investigation should be carried out by the facility as soon as practicable. The investigation should either identify ways of improving practice by using the appropriate amount of radiation, or clinically justify the use of such higher (or lower) amounts of radiation.

(51) Compliance with DRL values does not necessarily indicate that image quality is appropriate and that the examination is performed with an optimal amount of radiation. Image quality must be assessed as part of the optimisation process. Comparison of the median value of the DRL quantity at the facility to the median value of the distribution used to determine the DRL value may also help in the optimisation by indicating when attention should be directed first to an evaluation of image quality (Section 2.6.2).

2.2. Approach to setting DRL values

(52) The first and perhaps the most difficult step is setting the DRL value. This should be tied to defined clinical and technical requirements for the medical imaging task. A selected numerical value for one situation may not be applicable to different clinical and technical requirements, even if the same area of the body is being imaged. The requirements can be general or specific.

(53) In general, and for the majority of types of examinations, DRL values should be based on measurements made in surveys of patient examinations. It is difficult to determine what value of a DRL quantity is just low enough and what image quality is just good enough to provide the required diagnostic information. Pooling of data from surveys provides results from which it is possible to decide that the majority of radiologists agree that a particular value of the DRL quantity produces an image that is adequate for diagnosis.

(54) Phantoms can be useful for assessing general radiographic exposures obtained with automatic exposure control (AEC) for comparison of the performance of different x-ray units (Conway et al., 1992) or for checking the performance of mammography units, but setting DRL values by using phantom-based surveys is not appropriate. Phantom data do not necessarily reflect the clinical and technical requirements for the medical imaging task. Also, they do not incorporate operator performance and may not incorporate protocol use in the same way as patient data obtained from surveys. If phantoms are used, their use should be just the first step in setting up a more complete system based on patient measurements.

(55) The one exception to using data from patient surveys to set DRL values is dental radiography equipment (Chapter 3). Since the same standard exposure settings, linked to the teeth being imaged, are used for the majority of adults, a measurement of output with the appropriate settings can be considered as the median incident air kerma or patient dose for each dental unit. DRLs can then be set based on the distribution of the measurements of output for different dental units.

(56) A summary of approaches recommended for different types of diagnostic examination is given in Table 2.1.

Table 2.1. Examination selection.

Examination	DRL recommended	Method of assessment
Mammography	Yes	Patient survey and phantom measurements
Dental radiology	Yes	Output measurement on standard settings
CT	Yes	Patient survey
Radiography of the trunk	Yes	Patient survey preferred

Skull radiography	Yes	Patient survey
Paediatric radiology	Yes	Patient survey
Extremity radiography	Yes (lower priority)	Patient survey
Mobile radiography	Yes (lower priority)	Patient survey
Neonatal radiography	Yes	Patient survey
Paediatric mobile radiography	Yes (for dedicated children's hospitals)	Patient survey
Barium studies	Yes	Patient survey
Interventional radiology and cardiology	Yes	Patient survey
Other fluoroscopy	Possibly, depending on level of use	Patient survey
Nuclear medicine - adult	Yes	Based on administered activity
Nuclear medicine - paediatric	Yes	Based on administered activity with adjustments for the size or weight of the child
Bone densitometry	Yes (lower priority)	Patient survey

(57) National and regional DRLs need to be based on valid comparisons. DRLs should be created for specific examinations. Comparisons must be like-for-like if they are to be meaningful. Moreover, DRLs should be derived from a group of facilities that is both large enough and sufficiently diverse to represent the range of practices within the country or region for the particular examination or procedure.

(58) Since practices and equipment will vary from one country or region to another, it is important that national and regional DRLs are representative of procedures performed in the country or region where they are applied.

(59) The best source for a DRL value is patient-based data for the country or region in which it will be used. Methods through which such DRLs can be derived are described in subsequent sections in this chapter. DRL values obtained from other sources can also provide useful data. These data can be used in the first instance for establishment of initial DRL values and for comparisons.

(60) DRL values published by other national or international organisations can be referred to when setting national DRLs. Examples are available from a number of sources,

including EC (1996a,b, 1999a,b, 2014), the HPA (2012) and NCRP (2012). However, these DRLs will not necessarily be appropriate for many countries and states, since diagnostic procedures may be defined differently (e.g. “abdomen CT” may be a CT of the abdomen or a CT of the abdomen and pelvis), the available hardware, software and expertise may vary (different radiological devices, technologies or procedures), and population groups, including typical pathologies, the purpose of the examination, and patient weight distribution may vary.

2.3. Survey considerations

2.3.1. Responsibility for conducting surveys and establishing DRLs

(61) National DRLs should be appropriate for the range and numbers of medical procedures undertaken using ionising radiation in that country. Such DRLs provide targets that all facilities are encouraged to meet.

(62) Regional DRLs relate to groups of countries that are thought to use similar practices, where a pooling of resources can reduce the workload and provide DRLs based on a more substantial data set. Establishment of regional DRL values should be accomplished in a manner consistent with the concepts expressed in this report, and the methodology should be agreed upon among the competent authorities of all participating countries.

(63) The establishment of national or regional DRLs requires surveys of patients across a whole country or region, and should be co-ordinated by a national or regional organisation, with support from national governments. This will require the provision of necessary resources.

(64) Regulatory requirements for setting DRL values, the application of DRLs, and the optimisation of protection for medical exposures are recommended in order to promote good practice. There are wide variations in the approach to management of patient dose in different parts of the world (Martin et al., 2013). Thus, there is a need for flexibility in the manner in which DRLs are established and optimisation programmes are implemented.

(65) National or state legislation should clearly identify organisations having responsibility for different components of the task. Collation of patient data and setting of national or regional DRLs needs to be done at a national or regional level. However, many different groups may carry out the actual measurements and collection of patient data.

(66) Organisations that undertake surveys of patients may be government institutions, health authorities, scientific or professional societies, academic institutions, hospitals, radiology facilities or clinics. These surveys could be accomplished by medical physicists or other staff with responsibilities in radiological protection, either employed by the organisation or through private contracts, or by training of in-house radiographers.

(67) Geographical areas within a country (e.g. states, provinces, counties) may have the infrastructure and necessary collaboration between professionals to develop their own

DRL values where there is a perceived need. Such collaborative groups may be able to perform surveys more quickly once an infrastructure is in place and so react more quickly to address perceived changes in practice.

(68) Local DRL values set by a group of radiology departments or even a single facility can also play a role. By their nature, national and regional DRLs can take longer to assess, review and revise. Larger hospitals or groups of hospitals may already have invested the effort to achieve a higher level of optimisation. Where this is the case, the group could choose to set its own, lower, local DRL value based on more regular surveys of local practice. A local DRL value will normally be lower than the national DRL value, unless it is designed for a different clinical task or on a group of patients with a more demanding clinical condition. The Institute of Physics and Engineering in Medicine (IPEM, 2004) contains a comprehensive report on the implementation and use of local DRLs.

(69) Local DRL values can also be established for newer technologies that enable lower dose levels to be used in achieving a similar level of image quality or diagnostic information. Examples of this are where iterative reconstruction techniques are used for CT images instead of filtered back projection, or where more sensitive digital radiography detectors (DR) replace computed radiography (CR) for general radiography or dental imaging.

(70) Local DRLs can be of value where a facility performs large numbers of specialised examinations for which there is no national DRL. This could apply to a major centre for a specific type of specialist treatment.

(71) Where local DRL values are set, the facility may need to base these mainly on its own practice if there are no national DRL values available. However, countries throughout the world are now setting DRL values for different imaging tasks, and reference to values used by other centres can provide a useful guide as to whether further optimisation is required.

(72) In some countries, government departments or universities have undertaken surveys in the past (Martin et al., 2013). The experience of established groups may be utilised, but will require co-ordination and supervision in order to ensure accuracy and consistency of data collection, and uniform coverage of x-ray facilities.

(73) Since an understanding of the imaging and radiation performance of the equipment is required for optimisation, periodic constancy testing should be carried out, and the results should be evaluated by a qualified medical physicist. This may be mandated through regulations. In the U.K., where DRLs have been employed successfully in the optimisation process for many years, medical physicists oversee both performance tests on x-ray equipment and patient surveys.

(74) In order to ensure that the setting of DRL values leads to optimisation of protection for medical exposures, both staff who operate the equipment and carry out the procedures and staff who perform constancy testing need to be made aware of the results and need to work together in the optimisation process. Close collaboration between the different groups is essential if optimisation is to be fully realised.

2.3.2. Facilities

(75) The first step in setting DRLs is to carry out surveys of patient examinations across the geographical area to which the DRL will apply. In a developed country with hundreds of healthcare facilities, a survey of them all would be a mammoth task. A random selection of a small proportion of all the healthcare facilities as a sample can provide a good starting point. Thus, results from 20-30 facilities are likely to be sufficient in the first instance, if a sufficient number of patients from each facility are included (Section 2.3.3). In a small country with fewer than 50 facilities, an initial survey of 30% to 50% of the facilities may suffice. In subsequent surveys, as the data collection infrastructure improves, the number of facilities included can be extended to give more representative coverage.

(76) Selection of a representative sample of facilities is normally sufficient, as shown by experience in the U.K. The first set of guideline doses (i.e. DRL values) in the U.K. was derived from mean values for particular examinations for each x-ray room in 20 hospitals selected at random. Patients included in the study had weights within a restricted range.

(77) The facilities included should have a sufficient workload to ensure that data for a representative selection of patients can be obtained. They would normally be larger or medium size hospitals, since the patient cohort in a small hospital or other healthcare facility may be insufficient to allow a reasonable sample to be obtained in a realistic time frame.

(78) The sample should also cover a representative selection of healthcare providers. In a majority of countries, these may be both public and private, hospital and freestanding, and priorities for optimisation may be different in different facilities. Smaller facilities with limited numbers of radiographers may employ unusual practices that do not reflect those used widely across the country. Although it is important to be aware of these practices, they should be identified in the next round of patient surveys when comparisons are made with the DRL values that have already been established.

(79) The first survey of healthcare facilities in a geographical area will need to be organised centrally. Where there are only a few diagnostic radiology medical physicists, a medical physicist may need to visit each facility to carry out quality control (QC) testing, including measurement of x-ray equipment output, and to make arrangements for data collection.

(80) The U.K. first introduced guideline doses (precursors of DRLs) in 1989 (Shrimpton et al., 1989) and has developed the application of the concept over the last 25 years. National DRL values have been set in the U.K. at the arbitrary level of the third quartile of the mean (not median) values of DRL quantities measured in large-scale hospital surveys. Thus, by definition, one quarter of the mean values for each examination in the survey exceeded the proposed DRL. However, a few outlier data points can affect a hospital's mean value substantially. Therefore, the Commission now recommends use of the median value of the local data. Also, local data should be obtained from a representative sample of typical patients.

(81) The initial establishment of national or regional DRL values is the first step in a continuing process. Thereafter, surveys will need to be repeated periodically to evaluate changes. Once initial DRL values have been set, subsequent surveys may take the form of collation of measurements made by local medical physicists or radiology staff.

(82) Once a DRL framework has been put in place, a suitable interval between national or regional data collection surveys may be 3 years to as much as 5 years (the interval used in the U.K.), but this will depend on the examination levels, the degree of variability of the survey results, the introduction of new technology or imaging post-processing software, and the availability of staff to undertake the analysis. In one Spanish university hospital, Vaño et al. (2007) used an automated collection system with a database of 204,660 data points to evaluate changes in patient radiation levels during the transition from film-screen to digital radiography. They demonstrated the importance of frequent patient audits when imaging technology changes.

(83) Where there has been a drive to encourage healthcare facilities throughout a geographical area to perform their own patient surveys, then collection of further data on a time scale of a few years may be achievable. Once optimisation is started, the amount of radiation administered to patients is likely to decrease, so it is important to review the data and update DRL values to maintain the momentum of improvement.

2.3.3. Patients

(84) The majority of the discussion in this chapter is devoted to the collection of data on DRL quantities for individual patients, and the determination of DRL values based on these data. However, there are some limited circumstances in which the performance of equipment with regard to the amount of radiation used can be assessed by simple measurements or by using phantoms. These include dental radiography, mammography, and, to some extent, radiography and diagnostic fluoroscopy. Such measurements should be regarded as useful adjuncts performed during QC assessments, but in general should not replace surveys of patients. Use of phantoms is discussed further in Chapter 3 in the subsection for each imaging modality.

(85) Since attenuation of the x-ray beam depends on the amount of tissue the beam has to penetrate, it is important to have some standardisation of patient size if the number of patients for whom data are collected is limited. Standardisation of patient size is usually accomplished through weight restriction. For adults, this is achieved typically by using data from patients with weights within a certain range, e.g. a range of 50 kg to 90 kg can be used to achieve a 70 kg mean. A mean weight of 70 kg ± 5 kg was chosen as a reference weight in the U.K., as representing the average in the U.K. at the time (IPSM, 1992). This mean weight is not necessarily appropriate for other countries with different weight distributions in their population, and with current trends in population weight, it may not be appropriate for the U.K. in the future. The mean weight chosen should be close to the average weight in the population being considered. A mean weight of 70 kg ± 10 kg may be appropriate for some countries.

(86) Where automated methods of recording values of DRL quantities are available, it may be possible to collect data for large numbers of patients (>100) at each facility (Goenka et al., 2015; MacGregor et al., 2015). Where this is possible, restrictions on weight can be removed. Results rely on the accuracy of data entry, and may not include patient weight. Exclusion of the highest and lowest 5% of the data will eliminate outliers and data with gross errors from the analysis. Specific considerations for development of DRLs for paediatric patients are discussed in Chapter 6.

(87) Where collection of data is only possible for smaller numbers of patients, the uncertainty in the median or mean may be large. The interquartile range serves as an indicator of dispersion of the data (see Section 7.1).

(88) A survey of the DRL quantity for a particular examination in a hospital would normally involve the collection of data for at least 20 patients for radiographic examinations (IPSM, 1992). However, data for more patients will be required when there are a greater variation and wide range of results. This is especially true for fluoroscopy, where differences in patients' disease states and operator technique contribute to the variation. A group of at least 30 patients within the agreed weight range is preferable for diagnostic fluoroscopy procedures (IPSM, 1992). Even larger numbers of patients may be needed for interventional procedures (Chapter 4). For mammography, 50 patient measurements are recommended because of variation in breast size.

2.3.4. Examinations and DRL quantities

(89) The first priority in selecting examinations and imaging procedures for which DRL values should be set is to include those common examinations performed in the region, with priority given to those that are performed with the highest frequency or that result in the highest patient radiation dose. These should also be examinations for which dose assessment is practicable and should encompass all groups of operators. The choice of examinations will also be influenced by the expertise of the personnel available to oversee the survey and to advise about subsequent optimisation required. Table 2.1 categorises certain examinations. The aim should be to eventually provide DRL values for all procedures commonly performed.

(90) In the first instance, it may be decided that radiography should be surveyed, as it is the most widely used technique, measurement of DRL quantities is relatively simple, and optimisation of protection is relatively straightforward. Alternatively, CT may be chosen, as it is frequently performed and results in relatively high patient radiation doses. For CT, it is particularly important that appropriately trained medical physicists are involved to provide advice on the optimisation of protection.

(91) Setting DRL values for multiple quantities rather than a single quantity provides a guide to good practice and can simplify the investigation of practices at a facility by drawing attention to a specific area for improvement. This can form a useful part of an optimisation programme to encourage improvement in skills and practices of individuals.

Table 2.2. ICRU symbols for DRL quantities.

ICRU Symbol*	Meaning	Other Common Symbol
$CTDI_{vol}$	Volume Computed Tomography Dose Index	
DLP	Dose Length Product	
Ka,i	Incident air kerma	IAK
Ka,e	Entrance-surface air kerma	ESAK, ESD
Ka,r	Incident air kerma at the Patient Entrance Reference Point	CAK
D_G	Mean glandular dose	MGD, AGD
P_{KA}	Air kerma-area product	KAP, DAP

*This report uses ICRU symbols. Other common symbols are shown for the convenience of the reader.

(92) Data collected for patient surveys should, when feasible, include the equipment manufacturer and model, the examination name, patient weight, and P_{KA} and other DRL quantities (e.g. $CTDI_{vol}$, DLP, Ka,e, Ka,r) if appropriate and available for the types of examination being surveyed (for the convenience of the reader, Table 2.2 lists the symbols for DRL quantities and their meaning). The quantities recommended by the Commission are given in Table 2.3. For fluoroscopy and CT, all of the quantities listed should be recorded if they are available. The quantities chosen should be easily measured, such as absorbed dose in air or tissue equivalent material at the surface of a representative patient (or, for certain specific examinations, a representative phantom) for diagnostic radiology, and administered activity for diagnostic nuclear medicine. The DRL quantity selected (e.g. $CTDI_{vol}$, DLP, administered activity) should allow assessment of the amount of ionising radiation used to perform the medical imaging task, and is not (with the exception of D_G for mammography) the absorbed dose in a tissue or organ of the body.

Table 2.3. Quantities suitable for setting DRLs.

Equipment	Recommended quantity	Recommended unit
Radiography	Ka,e	mGy
	P_{KA}	$mGy \cdot cm^2$
Mammography, breast tomosynthesis	Ka,e Ka,i or D_G*	mGy
Dental intra-oral	Ka,i	mGy
Dental panoramic	P_{KA} (or dose width product)	$mGy \cdot cm^2$ (mGy·cm)
Diagnostic fluoroscopy, interventional fluoroscopy	P_{KA}	$Gy \cdot cm^2$

	Ka,r	Gy
	Fluoroscopy time	seconds
	Number of images in cine or digital subtraction angiography (DSA) runs	number
CT, interventional CT	$CTDI_{vol}$	mGy
	DLP	mGy·cm
Cone-beam CT (depending on availability of the quantity)	Ka,r	mGy
	P_{KA}	mGy·cm^2
	$CTDI_{vol}$	mGy
	DLP	mGy·cm
Nuclear medicine	Administered activity	MBq

*For mammography and tomosynthesis, the recommended DRL quantity is one or more of Ka,e, Ka,i or D_G, with the choice of quantity depending on local practices.

(93) Calibrations of meters and displays should be verified, preferably at intervals of 1-2 years. Calibration of instruments used to confirm the accuracy of P_{KA} meters, CT scanner displays of $CTDI_{vol}$ and DLP, and TLDs used for patient dosimetry should be performed regularly and should be traceable to a national or international standard. Measurements of equipment output and other exposure variables should be carried out as part of standard QA programmes. Constancy tests should be performed at least annually on all medical equipment that emits x rays, except that a three-year interval may be employed for dental radiography equipment. This exception does not include dental cone-beam CT units.

2.4. Procedure selection

(94) Procedure selection is important in ensuring DRLs are fit-for-purpose. When data on DRL quantities are collected, it is important that all of the data come from procedures that are similar across all participating facilities. This ensures that comparisons among facilities remain valid and useful. There are two aspects to this. First, it is important to specify in detail both the views normally included [e.g. PA and lateral (LAT) chest radiographs]. Second, the clinical task associated with the procedure should be specified. This is important where different exposure factors, different views, or different numbers of views are employed for different clinical indications. A decision would then be required as to whether the DRL value would be based on all exposures or only a specific subset.

(95) Organisations that conduct surveys of DRL quantities will also need to consider whether or not to distinguish between those procedures performed within a dedicated,

fixed x-ray facility and those performed using mobile equipment. Often the latter provide unique challenges to the radiographer that may affect the amount of radiation delivered and thus, potentially, the DRL.

2.5. Data collection methods

(96) There are various options for data collection. If database facilities for automated recording are limited, paper forms tailored to the examination may be used. These are time consuming for the operator to complete, and the validity of the results depends on the accuracy of data entry and subsequent data transfer. This method was used for many years in the U.K., other European countries, and the U.S. (FDA, 1984).

(97) The advent of Hospital Information Systems (HIS) and Radiology Information Systems (RIS) has allowed review of patient examination data to be performed retrospectively. RIS data collection has the advantage that far greater numbers of patients can be included, but results may be for multiple views such as PA and LAT projections in radiography. The results also rely on the accuracy and consistency of data entry, particularly with regard to the proper identification of the procedure and the correct units for the dosimetric quantities, and may not include patient weight. Because much larger numbers of patients can be included in data collected via a RIS, these problems can be overcome, to some extent, through the exclusion of outliers.

(98) Modality Performed Procedure Step (MPPS) services can send x-ray procedure, patient and image information from Digital Imaging and Communications in Medicine (DICOM) headers to the HIS/RIS server upon completion of the examination (Ten et al., 2015; Vano et al., 2008, 2013). Collation of data in Radiation Dose Structured Reports (RDSRs) allows access to procedure data in a structured format and can be used to notify clinical staff and medical physicists when dosimetric quantities exceed pre-set levels. This allows for convenient and systematic follow-up of patients at risk of developing tissue reactions such as skin injuries (Fernandez-Soto et al., 2015).

(99) Another option that will become more widely available in the future is the use of data from Picture Archiving and Communication Systems (PACS). Exposure data recorded in the RDSR, MPPS or the DICOM header can be transmitted to the PACS. Currently, data access is not straightforward, but patient dose management systems are now available which facilitate the establishment of databases as repositories of dosimetric data in the future (Cook et al., 2011; Sodickson et al., 2012; Ikuta et al., 2012; Charnock et al., 2013; Vano et al., 2013). Alternatively, dosimetric data can be transmitted to a separate, stand-alone data archive intended to aid in radiological protection QA and quality improvement.

(100) As programmes for collection and analysis of dosimetric data become more established, the number of examinations and patients included in surveys can be expanded. For example, the U.K. now has a system whereby dosimetric data collected by medical physicists in hospitals throughout the U.K. are sent to PHE for collation and analysis. The

U.K. survey performed in 2010 collected data for 165,000 Ka,e measurements for radiographs, 185,000 P_{KA} measurements for radiographs and 221,000 P_{KA} measurements for fluoroscopy (Hart et al., 2012). Similarly, the American College of Radiology's Dose Index Registry has used automated methods to collect data on more than 5 million CT examinations (Bhargavan-Chatfield et al., 2013; Spelic et al., 2009). Regardless of the data source used, the validity of the dosimetric indicators must be verified by calibration.

2.6. Determining DRL values

2.6.1. Distributions of DRL quantities

(101) Once a patient survey of DRL quantities is complete, a decision must be made about how national or regional DRL values will be set. If the data for each facility relate to a limited number of 20-50 patients within a specified range of patient characteristics, then the median value of the DRL quantity from each facility can be derived from the distribution of the dosimetric data for each type of examination.

(102) If large numbers of patients have been included from an electronic data collection system, then the distribution should first be reviewed to identify obvious outliers with nonsensical values for DRL quantities. These outliers should be removed. A few high values, either from incorrect data entry or exceptionally large patients, could have a significant effect on the mean of the distribution, but should have minimal influence on the median. If specialised software for the task is not available, unusual results in the high and low tails of the distribution can be identified by viewing the ordered distribution in a spreadsheet or graphically (Fig. 2.1). The data points in the highest and lowest 5% tails of the distribution can be excluded, but will have minimal effect on the median value for each facility. Results can then be included in a distribution of facility-related median values.

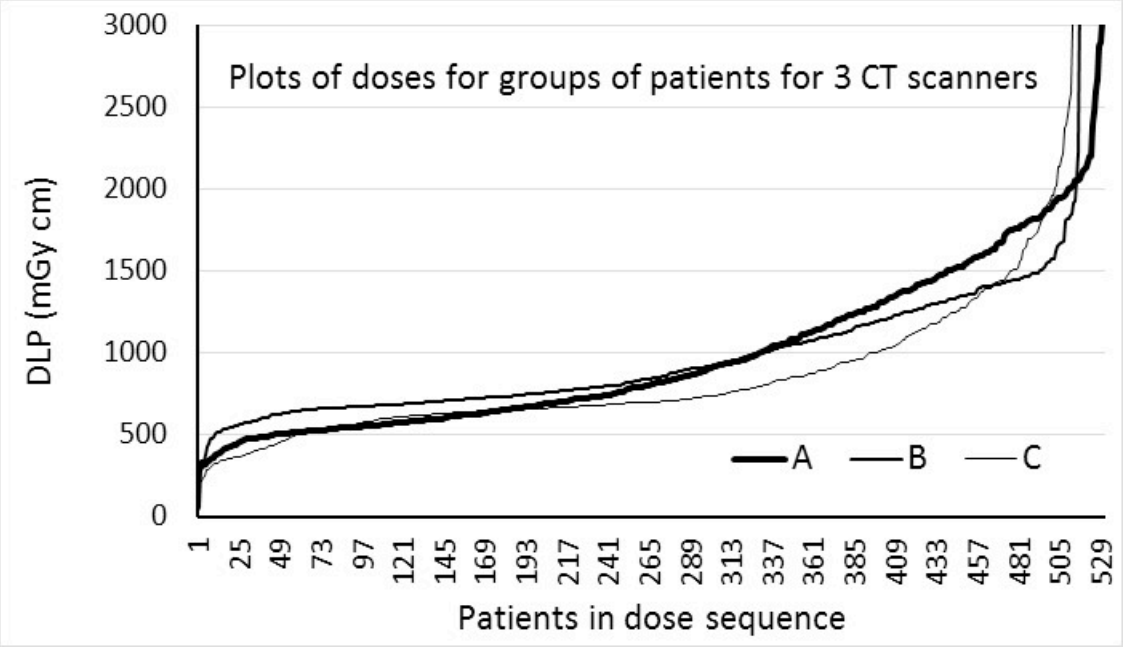

Fig. 2.1. Examples of data on DLP for chest-abdomen-pelvis scans on three CT scanners operating under automatic tube current modulation plotted sequentially in terms of increasing DLP (Martin, 2016). Outliers can be identified readily and omitted from the data analysis.

(103) Typical distributions of values of DRL quantities obtained from multiple facilities are approximately log-normal, and often contain data from a few facilities with uncommonly high values. The distribution of individual values of entrance surface dose per image from two types of radiographic examinations for patients from 20 hospitals in an early survey of English hospitals is shown in Fig. 2.2. The data from two hospitals with very low and very high values of entrance surface dose per image are highlighted. In the early days of an optimisation programme, it is these hospitals and clinics that need to be identified and targeted for optimisation.

(104) The form of the skewed pattern of the distribution of a DRL quantity has been repeated many times in surveys throughout the world, from many different types of examinations and for many DRL quantities (Shrimpton et al., 1986, Kwon et al., 2011; Miller et al., 2011), as there are inevitably always a few facilities where optimisation has not been fully implemented.

(105) DRL values have often been defined as the 75th percentile (third quartile) of the distribution. This can easily be understood at the national level with a large sample of facilities. The 75th percentile has been chosen as an initial separator between acceptable and excessive values, but it is arbitrary and has no real scientific basis. However, the 75th percentile usually lies well below the high dose 'tail' of the distribution and serves as a useful marker for identification of facilities whose results lie towards the upper end of the

distribution. It is reasonable to set the DRL value at the 75th percentile of the distribution, and the Commission now recommends this practice.

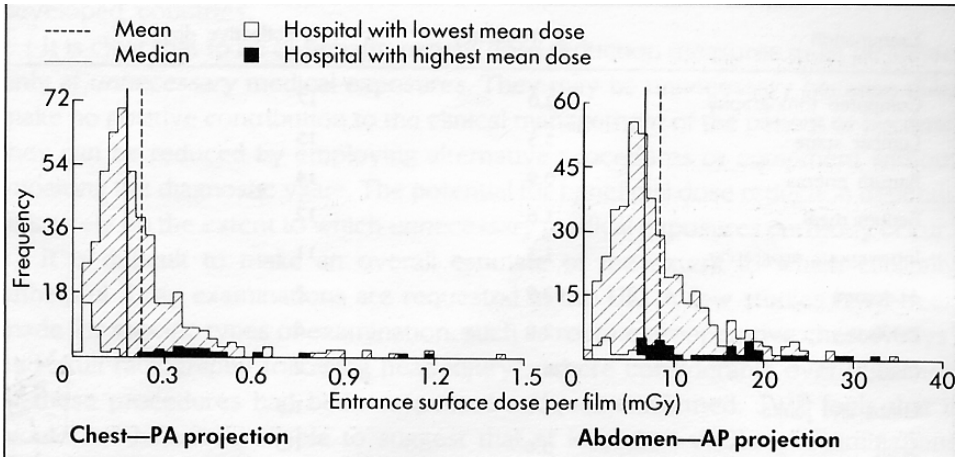

Fig. 2.2. Distributions of entrance surface dose per image for patients from 20 English hospitals included in an early survey performed by NRPB (now PHE) (Shrimpton et al., 1986). Distributions for the hospitals with the highest and lowest mean values are highlighted. [**PERMISSION FROM PUBLIC HEALTH ENGLAND IS NECESSARY**]

(106) DRL values are not static. The radiation administered to patients for radiological examinations is expected to decrease as emphasis is placed on optimisation of protection and as equipment improves. This has been demonstrated in U.K. surveys of radiography (Fig. 2.3) and fluoroscopy (Hart et al., 2012). As optimisation occurs and practice improves, DRL values require periodic updating.

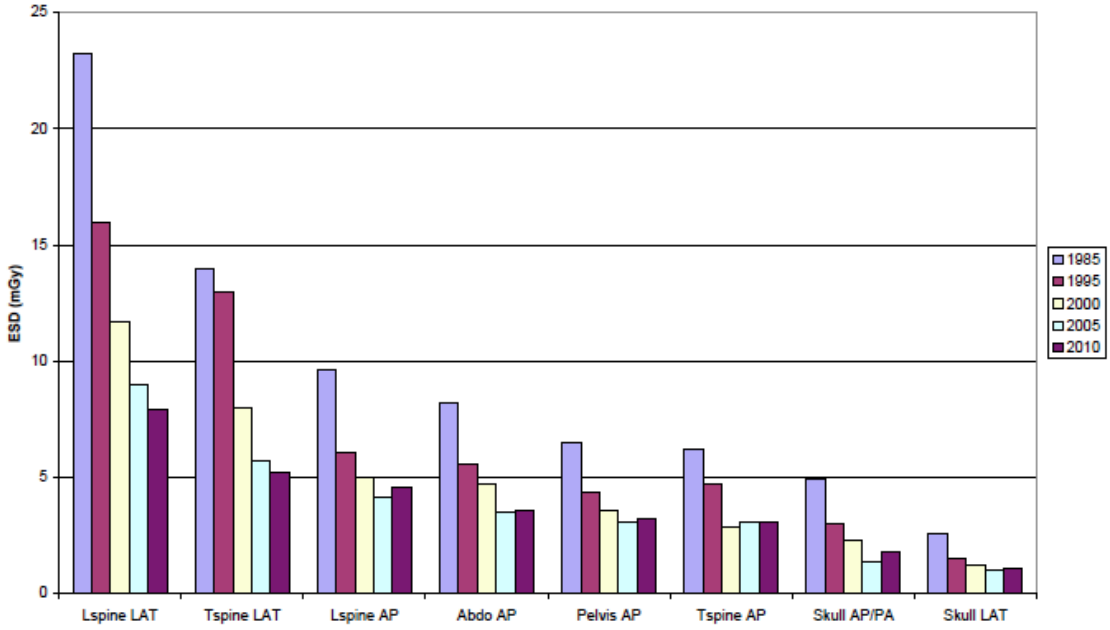

Fig. 2.3. 3rd quartile Ka,e measurements for radiographic examinations derived from NRPB/HPA surveys between 1985 and 2010 (taken from Hart et al., 2012). [**PERMISSION FROM PUBLIC HEALTH ENGLAND IS NECESSARY**]

(107) Findings from a recent survey of CT doses for hospitals throughout Scotland have revealed a different pattern from the log-normal distributions of DR quantities seen previously, and may demonstrate a new trend (Sutton et al., 2014). The number of CT scanners is more limited than other types of x-ray equipment, and in the U.K., there are more diagnostic radiology physicists engaged in optimisation of CT examinations. Since CT scanning is a relatively high dose imaging method, it has received a high priority for optimisation efforts. As a result, the majority of dosimetric measurements in the latest Scottish survey have started to cluster around a position just below the national DRL (Sutton et al., 2014). This has resulted in the high dose tail of the distribution disappearing. It may represent a particular circumstance where significant effort has been put into optimisation. However, it could represent a trend that will extend to other imaging modalities as dosimetric information becomes more readily available, the number of medical physicists involved in diagnostic radiology increases, and there is more widespread implementation of DRLs.

2.6.2. Use of national median values for optimisation

(108) The simple pooling of dosimetric data from surveys to derive DRL values is no longer completely satisfactory and may result in values of DRL quantities just below the DRL (Sutton et al., 2014) that do not represent true optimisation. A more proactive approach is needed to ensure the required level of image quality with optimisation of radiological protection. The establishment of a second quantity has been proposed, previously called AD,

which represents a level that could be achieved with reasonable practices (NRPB, 1999; NCRP, 2012). The use of the median value of the distribution used to determine the DRL value can serve as an additional tool to aid in optimisation. It potentially provides a better guide for judging good practice as optimisation efforts continue, since the DRL value is the 3rd quartile of the distribution. This median value can be used, along with the DRL value, to assist in optimising image quality and patient dose. Median values may provide a better alternative for this task than setting further local DRLs for examinations where a national DRL is available, as discussed in Section 2.3.1.

(109) The purpose of a DRL is to identify facilities where investigation of practices is advisable because protection is not optimised, that is, where the local median value of the DRL quantity is greater than the national or regional DRL value. However, at facilities where median facility values of DRL quantities are below the national or regional DRL value, improvement may still be possible, and staff with the experience necessary to take the optimisation process further forward may be present. The Commission recognises that median values from the national or regional DRL survey provide an additional benchmark against which such facilities can evaluate their performance. Since local median values of DRL quantities at most centres will be below the national DRL value, the national median value provides a reasonable goal towards which to aim with standard techniques and technologies.

(110) Good practice with regard to patient doses would be to attempt to achieve and maintain a median value of DRL quantities from local surveys at or below the national median value (NCRP, 2012). When implementing such dose reduction strategies, it is of the utmost importance to ensure that image quality remains commensurate with the clinical purpose of the examination (Section 2.7). If local median values of DRL quantities are too low, image quality (or diagnostic information, when multiple images are used) may be inadequate.

(111) If local median values of the DRL quantity are below the national median value, image quality should be considered as a priority in the optimisation process. The basis for this recommendation is that the national median value is the midpoint of the distribution of the data for the DRL quantity determined from surveys of many facilities. If practices at the local facility have already achieved levels of administered radiation that are below the national median value, further reduction in administered dose is not the principal concern. When local practices result in levels of administered radiation that are below average, image quality is a priority, and further optimisation of protection by reduction of administered radiation is secondary. Patient dose must not be reduced so much that the images become non-diagnostic. Dose reduction is not an end unto itself. *The adequacy of the image is paramount.* Image quality must never be reduced to the point where there is a risk that it is not sufficient for the medical imaging task.

2.6.3. Establishing regional DRL values

(112) Some regions of the world (such as the European Union) are trying to harmonise the radiation safety aspects of their health care systems. A requirement for regional

DRLs may be included in regional guidelines or regulations (e.g. European Directives). Countries in these regions may or may not already have national DRLs. As a result, the Commission is offering guidance on how to set regional DRL values. There are several options.

(113) Regional DRL values may be based on a single survey of a representative sample of facilities drawn from the entire region, or on national DRL values derived from separate national surveys. The specific method for setting a regional DRL value depends on whether it is based on data from a single regional survey of a representative sample of facilities or on national DRL values.

(114) When national DRL values exist for many or most countries within a region, the simplest and easiest method for establishing regional DRL values is to use the national DRL values as the basis for the regional values. Since the national values typically represent the 75th percentile values for the national distributions of DRL quantities, the median of the available national DRLs should approximate the 75th percentile value to be expected from a regional patient survey. The mean of the available national DRL values should not be used, as this method could result in excessive variation in regional DRL values if some of the countries in the region have very low or very high national DRL values.

(115) When relatively few national DRL values exist for the countries within a region, regional DRL values may be derived through a consensus of the region's competent authorities. This process should take into account existing national DRL values, but should also consider that a median that is derived from only a small number of national DRL values could be inappropriate.

(116) Using existing national DRL values as the basis for regional DRL values is efficient, but not ideal. This approach may overemphasise the survey data from smaller countries and countries where a relatively small number of facilities and patients are surveyed. Conversely, it may underemphasise the survey data from larger countries and countries where a relatively large number of facilities and patients are surveyed. This problem can be dealt with when calculating regional DRL values by weighting national DRL values according to the population of each participating country. However, the most accurate DRL values will be obtained from a single survey of a random sample of facilities throughout the region. Fortunately, this degree of accuracy is unlikely to be necessary, given that the purpose of a DRL is only to indicate when an investigation of local practices is necessary.

2.7. Image quality

(117) The approach used most frequently in discussions among physicists, radiologists, and radiographers on how to accomplish optimisation of protection is to achieve compliance with the DRL value for the examination. However, DRL quantities are not descriptors of image quality. Median values of DRL quantities at a health centre that are above or below a particular value do not indicate that images are adequate or inadequate for a

particular clinical purpose. Substituting compliance with national DRL values for evaluation of image quality is not appropriate.

(118) The highest priority for any diagnostic examination is achieving image quality sufficient for the clinical purpose, so that the images from the whole procedure provide all the diagnostic information required and the clinical purpose is not jeopardised. This does not mean that every image is of high quality; for some modalities (e.g. fluoroscopy), a series of images, each of poor quality, may together provide the necessary clinical information.

(119) Administered radiation doses that are so low that image quality is inadequate are as unacceptable as administered radiation doses that are too high. When image quality is inadequate for the clinical purpose, the administered radiation provides no clinical benefit, the examination must be repeated, and the patient receives additional radiation from the repeated examination. Because data from patient surveys are gathered from clinical sites, it has been assumed that the pooling of data on DRL quantities provides information on administered radiation doses that the majority of radiologists agree with to produce images that are sufficient for the clinical purpose.

(120) A focus on DRL quantities alone, without image quality criteria, could drive the value of the DRL ever downward, so that at some stage, image quality could be compromised. It is essential to assure that image quality appropriate for the diagnostic purpose is achieved when modifying imaging protocols. Therefore, optimisation must balance image quality and patient dose. Image quality must be maintained at an appropriate level as the amount of radiation is decreased.

(121) Prior to collection of DRL data, surveyors should ensure that imaging equipment is functioning acceptably and providing clinical images that are of a quality appropriate for the clinical task. Evidence-based criteria for judging image quality should be employed whenever possible. Guidance on the level of image quality required for different imaging tasks is limited. The EC (1996a, b, 1999b) has produced guidelines with criteria that can be used for scoring images when judging their diagnostic potential. These or similar criteria can be used for assessing image quality whenever changes are made that could affect image quality.

(122) Additional substantive data on appropriate image quality parameters for different examinations are needed. To aid in this process, more detailed analyses of acceptable levels of image quality for CT and other specialties are needed. Involvement of radiologists is necessary to evaluate clinical images using clinical image criteria. Additional data are also required on the magnitude of objective image quality variables linked to clinical imaging tasks.

(123) Chest radiography, where adequate image quality is required for both low and high attenuation regions, is a particular challenge and is the subject of a report by ICRU (1995).

(124) Restrictions on dose have been imposed in the past by the sensitivity of film/screen systems for radiography; recommendations on the appropriate speed class for general use resulted in a restriction on dose. Also, film blackening at high doses made excessive exposures obvious and deterred overexposure. Similar restrictions are not present with digital radiography or CT scanning. Hence, monitoring exposure parameters in CT and digital radiography and the exposure index in computed radiography is essential. The balance between image quality and patient dose is essential. Appropriate postprocessing may permit the use of lower exposure levels.

(125) There may be less agreement among radiologists regarding the appropriate level of image quality for CT examinations. The various factors that contribute to image quality should be discussed when CT and other digital imaging protocols are set up for a new scanner. The factors involved relate to (1) the contrast of the displayed image, as determined by window level and width, and (2) spatial resolution, in terms of focal spot size and the reconstruction kernel for digital filters. A report on image quality and dose assessment in CT has been prepared by ICRU (2012).

(126) Various metrics have been used for some time to characterise image contrast and the performance of imaging systems. These require specialist measurement techniques and are provided by the manufacturer for most imaging systems. Techniques through which hospital medical physicists can make these measurements are becoming more widely available. These metrics include modulation transfer function (MTF), the system transfer factor (K), and noise power spectra (NPS) (ICRU, 1995). They should provide useful information to the medical physicist to aid in selection of appropriate image quality levels as part of the optimisation process for digital imaging systems in the future.

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3. RADIOGRAPHY AND DIAGNOSTIC FLUOROSCOPY

- **DRL quantities should be easily assessed, preferably from a direct measurement for the examination. Either P_{KA} or Ka,e may be used for radiography. P_{KA} also takes account of collimation.**
- **For mammography, the recommended DRL quantity is one or more of Ka,i, Ka,e or D_G, with the choice of quantity depending on local practices.**
- **While P_{KA} and Ka,r are the recommended DRL quantities for fluoroscopy, setting DRL values for fluoroscopy time and the number of cine or digital subtraction angiography (DSA) images is also recommended.**
- **Phantoms may provide a convenient first step for evaluating the performance of mammography, radiography and fluoroscopy equipment, but their use should not replace patient surveys.**
- **A convenient method for setting DRL values for dental radiography is to use measurements of air kerma at the cone tip, the point at which x rays are incident on the skin, made with standard settings that are used in clinical practice. Separate measurements should be made for adults and children.**
- **For panoramic dental radiography, P_{KA} can be measured with an ionisation chamber, or the dose-width product can be measured with a detector positioned at the receiving slit.**

3.1. Radiography and diagnostic fluoroscopy examinations

(127) Radiography and diagnostic fluoroscopy include a wide range of examinations, but obtaining reasonable and sufficient data is only practical for those examinations most commonly performed. Nevertheless, these results should influence the technical factors used for other examinations. Optimisation efforts should be prioritised based on the potential risk of stochastic effects to patients, and priority given to those that result in substantial organ doses to radiosensitive organs.

(128) The examinations chosen for surveying should be those performed most frequently in the region for which dose assessment is practicable. They should also encompass the different techniques and equipment that are used. Table 3.1 gives the relative frequencies of various medical radiography and fluoroscopy examinations and their contributions to the collective effective dose for ten European countries.

Table 3.1. Relative frequencies of different diagnostic radiographic and fluoroscopic examinations and interventional procedures and percentage contributions to collective effective dose from radiology (data taken from EC, 2008).

Examination	Percentage of total frequency of all radiology exams	Percentage contribution to collective dose
Radiography		
Chest/thorax	12-29%	0.7-5.2%
Mammography	0.3-15%	0.6-4.7%
Abdomen, pelvis and hip	7.4-14.3%	2.9-14.1%
Spine (thoracic and lumbar)	3.8-12.7%	30.1%
Intravenous urography	0.3-2.0%	1.2-8.7%
Radiography/fluoroscopy		
Barium meal	0.3-0.9%	0.8-5.9%
Barium enema	0.1-2.0%	0.5-13%
Cardiac angiography	0.2-1.3%	2.8-9.4%

(129) In many countries, the most common radiographic examination is chest radiography (EC, 2008). Since chest radiography is a very common examination and involves exposure of several radiosensitive organs, it should be included in surveys of radiography. The largest contributions from radiography to collective effective dose are examinations of the abdomen, pelvis and spine, so these should also be included in any radiographic survey.

(130) It is recommended that skull x rays be included, as they involve exposure of the lens of the eye, and mammography because the breast is one of the sensitive organs. Moreover, these examinations employ different techniques, and the settings used will not necessarily reflect those for other procedures.

(131) The upper and lower extremities are examined frequently. However, these examinations are usually limited to a portion of the extremity, and the only radiosensitive organs exposed are parts of the bone marrow and skin. Thus, the estimated contribution to radiation risk is small. As a consequence, setting DRLs for these examinations is a lower priority, but optimisation is still necessary.

(132) Similar arguments can be applied to the choice of diagnostic fluoroscopy examinations to be studied. More common procedures are included in Table 3.1, but since practices vary in different healthcare facilities as well as in different parts of the world, those appropriate for the country/region/facility where the DRLs are to be applied should be reviewed in making the selection.

3.2. DRL quantities for radiography

(133) The DRL quantity should be one that is easily assessed, preferably from a direct measurement for the examination. Either P_{KA} or Ka,e may be used (Table 2.3), but assessment of both is preferable, when possible, in order to simplify evaluation of collimation.

(134) P_{KA} is ideal for radiography and fluoroscopy, as it includes all the radiation incident on the patient (assuming that the radiation field is collimated appropriately to the patient). Since P_{KA} is determined by both air kerma and the size of the radiation field, it takes into account all factors influencing patient radiation dose. It should be readily available in those systems where a P_{KA} meter is installed or the system calculates P_{KA}. It should be noted that P_{KA} results are influenced by whether or not the x-ray beam passes through the patient couch.

(135) Although P_{KA} values recorded by meters, calculated by the equipment, or given by the manufacturers and reported in the DICOM header should be reasonably accurate, there is no way to guarantee this. Patients could be receiving substantially higher values of P_{KA} than would appear to be the case unless the metered, calculated or provided values are verified periodically. The Commission recommends that an arrangement be in place to check the calibration of P_{KA} meters and the accuracy of P_{KA} values calculated and displayed by the x-ray equipment and recorded in the DICOM header.

(136) When no P_{KA} value is available, Ka,e (including backscatter) should be used as a tool for radiography. Ka,e can be measured on clinical images using dosimeters such as radiolucent thermoluminescent dosimeters (TLDs), as long as they do not interfere with the images. Alternatively, Ka,e can be calculated from knowledge of the exposure factors (kVp, mAs) and source-to-skin distance (SSD), combined with measurements of the x-ray unit output and a correction for the addition of backscatter. This is perhaps the simplest approach to take, since it involves less additional equipment, but it does require a measurement of x-ray unit output to be made.

(137) In countries where resources are very limited, it is possible to base a calculation of Ka,e on tabulated values of output per mAs at the appropriate tube potential, but this will reduce the accuracy by 20-30%, because the output varies with voltage waveform, anode angle, filtration and any damage to the anode, all of which will have to be estimated (Martin and Sutton, 2014; Le Heron, 1989). Results that could be used are given in Table 3.2, but it is strongly recommended that measurements be made wherever possible.

Table 3.2. Radiographic outputs (μGy/mAs at 1 metre, with 3.0–3.6 mm aluminium equivalent filtration).

	Waveform		
kVp	2 pulse[a]	6 and 12 pulse[a]	Constant potential[b]
70	20 ± 6	36 ± 10	42 ± 5
80	28 ± 8	50 ± 13	59 ± 6
90	35 ± 10	70 ± 18	
100	43 ± 12	94 ± 22	90 ± 9

Sources of data: [a] Le Heron (1989), [b] Martin and Sutton (2014).

(138) In any event, the kV, mAs, and SSD or some method of deriving it should be included to allow calculation of Ka,e. The dose detector index (DDI) displayed on digital systems, which relates to the amount of light generated from the phosphor, should also be recorded. The method of image recording (CR, DR or film), the system model and manufacturer for digital radiography, the film speed or equivalent and whether the exposure was under AEC should be noted for each room and type of examination whenever possible, to provide information for use in optimisation.

3.3. DRL quantities for fluoroscopy

(139) P_{KA} should always be used to set DRLs for fluoroscopic examinations, if it is available (Table 2.3). Many fluoroscopy units display both cumulative air kerma (Ka,r) at the patient entrance reference point (IEC, 2010) and P_{KA}. If Ka,r is available, it should also be used to set DRLs for specific diagnostic examinations, because comparison of Ka,r and P_{KA} values is useful in judging beam collimation.

(140) For diagnostic fluoroscopy procedures, fluoroscopy time and numbers of cine or DSA images should also be recorded in surveys. DRLs based on these quantities are useful as a guide to good practice and as an aid in optimisation. Where no facility for displaying or recording the values of these quantities is available on older fluoroscopy equipment, fluoroscopy time may be the only option for deriving data. The frame rate for digital subtraction imaging, the pulse rate for fluoroscopy, the image recording technique and exposure programme options used should be included. Interventional fluoroscopy is discussed in Chapter 4.

3.4. Use of phantoms in radiography and fluoroscopy

(141) Slabs of material with properties similar to those of tissue (slab phantoms) are used for measurement of dosimetric performance when AEC is used for radiography (Conway et al., 1992). For some applications, slabs of polymethylmethacrylate (PMMA) or polyethylene, or plastic containers filled with water, may be used for assessing the values of dose quantities employed in patient examinations. While these are not realistic surrogates for patients, they may be useful for estimating Ka,e for different phantom thicknesses that equate to patients of different sizes, particularly when exposure factors are selected automatically. Ka,e (including backscatter) can be measured with a flat plate ionisation chamber placed on the surface of such a slab phantom and the post exposure mAs recorded.

(142) Some standard slab phantoms made from PMMA and aluminium have been developed to replicate standard chest, abdomen and lumbar spine examinations (Conway et al., 1992). Here, an attempt is made to achieve a transmitted x-ray beam similar to that for an examination of the respective body part, so that the operation of the AEC on radiographic units can be tested. These standard phantoms can be used to compare and assess AEC set-ups on different x-ray units.

(143) Although phantoms can be helpful in assessing performance of x-ray units operating in an AEC mode, they should not replace surveys of actual patient examinations. Data from patient examinations provide the only definitive method for determining values of DRL quantities during clinical use.

(144) Slab phantoms can also be used to measure Ka,e rates for different pre-set protocols on fluoroscopic equipment, to provide information on the performance of the fluoroscope (Martin et al., 1998). The results can be compared to performance criteria, but these Ka,e rates are not DRL quantities. These measurements can be performed during QA tests and provide information valuable for constancy testing (Balter et al., 2004) and for the interpretation of possible causes of high results found in patient surveys.

3.5. Mammography

(145) In mammography, the only part of the body that receives a significant dose is the breast. Mammography employs x-ray tube potentials between 25 kV and 32 kV with x-ray tube anodes and filters made from different materials (e.g. molybdenum, rhodium) than the materials used in other x-ray systems. Meters used for radiation output measurements for mammography are specially designed, because of the lower energies of the x rays used. They require specific calibration with an x-ray spectrum in the range used for mammography, because of the influence of the attenuation of the entry window.

(146) Screening programmes for asymptomatic individuals should use the same DRL values as for examinations performed to investigate patients with clinical symptoms.

(147) Three DRL quantities have been used for surveys of mammography: Ka,e, Ka,i, and mean glandular dose (D_G). For both mammography and breast tomosynthesis, the Commission recommends using one or more of Ka,e, Ka,i, or D_G as the DRL quantity, with the choice of quantity depending on local practices. The Commission suggests using D_G as a DRL quantity, even though it is a measure of organ dose rather than the amount of ionising radiation used to perform a medical imaging task, due to the large variability of Ka,e and Ka,i with kV and with different anode/filter combinations, even for the same breast thickness.

(148) Ka,e was used initially as the DRL quantity. Measurement of Ka,e is straightforward, and no correction factors are required. It allows direct comparisons among mammography units with similar anode/filter combinations. However, there are now a variety of beam qualities resulting from the different materials used for anodes and K-edge filters that change the dependence of D_G on Ka,e. These differences should be taken into consideration when comparing results.

(149) Ka,i per mAs is derived from output measurements, made with the breast compression plate in position. This is then multiplied by the mAs used to obtain the Ka,i for the examination. The Ka,i will depend on the size of the breast; there are substantial variations among individuals. For this reason, the inclusion of more patients per facility, e.g. 50, is recommended for patient surveys.

(150) D_G gives a direct comparison relating to risk for different equipment, and so has been employed in many parts of the world. The relationship between Ka,i and D_G is highly dependent on breast thickness and composition, as well as beam quality, so there is more variation in potential risk with the DRL quantities that are measured directly, such as Ka,i and Ka,e, than for other examinations. This has been a persuasive argument for countries to use D_G to help in optimisation.

(151) D_G is calculated from the Ka,i used for the examination for a specified thickness of compressed breast. The Ka,i and D_G will depend on the size of the breast and its composition, which changes throughout a woman's life. There is extensive literature on the conversion from Ka,i to D_G, derived from Monte Carlo calculations for a wide range of beam qualities. These are a function of beam quality, i.e. half value layer (HVL) thickness, anode/filter combination, breast thickness and breast composition (Dance et al., 2000; IPEM, 2005).

(152) When Ka,e or Ka,i is used as the DRL quantity, evaluation programme arrangements should be based on recommendations by a qualified medical physicist, in order to ensure that dependence on breast thickness and differences in D_G are taken into account. Phantoms may provide a convenient method to help determine DRL values. However, since phantoms do not assess the full range of breast sizes for which examinations will be undertaken, and do not reflect clinical use of the equipment, surveys of patients are recommended as the main method of evaluating the amount of radiation applied in mammography.

(153) A phantom that is equivalent to the standard breast is used for routine QC in mammography. The 2006 European guidelines (EU, 2006) suggest imaging PMMA plates of various specified thicknesses and calculating the D_G for each thickness. In the U.K., the phantom typically might be a semi-circular PMMA phantom, 160 mm in diameter and 45 mm thick, with which D_G may be assessed under AEC using the mAs readout. The 45 mm thick PMMA breast phantom is equivalent to a 53 mm thick standard breast and can be used to compare the dosimetric performance of mammography units. D_G can be calculated from Ka,e measured at the surface of the phantom with a suitable calibrated detector using standard equations and conversion factors (Dance et al., 2000; IPEM, 2005). The D_G DRL value adopted as a comparator for this standard breast by the UK Breast Screening Programme (BSP) is 2.5 mGy.

(154) In the U.S., the standard phantom used for accreditation of mammography facilities is composed of a PMMA block, a wax insert, and a PMMA disk attached to the top of the phantom. It is intended to mimic the attenuation characteristics of a compressed "standard breast" of 4.2 cm thickness, composed of 50% adipose and 50% glandular tissue. U.S. Federal regulations limit the D_G to the phantom to 3 mGy per image. In 2006, the mean D_G was approximately 1.8 mGy with film-screen mammography, and 1.6 mGy for digital mammography (Spelic et al., 2007).

3.6. Dental radiography

(155) There are some examinations that are relatively independent of patient size. Examples are dental intraoral and panoramic imaging, which are usually performed with equipment that has a fixed kV and mA and a timer programmed for dental imaging. For dental units, dosimetric measurements made by a medical physicist visiting the clinic provide the best option, rather than measurements on individual patients. Surveys may be carried out by direct measurement with radiation detectors when QA checks are made on the x-ray units.

(156) A convenient method for setting DRL values and evaluating patient dose for dental radiography is to make measurements at standard settings. Intraoral units frequently have fixed tube potentials and currents, and the exposure is varied by adjusting the exposure time for the type of tooth under investigation. Exposure time is selected manually either with a dial calibrated for the tooth or by selection of exposure time. Measurements of the incident air kerma can be made at standard settings with a suitable calibrated detector placed at the end of the spacer cone of the x-ray set (Gulson et al., 2007). This measurement relates to the air kerma incident on the skin surface.

(157) The measurements made must utilise the exposure settings that the dentist uses regularly. Information must be obtained to confirm the settings. It is recommended that this be obtained before a survey is undertaken, possibly via a short questionnaire sent to the dentist for completion before the test, seeking this information together with other data on dental x-ray practices. Different settings will normally be used for adults and children, so dose measurements and DRL values will be required for both. Further consideration of the use of DRLs in dental radiography is given in Section 7.1.2.

(158) The x-ray equipment will normally always be left on the standard "film/detector speed" setting used. However, those testing such equipment should ensure, before making the measurement, that the dentist confirms that this is the setting actually used.

(159) An alternative survey method that does not require a visit to each dental facility is the use of calibrated test packs that incorporate film covered by a series of filters and that can be sent through the post to the dental practice from a central laboratory. These can evaluate x-ray equipment used with digital receptors as well as x-ray equipment used with film. These test packs provide a potential method for remote assessment (Gulson et al., 2007). However, considerable effort needs to be put into the development and calibration of such a system, and into ensuring that the dentist is given sufficient instructions in its use.

(160) Dentists should have had training in radiography and radiological protection as part of their education (ICRP, 2009). It is important that this is kept up to date and that it includes information on the role of DRLs. This should be reinforced through feedback on results from the dosimetric measurements that are carried out. Periodic refresher training in radiographic techniques and the optimisation of radiological protection is recommended.

(161) For panoramic dental radiography, techniques that measure the DRL quantity from the entire beam are required. P_{KA} can be measured with an ionisation chamber that is attached to the x-ray tube housing and intercepts the entire beam, as in standard radiography. Alternatively, smaller detectors (but still broader than the x-ray beam), calibrated in terms of the dose-width product (DWP) (mean air kerma in the beam × beam width) and positioned at the receiving slit, can be used (Holroyd, 2012; Mitchell and Martin, 2013). The DWP can be converted to P_{KA} through multiplication by the length of the x-ray beam at the receiving slit. Detectors smaller than the beam width have been used for measurement of the air kerma within the beam, and the result multiplied by the slit width to give the DWP. However, since the air kerma varies across the beam, this method is subject to a greater error.

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4. 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.**
- **DRLs should be assessed and used as a tool for optimisation of interventional procedures.**
- **The Commission recommends that data for all suitable DRL quantities, if available, be tracked for interventional procedures. This will aid in the optimisation process.**
- **The Commission recommends that the DRL process be applied to both interventional fluoroscopy and interventional CT.**
- **For interventional procedures, complexity is a determinant of patient dose, and ideally should be evaluated individually for each case. A multiplying factor for the DRL (e.g. 2, 3 or more) 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.**
- **If the values of DRL quantities for patients are higher than expected, the investigation should start with evaluation of the equipment, then evaluation of procedure protocols, and finally evaluation of operator technique. Equipment faults or incorrect set-up are the easiest to evaluate and correct, while operator performance is the most difficult process to analyse and influence.**
- **Cumulative fluoroscopy exposure time is a poor indicator of patient dose, but may be recorded and used as a subsidiary DRL quantity to aid in optimisation.**

4.1. Introduction

(162) DRLs were introduced for diagnostic radiology examinations in the 1980s and came into wide use in the 1990s (ICRP, 1991, 2003; Wall and Shrimpton, 1998). DRLs were originally developed with the underlying assumption that they are for a "standard" examination, where the patient dose for a specific examination performed on a specific radiographic unit will vary only as a function of body part thickness (or some other measure of body mass). The DRL methodology – use of a limited number of data points to determine median values from each facility – is predicated on this assumption.

(163) DRLs are most useful for diagnostic examinations, such as chest radiography, with relatively few procedural variables (NCRP, 2010). They are more challenging to

implement for interventional procedures, where the assumption of a 'standard' examination is not valid.

(164) For fluoroscopically guided interventional (FGI) procedures, e.g. interventional cardiology (IC) and interventional radiology (IR) procedures, the Commission has stated that in principle, DRLs could be used for dose management, but are difficult to implement because of the very wide distribution of patient doses, even for instances of the same procedure performed at the same facility (ICRP, 2007b; Padovani and Quai, 2005). The amount of administered radiation in FGI procedures is strongly affected by procedure complexity due to patient anatomy, lesion characteristics and disease severity (Bernardi et al., 2000; IAEA, 2009; Peterzol et al., 2005; Vehmas, 1997). DRLs for interventional procedures must be developed differently than those for other imaging modalities. However, even though the intent of these procedures is therapeutic, not diagnostic, the Commission recommends that the same name (DRL) be used, as the purpose is similar—providing a tool for optimisation—and the introduction of a different name is likely to cause confusion.

(165) In principle, for the most accurate comparisons of dosimetric data among populations undergoing FGI procedures, it would be desirable to normalise P_{KA} and Ka,r data by compensating for differences in patient body habitus and weight. These affect body part thickness, which in turn affects x-ray beam attenuation [such normalisation is not necessary for fluoroscopic time because this quantity is not related directly to body part thickness (Miller et al., 2009)]. However, a published analysis of quantities for FGI procedures, using data from all patients regardless of weight, yields results little different from an analysis limited to patients in the weight range of 65-85 kg (IAEA, 2009). This is consistent with previous studies showing that the amount of administered radiation for FGI procedures is affected much more by procedure complexity than by patient weight (IAEA, 2009; Miller et al., 2009).

(166) The use of phantoms is not appropriate for setting DRL values for FGI, but phantoms can and should be used in evaluating equipment performance, as they provide information essential for use in optimisation (Martin et al., 1998; Balter et al., 2011; NCRP, 2010; Vano et al., 2008, 2009b).

4.2. Complexity analyses

(167) Procedure complexity varies for interventional procedures because of variability in patints and in the lesions being treated. Patient variability refers to variability in patient anatomy and clinical factors (e.g. body habitus, anatomic variations of the vascular tree, diameter of normal blood vessels, tendency towards arterial spasm) that determine the technical parameters to be used (e.g. the x-ray projections necessary to visualise different vascular branches) and that contribute to complexity. Lesion variability refers to differences in the pathology being treated (e.g. stenosis vs. occlusion, presence or absence of calcification, location of a gastrointestinal bleeding site). For these reasons, interventional procedures demonstrate substantial variability in the amount of administered radiation for individual cases, due to patient, operator, type of materials (catheters, stents, etc.) and equipment factors

(Balter et al., 2004; IAEA, 2009; ICRP, 2003; Miller et al., 2003, 2012b; NCRP, 2010b; Wall, 2001).

(168) A potential approach to compensating for variability due to patient factors is to incorporate a measure of the complexity of the procedure (ICRP, 2003, 2007b). Some studies have explored the feasibility of establishing DRL values for certain IC procedures, using procedure complexity to normalise DRL quantities (Bernardi et al., 2000; Peterzol et al., 2005; Balter et al., 2008; IAEA, 2009). Complexity factors for PCI (number of vessels treated, number of lesions with American College of Cardiology/American Heart Association (ACC/AHA) complexity greater than B2, 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 (Balter et al., 2008; Bernardi et al., 2000; IAEA, 2009; Ryan et al., 1988).

(169) Only preliminary examples of complexity analyses for other IC and IR procedures are available. Padovani et al. (2008a) have proposed grouping radio-frequency (RF) cardiac ablation procedures performed to treat different arrhythmias: atrial fibrillation, atrial flutter, nodal tachycardia, ventricular tachycardia and Wolff-Parkinson-White syndrome, but the study provides estimation of DRL quantities from only a small sample of procedures. A recent study has classified 3 levels of complexity for some common IR procedures: transjugular hepatic biopsies, biliary drainage, uterine fibroid embolisation, colon endoprosthesis placement, femoropopliteal revascularisation, iliac stent placement and hepatic chemoembolisation, and provides national DRL values for these procedures for Spain (Ruiz Cruces et al., 2014).

(170) These examples show that it is possible to determine complexity factors for individual IR procedures, allowing grouping into simple, medium and complex cases, and to determine DRL values for each group. The method can be practical when a limited number of factors can explain differences in the amount of radiation that needs to be applied. For example, in the HPA study on PCI, the number of implanted stents was identified as the determinant that adequately described the complexity of these procedures (Hart et al., 2007). However, since assessing procedure complexity requires substantial clinical data that often are not available, many recent published studies have presented DRL values for interventional procedures without consideration of procedure complexity (Balter et al., 2008; Miller et al., 2009; Neofotistou et al., 2003; Peterzol et al., 2005; Vano et al., 2009a).

4.3. Data sets for interventional fluoroscopy procedures

(171) A different method can be used to characterise and analyse the amount of administered radiation for FGI procedures, without the need for the clinical data (pathology information and technical and clinical complexity factors) that are usually difficult to collect (Balter et al., 2011; NCRP, 2010a). It requires collection and analysis of data from a greater number of cases than that used to determine DRL values for diagnostic imaging (e.g. radiography). This method requires information on the full distribution for the DRL quantities of interest (Marshall et al., 2000). It provides a benchmark in the form of a data set that includes the values of the DRL quantities for all of the cases of that procedure done in each of

a large number of facilities (Balter et al., 2011; IAEA, 2009; Sánchez et al., 2011, 2014; Vano et al., 2009a; Smans et al., 2008). This is different from the application of DRLs for diagnostic procedures, because for diagnostic procedures, the DRL value is determined from summary data derived from a limited number of cases.

(172) When this method is used to conduct an audit, it requires both a regional or national benchmark data set comprising dosimetric data for every case of a procedure from a large number of facilities, sometimes referred to as an Advisory Data Set (ADS) (NCRP, 2010), and a local data set of the dosimetric data for every case of the same procedure performed at the local facility, sometimes referred to as a Facility Data Set (Balter et al., 2011; NCRP, 2010). The method utilises data from every case of a procedure, rather than a limited sample of cases, to compensate for the large variability in the values of the DRL quantities for these procedures (Padovani and Quai, 2005).

(173) Determination of the need for an investigation is the same as with other data sets used for DRLs—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 of the benchmark data. The local mean value should not be used because it can be strongly influenced by the high-dose tail of the distribution (Wall, 2001). High radiation doses may reflect poorly functioning equipment or incorrect equipment settings, suboptimal procedure performance, operator inexperience or high clinical complexity. 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. Low radiation usage might be attributable to incomplete IC cases, inadequate image quality, or superior dose management. For better assessment of the local data, comparison of the median, 25th and 75th percentile values of the facility data to the corresponding percentile values of the benchmark data has been recommended (NCRP, 2010).

4.4. Use of multiple DRL quantities for interventional fluoroscopy

(174) The quantity used should be easily measurable (ICRP, 2007b). Cumulative fluoroscopy time is readily available, but has been shown to correlate poorly with $D_{skin,max}$ (Fletcher et al., 2002). For fluoroscopically guided procedures, Ka,r and P_{KA} have been developed as estimators of the risk of radiation-related tissue reactions and stochastic effects, respectively.

(175) P_{KA} is a surrogate measure of the amount of energy delivered to the patient, and thus a reasonable indicator of the risk of stochastic effects (Chambers et al., 2011; Hirshfeld et al., 2004; Miller et al., 2003, 2012a; NCRP, 2010). Ka,r is a useful predictor of $D_{skin,max}$, and therefore of the risk of tissue reactions, such as radiation-induced skin injury (Chambers et al., 2011; Hirshfeld et al., 2004; Miller et al., 2012a; NCRP, 2010; Jones et al., 2014).

(176) In Europe, P_{KA} is commonly used. In the U.S., Ka,r is more available, likely because the U.S. Food and Drug Administration has required that all fluoroscopic units manufactured after mid-2006 display reference air kerma, but has not required display of P_{KA}.

Display of both Ka,r and P_{KA} on interventional fluoroscopy systems is also required for compliance with the standards of the International Electrotechnical Commission (IEC, 2000, 2010). For purposes of comparison to DRLs, both quantities are acceptable (ICRP, 2007b; NCRP, 2010).

(177) Several authors have proposed DRL values for FGI procedures using multiple quantities: P_{KA}, Ka,r, fluoroscopy time and number of acquired images (Miller et al., 2009, 2012b; Vañó and Gonzalez, 2001). This approach helps identify the cause when radiation use is not optimised. For example, if P_{KA} exceeds the DRL value, but Ka,r is within an acceptable range, there may be insufficient attention to collimation. Also, if the median P_{KA} and/or Ka,r in a particular institution exceeds the corresponding DRL value, evaluation of fluoroscopy time and the number of acquired images may help determine whether these are contributing factors. The Commission recommends that data for all suitable DRL quantities that are available be tracked for interventional procedures at facilities where these procedures are performed.

(178) If the median values of the DRL quantities are higher than expected, investigation of the fluoroscopic equipment is appropriate. Phantoms made from PMMA slabs that simulate patients provide an excellent method for evaluating equipment performance in terms of Ka,e and air kerma rate. They can provide assessments of radiation levels from different imaging programmes, information that is essential for optimisation (Martin et al., 1998; Ubeda et al., 2011; Padovani et al., 2008b; Vano et al., 2005). If the fluoroscopic equipment is functioning properly and within specification, procedure protocols and operator technique should be examined (NRPB, 1990; NCRP, 2010; Vañó and Gonzalez, 2001; Wall, 2001). This sequence has been recommended because equipment faults or incorrect set-up are the easiest to evaluate and correct, while operator performance is the most difficult process to analyse and influence (Balter et al., 2011; Vañó and Gonzalez, 2001).

(179) Cone-beam CT (CBCT) has become a routine part of some interventional fluoroscopy procedures. Optimisation of this portion of the procedure has therefore become important. Recording P_{KA} and Ka,r for the CBCT portion of interventional procedures, when this information is available, may be helpful in optimisation of this portion of interventional procedures (Section 5.3.3).

4.5. Interventional CT

(180) Interventions can be performed with CT guidance. Relatively little data are available on the number of procedures performed or on temporal trends, but it is clear that the numbers and types of procedures are increasing. For example, the percentage of image-guided percutaneous lung biopsies performed with CT guidance (as opposed to fluoroscopy guidance) at the Mayo Clinic in the U.S. increased from 66% in 1996-1998 to 98% in 2003-2005 (Minot et al., 2012). CT is used primarily to guide biopsy of small or deep lesions in the chest, abdomen and pelvis that are not seen well with ultrasound or fluoroscopy. CT provides high-resolution images and the ability to visualise bowel and bone.

(181) CT-guided interventions can be performed by using intermittent CT scans performed while the physician steps out of the scanner room, or by using CT fluoroscopy (physician-controlled real-time intermittent or continuous CT exposure during needle or device manipulation). CT fluoroscopy is a CT imaging method, not a fluoroscopic imaging method. CT fluoroscopy facilitates CT-guided biopsy procedures by allowing visualisation of the needle trajectory from skin entry to the target point. The principal advantage of CT fluoroscopy over standard CT guidance is the ability to use real-time monitoring to access lesions that move within the body as a result of patient breathing or other motion. Its use can permit procedures to be performed more rapidly and efficiently (Gianfelice et al., 2000b), and it is therefore increasingly popular.

(182) CT fluoroscopy is applicable to a wide variety of non-vascular interventions (Daly and Templeton, 1999). It is used for needle guidance during drainage of fluid collections, spinal pain management procedures, tumour ablation and percutaneous needle biopsy in the chest, spine, abdomen and pelvis (Buls et al., 2003; Hoang et al., 2011; Joemai et al., 2009; Trumm et al., 2012). Unfortunately, CT fluoroscopy results in relatively high radiation doses to both the patient and the physician operator, and there is a steep learning curve (Gianfelice et al., 2000a; Kim et al., 2011; Saidatul et al., 2010).

(183) Variability in patient dose from CT-guided interventions is dominated by procedure complexity, not patient size. In centres where a large number of these procedures are performed, it is recommended that the values for DRL quantities be analysed according to the framework described for setting DRLs for interventional fluoroscopy procedures. Similar methods for application of the DRL process (complexity analysis and evaluation of all procedures performed) are likely to be useful. Unfortunately, complexity factors for CT-guided procedures have not been established, and there are few data from which to establish DRL values. As with interventional fluoroscopy, the Commission recommends that DRLs be established for all quantities that are available: $CTDI_{vol}$, DLP, the number of CT sequences obtained, and CT fluoroscopy time.

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5. DIGITAL RADIOGRAPHY, CT, NUCLEAR MEDICINE, AND MULTIMODALITY PROCEDURES

- **The general points mentioned in Chapter 2 apply to all modalities unless otherwise specified.**
- **DRLs developed for advanced digital radiographic techniques (e.g. tomosynthesis, dual-energy subtraction, contrast-enhanced subtraction, cone-beam CT) need to take into account the 'multiple image' aspect of the technique and should distinguish these procedures from more standard procedures.**
- **CT utilises $CTDI_{vol}$ and DLP as DRL quantities. The number of scan sequences in the examination may be helpful as well. Size-specific dose estimates (SSDE) may be used as an additional step for optimisation.**
- **For CT, the DLP value used is the cumulative DLP for the entire examination. The $CTDI_{vol}$ value used is the displayed $CTDI_{vol}$ for each sequence. DLP values for individual scan sequences can be useful as well, and may be used in addition to the cumulative DLP.**
- **For nuclear medicine, the Commission recommends that DRL values be established in terms of the administered activity per kg body weight of a specific radionuclide for a specific clinical task and, if relevant, the radiopharmaceutical used.**
- **Weight-based administered activities may not be appropriate for examinations where the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid scans, lung perfusion scans).**
- **The administered activity for examinations of individual patients may be adjusted upwards when there are sound clinical reasons. Setting of a fixed maximum activity for very obese patients may also be considered.**
- **Since DRLs for nuclear medicine procedures and CT procedures apply to radiation from very different modalities, and use different DRL quantities, it is appropriate to set and present DRL values for each modality independently.**

5.1. Digital radiography detectors

(184) For the purpose of this report, digital radiography refers to the planar imaging of patients utilising either direct or indirect digital detector systems, including digital mammography. It also includes advanced imaging techniques such as tomosynthesis. Digital detectors include the following: storage-phosphor techniques (often referred to as 'computed radiography'); charge-coupled device (CCD) based detectors; flat-panel detectors with direct or indirect conversion; and photon counting detectors. Mammography is discussed separately in Chapter 3.

(185) Storage-phosphor was the first available technique for digital radiography. Since storage plates are exposed in cassettes with standard dimensions, no change of generator, x-ray tube, or wall- or table-mounted Bucky system is necessary. Bedside,

examinations and other special projections are possible. In general, there is no connection between the generator and the reader that processes the storage-phosphor plate post-exposure. The generator settings employed for the exposure determine the patient exposure. The reader only senses the signal received by the detector. The disconnect between generator settings and detector signal has a bearing on suitable quantities for DRLs for these systems.

(186) CCD systems represent a small share of the market in most countries. The image of a luminescent screen is recorded with CCD cameras and converted into digital images.

(187) More recently, flat-panel detectors have gained a large share of the market. They utilise direct or indirect conversion of x rays into electrical signals. These detectors provide high quantum efficiency, excellent image quality, and enable a substantial reduction in patient dose. Portable and wireless versions of these detectors have enabled a broad range of examinations to be performed in all healthcare settings.

(188) The most recent type of detector to gain market share is the photon-counting detector. These detectors use photon counting as opposed to the energy integration used by the other detector types. They demonstrate excellent efficiency and also allow the introduction of advanced image processing techniques such as tissue discrimination. They are currently used for mammography, and are being introduced for CT and digital radiography.

5.2. DRLs in digital radiography

(189) All digital detector systems have a high dynamic range. Due to the direct relationship between the dose received by the detector (and consequently patient dose) and image quality, high doses provide high image quality without the saturation seen in film-based imaging techniques. The absence of deterioration of image quality at high doses means that QA and audit programmes are needed to ensure patient dose is optimised to the clinical task and that ‘dose creep’ (use of unnecessarily high levels of radiation) (Williams et al., 2007; ICRP, 2004) does not occur. Application of DRLs is an essential part of a QA system. Also, as digital detectors are often more sensitive than the film-based systems they are replacing, DRLs should be set explicitly for digital detectors (not copied from film techniques) whenever digital detectors are installed.

(190) In Chapter 2 of *Publication 93* (ICRP, 2004), the issues described above are expanded upon with specific recommendations concerning the transition from screen-film radiography to digital radiography, including the recommendation that digital radiography-specific DRLs be developed. The pitfalls of dose creep are explained in greater detail.

(191) DRLs for digital radiography should be set taking into account the principles set out in this report. In collecting patient data on DRL quantities for digital radiography, it is important to know the detector type used so that the data may be analysed by detector type, as the values of the DRL quantities for specific examinations may vary by detector type due to

sensitivity differences. In some cases, it may be worth considering establishing different DRL values for flat-panel detectors and storage-phosphor detectors, even for the same procedure.

5.2.1. DRL quantities

(192) The specific DRL quantity to be utilised in the development of DRLs for digital radiography will be determined by the type of digital imaging system and technical considerations. Recommendations are provided in Chapter 2. The choice of quantity should also take into account the DRL quantity used in other literature and DRL values.

(193) The quantities used to define DRL values for digital radiography depend upon the digital detector system in question, but include P_{KA} and Ka,e. Use of both P_{KA} and either Ka,e or Ka,i is recommended, if available. P_{KA} may be recorded automatically if the radiography system has the capability to measure or calculate it, so users can compare these data with DRL values directly. There is much historical data available for Ka,e, but assessment involves either calculation or labour intensive measurements and so assessment may not always be possible. Where routine QC tube output data or direct measurement capabilities are not available to calculate Ka,e, standard output data may be used (Asada et al., 2014).

(194) For projection radiography, the Commission recommends using two quantities to set DRLs: P_{KA} and either Ka,e or Ka,i in order to simplify evaluation of the proper use of collimation.

5.2.2. Procedure selection

(195) With the advances in image processing made available by the implementation of digital imaging, many advanced radiographic techniques are becoming available. Examples of these include tomosynthesis, dual-energy subtraction, and contrast-enhanced subtraction. These advanced techniques have in common the use of multiple low-dose radiographs as input to advanced image-processing software that produces final images with added information, such as tissue discrimination or cross-sectional ‘slices’. Therefore, any DRL developed for these techniques needs to take into account the ‘multiple image’ aspect and should distinguish these procedures from more standard procedures. For example, DRL values will differ between breast tomosynthesis and a standard two-view craniocaudal and mediolateral oblique mammogram.

5.3. Computed Tomography

5.3.1. DRLs in CT

(196) There are many examples in the literature of DRLs values established for CT (ICRP, 2007; NCRP, 2012; Foley et al., 2012). For the purpose of this report, the term ‘CT’ applies to both single and multi-detector CT scanners.

(197) CT procedures deliver approximately 50% of the collective effective dose from medical and dental exposures in many countries, due to the relatively high-dose nature of CT

procedures compared to other diagnostic imaging modalities (NCRP, 2009). This contribution is also increasing. For instance, in the U.K., the contribution of CT to the collective effective dose from medical and dental exposures has risen to 68% (HPA, 2010).

(198) All CT digital detector systems have a high dynamic range. Coupled with the direct relationship between dose to the detector (and consequently patient dose) and image quality, this means that high doses will provide high image quality without the saturation seen in film-based imaging techniques. This means that, as with digital radiography, QA and audit programmes are essential to ensure that patient dose is optimised for the clinical task. DRLs are an essential tool within such a QA programme.

(199) It is important that the data set in patient surveys for developing DRL values for CT includes detector technology, detector configuration, and the image reconstruction algorithm, so that differences between detector types and reconstruction algorithms are identified correctly. It may be useful to develop different DRL values locally for different CT technologies (e.g. single slice vs. multi-slice scanners, filtered back projection vs. iterative reconstruction), even for the same procedure.

5.3.2. Considerations for DRL surveys in CT

(200) DRL values for CT should be set taking into account the principles set out in this report. There are specific issues that must be decided prior to surveying DRL quantities and setting DRL values for CT.

(201) Patient selection is an important aspect of setting DRLs. In CT, as in other imaging modalities, patient size plays a significant role in the determination of the required amount of radiation to achieve adequate image quality for a given procedure (Samei and Christianson, 2014). The choice is either to set a patient thickness range (often stipulated as a weight range), or to utilise large-scale electronic patient data from radiology information systems or PACS systems. With a reduced range in patient size, variation in DRL quantities is reduced substantially. As a result, data from fewer patients are required for the determination of DRL values (IPEM, 2004).

(202) Another important aspect of setting DRLs is the choice of quantity. The options include CTDI as either $CTDI_w$ or $CTDI_{vol}$, and DLP. CTDI is defined and explained in detail in *Publication 102* (ICRP, 2007). DLP is a quantity that utilises both CTDI and the scan length for a given patient. It therefore also includes operator issues that are important to consider when setting DRLs for CT, as they reflect practice on real patients. Both of these metrics reflect the amount of ionising radiation applied to perform the medical imaging task and are indicative of the scanner settings employed within the CT protocol. They are useful metrics for optimisation.

(203) The precise quantity to be utilised in the development of DRLs will be determined by the organisation setting the DRL. However, it would be prudent to take account of the quantities used in other literature and published DRL values. Where possible,

the Commission recommends that both $CTDI_{vol}$ and DLP be assessed in patient surveys performed for the purpose of setting DRL values, as is the practice in France and the U.K. (Roch and Aubert, 2013, Shrimpton et al., 2014). Modern CT scanners permit determination of effective diameter or patient equivalent thickness. This should be considered as an additional refinement for setting paediatric DRL values (Chapter 6). Size-specific dose estimates (SSDE) may be used in addition to the recommended DRL quantities as an additional source of information for optimisation.

(204) When optimisation is performed for CT, it is necessary to consider both the examination as a whole (all scan sequences) and each sequence (e.g. non-contrast-enhanced, contrast-enhanced, delayed) individually. The DLP quantity used is the cumulative DLP for the entire examination, as this gives a good representation of the total amount of ionising radiation applied during the examination. DLP values for individual scan sequences can be of value as well, and may be used in addition to the cumulative DLP.

(205) Use of tube current modulation can reduce patient dose by 30%-40% per scan, and has therefore been adopted widely. However, $CTDI_{vol}$ in an individual scan is not constant when tube current modulation is used. In this setting, the displayed $CTDI_{vol}$ after the scan sequence has been performed is usually the average $CTDI_{vol}$ over the length of the scan. The displayed $CTDI_{vol}$ should be recorded for each scan sequence, as it is often different for each scan sequence. However, users should check that the $CTDI_{vol}$ value recorded corresponds to what they think it is, since some manufacturers have used other values such as the maximum $CTDI_{vol}$ during a scan. It can also be helpful to record the number of scan sequences for the examination, as this may also help explain differences in cumulative DLP.

(206) This approach has the advantage of simplifying certain aspects of the optimisation analysis. For example, if, in local practice, the median cumulative DLP exceeds the DRL value, but the median $CTDI_{vol}$ for each scan sequence does not, this suggests that attention should be directed at scan length and the number of scan sequences.

(207) Procedure selection is also important in ensuring that DRLs are fit-for-purpose. There are two aspects to this. It is important when developing DRLs that all of the dosimetric data collected comes from similar procedures across all participating clinical facilities. This ensures that comparisons between facilities remain valid and useful. A common problem is that typically there is no standard for describing or naming examination types across facilities—the same examination (e.g. an adult CT scan of the head without intravenous contrast material) is often named differently at different facilities (Morin et al., 2011).

(208) It may also be important to specify in detail both the clinical task associated with the procedure and the body region scanned, as differences between similar procedures may affect patient dose and hence DRL values. Scans of the kidney for kidney stones, for instance, may employ a much lower amount of radiation than scans of the kidney designed to detect cancer. More radiation is required for detection of cancer in order to distinguish between objects with intrinsically low differences in attenuation. Ideally, the scan protocol should be specified, including data for different sequences if more than one is used, start and

end positions, tube potential, whether fixed mAs or tube current modulation is used, collimation, rotation time and pitch.

(209) The type of data collected will require both anatomical groupings and protocol types. The standard anatomical groupings are separate examinations of the head, abdomen, and chest, and combined examination of the abdomen and pelvis or chest, abdomen and pelvis. Protocols include a variety of imaging tasks (e.g. angiography, perfusion, renal stone identification).

(210) For each patient, the $CTDI_{vol}$ and DLP values displayed by the CT scanner should be recorded, but it is important to check the calibration. If $CTDI_{vol}$ is not displayed, then it will have to be calculated from the $CTDI_w$ and pitch. The DLP for the complete examination is obtained by adding together the contributions from the individual scan sequences.

(211) If data collection is via paper forms, the number of patients will be limited, but should be at least 30. With restricted numbers, information on patient sizes should be recorded, if possible, or at least the range of sizes restricted with very large and very small patients being excluded. DRL values are designed to help determine whether the amount of ionising radiation applied for a medical imaging procedure in a representative sample of standard-sized patients, for a defined clinical task, is too high or too low. For CT, as for radiography and fluoroscopy, it is well understood that the optimal radiation dose varies with patient size (Samei and Christianson, 2014). It is therefore necessary to ensure that the survey data reflect values for standard-sized patients.

5.3.3. Cone-beam CT

(212) CBCT typically includes dental and maxillofacial CBCT systems, CBCT utilised as an imaging modality on fluoroscopes, and radiotherapy verification systems. Dental and maxillofacial procedures are intended to display high contrast objects (bone and air) with low radiation exposure as compared to conventional CT, whereas fluoroscopy and radiotherapy applications require visualisation of soft tissue structures and substantially higher exposures, comparable to conventional CT.

(213) CBCT is the subject of a recent Commission's report (ICRP, 2015). The Commission recommends the use of P_{KA}, Ka,r, $CTDI_{vol}$ and DLP as DRL quantities, depending on availability (Table 2.3). P_{KA} and Ka,r are more likely to be available and useful for fluoroscopes and dental CBCT systems (HPA, 2010), while $CTDI_{vol}$ and DLP are used for radiotherapy imaging systems and some dental CBCT systems.

(214) As of 2015, little progress has been made toward setting DRLs for CBCT. Based on a preliminary audit of P_{KA} values on 41 dental and maxillofacial CBCT units, HPA (2010) proposed a tentative DRL (though termed an 'achievable dose') of 250 mGy cm^2, normalised to an area corresponding to 4 x 4 cm at the isocentre, for placement of an upper first molar implant in a standard adult patient. This value was adopted by the SEDENTEXCT Consortium (EC, 2012), with the remark that "further work involving large scale audits is

needed to establish robust DRLs" for various dental and maxillofacial CBCT applications. This remark is also relevant for other CBCT applications. Dental and maxillofacial CBCT procedures should not exceed the dose of comparable CT procedures for high contrast objects (typical $CTDI_{vol}$ <10 mGy).

(215) CBCT is also becoming increasingly important during interventional fluoroscopy procedures (Wallace et al., 2008; Lightfoot et al., 2013; Corredoira et al., 2015). It can provide information and guidance that is not otherwise available during the procedure, and can increase the safety of the procedure (Lee et al., 2014). The portion of the administered radiation from the procedure that is due to CBCT can be substantial. Corredoira et al. (2015) analysed the total P_{KA} measured in paediatric IC procedures and observed that CBCT contributed 33% of the administered radiation in therapeutic procedures and 16% of the administered radiation in diagnostic procedures.

5.4. DRLs in planar and SPECT nuclear medicine imaging

(216) For the purpose of this report, planar nuclear medicine imaging refers to two-dimensional (2D) imaging, utilising digital imaging detector systems, of patients who have had radiopharmaceuticals administered. The digital detector systems normally are scintillation gamma cameras equipped with various types of collimators. For all types of diagnostic nuclear medicine procedures, radiopharmaceutical administration is either by injection, by mouth or through inhalation.

(217) SPECT is a nuclear medicine tomographic functional imaging technique that uses γ rays produced from administered radiopharmaceuticals. It is similar to conventional nuclear medicine planar imaging, but uses one or more rotating gamma cameras and is able to provide three-dimensional (3D) information. This information is typically presented as cross-sectional images of the patient. These images can be freely reformatted and presented. SPECT is mainly carried out using conventional scintillation gamma cameras, which rotate around the patient. Recently, gamma cameras based on solid-state detectors [e.g. cadmium-zinc-telluride (CZT)] have been developed and are now commercially available.

(218) The administered activity of a radiopharmaceutical determines the patient dose for a patient of standard size and standard biokinetics. Dose calculations for a number of radiopharmaceuticals are presented in the Commission's publications on radiation dose to patients from radiopharmaceuticals (ICRP, 1987, 1998, 2008). The Commission recently published a compendium summarising all current information related to frequently used substances (ICRP, 2015).

(219) For planar nuclear medicine imaging, DRLs are surveyed and have been set either by administered activity (MBq) (EC, 1999) or, preferably, by administered activity per unit of body weight (MBq/kg). The latter approach is practical and simple to adopt (Roch and Aubert, 2013). The Commission recommends the establishment of weight-based administered activities (MBq/kg) for all types of nuclear medicine investigations except for those where the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid, sentinel node imaging, pulmonary ventilation and perfusion studies). Setting of a fixed maximum

activity for very obese patients may also be considered. Appropriate administered activities for children are discussed in Chapter 6.

(220) For SPECT imaging procedures, DRL values should be set in the same way as for planar nuclear medicine procedures. The Commission recommends the establishment of weight-based administered activities (MBq/kg). Very limited data on DRL values for SPECT exist as of 2015 (Avramova-Cholakova et al., 2015). In some countries (e.g. the U.K.), DRL values for SPECT studies are slightly higher than for the same radiopharmaceuticals used for planar imaging.

(221) Guidance documents produced by various countries have recommended maximum administered activities for established diagnostic procedures using specific radiopharmaceuticals (CRCPD, 2006; ARSAC, 2006; NCRP, 2012). The recommended administered activity provided by an authority or a national association of nuclear medicine (SNMMI, 2015; EANM, 2015) for an average adult patient may not be entirely representative of the real situation. However, in a U.K. survey (HPA, 2008), most nuclear medicine centres used administered activities that were very close to those recommended. Since the majority of hospitals and clinics use recommended administered activity levels or lower levels, there is less inter-departmental variation in patient dose than in diagnostic radiology. If this method is followed, individual practitioners are encouraged to use lower administered activities if their equipment or software permits and the resultant image quality is adequate for diagnosis.

(222) The administered activity for individual patients may be adjusted upwards where there are sound clinical reasons, e.g. to allow an examination to be performed in a shorter time for a patient who is in extreme pain and cannot endure the normal investigation time or for a patient who is obese. If the DRL will routinely be adjusted [e.g. for myocardial perfusion imaging (Notghi et al., 2003)], a written protocol should be followed and any potential change in the relative radiation risk (i.e. the relative increase in the administered activity) to a patient should always be weighed against the corresponding change in benefit (e.g. patient discomfort, accuracy of the investigation, etc.).

(223) In nuclear medicine, increasing the administered activity not only improves imaging quality but also reduces acquisition time. Reducing administered activity while maintaining image quality can be achieved by increasing acquisition time. However, prolonged acquisition times are not practical because patients cannot remain still and motion artefacts result in blurred images. Some institutions where a large volume of nuclear medicine procedures is performed administer more activity to patients in order to achieve higher patient throughput. From a radiological protection point of view, this is not desirable.

5.5. Considerations for DRL surveys for nuclear medicine

(224) DRL values for nuclear medicine imaging should be set taking into account the principles outlined in this report, and surveys should be performed in accordance with the guidelines given in Chapter 2. It can be expected that DRL values will decrease with advances

in technology, such as iterative reconstruction and CZT solid-state detectors (Piccinelli and Garcia, 2015; Gunalp, 2015).

(225) There are specific issues that must be decided prior to setting DRLs for nuclear medicine imaging. For most planar nuclear medicine procedures, there are only minor variations in the activity needed. However, for some diagnostic nuclear medicine investigations, administered activities are highly dependent on the intended procedures. An example is for cardiac studies, where there are one-day and two-day protocols for stress and rest imaging and also variation between these procedures. It is difficult to compare administered activities without knowing the precise protocol used. National DRL values are based in some countries on the whole protocol with two injections, and in other countries DRL values are provided separately for stress and rest imaging.

(226) Patient selection is an important aspect of setting DRL values. In nuclear medicine, as in other imaging techniques, patient size plays an important role in the determination of required activity to achieve adequate image quality for a given procedure. Generally, surveys set a patient weight range. DRL values in adult nuclear medicine are normally based on the administered activities used for average-sized patients (i.e. 70 ± 10 kg), and then a DRL value for administered activity per unit body weight (MBq/kg) is calculated. DRL values for paediatric nuclear medicine are discussed in Chapter 6.

5.6. Hybrid imaging (PET/CT, SPECT/CT and PET/MRI)

(227) PET and SPECT have been combined with CT (PET/CT and SPECT/CT), and PET has been combined with MRI, because these combinations increase diagnostic accuracy by providing both functional and anatomical images of the body.

(228) The acquisition of accurately co-registered anatomical and functional images is a major strength of combined modality (hybrid imaging) devices. A further important advantage in use of the CT images is the capability for attenuation correction of the PET and SPECT emission data. PET/CT has become one of the most rapidly growing medical imaging modalities.

(229) For the purpose of this report, the terms PET/CT and SPECT/CT apply to a hybrid imaging procedure where an imaging device that combines a nuclear medicine camera with a CT scanner permits acquisition of a PET or a SPECT image with a CT image. Both CT and nuclear medicine images are obtained during the same session. The patient dose from a PET/CT or SPECT/CT examination is the combination of the radiation exposures caused by the radiopharmaceutical and by the CT study. The MRI component of PET/MRI does not increase patient dose, so from a radiological protection point of view, PET/MRI can be considered a PET scan.

(230) Since DRLs for nuclear medicine procedures and CT procedures apply to radiation from very different modalities, and use different DRL quantities, it is appropriate to set and present DRL values for each modality independently. It is important that the detector type and configuration in both PET/CT and SPECT/CT are recorded as part of the survey data

when developing DRLs, so that differences between detector types are correctly identified. Considerations for PET, SPECT and CT in hybrid imaging are considered below.

5.6.1. PET

(231) PET is a nuclear medicine tomographic functional imaging technique that uses a positron-emitting administered radiopharmaceutical that produces, as a result of positron emission decay, pairs of 511 keV γ photons at almost 180 degrees to each other. These pairs of annihilation photons are detected in a stationary detector ring around the patient. 3D images of the activity concentration within the body are then constructed.

(232) Different radiopharmaceuticals may be used for PET imaging, depending on the purpose of the study. ^{18}F Fludeoxyglucose (^{18}FDG) is used for diagnosing and determining the extent of cancer, inflammation, viable myocardium, and brain diseases by revealing relative glucose metabolic activity in tissues and organs. ^{13}N-ammonia or ^{82}Rb are used to assess myocardial perfusion. ^{68}Ga-DOTA-TATE and DOTA-TOC reflect the status of somatostatin receptors in various neuroendocrine tumours. Since the physical half-lives of radionuclides and biological half-times of radiopharmaceuticals are different, DRL values have to be set for each radiopharmaceutical. Since more than 90% of current PET examinations use ^{18}FDG, this section discusses only ^{18}FDG PET and PET/CT.

(233) While some institutions still use fixed administered activity for adults, the Commission recommends adjusting the administered activity for patient weight. Less activity is sufficient to generate good image quality for thin people, since attenuation and scatter effects of γ photons in these individuals are less than those in obese individuals. U.S. guidelines only recommend a range of 370-740 MBq for adult patients (ACR-SPR, 2014). European guidelines provide a calculation system according to body weight, image acquisition method (2D or 3D), scan speed (min/table position) and table overlap during consecutive PET acquisitions (≤30% or >30%) (Boellaard et al., 2015).

(234) Since increasing the administered activity will not only improve imaging quality but also reduce acquisition time, it might seem appropriate to employ a higher-than-recommended administered activity in order to reduce the duration of the scan, especially for obese patients. For obese subjects (>90 kg), increasing scanning time (time per table position), rather than increasing administered activity, is recommended to improve image quality. Administered activity for ^{18}FDG should be kept to less than 530 MBq (Boellaard, et al., 2015) for PET-systems equipped with LYSO scintillation detectors so as not to affect the image quality.

(235) Hydration and voiding are also important for patient preparation prior to a PET/CT procedure. The patient should be encouraged to drink water and then void prior to scanning, in order to limit the radiation dose to bladder.

(236) Acquisition sensitivities vary, depending on the individual PET system. Older PET systems had a 2D acquisition mode that used axial collimators. As computation power and electronics improved, a 3D acquisition mode was developed. All collimator septa were

removed, resulting in a 4-8 times higher sensitivity. In 3D acquisition mode, the administered activity can be reduced without affecting image quality. The European Association of Nuclear Medicine (EANM) recommends using administered activities of 380 MBq for 2D and 190 MBq for 3D for a 'standard' adult patient (75 ± 5 kg) (Boellaard et al., 2015).

(237) Newer PET/CT scanners offer time-of-flight (TOF) technology, which can help overcome poor signal from large patients. TOF accurately measure the actual time difference between the detection of the two annihilation photons. This permits improved image contrast and higher sensitivity. Use of TOF technology permits a decrease in the average administered activity of ~20% (from 4.3 MBq/kg to 3.5 MBq/kg) without loss of image quality (Etard et al., 2012).

(238) A national survey of patients undergoing whole-body PET/CT examinations was conducted in all French nuclear medicine departments in 2011 (Etard et al., 2012). The average injected ^{18}FDG activity was 4.3 MBq/kg, in agreement with contemporary European recommendations (Boellaard et al., 2015).

5.6.2. CT in PET/CT and SPECT/CT

(239) For CT imaging in PET/CT and SPECT/CT, patient dose depends on the purpose of the CT examination. In the framework of a PET/CT or SPECT/CT examination, the CT portion of the examination comprises a topogram and the helical CT scan. If the CT is used for a full diagnostic CT examination, DRL values as described in Section 5.3 are appropriate, but a lower patient dose (and thus a lower DRL value) is appropriate when CT is performed only for attenuation correction and anatomical localisation. If a CT is solely performed for attenuation correction and co-localisation, the acquisition parameters (tube current, voltage, slice thickness, rotation time, and pitch) should be selected in order to minimise the patient's radiation exposure.

(240) For a diagnostic contrast-enhanced CT, standard protocols should be used. It is preferable to perform a diagnostic CT only for limited portions of the body. For the rest of the body, a low-dose CT is sufficient for attenuation correction and anatomic localisation. Current DRL values for diagnostic CT of the trunk are too high for the CT component of PET/CT if the CT is performed only for attenuation correction and localisation. Despite wide variations between PET/CT systems (4-fold variations in $CTDI_{vol}$), CT DRL values of 8 mGy ($CTDI_{vol}$) and 750 mGy·cm (DLP) have been proposed for whole-body PET/CT (Etard et al., 2012).

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6. PAEDIATRICS

- **Establishing DRLs for children is more challenging than for adults, due to the broad range of sizes and ages of paediatric patients. Weight in children can vary by a factor of more than 100 from a premature infant to an obese adolescent. A single 'standard patient' should not be used to define DRLs for paediatric imaging.**
- **The amounts of administered radiation for examinations of children can vary tremendously due to the great variation in children's size and weight. Variation in patient dose due to patient weight is appropriate, but variation in patient dose due to inappropriate technique or failure to adapt the imaging protocol to patient size and the clinical task is not.**
- **The smaller body size of most children, as compared to adults, means that in children more organs are likely to be within or near the primary beam, so that precise collimation is both more important and more difficult. For projection radiography, the relevance of appropriate collimation is higher in paediatrics.**
- **Patient age categories have been used in the past to define groups of children for the purpose of establishing paediatric DRLs. It has become apparent that age alone is not a good indicator. Weight categories are preferred, and should be used whenever possible.**
- **Weight bands (with 10 kg intervals) are recommended for establishing paediatric DRLs. Weight bands should be promoted for paediatrics. Age bands (<1 y; 1-<5 y; 5-<10 y and 10-<16 y) can be used if age is the only available measure.**
- **To overcome the problem of collecting sufficient data, caused by the need for weight bands and the general paucity of dosimetric data for patients in paediatric imaging, it has been suggested that the DRL quantity can be presented as a function of patient weight instead of presentation in weight bands. This option should be explored further.**
- **For CT, the DRL quantities are $CTDI_{vol}$ and DLP, based on calibration with a 32 cm phantom for body examinations and a 16 cm phantom for head examinations. Values for these quantities should be obtained from patient examinations.**
- **Modern CT scanners permit determination of effective diameter or patient equivalent thickness. This should be considered as an additional refinement for setting paediatric DRL values. Size-specific dose estimates (SSDE) may be used in addition to the recommended DRL quantities as an additional source of information for optimisation.**
- **For nuclear medicine imaging, DRLs are surveyed and DRL values are set by administered activity (MBq) or administered activity per unit of body weight (MBq/kg), since this approach is both practical and simple. Activities for administration should be adjusted based on agreed factors linked to size or weight.**

- **When regional or national DRL values are not available, local practice may be compared to appropriate available published data. This is especially relevant for paediatrics due to the scarcity of national or regional DRLs.**

6.1. Considerations relevant to paediatric DRLs

(241) Optimisation of paediatric imaging is of particular importance, because the risk of many harmful radiation effects is greater in children than in adults and they have a longer life expectancy during which these effects may manifest. Moreover, the smaller body size of most children as compared to adults means that in children more organs are likely to be within or near the primary beam, so that precise collimation is both more important and more difficult (ICRP, 2013). The short exposure times required for paediatric examinations mean that manual exposures are often used instead of AEC systems.

(242) The amount of administered radiation for examinations of children can vary tremendously due to the great variation in patient size and weight, from neonates to adult-sized adolescents. This variation in patient radiation dose is appropriate. However, additional variation in patient radiation dose may occur, due to inappropriate technique or to failure to adapt imaging protocols to account for both paediatric diseases and paediatric patient sizes. This variation in patient radiation dose is not appropriate. Weight or size-adjusted paediatric DRLs are therefore particularly important as an aid in optimisation. Simple adaptation of adult imaging protocols to account for paediatric diseases and patient sizes is not acceptable.

(243) A number of factors need to be considered when discussing developing DRLs for children. Some factors are the same for adults and children. These include the choice of DRL quantities, the percentile of the distribution of the DRL quantity, and whether to use surveys of patients or measurements with phantoms. For other factors, particularly patient weight and size, specific considerations apply for children.

(244) DRLs for adults are defined for a ‘standard patient’. For children, there cannot be a single standard patient, due to the large size range of paediatric patients. Adults vary in body weight by approximately a factor of 4 (40–160 kg), while weight in children can vary by a factor of more than 100, from that of a premature infant (300-400 g) to that of an obese adolescent (>100 kg). Within the first six months of life, a typical baby’s body weight doubles, and during the first year, it increases threefold. The AAPM uses several different standard paediatric phantoms to help in optimisation for paediatric imaging (AAPM, 2011).

(245) The Commission has not previously provided guidance on representative child sizes for defining paediatric DRLs. In the past, patient age has been used to define groups of children for the purpose of establishing paediatric DRLs. Typically ages of 0 (neonate), 1, 5, 10 and 15 years have been used (ICRP, 2007, 2013), mirroring available standard phantoms. To ensure reasonably accurate results, data for at least 30 patients in a particular age group should be collected if patient weight is not known (Section 2.3.3). A recent paper suggests a pragmatic approach of using four age groups, <1 y, >1-5 y, >5-10 y, >10-15 y (Vassileva and Rehani, 2015). However, there are large variations, even within these groups, and Kleinman et al. (2010) have demonstrated that individual patient size does not correlate well with patient

age, even though fitted average patient sizes are age-dependent. This study suggested that it is preferable to use groupings based on paediatric patient body size, and that body size should be determined for individual patients before performing diagnostic imaging procedures that entail radiation risk.

(246) Weight is a more reliable factor to link with the DRL quantity than age (Järvinen et al., 2012). Use of weight bands should be promoted. A number of different grouping schemes for patient size and for patient weight have been described in the literature. The Commission recommends the use of weight bands, generally with 10 kg intervals with about seven groupings. Age bands (<1 y; 1-<5 y; 5-<10 y and 10-<16 y) can be used if age is the only available measure. If weight is available, this parameter should be collected to present DRLs in the form of weight bands. In the future, DRLs based on patient dimensions could also be used.

(247) For future DRL surveys, DRL values based on patient age will be of value primarily to facilitate comparison with older data. Note, however, that empirical equivalencies have been studied to convert existing age-based data into corresponding patient sizes for comparison of weight-based data with older data (AAPM, 2011; Seidenbusch and Schneider 2014).

(248) For local DRLs, and for comparison with national or regional DRLs, the mean weight in the facility's data should be within 5-10% of the mean weight of the sample on which the DRLs were based. Comparison of results from different surveys should always be performed with caution, taking into consideration the method of grouping paediatric patients.

(249) Recent research has led to efforts to develop indices that more closely correlate with radiation attenuation in paediatric patients. Most modern radiography, fluoroscopy and CT systems have some form of automatic exposure control or tube current modulation. The exposure is determined by effective attenuation in the path of the x-ray beam. For CT scanners, attenuation and tube current can vary throughout each scan rotation. In order to develop useful values for paediatric DRLs, consideration should be given in the future to grouping survey data into attenuation-based bands.

(250) For radiography, fluoroscopy, and nuclear medicine examinations, weight should be used as the parameter for grouping paediatric patients into categories for the purpose of determining DRL values and evaluating local practice.

(251) Updating of existing paediatric DRLs has been very slow in comparison with the rapid development of imaging technology. In most countries, current paediatric DRLs are the first ones ever implemented, and were established many years ago. Only a few countries have trend data for paediatric procedures based on successive surveys of DRL quantities.

(252) Since paediatric imaging is performed only occasionally in most hospitals, data collection for these examinations is a particular problem. There are likely to be only a few examinations in any age, weight or size group in a typical hospital. In view of these limited numbers, surveys to establish DRL values may need to focus primarily on the main hospital(s)

in the region that provide paediatric imaging. An alternative to surveys is the establishment of a registry to which healthcare facilities submit dose data.

(253) To overcome the problem of insufficient data caused by the need for several patient groups, and the general paucity of data for DRL quantities in paediatric imaging, it has been suggested that the DRL quantity could be presented as a function of patient weight instead of by presentation in weight bands. Patient equivalent thickness could also be used for CT. An example of the data used to define a DRL quantity-weight curve is shown in Fig. 6.1 (Kiljunen et al., 2007; Järvinen et al., 2015). To compare local patient data with this curve, the user obtains data for a limited number of patients (e.g. ten consecutive patients) regardless of their age, size or weight, and overlies these data points on the DRL quantity-weight curve. This alternative has been used with some success in Scandinavia, but as of 2015 experience is limited.

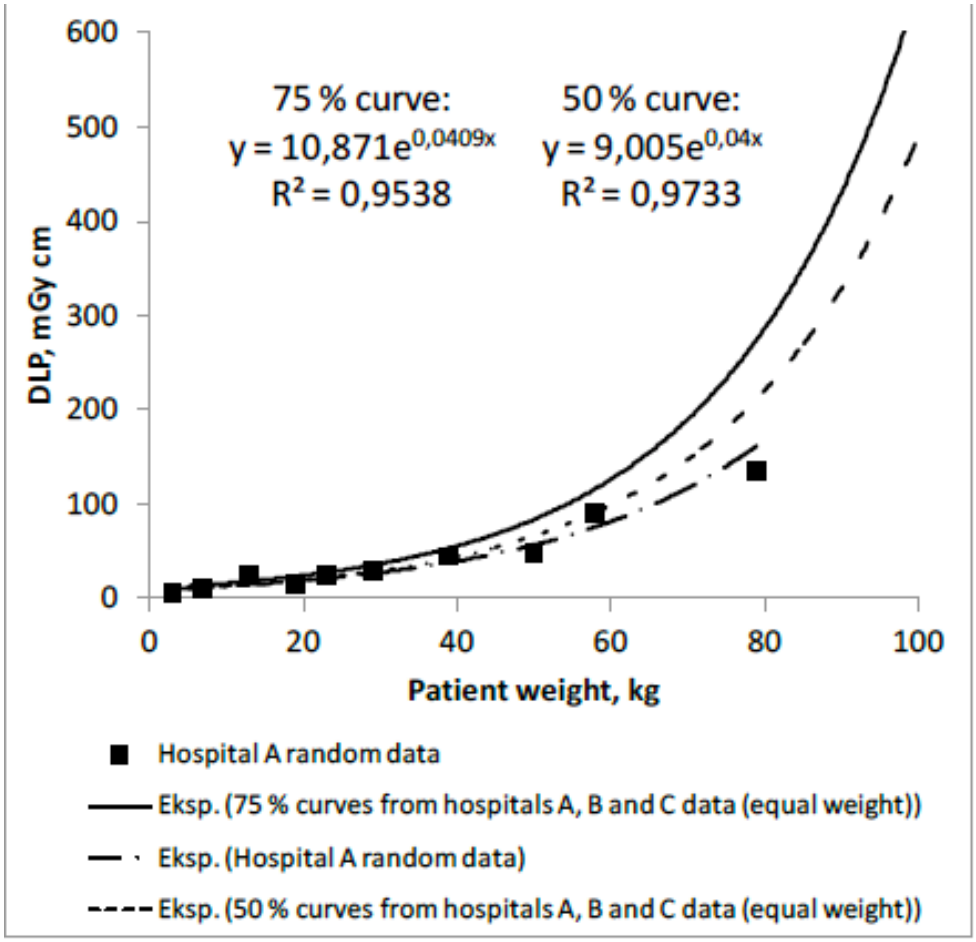

Fig. 6.1. An example of DRL quantity-weight curves for CT of the chest, with DLP as the DRL quantity. “Eksp” means exponential fitting. The DLP values relate to the 32 cm diameter

CT dosimetry phantom. The lowest curve shows an example of using this methodology to provide comparison for a limited data set from an individual hospital (Järvinen et al., 2015).

6.2. Paediatric DRLs for CT

(254) $CTDI_{vol}$ and DLP for patient examinations are determined by reference to a specific standard reference phantom, either 16 cm (head) or 32 cm (body) in diameter. For a given patient's CT scan, $CTDI_{vol}$ and DLP are displayed on the CT console for the reference phantom selected by the scanner. In general, for examinations using a head bow-tie filter or head scan protocol, the 16 cm diameter phantom is used. For examinations of the chest, when a body bow-tie filter or body scan protocol is used, the 32 cm diameter phantom is used. Until recently, some manufacturers used the 16 cm diameter phantom and others used the 32 cm diameter phantom as the reference for calculating $CTDI_{vol}$ and DLP for paediatric body CT protocols. In 2012, the IEC amended the CT standard to specify that a 32 cm phantom should be used for all body examinations, both paediatric and adult (IEC, 2012).

(255) To compare $CTDI_{vol}$ or DLP values for patient examinations on a specific CT scanner to other reported values, the phantom diameter used for the specific scanner model and software version must be known. In most cases, the phantom diameter used is now displayed on the user console along with $CTDI_{vol}$ and DLP, or is present in the DICOM report. Older scanner models and software versions, however, may not provide this information in a readily accessible location. The scanner manufacturer should be consulted in such case.

(256) Phantom size does not address issues of patient size, and patient size has a large effect on the amount of radiation applied for a procedure. AAPM Report 204 introduced a parameter known as the Size-Specific Dose Estimate (SSDE) to allow estimation of patient dose based on $CTDI_{vol}$ and patient size (AAPM, 2011). The SSDE is the $CTDI_{vol}$ adjusted for patient equivalent thickness based on a set of standard coefficients.

(257) Some caution is required in interpreting $CTDI_{vol}$ and DLP data for smaller paediatric patients. If a 32 cm phantom is used to determine the reference $CTDI_{vol}$, rather than a 16 cm phantom, patient dose could be underestimated by a factor of 2-3. SSDE calculations take into account the effect of different phantom diameters, so if the phantom diameter is known (as it should be), its effect on patient dose will be accounted for.

(258) DRLs for paediatric CT are available for very limited types of examinations and were included in earlier ICRP publications (ICRP, 2007, 2013; Vassileva and Rehani, 2015; Vassileva et al., 2015). In some cases, it is not clear whether the $CTDI_{vol}$ values were based on 16 or 32 cm phantoms. Also, automatic tube current modulation may not have been used when the earlier DRL values were determined. When it can be employed, the use of tube current modulation for CT scan protocols may reduce patient doses.

(259) For CT, many current scanners permit determination of an effective diameter or patient equivalent thickness. The patient equivalent thickness is derived from the patient's anteroposterior (AP) and lateral dimensions (effective diameter = $\sqrt{[AP \times LAT]}$). When both

the AP and lateral dimensions of the patient are known, the product of these two dimensions can be used to estimate effective diameter.

(260) Use of patient equivalent thickness for grouping patients for the purpose of determining DRLs may be considered as an alternative or additional refinement. Manufacturers are encouraged to provide the capability to determine and record these parameters so that they are included in patient image files, along with values of the DRL quantities, in order to make them readily available for refining the determination of DRL values.

(261) ICRU Report 74 provides data on the relationship of patient effective diameter to age (ICRU, 2005). These data can be used to correlate age and effective diameter, but age should only be used to facilitate comparisons with older data. Dose estimates based on patient size are considered more accurate and should be used when size information is available (AAPM, 2011).

6.3. Paediatric DRLs for radiography, nuclear medicine and interventional procedures

(262) There is a need to establish DRLs for radiography, nuclear medicine and interventional procedures. The DRL quantities recommended for adults apply equally to paediatric DRLs. Other considerations relevant to adult DRLs also apply to paediatric DRLs except that, as discussed in Section 6.1, patient size and weight are of critical importance for paediatric DRLs.

(263) During the last three decades, the U.K. has demonstrated the widest experience in periodically reviewing and revising DRLs for paediatric imaging. Even in the U.K., paediatric DRL values have been established only for very limited types of examinations (e.g. for radiography, only for examinations of the skull, chest, abdomen, and pelvis). When applicable regional or national DRL values are not available, local practice may be compared to any available published data.

(264) For diagnostic fluoroscopy, current national DRL values in European countries are given only for micturating cystourography (MCU) except in the U.K., where DRL values have also been set for barium meal and barium swallow examinations. All the DRL values for fluoroscopy use P_{KA} as the DRL quantity. There are no current national DRLs for paediatric IR or IC. Attempts at establishing local paediatric DRLs for interventional procedures have been made in a number of countries, mainly in Europe but also in Asia (IAEA, 2009; Kloeckner et al., 2012; Tsapaki et al., 2008; Vitta et al., 2009).

(265) For nuclear medicine imaging, DRLs are surveyed and DRL values are set using administered activity (MBq) or administered activity per unit of body weight (MBq/kg) as the DRL quantity, since this approach is both practical and simple. Activities for administration to children should be adjusted based on agreed factors linked to size or weight (Lassmann et al., 2007, 2014). Standardisation of administered activities and the use of administered activity/weight charts are important for all paediatric nuclear medicine

procedures, as sizable variations in administered activity have been shown to occur when they are not used.

(266) Weight-based radiopharmaceutical consensus values have been developed by EANM (www.eanm.org) and Image Gently for nuclear medicine/PET imaging (www.imagegently.org). Weight-based activities for paediatric nuclear medicine are available in several countries. These have been tested in children's hospitals to ensure that adequate image quality is maintained with optimised radiological protection. A compendium that summarises current information for frequently used substances was published in 2015 (ICRP, 2015). However, caution should be exercised to ensure that the amount of activity administered is not so low as to give a non-diagnostic examination.

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7. APPLICATION OF DRLS IN CLINICAL PRACTICE

- **Local surveys of DRL quantities should normally be carried out as part of the clinical audit for diagnostic radiography and diagnostic fluoroscopy. A representative selection of examinations for each x-ray unit should be surveyed at intervals of about three years, and when substantial changes in technology or software have been introduced.**
- **Local surveys of DRL quantities, as part of the clinical audit, should be more frequent (annual) for CT and interventional procedures. Annual surveys are also appropriate as part of the clinical audit for SPECT/CT and PET/CT.**
- **Median values of DRL quantities for diagnostic procedures for a specific x-ray room or for a radiology department or other facility should be compared with DRL values to identify whether the local median values are substantially higher or lower than might be anticipated, so that the management of radiological protection can be reviewed and optimised if necessary.**
- **A DRL value is considered to be exceeded when the local median value of a DRL quantity for a representative sample of standard-sized patients is greater than the DRL value.**
- **DRLs should never be applied to individual patients, as some patients will require higher amounts of administered radiation than others due to their size, a particular diagnosis, or the complexity of the procedure.**
- **If an audit reveals that a local or national DRL value is 'consistently exceeded' (i.e. the median value in a particular facility exceeds the local or national DRL value), an investigation should be undertaken without undue delay and an appropriate corrective action plan should be implemented and documented.**
- **The investigation should include review 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.**
- **When corrective action to optimise protection is required, it is necessary to keep in mind that DRL values are not dose limits.**
- **In the optimisation process, account must always be taken of the image quality and diagnostic information required for the medical imaging task. Image quality must always be adequate to provide the information required for the clinical purpose of the examination.**
- **The median (the 50th percentile) of the national or regional DRL survey distribution represents what can be accomplished with radiological practice that optimises dose management with respect to clinical image quality goals. These**

median values provide additional information that can assist in optimising image quality and patient dose.

- **When the median value of a DRL quantity at a facility is lower than the median value of the benchmark national or regional DRL survey distribution, image quality (or diagnostic information, when multiple images are used) should be examined as a priority in the review.**
- **The DRL audit 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.**
- **If continuous collection of data on DRL quantities is possible through automated collation of data from electronic databases, then the dose management process may take the form of a regular review of all the data to identify any adverse trends.**

7.1. Patient audits of DRL quantities for x-ray examinations

(267) Local surveys of DRL quantities should be undertaken routinely in healthcare facilities where imaging procedures are performed with ionising radiation. These are part of the clinical audit process, and are performed for guidance on performance and whether optimisation is required. They may also contribute to the setting of national or regional DRL values. Facility audits are normally carried out for a representative selection of examinations for each x-ray unit. In regions with limited infrastructure for data collection, intervals of about three years will be appropriate for many diagnostic radiography and diagnostic fluoroscopy examinations if there are no substantial changes in equipment or software. Annual audits are recommended for CT and interventional procedures (Fig. 7.1), because they subject patients to higher amounts of radiation. As automated systems for patient data collection and management become more widely available, the frequencies for audits of all examinations should be reduced to annual. If continual collection of data on DRL quantities is possible through automated collection of data from electronic databases, then the dose management process may take the form of a regular review of all the data to identify any adverse trends at as early a stage as possible.

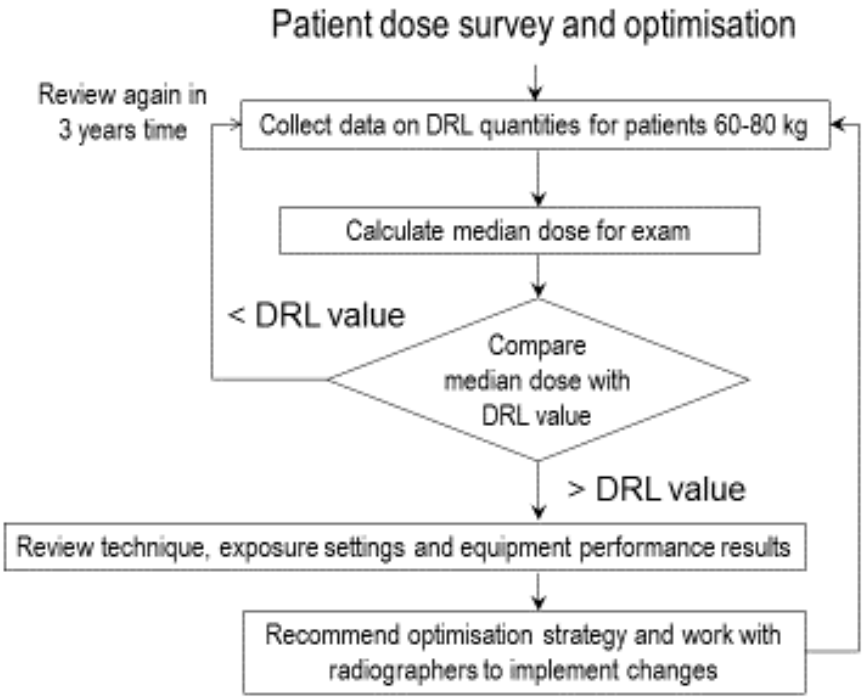

Fig. 7.1. Example of audit cycle and optimisation flow chart.

(268) When new imaging equipment is introduced, or changes are made to such equipment that have the potential to affect patient dose, acceptance testing should be performed to ensure that the equipment is functioning properly. A survey of patient doses should then be undertaken, within the first year and once practices have become established, in order to determine whether local median values of DRL quantities have changed.

(269) The DRL process provides a tool through which x-ray examinations, equipment and facilities using higher radiation doses can be identified. However, this is just the start of the dose audit process. Once equipment and procedures have been identified, staff need to undertake corrective action in order to optimise protection. This responsibility must be given to appropriate staff who have the necessary expertise. The groups of staff involved will depend on arrangements in each country or region, and may be medical physicists, radiographers, medical physics technologists, or radiologists who may be employed by the healthcare provider or under contract to the provider (Martin et al., 2013). Those responsible may also in some cases be employed directly by the responsible government department.

7.1.1. Setting up an audit programme in healthcare faciities

(270) Each facility should review carefully which examinations ought to be included in local audits. The following criteria should be considered when identifying examinations for inclusion in the survey programme:

a. Examinations must be performed at a reasonable frequency in the facility and should be representative of all equipment.
b. Audits should not be limited to the radiology department or outpatient radiology facility, but should include all areas of the facility where ionising radiation is used for medical or dental imaging.
c. Examinations should be representative of the clinical workload of the facility.
d. Data collection must be feasible.
e. Ideally, there should be at least one examination performed on each item of equipment that makes a significant contribution to the workload of the department.

(271) Other aspects that should be taken into account are:

a. Examinations should cover the work of all groups of operators who carry out x-ray procedures in the department, i.e. radiographers (also known as radiologic technologists), radiologists, non-radiologist clinicians (e.g. cardiologists, surgeons) and others.
b. It is helpful to include examinations for which there is a national DRL or other comparator available, although this is not essential.
c. More examinations than necessary should not be included, as analysis can be time consuming.
d. For fluoroscopy, most complex examinations should be suitable for the development of protocols, and many will also be well suited for setting of local DRLs.

(272) When the specific examinations to be included have been determined, the next stages are to identify the rooms to be audited and the procedures carried out in those rooms, and to decide how to obtain data on the DRL quantities. For hospitals, audits of mobile fluoroscopy and radiography equipment should also be considered.

(273) As discussed in Section 2.3.3, surveys for a particular examination should generally include at least 20 patients and preferably 30 or more for diagnostic fluoroscopy examinations (IPSM, 1992) and 50 patients for mammography. All the selection criteria and methods for collection discussed in Section 2.3 apply. A suitable weight selection criterion should be chosen, with the aim of achieving the mean weight chosen for the DRL. Commonly, the weight criterion has been 70 ± 10 kg or 70 ± 20 kg, with the goal of a mean weight of 70 ± 5 kg. The weight inclusion criterion can be relaxed if data from a RIS or PACS for a large number of examinations are analysed.

(274) Surveys of DRL quantities for paediatric examinations (see Chapter 6) are more difficult to carry out because examinations of children are performed less frequently in most hospitals, and the numbers of patients within any age/weight range are likely to be small. Local surveys of DRL quantities in smaller hospitals may have to be based on standard factors

used by radiology staff for children of different weights/ages. This can still be useful, as it helps identify where the factors that would be used are inappropriate, so that operators can review them and ensure that they are correct when examinations are required.

(275) Comparisons of the medians of all the DRL quantities for each examination with the relevant DRL values are then used to identify procedures within a department for which further optimisation is required (Fig. 8.1). Since neither the DRL value nor the measured DRL quantity is without uncertainty, the direct comparison of the two numbers should take the uncertainty into account when the number of patients is limited. For interventional procedures, comparison with the relevant DRL values should, when possible, take into account the level of complexity of the procedures in the sample. When this information is not available, median, 25th and 75th percentile values of the facility data should be compared to the corresponding percentile values of the benchmark data. Ideally, data shoulld be collected for all cases of the procedure at the facility.

(276) Where collection of data is only possible for small numbers of patients, the uncertainty in the median or mean could be large. The interquartile range serves as an indicator of dispersion of the data. While the Commission recommends use of median values in preference to mean values, it may be helpful to consider the standard error of the mean = SD/√N, where N is the number of data points (number of examinations surveyed). The mean for 95% of results will lie within two standard errors of the true mean. Although this is not the error of the median, it gives an indication of the reliability of the comparison. A larger number of examinations should be included in the survey when the range of patient sizes is larger.

7.1.2. Audits for dental radiography

(277) The application of DRLs is important in dental radiography, because changes in x-ray equipment exposure settings required to take advantage of the introduction of more sensitive imaging methods are not frequently made when new techniques are introduced (e.g. use of faster E- or F-speed film instead of D-speed, or digital radiography receptors). Establishment of national or regional DRL values for adult and child examinations is recommended in terms of single values, but because of the substantial increase in sensitivity of digital radiography (DR) over film and CR, the introduction of separate local DRL values for DR systems can prove useful (Martin, 2016).

(278) The method for managing and achieving optimisation for dental radiography differs from the method for other x-ray applications, since dental units are used across large numbers of facilities by personnel for whom radiological imaging is only a small component of their speciality. Surveys of dental clinics show wide ranges in dose levels, because many dentists have not changed their exposure times when switching to faster film or installing digital radiography equipment, and have not set the shorter exposure times that would be appropriate for the more sensitive DR image receptors (Gulson, 2007; Holroyd, 2012; Farris and Spelic, 2015).

(279) All dental facilities should measure the dose and imaging performance of x-ray equipment at installation and at intervals, typically of three years, thereafter. Dental DRL values are set for specific examinations using Ka,i as the DRL quantity. The radiation dose for intraoral radiography is determined by the x-ray machine settings, selected in terms of tooth type, linked to exposure time. In order to realise a dose reduction by changing to a more sensitive imaging detector, the x-ray equipment settings must be adjusted to alter the exposure times. Based on test results, recommendations can be made on changes to equipment settings and adjustments made in consultation with the dentists.

(280) Programmes involving regular testing of dental x-ray equipment and measurement of DRL quantities allow the identification of units with unnecessarily long exposure times. The investigator should work with the dentist to optimise protection. Improvement in protection can be realised which otherwise might not be achieved. Martin (2016) has described an example of the reductions in dental doses achieved in the West of Scotland through this approach. If there is no planned dose audit and optimisation programme, a substantial proportion of dental x-ray units are likely to continue to use exposure times designed for older, less sensitive image detectors.

7.1.3. Corrective action

(281) If an audit reveals that a DRL for any procedure is consistently exceeded (i.e. the median value of the DRL quantity observed in the audit exceeds the DRL value), then an investigation should be undertaken without undue delay, and appropriate corrective action should be performed (EC, 2014).

(282) Corrective action (optimisation of protection) should include review of equipment performance, the settings used, and the examination protocols (Martin, 2011). Generally, it is easiest to check the x-ray system settings first, as this is less time consuming, then review of the examination protocols, and finally how the operators use the examination protocols.

(283) As discussed in Section 2.6.2, when the median value of a DRL quantity at the facility is lower than the median value of the benchmark national or regional DRL survey distribution, image quality (or diagnostic information, when multiple images are used) should be examined as a priority in the review.

(284) The audit process does not stop after a single assessment. Repeat surveys will be required following any optimisation, and the whole process should be repeated after an appropriate time interval. For most radiography and diagnostic fluoroscopy examinations, a representative selection of examinations for each x-ray unit should be surveyed at intervals of about three years, and also when substantial changes in technology or software have been introduced. Local audits of DRL quantities should be more frequent (annual) for CT and interventional procedures. Annual audits are also appropriate for SPECT/CT and PET/CT.

(285) It is important that all dose audits are documented and that records are maintained, so that knowledge of the optimisation processes undertaken is available for users of the equipment in the future.

7.2. Factors to consider if a DRL value is exceeded

(286) Clinical audit is a quality improvement process that seeks to enhance patient care through systematic review and evaluation against explicit criteria, and implementation of change. Surveys of DRL quantities and comparisons with DRL values can help identify where optimisation should be targeted.

(287) As noted above, if a DRL value (and especially if a national DRL value) is exceeded, this should be investigated without undue delay (Fig. 7.1). The outcome of the investigation should be to identify why the DRL value has been exceeded. In the body of patient data used to compare DRL values, there may be a number of patient cases where a larger amount of radiation was needed in order to achieve the image quality required to provide the diagnostic information. If needed, remedial measures should be identified and instituted prior to commencing the next audit cycle. The factors that are most likely to be require remediation are:

a. Survey methodology, including the performance of the survey instrument used and the selection of patients included in the survey.
b. Equipment performance, including the imaging device, technical factors set by the manufacturer or medical physicist, and film processing or digital reader.
c. Procedure protocol, relating to technique factors used at the facility.
d. Operator skill, including individual technique and operator training.
e. Procedure complexity and case mix, where patients within the group represent a special category that makes the investigation more difficult, because of their disease, physical status or other reason.

(288) Each of the preceding factors is discussed in more detail below. It is important to remember that DRLs cannot be applied to judge the appropriateness of the radiation dose for an individual patient. There is a much greater variation in the radiation dose for individual patients than in median values of patient radiation dose at a facility.

7.3. Survey methodology

(289) The first thing to be considered if the median value of the DRL quantity exceeds the DRL value is whether the survey was carried out in a sound manner that was consistent with the way in which the DRL value was set in the first place. The types of questions that should be asked include the following.

a. Was the measurement device or system that was used calibrated correctly?
b. Were any TLDs that were used calibrated appropriately and were background corrections carried out correctly?
c. If a P_{KA} meter was used, was it calibrated correctly for an undercouch tube or for spot imaging? Alternatively, was the proper patient table attenuation factor for an

undercouch tube applied to the P_{KA} readings (P_{KA} meters are usually calibrated without the patient table in the beam)?

d. For CT scanners, were the $CTDI_{vol}$ or mAs values representative of the true values or (for tube current modulation) the average mAs set?
e. Were the displayed CT technique factors (e.g. kVp, slice thickness, $CTDI_w$) calibrated correctly?
f. Were all calculations performed using appropriate correction and calibration factors and based on output measurements?
g. Were data for any patients who did not qualify for the group included inadvertently (e.g. very large and very small patients)?

7.4. Equipment performance

(290) Wherever new or more complex equipment has been installed, operators must be made aware of, and trained in the use of, relevant dose saving technologies so that they can utilise the equipment effectively. Surveys of DRL quantities are recommended once operators have established their new routines.

(291) The imaging equipment, or the manner in which it is set up, might be the reason why a national or regional DRL has been exceeded. Possible reasons for this relating to different types of equipment are given in the following subsections.

7.4.1. Radiography and fluoroscopy

(292) Radiography (general)

a. Use of a lower tube potential than is required (Martin et al., 1993).
b. Use of an inappropriate grid.
c. Using a focussed grid at the wrong focus-to-image distance.
d. Use of a short focus-to-image receptor distance.
e. Use of a patient couch not designed for x-ray imaging or of an older design with a higher attenuation.

(293) Film radiography

a. Slow speed (class ≤200) film-screen systems.
b. Different film-screen combinations.
c. Film not matched to the intensifying screen in the cassette.
d. Poor film processing.

(294) Computed radiography (CR) or direct digital radiography (DR)

a. AEC not set up correctly.
b. Use of a combination of CR/DR and film techniques in the same facility.
c. Differences in grid usage.

(295) Mammography

a. Slow film-screen combination.
b. Suboptimal film processing.

c. Insufficient breast compression.
d. Grid used where not required.
e. AEC not set up correctly for digital mammography.
f. Manual exposure settings used instead of AEC.
g. Faulty detector.

(296) Dental radiography

a. Use of a slow speed film (D-speed rather than E or F).
b. Developer chemicals not changed frequently enough.
c. Development temperature incorrect.
d. Use of incorrect exposure settings for digital radiography.

(297) Fluoroscopy and FGI procedures

a. Old or outdated fluoroscopy equipment.
b. Image detectors from different manufacturers.
c. Incorrect dose programme options employed by equipment users or set by service engineers, with too high an image receptor dose, exposure factors with too low a kVp, too high a fluoroscopy pulse rate, or too high an image acquisition rate (Martin and Hunter, 1994).
d. Copper or spectral filter options not properly set up or not utilised.
e. Inappropriate use of magnified field sizes that utilise higher dose rates.
f. Insufficient collimation.
g. Insufficient use of semi-transparent (triangular or wedge) filters.
h. Use of projections with unnecessarily steep gantry angulation.

7.4.2. CT

(298) CT scanners are complex, and the interplay of many factors needs to be taken into account. Optimisation requires close collaboration among radiologists, medical physicists and radiographers who each have knowledge of different aspects of the imaging process. Examples of some of the equipment factors involved are given below with possible ways in which controls might vary on different scanners. These factors will need to be specified in clinical protocols. These settings are discussed further in Section 7.5.2. CT scanners with solid-state detectors are preferred to CT scanners with gas detectors (Fuchs et al., 2000).

(299) Images of thinner slices tend to be noisier, as they use fewer photons. The way in which CT scanner controls are set depends on the manufacturer and model. On some scanners, the selection of thinner slices may result in noisier images, while other scanners may maintain the same image quality by increasing the tube current (and so the amount of radiation applied) when thinner slices are imaged. The behaviour may also depend on the stage at which the selection of image thickness is made. Thus, a choice of thinner image slices than is required may increase patient dose.

(300) Different CT scanner manufacturers adjust scan parameters in different ways, so it is important that staff have a proper understanding of the capabilities of their scanner and how these function in practice. One example is the selection of the pitch of a helical scan.

Some manufacturers (many GE and Toshiba models) maintain the same tube current (mAs per rotation), so that extending the pitch will reduce dose and decreasing pitch will raise dose. Other manufacturers (many Siemens and Philips models) adjust the tube current when the pitch is changed, to maintain a similar dose level.

(301) A tube potential of 120 kV has been used for many years for the majority of CT scans. However, a lower tube potential can give better image quality and result in a lower patient dose. A qualified medical physicist should be involved when changes in tube potential are considered.

(302) All CT scanner manufacturers now include automatic tube current modulation, which reduces the tube current and therefore the amount of radiation applied in regions of lower attenuation. Tube current may be adjusted for the scan both along the z-axis (length) of the body and as the tube rotates around the elliptical cross section of the body. However, different manufacturers implement these systems in different ways. Some (e.g. GE and Toshiba models) use a measure of image quality based on the noise level in the image. Such systems increase the tube current proportionately with the size of the patient. Other systems use comparisons with a reference image or reference mAs, thus allowing a higher level of noise for larger patients (Siemens and Philips). The images from larger patients have better separation of organs and other structures due to interposed fatty tissue, so a higher noise level can be tolerated without impairing diagnosis (Sookpeng et al., 2014).

(303) Most scanners use the x-ray attenuation of the topogram/scout for tube current modulation planning. Hence, it is essential to keep protective devices out of the scan range or to use them after the topogram/scout has been performed.

(304) Selection of other parameters, such as filter options, can affect the function of the tube current modulation. The reconstruction kernel should match the resolution and image noise requirements of the clinical task. A smooth filter will reduce noise, whereas a sharp filter will accentuate boundaries, improving resolution but increasing noise. The appropriate filter depends on the imaging task. On some CT scanner models, selection of a sharper filter that increases the noise will cause the tube current modulation to increase the tube current and therefore the amount of radiation in order to maintain the same noise level, while for other scanner models the appearance of the image will change, but the amount of radiation will remain relatively unchanged (Sookpeng et al., 2015).

(305) Newer CT scanners have the ability to employ iterative image reconstruction techniques. These require more computing power than conventional back projection methods, but can reduce the amount of radiation considerably where they are applied. These techniques should be employed wherever available and practicable, and setting of lower DRL values linked to the reconstruction technique should be considered.

(306) It is important for users to obtain detailed instruction in CT scanner operation from the manufacturer's applications specialist at installation and for medical physics staff to

undertake tests to confirm the performance of relevant controls during the period when clinical protocols are being set up.

(307) Because tube current modulation operates in different ways on different CT scanner systems, the relationship between patient dose and patient size or weight varies. It is recommended that surveys of DRL quantities for CT include measurements for patients of different sizes. This may be done by taking data for different weight groupings or through the fit of an exponential equation to DLP versus weight data (Järvinen et al., 2015). Alternatively the patient diameter or the cross sectional area, either of which can be measured from the scanner display, may be recorded and used to group patients (Sookpeng et al., 2014). If data are recorded either in a RIS or other patient dose management system, so that results for large numbers of patients are available, then the 1st and 3rd quartiles may be recorded as well as the median value (Martin, 2016). If data collection and patient size assessment are automated, then plots of DRL quantities such as $CTDI_{vol}$, DLP or SSDE against a patient size factor may be useful (Samei and Christianson, 2014). The method that is most appropriate will depend on the local availability of hardware and software. Comparisons of the values of DRL quantities among scanners, in addition to comparison to DRL values, can be useful in the evaluation.

7.4.3. Nuclear medicine

(308) Since the DRLs for nuclear medicine are based on the activity administered, the approach to optimisation is different in character from that used for the other imaging modalities discussed in this report.

(309) When a facility consistently exceeds the recommended DRL value, it represents a choice made by the clinician and the operator. If images are inadequate, this may indicate that the imaging equipment is less than optimal and may require maintenance. If equipment performance cannot be improved, then whether the equipment can and should be replaced will involve issues of funding, the availability of alternatives, and the risks of continuing with the current regime.

(310) If values of $CTDI_{vol}$ or DLP for the CT component of hybrid imaging (i.e. PET/CT and SPECT/CT) are above the DRL value, then the purpose of the imaging task, whether it is primarily a diagnostic test or performed for attenuation correction or positioning, should be considered.

7.5. Procedure protocols

(311) Clinical protocols should be reviewed and revised when new equipment is installed, in order to ensure that all available dose-saving technologies are used effectively. Audit results should be taken into account when clinical protocols undergo periodic review.

7.5.1. Radiography and fluoroscopy protocols

(312) There is general agreement on what constitutes good radiographic technique (EC, 1996a,b), so clinical protocols should have been standardised. Technique should not generally be the cause of local or national DRL values being exceeded in radiography.

However, technique-related data should be reviewed for any indication of why values for DRL quantities might be high, such as use of too low a tube potential for examinations of the spine. Comparisons can be made with recommended techniques and exposure factors (EC, 1996a,b). Chest radiography requires imaging of both the low attenuation region of the lungs and the high attenuation mediastinum. The appropriate exposure factors have been an area of particular study (ICRU, 1995).

(313) Examinations that involve fluoroscopy are less standardised. However, the fluoroscopy programme (protocol) determines the image receptor dose rate and the relative rates at which tube current and potential are increased, and has a considerable influence on both patient dose and image quality. The choice of copper filtration options to reduce skin dose (i.e. spectral filtration), especially in interventional fluoroscopes, also has a significant influence on patient dose.

(314) A review of technique may identify a need to improve a clinical protocol to further optimise protection. For the majority of procedures, technique is not a good reason why a locally derived DRL value should be exceeded, and should not be a reason for increasing a local DRL value. If a given protocol results in a higher value for one or more DRL quantities (e.g. P_{KA}), the protocol should be reviewed.

7.5.2. CT protocols

(315) When median values of the DRL quantities for CT are too high or too low, there are many possible reasons, so careful analysis of the clinical protocols and the scanner settings is required. As discussed in Section 7.4.2, the ways in which controls affect patient dose and image quality for CT scanner models from the various manufacturers are different, so it is important that operators and medical physicists understand how the controls on their particular scanner affect the imaging process (ICRU, 2012). Because CT scanner models are so different, clinical protocols must never be transferred between CT scanners without adjustment, unless the CT scanners are identical models.

(316) First, check whether the clinical imaging task for which the DRL has been set is similar to one for which the scan is used. Then check whether DLP and $CTDI_{vol}$ are both too high. If the DLP is high, but the $CTDI_{vol}$ is within the normal range, then the scanned region may be longer than necessary or the number of scan sequences may be too great. A common reason for higher values of DRL quantities is the use of scan sequences both without and with enhancement with contrast material. Consideration should be given to whether these sequences are all necessary for the clinical task in hand.

(317) If both the DLP and $CTDI_{vol}$ are too high then these scan parameters should be reviewed:

a. Slice thickness.
b. Beam collimation.
c. Geometric efficiency.
d. Tube voltage.

e. Beam-shaping filter.
f. Is the helical pitch appropriate for the selected mAs?
g. Is the relationship of helical pitch and the mAs indicator understood?
h. Is the selected tube current modulation image noise indicator appropriate for the slice thickness?

(318) The operation of tube current modulation has an important effect on patient doses for individual patients, as discussed in Section 7.4.2. When CT protocols are set up, the process should take into account how the interaction of the different variables that can be set. Tube current modulation systems that use noise as an image quality indicator may require that higher noise levels be set for larger patients.

(319) The technique factors required for a CT examination and the resulting values of DRL quantities are dependent on patient size. Scans of larger patients may not require as low a noise level, because there is better delineation of internal organs than in thin patients. Each CT facility should establish specific scan protocols for different groups, based on patient size:

a. Paediatric patients: Weight, cross sectional area or age.
b. Adult patients within different weight ranges: Weight, equivalent diameter or cross sectional area.
c. Bariatric patients: Equivalent diameter or cross sectional area.

(320) Image quality should also be taken into account when median values of DRL quantities are too high or too low. This is a complex multi-factorial task and some of the factors involved are listed below:

a. Image display (field of view, window level and width).
b. Spatial resolution (focal spot size and reconstruction kernel for filter).
c. Temporal resolution (rotation time, reconstruction mode).
d. Timing of contrast material bolus (scan delay, rotation time and pitch).

7.5.3. Nuclear medicine protocols

(321) If the survey results exceed the local or national DRL value, but the imaging equipment performance is adequate according to QA tests, then justification for the use of an activity higher than the DRL value is a matter that requires discussion with the responsible clinician.

7.6. Operator skill

(322) Use of appropriate protocols for individual examinations depends on the operator's knowledge, skill and training, especially where new technology has been introduced. Practices of individual operators may vary, and staff with less experience may not be as adept. Operator skill also extends to the awareness and management of dose-saving features of the equipment.

(323) Variations in operator skill can result in large variations in values of DRL quantities (e.g. P_{KA}, Ka,r, $CTDI_{vol}$, DLP) for the same procedure. Comparison of multiple DRL quantities (Table 3.2) with local or national DRL values and among operators can be valuable. For fluoroscopy, fluoroscopy time and the number of images in digital sequences can provide an obvious comparator, while review of relative values for Ka,r and P_{KA} will provide additional information on the extent of beam collimation by different operators. Similarly, comparison of both $CTDI_{vol}$ and DLP can be useful for CT.

(324) Radiographers perform barium enemas routinely in some healthcare facilities, and suitably trained nurse practitioners can perform limited interventional procedures. Clinical protocols should be refined before groups with less general medical or radiology education than physicians are trained to carry them out.

(325) As operators gain more experience, patient doses may decrease to some extent. Thus, results from surveys and comparisons between different operators, while useful, must be put into context and used appropriately to advise staff and contribute to improving technique where appropriate. As the sophistication of the examination increases, the evidence base shrinks. Different operators may employ different techniques to perform similar procedures.

(326) Where median values for individual operators are found to be higher than for other operators, and especially when they exceed the DRL value, training on specific equipment may be necessary, particularly with respect to the dose saving features. Retraining of operators will be required when new techniques have been introduced, but may also be required when operators have developed bad habits that result in patient doses that are not optimised.

7.7. Procedure complexity and case mix

(327) Case mix can be a factor at a facility for some examinations, meaning that it may not be appropriate to compare DRL quantities for procedures performed in certain patient populations with DRL values determined from surveys of the general population. Some examples are:

a. Patients with more complex clinical conditions or other specific patient groups may be sent for interventional examination or treatment to a particular department or hospital, resulting in more prolonged examinations and higher patient doses in that department.
b. Expertise may lead to particular physicians carrying out the more difficult cases, the consequence of which is that values of the DRL quantities for the procedures that they perform are higher.
c. Chest x rays in a specialist clinic may require a higher level of image quality for specific diagnoses.
d. Other radiographs in a specialist clinic, obtained for specific indications, may require additional views beyond those used typically.

(328) It may be appropriate for median values of DRL quantities from certain case mixes, such as in the examples above, to exceed the national DRL value. In such cases, a separate local DRL value that is greater than the national/regional value could be set for that environment, based on local surveys and taking into account the differences in patients and practice.

7.8. Outcome of the investigation

(329) Comparisons of local audit data to the national DRL value should trigger the first step in the optimisation process and inform the responsible individuals where to prioritise the optimisation effort. Once the investigation has revealed the reason(s) for any higher values of DRL quantities, remedial action needs to occur (Fig. 7.1). This should be within the context of the risk management strategy of the organisation.

(330) Findings relating to deficiencies in equipment performance might reinforce the expected outcome and provide further support for the case to replace equipment. However, if the findings are unexpected, then a critical review of QA and maintenance programmes might be required. Examples include:

a. High values of DRL quantities for CR or DR might trigger adjustment of the AEC. A qualified medical physicist should work together with the service engineer to advise on and check the performance of the AEC.
b. For radiography, if the conclusion is that technique is responsible, then standard operating procedures and protocols will have to be reviewed.
c. For fluoroscopy, the action taken will depend on the complexity of the examination and findings of the subsequent investigation. Those involved should review the technique critically and question the appropriateness of different components.
d. For CT, it is likely that a review of the clinical protocol and the way in which the scanner controls are set is required. This is likely to require input from a radiologist, a medical physicist and a radiographer.
e. If the national DRL value is exceeded because of case mix, there is a sound reason for increasing the local DRL.

(331) Many dose savings can be made without affecting the image adversely. However, patient dose must not be reduced so much that the images become non-diagnostic. Dose reduction is not an end unto itself. *The adequacy of the image is paramount.* Image quality must never be reduced to the point where there is a risk that it is not sufficient for the medical imaging task. If it is suspected or possible that the diagnostic potential of the image could be affected by any changes made, then appropriate tests must be undertaken to confirm that this is not the case before the changes are implemented.

(332) Once optimisation of protection has been undertaken, a repeat survey should be carried out to determine whether the DRL quantities have been brought down to an appropriate level.

7.9. References

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8. SUMMARY OF THE COMMISSION'S RECOMMENDATIONS

8.1. General

1. Diagnostic reference levels (DRLs) should be used to evaluate whether, in routine circumstances, the amount of ionising radiation applied for a medical imaging procedure at a local healthcare facility, when assessed for a representative sample of standard-sized patients (not individual patients) for a defined clinical task, is too high or too low. The DRL process allows identification of equipment and procedures for which radiation dose levels are high, so that optimisation of protection can be undertaken.
2. A DRL value is considered to be exceeded when the local median value of a DRL quantity for a representative sample of standard-sized patients is greater than the local, national, or regional DRL value.
3. DRLs may be established by authorised bodies. The numerical values of DRLs are advisory. However, an authorised body may require implementation of the DRL concept.
4. Organisations responsible for different components of the tasks of collating data on DRL quantities and setting national DRLs should be identified in each country or region.
5. DRLs should not be used to evaluate medical imaging tasks where the relative tissue dose distribution in the body is appreciably different from that of the medical imaging task used to establish the DRL.
6. DRL values shall not be used for individual patients or as trigger (alert or alarm) levels for individual patients or individual examinations.
7. Comparison of local practices to DRL values is not sufficient, by itself, for optimisation of protection. Image quality or, more generally, the diagnostic information provided by the examination (including the effects of post-processing), must be evaluated as well, and methods to achieve optimisation should be implemented.
8. All individuals who have a role in subjecting a patient to a medical imaging procedure should be familiar with DRLs as a tool for optimisation of protection.
9. 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.

8.2. DRL quantities

10. Quantities used for DRLs should assess the amount of ionising radiation applied to perform a medical imaging task, and should be easily measured or determined. DRL quantities assess the amount of ionising radiation used for a medical imaging

procedure, not absorbed dose to a patient or organ. The one exception is mammography, for which mean glandular dose (D_G) may be used.

11. DRL quantities should be appropriate to the imaging modality being evaluated.

12. The Commission stresses that effective dose (radiological protection quantity used for other purposes in the ICRP system of radiological protection) should not be used as a DRL quantity. It introduces extraneous factors that are neither necessary nor pertinent for the purpose of a DRL.

13. For projection radiography, two DRL quantities are recommended: entrance surface air kerma, Ka,e (or incident air kerma, Ka,i), and kerma-area product (P_{KA}), in order to simplify assessing proper use of collimation, especially in paediatrics.

14. DRLs developed for advanced radiographic techniques (e.g. tomosynthesis, dual-energy subtraction, contrast-enhanced subtraction, cone-beam computed tomography) need to take into account the 'multiple image' aspect of the technique and should distinguish these procedures from more standard procedures.

15. For mammography, the recommended DRL quantity is one or more of incident air kerma (Ka,i), entrance surface air kerma (Ka,e), and mean glandular dose (D_G), with the choice of quantity depending on local practices.

16. For mammography, a simple approach could be setting DRLs for breasts of 5.0 cm ± 0.5 cm thickness. Establishing DRLs for different breast thicknesses is a more complex but better approach to refine DRLs for mammography.

17. For interventional radiology, all of the following DRL quantities are recommended (if available): air kerma-area product (P_{KA}), cumulative air kerma at the patient entrance reference point (Ka,r), fluoroscopy time, and the number of radiographic images (e.g. cine images in cardiology and digital subtraction angiography images in vascular procedures).

18. The recommended DRL quantities for CT are volume-weighted computed tomography dose index ($CTDI_{vol}$) and dose length product (DLP). The number of scan sequences in the examination may be helpful as well. Size-specific dose estimates (SSDE) may be used in addition.

19. The recommended $CTDI_{vol}$ value is the $CTDI_{vol}$ for each sequence. The recommended DLP value is the cumulative DLP for the entire examination. DLP values for individual scan sequences can be useful as well, and may be used in addition to the cumulative DLP.

20. For nuclear medicine, the appropriate DRL quantity is the administered activity per kg body weight of a specific radionuclide for a specific clinical task and, if relevant, the radiopharmaceutical used. Setting a fixed maximum administered activity for very obese patients may also be considered. It is recognised that in many countries, a standard activity is used in clinical practice for adult patients.

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

22. Since DRLs for nuclear medicine procedures and CT procedures apply to radiation from very different modalities, and use different DRL quantities, for hybrid imaging procedures, it is appropriate to set and present DRL values for each modality independently.

8.3. Use of median values of the DRL survey distribution

23. Compliance with DRLs does not indicate that the procedure is performed at an optimised level with regard to the amount of radiation used. The Commission recognises that additional improvement can be obtained by using the median value (the 50th percentile) of the distribution used to set the national or regional DRL value.

24. This median value can serve as an additional tool to aid in optimisation, and may be a desirable goal at which to aim using standard techniques and technologies, and represents a more optimum use of the applied radiation.

25. When the facility's median value of a DRL quantity is lower than the median value of the national or regional DRL survey distribution, image quality (or diagnostic information, when multiple images are used) may be adversely affected and should be considered as a priority in the review.

8.4. DRL surveys

26. The Commission recommends setting local and national DRL values based on surveys of the DRL quantities for procedures performed on appropriate samples of patients. The use of phantoms is not sufficient in most cases. When phantoms are used, the effects of operator performance, the selected imaging protocol, and patient variability are not taken into account.

27. The use of phantoms is important in the investigation of x-ray equipment performance, and is important in evaluating the performance of fluoroscopy and CT equipment with respect to the amount of radiation used during the optimisation of protection.

28. Calibrations of all dosimeters, kerma-area product meters, etc., used for patient dosimetry should be performed regularly and should be traceable to a primary or secondary standard laboratory.

29. The accuracy of DRL quantity data produced by and transferred from x-ray systems should be periodically verified by a medical physicist.

30. The examinations/procedures included should, in general, represent the most frequent examinations performed in the region for which dose assessment is practicable, with priority given to those that result in the highest patient radiation dose.

31. National surveys for setting DRLs should normally include medium- and large-sized healthcare facilities that have a sufficient workload to ensure that data for a representative selection of patients can be obtained. The sample should also cover the range of healthcare providers.

32. For large countries, a survey of a random selection of a small proportion of all the healthcare facilities in the country can provide a good starting point for setting

national DRLs. Results from 20-30 facilities are likely to be sufficient in the first instance. In a small country with fewer than 50 facilities, an initial survey of 30%-50% of them may suffice.

33. A survey for a particular examination in a facility should normally involve collection of data on DRL quantities for at least 10-20 patients, and preferably 20-30 for diagnostic fluoroscopy examinations and 50 patients for mammography. For paediatrics, these figures may need to be decreased for facilities where relatively few children are examined.

34. There should be some standardisation of weight for adult patients included in surveys of diagnostic procedures if data are collected from fewer than 50 patients, e.g. patients with weights between 60 kg and 80 kg for a mean weight of 70 kg ± 5 kg.

35. Hospital Information Systems and Radiology Information Systems can provide data for large numbers of patients. As with all DRL surveys, the results rely on the accuracy of data entry, and may not include patient weight.

36. Radiology Information Systems and associated software may permit data on DRL quantities to be obtained in an automated fashion. When automated processes are used, the data for all cases of a specific procedure should be obtained and used for optimisation.

8.5. Setting DRL values

37. The numerical value of the DRL should be tied to defined clinical and technical requirements for the selected medical imaging task.

38. The appropriate image quality or diagnostic information needed for the clinical task should be the priority when setting DRLs. DRLs may differ for different clinical tasks, especially for CT.

39. It is important when developing DRLs that all data collected come from similar procedures across all participating facilities. This ensures that comparisons among facilities remain valid and useful.

40. It may be important to specify in detail the views normally included and the clinical task associated with the procedure. This may be required where differing exposure factors or different views (or numbers of views) are employed for different clinical indications.

41. When two imaging modalities are used for the same procedure (e.g. PET/CT, SPECT/CT), it is appropriate to set and present DRLs for both modalities independently.

42. DRL values are dependent on the state of practice and the available technology (including post-processing software) at a particular point in time.

43. Median values (not mean values) of the distributions of data collected from a representative sample of standard-sized patients should be used for comparison to DRLs. The mean can be affected substantially by a few high or low values.

44. National DRLs should be set as the 75th percentile of median values obtained in a sample of representative centres.

45. If regional (multinational) DRLs are created, they should be set as the median value of the national DRLs (each of which is set at the 75th percentile) for the countries in the region. If the sample of available data is small, other approaches may be used by agreement among the involved countries.

46. The process to set and update DRLs should be both flexible and dynamic. Flexibility is necessary for procedures where few data are available (e.g. interventional procedures in paediatric patients), or from only one or a few centres. A dynamic process is necessary to allow initial DRLs to be derived from these data while waiting for a wider survey to be conducted.

47. When a procedure is not performed on a regular basis in most hospitals, local DRL values may be determined using the data from a single large hospital with a relevant workload of procedures (e.g. a specialised paediatric hospital).

48. Local DRLs set by a group of radiology departments or even a single facility can play a role, where effort has already been invested in optimisation. The group could set a local DRL value based on more regular surveys of local practice that will normally be lower than any national DRL value. Local DRL values can also be set for newer technologies that enable lower dose levels to be used in achieving a similar level of image quality.

8.6. DRLS for interventional procedures

49. The Commission recommends retaining the term “diagnostic reference level” for the DRL process as applied to interventional procedures.

50. For interventional procedures, complexity of the procedure may be considered in setting DRLs and a multiplying factor for the DRL value (e.g. 2, 3 or more) may be appropriate for more complex cases of a procedure.

51. If possible, the data from all interventional procedures performed (not just from a limited sample) should be collated to derive local and national DRLs.

8.7. Paediatric DRLs

52. A single ‘representative patient’ should not be used to define DRLs for paediatric imaging, since weight in children can vary by a factor of more than 100 from a premature infant to an obese adolescent.

53. The amount of administered radiation for examinations of children can vary tremendously due to the great variation in patient size and weight, from neonates to adult-sized adolescents. This variation in patient radiation dose is appropriate. Variation in patient radiation dose due to incorrect technique or failure to adapt the imaging protocol from adults to children to account for both paediatric diseases and paediatric patient size is not appropriate.

54. Appropriate weight bands (generally with 10 kg intervals) are recommended for establishing paediatric DRLs and should be promoted for paediatrics. Age bands (<1 y; 1-<5 y; 5-<10 y and 10-<16 y and older ages, if appropriate, in another additional group) can be used if age is the only available measure.

55. For CT, the DRL quantities are $CTDI_{vol}$ and DLP, based preferably on calibration with a 32 cm phantom for body examinations and a 16 cm phantom for head examinations. Values for these quantities should be obtained from patient examinations. Size-specific dose estimates (SSDE) may be used as an additional source of information for optimisation.

56. Modern CT scanners permit determination of effective diameter or patient equivalent thickness. This should be considered as an additional refinement for setting paediatric DRLs.

57. For nuclear medicine imaging, administered activities should be adjusted based on agreed factors linked to size or weight. This is especially relevant for paediatrics.

8.8. Application of DRLs in clinical practice

58. National and regional DRL values should be revised at regular intervals (3-5 years) or more frequently when substantial changes in technology, new imaging protocols or post-processing of images become available.

59. Median values of the DRL quantity for medical imaging procedures in a representative sample of standard-sized patients for a specific x-ray room, radiology department, or other facility should be compared with local, national or regional DRL values to identify whether the data for that location are substantially higher or lower than might be anticipated.

60. If a local or national DRL value for any procedure is exceeded, an investigation should be carried out without undue delay, and appropriate corrective action should be taken.

61. When corrective action is required, it is necessary to keep in mind that DRL values are not dose limits.

62. Corrective action (optimisation of protection) should include a review 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.

63. In the optimisation process, account must always be taken of the level of image quality required for the medical imaging task. Image quality must always be adequate to provide the information required for the clinical purpose of the examination.

64. When a facility's median value of a DRL quantity is too low, image quality (or diagnostic information, when multiple images are used) may be affected adversely. Image quality should be examined as a priority when the examination protocol is reviewed.

65. The DRL audit 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.

66. Local surveys of DRL quantities should normally be carried out as part of the clinical audit. A representative selection of examinations for each x-ray unit should be surveyed at intervals of about three years, and whenever substantial changes in technology or software have been introduced.

67. Local surveys of DRL quantities, as part of the clinical audit, should be performed annually for CT and interventional procedures. Annual surveys are also appropriate as part of the clinical audit for SPECT/CT and PET/CT.

68. If continuous collection of data on DRL quantities is possible through automated collation of data from electronic databases, then the dose management process may take the form of a regular review of all the data to identify any adverse trends.

69. The method for managing and achieving optimisation for dental radiography differs from the method for other x-ray applications. Dental DRL values are set in terms of incident air kerma measured during routine tests. Based on test results, recommendations can be made on changes to equipment settings and adjustments. The investigator should work with the dentist to optimise protection. Improvement in protection can be realised which otherwise might not be achieved.

Annex A. PREVIOUS ICRP RECOMMENDATIONS ON DRLS

Key Points

- **DRLs are used in the optimisation of radiological protection in medicine. A DRL is a form of investigation level to identify unusually high (or low) levels, which calls for local review if consistently exceeded (or below).**
- **DRLs should be used by regional, national and local authorised bodies. Implementation of the DRL concept may be required by an authorised body.**
- **The numerical value of a DRL is advisory. The numerical value is not for regulatory or commercial purposes, not a dose constraint, and not linked to limits or constraints.**
- **The concept of DRLs allows flexibility in their selection and implementation.**
- **The Commission's previous advice did not specify quantities, numerical values or details of implementation for DRLs. This has been the task of the regional, national and local authorised bodies, each of which should meet the needs in its respective area.**
- **The rationale for the previous advice was that any reasonable and practical approach, consistent with the advice, will improve the management of patient doses in medical imaging.**

A.1. Introduction

(A1) Previously, advice was provided to regional, national and local authorised bodies and the clinical community on the application of DRLs as a practical tool in diagnostic radiology and nuclear medicine (ICRP, 2001). Achieving acceptable image quality or adequate diagnostic information, consistent with the medical imaging task, is the overriding clinical objective. DRLs are then used to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose. At that time, a review was conducted of the various approaches that had been taken by authorised bodies, working in concert with professional medical groups, to establish DRLs for medical imaging tasks. While the approaches were not uniform in aim and methodology, it was concluded that there were a variety of ways to implement the concept of DRLs, depending on the medical imaging task of interest, the regional, national or local state of practice, and the regional, national or local preferences for technical implementation.

(A2) The existing ICRP guidance was briefly reviewed, the approaches that had been taken were summarised, and additional advice was presented (ICRP, 2001). The advice given then provided a framework for DRLs that was consistent with earlier ICRP guidance, but allowed more flexibility in their selection and use. While some illustrative examples were given, the advice did not specify the quantities to be used, the numerical values to be set for the quantities, or the technical details of how regional, national or local authorised bodies should implement DRLs. A review and summary of that information are given here.

A.2. Existing ICRP guidance

(A3) *Publication 60* (ICRP, 1991) provided the following recommendation in the section on optimisation of protection in medical exposure in paragraph (S34):

> "Consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional or regulatory agency, for application in some common diagnostic procedures. They should be applied with flexibility to allow higher doses where indicated by sound clinical judgment.".

(A4) *Publication 73* (ICRP, 1996) introduced the term "DRL", explained its place in the broader ICRP concept of reference levels, and expanded the *Publication 60* recommendation in (S34) in more detail [paragraphs (99) through (106) of *Publication 73*]. The main points are summarised below.

(a) The term used is DRL.

(b) DRLs are a form of investigation level, intended for use as a simple test to identify situations where levels of patient dose are unusually high. If it is found that procedures are consistently causing the relevant DRL to be exceeded, there should be a local review of the procedures and equipment in order to determine whether protection has been adequately optimised. In principle, there could also be a lower level (i.e. below which there is insufficient radiation dose to achieve a suitable medical image).

(c) DRLs are supplements to professional judgment and do not provide a dividing line between good and bad medicine. It is inappropriate to use them for regulatory or commercial purposes. They are not a dose constraint, and not linked to limits or constraints. The numerical value of a DRL is advisory.

(d) The examination types include diagnostic radiology and nuclear medicine (i.e. common exams and broadly defined types of equipment).

(e) Their selection is by professional medical bodies, using a percentile point on the observed distribution for patients, and specific to a country or region.

(f) The quantities should be easily measured, such as absorbed dose in air or tissue equivalent material at the surface of a simple standard phantom or representative patient for diagnostic radiology, and administered activity for diagnostic nuclear medicine.

A.3. Previous review of reference levels in medical imaging

(A5) Previously, there had been a number of approaches to reference levels (the earlier terminology for DRLs) used for medical imaging. Typically, reference levels were used as investigation levels (i.e. a QA tool), and their numerical values were advisory. However, authorised bodies could require implementation of the concept of a DRL.

(A6) There had been fairly consistent criteria for selecting reference levels, although the criteria used at that time differed for diagnostic radiology and nuclear medicine (and still do). In diagnostic radiology, reference levels usually had been derived from distributions of dosimetric quantities for patients observed in practice in the relevant region or country. Usually, only upper levels were defined, and lower levels were not specified. In nuclear medicine, reference levels were usually derived from pragmatic values of administered activity based on accepted custom and practice. Typically, all reference levels were developed through cooperation between authorised bodies and professional groups or specialists (i.e. clinical peer involvement).

(A7) There had been different aims for various reference levels. While reference levels apply to a selected medical imaging task, often the clinical and technical conditions were not fully defined, with the degree of definition dependent on the aim. At least three general aims could be identified:

(a) To improve a regional, national or local distribution observed for a general medical imaging task, by identifying and reducing the number of unjustified high or low values in the distribution;

(b) To promote good practice for a more specific medical imaging task; and

(c) To promote an optimum range of values for a specified medical imaging protocol.

(A8) There had been a number of different quantities used for reference levels. The quantity selected was dependent on the type of clinical procedure, for example, whether it was an individual radiographic projection, a procedure or examination consisting of multiple projections or field locations, or a diagnostic nuclear medicine procedure (i.e. a specific radiopharmaceutical and clinical purpose). The quantity used was also dependent on the body setting the reference level, and was related to the desired aim, local preference and the unique irradiation conditions.

(A9) The observations given above highlight the array of considerations and approaches to reference levels, whose features were displayed in Table 1 (Approaches to Reference Levels) and Table 2 (Listing of Reference Levels) of ICRP Supporting Guidance 2 (ICRP, 2001). Tables 1 and 2 listed approaches and values that had been selected by a number of authorised bodies prior to that time. Tables 1 and 2 were for background information and were not part of the additional advice given in ICRP (2001) and in this recap.

A.4. Underlying considerations

(A10) In order to interpret correctly the relationship between a change in the numerical value of a quantity used as a DRL and the corresponding change in patient tissue doses that determine the relative patient risk, the following considerations are important:

(a) The numerical value of the DRL should be tied to defined clinical and technical requirements for the medical imaging task. The requirements can be general or specific.

(b) The relative tissue dose distribution in the body should not change appreciably among patients undergoing the selected medical imaging task. A proportional change in the measured quantity should correspond to a proportional and uniform percentage change in the individual tissue doses. If the relative tissue-dose distribution in the body is appreciably different from that used to establish the DRL, due to a different field size, field location, beam quality or other technical factor that alters the internal dose distribution, then interpretation of a change in the measured quantity with regard to the change in tissue doses (and therefore the patient risk) would be ambiguous. In setting DRLs, regional, national and local authorised bodies and professional groups should be cognizant of these considerations.

A.5. Advice on DRLs provided in ICRP (2001)

A.5.1. Objective of a DRL

(A11) The objective of a DRL is to help avoid radiation DRL quantity to the patient that does not contribute to the clinical purpose of a medical imaging task. This is accomplished by comparison between the numerical value of the DRL (derived from relevant regional, national or local data) and the mean or other appropriate value observed in practice for a suitable reference group of patients or a suitable reference phantom. A reference group of patients is usually defined within a certain range of physical parameters (e.g. height, weight). If an unselected sample of patients were used as a reference group, it would be difficult to interpret whether the observed value for the sample is higher or lower than the DRL. A DRL is not applied to individual patients.

A.5.2. Uses for a DRL

(A12) A DRL can be used:

(a) To improve a regional, national or local distribution of observed results for a *general medical imaging task*, by reducing the frequency of unjustified high or low values;

(b) To promote attainment of a narrower range of values that represent good practice for a *more specific medical imaging task*; or

(c) To promote attainment of an optimum range of values for a *specified medical imaging protocol*.

(A13) A “general imaging task” is an imaging task performed for a general clinical purpose, with minimum specification of other factors e.g. a posteroanterior (PA) chest

radiograph with the clinical purpose and technique factors unspecified. A "more specific medical imaging task" is an imaging task for a clearly defined clinical purpose, but with allowance for differences among medical facilities in other technical and clinical details, e.g. a PA chest radiograph with the clinical purpose and the general technique (such as high kVp) specified, but the detailed technique factors unspecified. A "specified medical imaging protocol" is a clinical protocol with a fully defined set of specifications that is followed, or serves as a nominal baseline, at a single facility (or several allied facilities), e.g. a protocol for a PA chest radiograph that specifies the clinical purpose, the technical conduct of the procedure, the image quality criteria, any unique patient characteristics, and other appropriate factors. Uses (a), (b) and (c) are differentiated by the degree of specification for the clinical and technical conditions selected by the authorised body for a given medical imaging task.

(A14) Appropriate local review and action are taken when the value observed in practice is consistently outside the selected upper or lower level. This process helps avoid unnecessary tissue doses being received by patients in general and, therefore, helps avoid unnecessary risk for the associated radiation health effects.

A.5.3. Definitions and examples

(A15) This section provides the examples of quantities and their application to DRLs previously given by the Commission (ICRP, 2001) for the uses referred to in Section 2.5.2. The examples do not constitute recommendations; however, they illustrate generally the advice. More focussed discussions of desirable quantities for various medical imaging modalities are found in the relevant chapters of this report.

(A16) Examples of quantities and their application to improve a regional, national or local distribution of observed values for a *general medical imaging task* are:

(a) Incident air kerma (in air, no backscatter) (Ka,i) or entrance-surface air kerma (in air, with backscatter) (Ka,e) in mGy, for a given radiographic projection (e.g. PA chest);

(b) Air kerma-area product (P_{KA}) in Gy·cm^2 or mGy·cm^2 for a given type of fluoroscopic examination that has a well-defined anatomical region of clinical study (e.g. barium enema); and

(c) Administered activity (A) in MBq for a given nuclear medicine imaging task using a given radiopharmaceutical [e.g. lung perfusion with Tc-99m macroaggregated albumin (MAA)].

(A17) Examples of quantities and their application to promote attainment of a narrower range of values that represent good practice for a *more specific medical imaging task* are:

(a) Incident air kerma (in air, no backscatter) (Ka,i) or entrance-surface air kerma (in air, with backscatter) (Ka,e) in mGy, for a specific radiographic imaging task. The clinical

purpose is defined, but the x-ray equipment, technique factors, and image quality criteria may vary among facilities;

(b) Air kerma-length product (P_{KL}) in mGy·cm for a given type of computed tomography (CT) examination that has a well-defined anatomical region of clinical study (e.g. routine abdominal CT scan), with specified clinical objective, image quality criteria and technical factors. The x-ray equipment (i.e. the CT system) may vary among facilities; and

(c) Air kerma-area product (P_{KA}) in mGy·cm^2 for a specific fluoroscopic examination. The clinical purpose is clearly defined, but the type of equipment, technique factors and patient characteristics may differ within or among facilities. The relative tissue dose distribution is expected to be minimally variable, such that a proportional change in P_{KA} corresponds to a nearly proportional change in absorbed dose for each of the irradiated tissues.

(A18) Examples of quantities and their application to promote attainment of an optimum range of values for a *specified medical imaging protocol* are:

(a) Tube potential (kVp) for a specific CT protocol. The clinical purpose, type of equipment, technique factors and patient characteristics are defined.

(b) Administered activity (A) in MBq for a specific imaging protocol using a specific radiopharmaceutical for SPECT. The clinical purpose, type of equipment, technique factors and patient characteristics are defined.

A.5.4. Note on fluoroscopically-guided interventional procedures

(A19) For FGI procedures, DRLs, in principle, could be used to promote the management of patient doses with regard to reducing the probability of stochastic radiation effects. However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure are strongly dependent on the individual clinical circumstances. A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative "complexity" of the procedure. More than one quantity (i.e. multiple DRLs) may be needed to evaluate patient dose and stochastic risk adequately.

(A20) DRLs are not applicable to the management of tissue reactions (e.g. radiation-induced skin injuries) from FGI procedures. In this case, the objective is to avoid tissue reactions in individual patients undergoing justified, but long and complex procedures. The need here is to monitor in real time whether the threshold doses for tissue reactions are being approached or exceeded for the actual procedure as conducted on a particular patient. The relevant risk quantity is absorbed dose in the skin at the site of maximum cumulative skin dose. A helpful approach is to select values for maximum cumulative absorbed dose in the skin at which various clinical actions regarding the patient's record or care (related to potential radiation-induced skin injuries) are taken (ICRP, 2000). Then, during actual procedures, appropriate quantities that can help indicate the maximum cumulative absorbed

dose in the skin are monitored [The Commission has since provided advice on monitoring maximum cumulative absorbed dose in the skin (peak skin dose) (ICRP, 2013)].

A.5.5. Local flexibility in setting DRLs

(A21) DRLs should be used by authorised bodies to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose.

(A22) The concept of a DRL permits flexibility in the choice of quantities, numerical values, and technical or clinical specifications, in order to allow authorised bodies to meet the objectives relevant to their circumstances. The guiding principles for setting a DRL are:

(a) The regional, national or local objective is clearly defined, including the degree of specification of clinical and technical conditions for the medical imaging task;

(b) The selected value of the DRL is based on relevant regional, national or local data;

(c) The quantity used for the DRL can be obtained in a practical way;

(d) The quantity used for the DRL is a suitable measure of the relative change in patient tissue doses and, therefore, of the relative change in patient risk for the given medical imaging task; and

(e) The manner in which the DRL is to be applied in practice is clearly illustrated.

(A23) Authorised bodies, in conjunction with professional medical bodies, are encouraged to set DRLs that best meet their specific needs and that are consistent for the regional, national or local area to which they apply.

A.6. References

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