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Diagnostic Reference Levels in Medical Imaging

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Aims and Scope

The International Commission on Radiological Protection (ICRP) is the primary body in protection against ionising radiation. ICRP is a registered charity and is thus an independent non-governmental organisation created at the 1928 International Congress of Radiology to advance for the public benefit the science of radiological protection. ICRP provides recommendations and guidance on protection against the risks associated with ionising radiation from artificial sources such as those widely used in medicine, general industry, and nuclear enterprises, and from naturally occurring sources. These are published approximately four times each year on behalf of ICRP as the journal *Annals of the ICRP*. Each issue provides in-depth coverage of a specific subject area.

Subscribers to the journal receive each new publication as soon as it appears so that they are kept up to date on the latest developments in this important field. While many subscribers prefer to acquire a complete set of ICRP publications, single issues of the journal are also available separately for those individuals and organisations needing a single publication covering their own field of interest. Please order through your bookseller, subscription agent, or direct from the publisher.

ICRP is composed of a Main Commission, a Scientific Secretariat, and five standing Committees on: radiation effects, doses from radiation exposure, protection in medicine, the application of ICRP recommendations, and protection of the environment. The Main Commission consists of a Chair and twelve other members. Committees typically comprise 10–15 members each.

ICRP uses Task Groups to prepare its reports. A Task Group is usually chaired by an ICRP Committee member and usually contains a number of specialists from outside ICRP. Thus, ICRP is an independent international network of specialists in various fields of radiological protection, and, at any one time, about two hundred eminent scientists and policy makers are actively involved in the work of ICRP. The Task Groups are assigned the responsibility for drafting reports on various subjects, which are reviewed and finally approved by the Main Commission. These reports are then published as the *Annals of the ICRP*.

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Diagnostic Reference Levels in Medical Imaging

Editor-in-Chief
C.H. CLEMENT

Associate Editor
H. OGINO

Authors on behalf of ICRP
E. Vañó, D.L. Miller, C.J. Martin, M.M. Rehani, K. Kang,
M. Rosenstein, P. Ortiz-López, S. Mattsson, R. Padovani,
A. Rogers

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Editorial

DIAGNOSTIC REFERENCE LEVELS – KEEPING 'THE SYSTEM' SIMPLE

What is a DRL? An internet search tells me it is an initialism (i.e. an abbreviation that uses the first letter of each word in a phrase), not an acronym, and with 38 definitions on the internet, 'diagnostic reference level' comes eighth in a table of such an initialism, with 'daytime running lights' placed first.

It is easy for radiological protection professionals to assume that everyone knows what DRL stands for and what it means. Diagnostic reference levels (DRLs) have been an essential tool in the International Commission on Radiological Protection's (ICRP's) radiological protection armamentarium for the last 20 years, and it is 15 years since specific advice on the subject was last written by the Commission.

All aspects of medicine have developed rapidly in the last few decades, but this applies particularly to medical imaging and treatments using ionising radiation. Not surprisingly, it is a challenge for healthcare professionals to keep up with such changes and to meet the expectations of an increasingly demanding public. As an advisory body, ICRP aims to provide relevant and up-to-date guidance for different sectors, including medicine; hence, this latest publication on DRLs is timely. The language of radiological protection is complex, and, at times, confusing to those who are not experts in the field. As such, it is important for ICRP to provide practical information on the application of DRLs for different types of imaging and to clarify terminology.

A few facts regarding DRLs are also easy to overlook. They are not intended to be applied to individual patients and should not be used as dose limits. Instead, the DRL is an essential tool in the optimisation process, especially as dose limits are not relevant in the medical exposure of patients. In surveys performed to acquire dose information for different procedures, it is important to identify radiation doses that are too low as well as too high, as both may have consequences for the patient.

This publication introduces the terms 'DRL quantity' and 'DRL value', and recommends the use of a facility's median value (rather than mean value) for DRL quantity as this is recognised to be more robust and representative of the patient population. The effectiveness of DRLs can be documented by comparing data over time and reviewing trends. DRL values, and hence doses, in the UK have fallen significantly in surveys performed over the last 30 years.

Use of the DRL has broadened with the introduction of newer medical technology and procedures, and DRL values have been established for interventional as well as diagnostic procedures. This is a challenge due to the wide distribution of patient doses for the same procedure, even in the same facility. However, data have been collected for many different interventional procedures, and databases have been established successfully.

It could be argued that a DRL is not appropriate for a 'therapeutic' procedure rather than a 'diagnostic' procedure. Perhaps ICRP should consider a 'therapeutic reference level' (TRL) or 'interventional reference level' (IRL). There are 42 and 31 definitions of TRL and IRL, respectively, on the internet. Introducing an IRL, in particular, would cause huge problems in radiological protection, as similar language is already used in a different context.

At present, and for the foreseeable future, ICRP is aiming to provide clarification rather than confusion. As such, the Commission recommends that the term 'DRL' should continue to be used for both diagnostic and interventional procedures, as the purpose of providing a tool for optimisation is the same, and the introduction of a new name would cause more confusion.

This brings me back to where I started; what is in a name or initialism? For those struggling to differentiate an initialism from an acronym or even an abbreviation, ICRP is hoping to keep the system simple with the well-known DRL.

CLAIRE COUSINS
CHAIR, ICRP

ICRP Publication 135

DIAGNOSTIC REFERENCE LEVELS IN MEDICAL IMAGING

ICRP PUBLICATION 135

Approved by the Commission in May 2017

Abstract–The International Commission on Radiological Protection (ICRP) first introduced the term 'diagnostic reference level' (DRL) in 1996 in *Publication 73*. The concept was subsequently developed further, and practical guidance was provided in 2001. The DRL has 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 DRLs, and application of the DRL concept to newer imaging technologies. This publication is intended as a further source of information and guidance on these issues. Some terminology has been clarified. In addition, this publication recommends quantities for use as DRLs for various imaging modalities, and provides information on the 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 highlights the importance of including information on DRLs in training programmes for healthcare workers. The target audience for this publication is national, regional, and local authorities; professional societies; and facilities that use ionising radiation 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

AUTHORS ON BEHALF OF ICRP
E. VAÑÓ, D.L. MILLER, C.J. MARTIN, M.M. REHANI, K. KANG,
M. ROSENSTEIN, P. ORTIZ LÓPEZ, S. MATTSSON, R. PADOVANI, A. ROGERS

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 USA and the UK. In the 1970s, the Nationwide Evaluation of X-ray Trends surveys began in the USA, and in the 1980s, the National Radiological Protection Board (now Public Health England) surveys in the UK 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 USA, then in the UK, 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 supporting guidance expanding the use of DRLs to interventional radiology, and giving further advice on flexibility in their selection and implementation. This publication is the result of the work of a Working Party of ICRP Committee 3, which was created during the annual meeting held in Bethesda, MD, USA on 22–28 October 2011. Digital techniques and interventional procedures, and new combined imaging techniques such as positron emission tomography-computed tomography require new and updated advice. Committee 3 realised that the proper use of DRLs was still rather poor within the medical community. The target audience for this publication is medical physicists, radiologists, nuclear medicine specialists, radiographers, industry, and health and regulatory authorities.

The membership of the Working Party was as follows:

E. Vañó (Chair)	C.J. Martin	M.M. Rehani
K. Kang	D.L. Miller	

The corresponding members were:

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

Main Commission critical reviewers were:

J. Boice	C. Cousins

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

(*2009–2013*)

E. Vañó (Chair)	I. Gusev	H. Ringertz
J-M. Cosset (Vice-Chair)	J.W. Hopewell	M. Rosenstein
M.M. Rehani (Secretary)	P-L. Khong	Y. Yonekura
K. Åhlström Riklund	S. Mattsson	B. Yue
M.R. Baeza	D.L. Miller	
L.T. Dauer	P. Ortiz López	

(*2013–2017*)

E. Vañó (Chair)	L.T. Dauer	P. Ortiz López
D.L. Miller (Vice-Chair)	S. Demeter	P. Scalliet
M.M. Rehani (Secretary)	K. Kang	Y. Yonekura
K. Åhlström Riklund	P-L. Khong	B. Yue
K. Applegate	R. Loose	
M. Bourguignon	C.J. Martin	

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 Supporting Guidance (ICRP, 2001a). This development and the 2001 advice are summarised in Annex A.

(b) As the Commission stated in *Publication 103* (ICRP, 2007a), one of the principles of optimisation of protection in medical exposures is implemented through the use of DRLs. The DRL has 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, but they should be considered for imaging for treatment planning, treatment rehearsal, and patient set-up verification in radiotherapy.

(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 the DRL process, and application of the concept to certain newer imaging technologies [e.g. dual-energy computed tomography (CT), positron emission tomography-CT (PET-CT), single photon emission CT (SPECT-CT), cone-beam CT, digital radiography, tomosynthesis], and additional difficulties in paediatric practice, particularly due to the wide range in sizes.

(d) In this publication, the Commission recommends the use of four different DRL terms (defined in the Glossary):

- DRL (a form of investigation level used as a tool to aid optimisation of protection in the medical exposure of patients for diagnostic and interventional procedures).
- DRL quantity (a commonly and easily measured or determined radiation metric that assesses the amount of ionising radiation used to perform a medical imaging task).
- DRL value (an arbitrary notional value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of the DRL quantity obtained from surveys or other means).
- DRL process (the cyclical process of establishing DRL values, using them as a tool for optimisation, and then determining updated DRL values as tools for further optimisation).

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

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

(g) A full set of the Commission's recommendations is provided in Section 8 of this publication. In addition, each section is preceded by a set of main points that summarise the principal concepts in that section. A limited summary of the most important points and recommendations is presented below for the convenience of the reader.

2. Diagnostic reference levels

(h) The principles of justification and optimisation of protection are key and complementary radiological safety tenets. DRL is the Commission's term for 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 value is a selected level of a DRL quantity for broadly defined types of equipment for typical examinations for groups of patients within an agreed weight range or, in certain specific circumstances, a standard phantom. DRLs do not apply to individual patients. They are derived as an arbitrary threshold from radiation metric data 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.

(i) The application of the DRL process 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 postprocessing) must also be evaluated. Methods to achieve optimisation that encompass both the DRL process and image quality evaluation should be implemented. In some cases, optimisation may result in an increase in dose.

(j) A dose below a DRL value 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 national distribution of values of dose-related quantities to provide additional guidance for further optimisation efforts. If local median values of the DRL quantity are below the national median value, image quality, rather than the amount of radiation used, should be considered as a greater priority in this additional optimisation process. The basis for this recommendation is that if practices at the local facility have already achieved levels of radiation use that are below the national median value, further reduction in the amount of radiation used is not the principal concern. When local practices result in levels of radiation that are below the national median value, ensuring that image quality is adequate should be a priority.

3. DRL quantities and values

(k) DRL quantities 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 DRL values for both modalities independently.

(l) An authorised body may require implementation of the DRL process as a tool to promote optimisation, but DRL values should be considered advisory. 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 DRL values based on surveys of the appropriate DRL quantities for procedures performed on an appropriate sample of patients. The use of phantoms is not sufficient in most cases, as the effects of operator performance are not taken into account when phantoms are used.

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

(n) For interventional procedures, the complexity of the procedure may be considered in setting DRL values, and a multiplying factor for the DRL value may be appropriate for more complex cases of a procedure.

4. Local, national, and regional DRLs

(o) Organisations responsible for different components of the tasks of collating data on DRL quantities used for patient examinations and setting DRL values 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.

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

(q) 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 values. These may provide guidance on the need for optimisation or protection for neighbouring countries without their own DRL surveys or registries, and give an indication that further optimisation may be required for countries whose current national DRL values are above the regional DRLs.

(r) 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 postprocessing of images become available.

(s) As national DRLs for x-ray procedures need large surveys or registries, and these 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, or where no national DRL values exist, 'local DRLs or typical values' based on surveys might be introduced to further assist the optimisation process (Table 2.2). Examples of their use are to account for the substantial dose reduction that could be achieved through the application of iterative reconstruction techniques in CT, the replacement of computed radiography with flat-panel digital radiography, and the introduction of digital radiography detectors into dental radiography. Another example is the introduction of new methods for postprocessing of images. In small healthcare facilities, 'typical values' can be used (Table 2.2).

5. Using DRLs for optimisation of protection

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

(u) A DRL value is considered to be 'consistently exceeded' at a facility when the median value of the DRL quantity at the facility for a representative sample of patients within an agreed weight range is greater than the local, national, or regional DRL value.

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

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

(x) The highest priority for any diagnostic examination is achieving image quality sufficient for the clinical purpose, so that the images from the whole examination provide all the diagnostic information required and the clinical purpose is not jeopardised.

6. Considerations for paediatric examinations

(y) The radiation exposure for examinations of children, whether from radiological imaging or nuclear medicine, can vary tremendously due to the great variation in patient size and weight. This variation in patient radiation dose is appropriate. However, variation in patient radiation dose due to inappropriate technique or failure to adapt imaging protocols from adults to children to account for both paediatric diseases and different patient sizes is not appropriate, and requires optimisation of protection.

(z) Weight bands (see Section 6) are recommended for establishing paediatric DRLs for x-ray examinations of the trunk, and should be promoted for paediatrics.

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 (measured in mGy cm^2). The older terminology is 'dose-area product', which was abbreviated as DAP.

Air kerma at the patient entrance reference point ($K_{a,r}$)

The air kerma at a point in space located at a fixed distance from the focal spot (see Patient entrance reference point) cumulated from a whole x-ray procedure, expressed in Gy. The International Electrotechnical Commission (IEC, 2010) refers to this quantity as 'reference air kerma'. The US Food and Drug Administration uses the term 'cumulative air kerma'. The International Commission on Radiation Units and Measurements (ICRU) has not defined a symbol for this quantity – $K_{a,r}$ 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'.

Clinical audit

A systematic examination or review of medical radiological procedures that seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary (EU, 2013).

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

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

Consistently exceeded

A term used when comparing the median value of a DRL quantity at a facility with the appropriate local, national, or regional DRL value. The intended meaning of 'consistently' is 'in a majority of cases' and not 'over a period of time'.

Cumulative air kerma

See 'Air kerma at the patient entrance reference point'.

Detector dose indicator (DDI)

Indicator displayed on digital radiography equipment (computed radiography or digital radiography) related to the exposure of the image receptor and thereby linked to image quality. Ranges of DDI that should give acceptable images are recommended by equipment manufacturers to give radiographers who operate x-ray equipment an indication of exposure level. Also called 'exposure index'.

Deterministic effect

See 'Tissue reaction'.

Detriment

The total harm to health experienced by an exposed group and their descendants as a result of the group's exposure to a radiation source. Detriment is a multi-dimensional concept. Its principal components are 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 form of investigation level used as a tool 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 amount of radiation used for a specified procedure is unusually high or low for that procedure. For nuclear medicine, the administered activity (amount of radioactive material), or preferably the administered activity per unit of body weight, is used. 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 computed tomography scan of length L. By convention, the DLP is reported in the units of mGy cm. See ICRU Report 87 (ICRU, 2012) for more details.

DRL quantity

A commonly and easily measured or determined radiation metric (e.g. $K_{a,e}$, $K_{a,i}$, $CTDI_{vol}$, DLP, P_{KA}, $K_{a,r}$, D_G, administered activity) 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 for mammography, these quantities are not the tissue or organ doses received by the patient or quantities derived from such doses, as these doses cannot be measured or determined easily.

DRL process

The cyclical process of establishing DRL values, using them as a tool for optimisation, and subsequently determining updated DRL values as a tool for further optimisation.

DRL value

An arbitrary notional value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of the DRL quantity observed at: (a) a few healthcare facilities (termed 'local DRL value'); or (b) multiple facilities throughout a country (termed 'national DRL value'). Also see 'Local DRL', 'National DRL', and 'Regional DRL'.

Entrance-surface air kerma ($K_{a,e}$)

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 either ESAK or the older term ESD (measured in mGy).

Exposure index

See 'Detector dose indicator'.

Incident air kerma ($K_{a,i}$)

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 (measured in mGy).

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, 2007a). 'Kerma' is an acronym for 'kinetic energy released in a mass'.

Local DRL

A DRL for an x-ray procedure set in healthcare facilities within part of a country for a defined clinical imaging task, based on the 75th percentile value of the distribution of the appropriate DRL quantity in a reasonable number (e.g. 10–20) of x-ray rooms. Local DRLs may be set for procedures for which no national DRL is available, or where there is a national value but local equipment or techniques have enabled a greater degree of optimisation to be achieved so that a value less than the corresponding national DRL can be implemented.

Mean glandular dose (D_G)

In mammography, D_G is the mean absorbed dose in the glandular tissue of the breast. Glandular tissue is the radiosensitive tissue of the breast. D_G is calculated from either the incident air kerma ($K_{a,i}$) or the entrance-surface air kerma ($K_{a,e}$) used for the specific mammography examination. The conversion from $K_{a,i}$ to D_G is a function of beam quality (i.e. half value layer), anode material, filtration, breast thickness, and breast composition. The conversion from $K_{a,e}$ 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) (measured in mGy).

Medical exposure

Radiation 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 DRL

DRL value set in a country based on data from a representative sample of healthcare facilities in that country. A DRL is defined for a specified clinical imaging task. DRL values are usually defined as the third quartile (75th percentile) of the distribution of the median values of the appropriate DRL quantity observed at each healthcare facility.

Notification value

A component of the National Electrical Manufacturers Association 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 from the isocentre in the direction of the focal spot.

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 Gy (NCRP, 2010).

Quality control testing

Measurements that evaluate the current state of x-ray equipment performance and image quality at regular intervals in time to ensure that no changes have occurred outside the tolerance values.

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 publications). 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. DRLs are not 'reference levels' because DRLs apply to medical exposures, including interventional procedures. Medical exposures are planned exposures rather than emergency or existing exposure situations.

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. The United Nations classification of regions is available at http://unstats.un.org/unsd/methods/m49/m49regin.htm or http://www.un.org/depts/DGACM/RegionalGroups.shtml.

Regional diagnostic reference levels

DRLs set in a region, based on either a representative sample of health facilities or on national DRL values. 'Regional' is used in this publication to refer to a group of countries. Also see 'Region'.

Registry

A collection of information. A registry is usually organised so that the data in it can be analysed. Registries generally do not have restrictive inclusion or exclusion criteria. They can be used to evaluate outcomes for diverse purposes ranging from the natural history of a disease, to the safety of drugs or devices, to the real-world effectiveness of therapies. This information can be used to inform healthcare professionals in improving care for patients.

Size-specific dose estimate (SSDE)

A patient dose estimate for computed tomography (CT) scans that considers corrections based on the size of the patient, using linear dimensions measured on or determined from the patient or on patient images. The American Association of Physicists in Medicine (AAPM) Report 204 bases SSDE values on the CT dose index (volume) reported on CT scanners, but future modifications may include SSDE correction factors based on attenuation data of the patient acquired during the projection scan(s) of the scanned patient (AAPM, 2011a).

Standard-size adult

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. The mean weight chosen should be close to the average weight in the population being considered. A mean weight of 70 ± 10 kg may be appropriate for some countries. For adults, this is achieved typically by using data from patients with weights within a certain range (e.g. a range of 50–90 kg can be used to achieve a 70-kg mean).

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 postirradiation procedures including health care and biological response modifiers.

Tomosynthesis (breast digital tomosynthesis)

Uses multiple x-ray exposures of the breast from many angles. The information is sent to a computer, where it is processed to produce three-dimensional images throughout the breast.

Typical value

The median of the distribution of the data for a DRL quantity for a clinical imaging procedure. The distribution includes data from a particular healthcare facility that has several x-ray rooms (or from a small number of healthcare facilities). These data are obtained from a local survey or a review of local data. Typical values can be used as a guide to encourage further optimisation in a facility by providing a local comparator, in a similar manner to local DRLs. Typical values are used when the number of x-ray rooms (or healthcare facilities) is too small to permit determination of a local DRL value. Typical values may be set for a single facility to provide a comparator linked to a new technology or technique.

Voxel phantom

See 'Reference phantom'.

1. INTRODUCTION

- **Diagnostic reference level (DRL) is the Commission's term for a form of investigation level used for optimisation of protection in the medical exposure of patients.**
- **The Commission recommends the use of two new terms 'DRL quantity' (a commonly and easily measured or determined radiation metric that assesses the amount of ionising radiation used to perform a medical imaging task) and 'DRL value' (an arbitrary notional value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of the DRL quantity).**
- **The DRL has 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 the DRL process 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 national distribution of a DRL quantity (the same distribution that was used to derive the national DRL value) to be a useful additional tool for improving optimisation.**
- **The radiation metric used as a DRL quantity should be easily measured or available, such as air kerma-area product (P_{KA}) and entrance-surface air kerma ($K_{a,e}$) for diagnostic radiology; volume computed tomography (CT) dose index ($CTDI_{vol}$) and dose–length product (DLP) for CT; and administered activity, or preferably administered activity per body weight, for diagnostic nuclear medicine.**
- **Effective dose is not appropriate as a DRL quantity. Effective dose is not a measurable quantity and does not assess the amount of ionising radiation used to perform a medical imaging task. Its use could introduce extraneous factors that are 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 at a facility should be compared with DRL values, but values of DRL quantities for individual patients should not, because the DRL process is intended for optimisation of protection for groups of patients, and is based on standard patients, not individual patients.**
- **The DRL process should be applied in a continual process of quality assurance (QA), with repeat surveys following any optimisation, and then repetition of the whole process after an appropriate time interval.**

1.1. Purpose

(1) This publication provides guidance for the practical use of DRLs for specific imaging modalities, reviews methods for determining DRL values, provides advice on periodic revision of DRL values, and recommends DRL quantities for use with specific

imaging modalities. Compilations of DRL values are available from many sources (Hesse et al., 2005; ICRP, 2007b; Lassmann et al., 2007; Padovani et al., 2008a; Botros et al., 2009; Hart et al., 2009, 2012; Miller et al., 2009, 2012a; Etard et al., 2012; Foley et al., 2012; NCRP, 2012; Samara et al., 2012; ARSAC, 2014; Lassmann and Treves, 2014; Sánchez et al., 2014). This publication discusses issues to be considered when setting and using DRL values, 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 publication uses symbols for DRL quantities defined by the International Commission on Radiation Units and Measurements (ICRU). For the convenience of the reader, Table 2.3 provides the names, ICRU symbols, and common symbols for the quantities.

1.2. Terminology

(3) In its 1990 Recommendations (ICRP, 1991), the Commission described 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. The DRL was introduced in 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 (ICRP, 1996). In this publication, the Commission recommends the use of two new terms: 'DRL quantity' (a commonly and easily measured or determined radiation metric that assesses the amount of ionising radiation used to perform a medical imaging task) and 'DRL value' (an arbitrary notional value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of the DRL quantity obtained from surveys or other means).

(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. Also, although the medical exposure of patients is a planned situation, the use of 'dose constraints' is not applicable.

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 USA and the UK. In the 1970s, the Nationwide Evaluation of X-ray Trends surveys began in the USA (FDA, 1984), and in the 1980s, the National Radiological Protection Board (NRPB, now Public Health England) surveys in the UK 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 USA (Jensen and Butler, 1978; CRCPD/CDRH, 1992), then in the UK (Shrimpton et al., 1989; NRPB/RCR, 1990), and subsequently in Europe (EC, 1996a,b, 1999a,b; Neofotistou et al., 2003; Padovani et al., 2008a). These recommendations were referred to variously as exposure guides, guideline doses, guidance levels (IAEA, 1996), reference doses, and, in *Publication 73* (ICRP, 1996), DRLs.

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

(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 by 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, if required, is taken without undue delay. Several research programmes were launched by the European Commission, beginning in 1990, to collect data on patient doses and image quality, produce guidance on image quality criteria for adult and paediatric radiology and CT, and promote the use of DRLs (EC, 1996a,b, 1999a,b). Between 1995 and 2005, additional programmes (SENTINEL, 2007; DIMOND, 2006) on digital and interventional radiology established initial DRL values for newer imaging modalities.

1.4. Effectiveness of DRLs

(8) The DRL process is an effective tool for optimisation of protection in the medical exposure of patients. The US Breast Exposure: Nationwide Trends mammographic 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 1-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 UK, where data have been collected approximately every 5 years since the mid-1980s, DRL values determined from the results of the 2005 survey were 16% lower than the corresponding values in the 2000 survey, and approximately half of the corresponding values in a mid-1980s survey (Hart et al., 2009, 2012). The value of this tool was recognised in the European Commission's 1997 Medical Exposure Directive (EC, 1997).

(10) The DRL process is a tool to assist in optimisation, but can only achieve this through the process of patient dose audit. The DRL process should be applied in a continual manner with repeat surveys following any optimisation, and then repetition of the whole patient dose audit after an appropriate time interval.

1.5. Issues with the current use of DRLs

(11) There are several issues with the application of the DRL process in current practice: misuse of DRL values 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. There are also problems in paediatric radiology with the paucity of studies and data that can be used in setting DRLs, because of the small numbers of patients of any particular size that are examined.

(12) With time, it has become evident that additional guidance is needed pertaining to the proper clinical implementation of the DRL process. Clarification is needed for definitions of some of the terms used in previous guidance, determination of DRL values, the appropriate interval for re-evaluating and updating these values, appropriate use of the DRL process in clinical practice, methods for practical application of this tool, and application of the DRL concept to certain newer imaging technologies [e.g. dual-energy CT, positron emission tomography (PET)-CT, single photon emission CT (SPECT-CT), digital radiography, tomosynthesis]. Section 7 provides recommendations for the implementation of the DRL process in clinical practice.

1.5.1. DRL values are not intended for individual patients

(13) 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, in some cases, weight-based.

(14) In 2010, the National Electrical Manufacturers Association 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 $\mathrm{CTDI_{vol}}$ or 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, 2011b) has suggested numerical values for the notification value, some facilities have elected to use DRL values instead. This use is not appropriate, as DRL values are intended for optimisation of protection for groups of patients, not individual patients.

1.5.2. DRL values are not dose limits

(15) 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,c). 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 breastfeeding infant) and their comforters and carers (caregivers) (other than occupational)' (ICRP, 2007c).

(16) 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, 2007c). It is therefore clear that DRL values are not intended as dose limits, and should not be used as such.

1.5.3. DRL values should be based on clinical practice

(17) For x-ray imaging, DRL values 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 DRL value 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.

(18) This publication 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.

(19) The Commission has previously recommended that the radiation metric used for a DRL (the 'DRL quantity') '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, 2001b). 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.

(20) The quantity 'effective dose', used for other purposes in the ICRP system of radiological protection, has been suggested for use as a DRL. However, it is not suitable for this purpose because it does not assess the amount of ionising radiation used to perform a medical imaging task directly, and introduces extraneous factors that are not needed and not pertinent for the purpose of DRLs. Also, effective dose is not always calculated in the same way, and may not be readily available. Therefore, it should not be used as a DRL quantity. Conversely, comparison of dose indicators cannot always be taken as a comparison of effective dose (for the same examination) as beam quality can make a considerable difference to the actual patient dose relative to the dose indicator.

1.5.4. Technology and clinical indication affect DRL values

(21) 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. Separate DRLs may be needed where technological advances or changes lead to significant, consistent, identifiable differences in doses. One example is the use of more sensitive digital radiography systems instead of computed radiography. Another 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.

(22) 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). Differences in technology between equipment also make setting DRL values for lower bounds problematic.

(23) 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 performed to exclude renal calculi will require a lower value of the DRL quantity than a CT of the abdomen performed 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. For some examinations, the setting of a DRL without an indication of clinical indication is of little value. The compilation of more information on dose and image quality requirements linked to clinical tasks is an area that requires more attention. Note that the European Society of Radiology uses the terms 'clinical indication' or 'clinical DRL' which are equivalent to the ICRP term 'clinical task'.

(24) 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.

(25) 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 performed for ureteric obstruction, where the renal collecting system is dilated, requires less radiation exposure to the patient than the same procedure performed 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

(26) The highest priority for any diagnostic imaging task 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. 'Image quality' can apply to a single image (e.g. for a postero-anterior chest radiograph), but application to a single image may not be relevant 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, either sequentially or combined with the use of recursive filtering, may be adequate in terms of information content.

(27) Criteria for characterising image quality have been defined and agreed upon in Europe for certain specific adult and paediatric radiographs (EC, 1996a,b). Criteria along similar lines have also been set out for CT (EC, 1999a), but these are now over 17 years old and so do not take account of more recent developments. Moreover, similar criteria are lacking for other imaging modalities. This is an area that needs to be revisited.

(28) In this publication, the Commission emphasises the importance of the link between the amount of radiation applied to the patient and image quality.

Application of DRL values 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, 2007c). 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 publication

(29) The Commission's most recent published guidance on DRLs is now nearly a decade old (ICRP, 2007c). 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. A major change is the use of the facility's median value of the DRL quantity for comparison with national and regional DRL values, rather than the facility's mean value of the DRL quantity. The median is considered to be a more robust estimator than the mean, and with data available from larger numbers of patient examinations due to the use of electronic data collection methods, it is seen as providing a quantity more representative of the patient population.

(30) Several terms used in earlier ICRP publications were not defined clearly. This publication clarifies and defines some of these terms, such as local, national, and regional DRLs and 'consistently exceeded'. There has been some confusion regarding the proper use of local DRLs in certain situations. In this publication, the Commission provides recommendations on the use of local DRLs. It also introduces the concept of a 'typical value' in facilities where different types or levels of technology are used, where the typical value is the median value of the distribution of the values of the DRL quantity for the facility or facilities involved. 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.

(31) The majority of published DRL values are based on 'standard' adults. In this publication, the Commission provides recommendations for establishing DRL values and the use of DRLs for paediatric patients (Section 6). It defines the size of a 'standard' adult. The publication utilises work undertaken by the European Commission on paediatric DRLs (EC, 2016).

(32) This publication discusses the use of DRLs in nuclear medicine, where DRLs have been assessed in a different way than in x-ray imaging (Section 5). Administered activity, either absolute or weight-adjusted, is used as the DRL quantity. In nuclear medicine, 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 publication, the Commission provides recommendations for applying the DRL process to optimisation of radiological protection for these modalities.

(33) 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 publication, the Commission suggests criteria for the timing of these revisions. The publication also suggests methods for using automated data collection and registries to provide data for establishing and revising DRL values.

(34) 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 introduced a proposed new tool, 'achievable dose', for this purpose (NRPB, 1999). Achievable dose was defined as a level of a DRL quantity 'achievable by standard techniques and technologies in widespread use, without compromising adequate image quality' (NRPB, 1999). 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. NRPB proposed values for achievable dose that were based on the mean values observed for a selected sample of departments that met the European Commission's recommendations on technique (NRPB, 1999).

(35) In 2012, the US National Council on Radiation Protection and Measurements (NCRP) discussed the concept of achievable dose further, and proposed that achievable dose values should 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 national distribution of a DRL quantity (the same distribution that was used to derive the national DRL value) as an additional tool for improving optimisation].

(36) The median of the national distribution of a DRL quantity may have an additional role in refining optimisation. 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). Defining a specific value is problematic because of the wide range of equipment in use, but it should be recognised that the median of the distribution used to derive the DRL value is the tipping point below which image quality should be regarded as being of greater priority than dose when additional optimisation efforts are performed. Particular attention should be given to image quality for those facilities with dose levels in the first quartile (25th percentile) of a distribution.

(37) The Commission has noted that, in principle, DRLs could be used for dose management in interventional fluoroscopy with regard to stochastic effects (ICRP,

2007c). Unfortunately, DRLs are challenging to implement for interventional fluoroscopy 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 (Vañó and Gonzalez, 2001; ICRP, 2007c). 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 (Neofotistou et al., 2003; Padovani et al., 2008a; Hart et al., 2009, 2012; Miller et al., 2009, 2012a). 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 (Bernardi et al., 2000) and a selection of interventional radiology procedures (Ruiz-Cruces et al., 2016). 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).

(38) 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 (NCRP, 2010; Balter et al., 2011; Miller et al., 2012a). In this publication, the Commission discusses the advantages and disadvantages of these different approaches to establishing DRL values for interventional fluoroscopy, and provides recommendations on quantities (Section 4).

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

1.7. Target audience

(40) 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 a manager. 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. The ideal approach is to have a dose and image quality optimisation team consisting of a radiologist, a radiographer, a medical physicist, and other concerned staff, but it is recognised that this will not be possible in many institutions.

(41) The target audience for this publication is national, regional, and local authorities; the educational academic community and the clinical community; professional societies; and 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

(42) DRLs have proven to be a useful and valuable tool for optimisation of radiological protection in medical exposures of patients. In this publication, 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 measurable.

2. CONSIDERATIONS IN CONDUCTING SURVEYS TO ESTABLISH DRLS

- **Where appropriate or required, national or state legislation should clearly identify organisations that have 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 examinations 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, or that are available from the imaging equipment (e.g. P_{KA}, $K_{a,e}$, DLP, $CTDI_{vol}$, administered activity), and that indicate the amount of radiation or administered activity applied.**
- **A national survey to establish a DRL value will normally comprise large- or medium-sized facilities that have a sufficient workload to ensure that data for a representative selection of patients can be obtained. The sample selected should also cover the range of healthcare providers. Registries may also serve as a source of data for establishing DRL values.**
- **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 patients for diagnostic fluoroscopy or CT examinations, and 50 patients for mammography).**
- **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 30–50% of them may suffice.**
- **Hospital and radiology information systems (HIS and RIS, respectively) can provide data for large numbers of patients, suitable for collection in a registry. Wherever possible, utilisation of electronic transfer of these data is recommended.**
- **There should be some standardisation of weight for patients included in surveys, unless large samples are used.**
- **Calibration of all dosimeters, P_{KA} meters, etc., used for patient dosimetry should be performed regularly and should be traceable to a primary standard laboratory. The accuracy of DRL quantity data produced by and transferred from x-ray systems should be verified periodically 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 postprocessing of images become available.**
- **Published DRL values should be accompanied by a statement from the local group, nation, or region from which the patient data were collected; the size of the 'standard' patient on whom the data are based; the details of the specific examination, as appropriate; and the date of the survey.**
- **Assessment of clinical image quality should be performed as part of the optimisation process. Objective measures should be used where these are available.**
- **Local DRLs and typical values may be used as additional tools for optimisation.**
- **Collated data from radiation dose structured reports (RDSRs) in a structured digital format can enhance dose analysis and contribute to further optimisation.**

2.1. Introduction

(43) This section 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 multi-modality procedures are also dealt with in Section 5, and specific considerations for paediatric examinations are dealt with in Section 6, but general principles that apply to all diagnostic imaging 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 a 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 Section 4.

(44) 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 patients within an agreed weight range 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 professional judgement, and do not provide a dividing line between good and bad practice.

(45) DRLs utilise 'DRL quantities' – commonly and easily measured or determined quantities or metrics [e.g. $K_{a,e}$, incident air kerma ($K_{a,i}$), $CTDI_{vol}$, DLP, P_{KA}, air kerma at the patient entrance reference point ($K_{a,r}$), mean glandular dose (D_G), or administered activity applied] that assess the amount of ionising radiation used to perform a medical imaging task. These quantities are correlated to the amount of radiation and not the actual absorbed doses in tissues and organs of the patient.

(46) 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 patients within an agreed weight range from a specified procedure is unusually high or low for that procedure.

(47) 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 DRL values. These may apply to procedures for which a national DRL value is not available to serve as an aid to optimisation, or to procedures for which a greater degree of optimisation has been achieved through local practices than is reflected in the national DRL. They may be used to set lower values for new technologies that allow lower patient doses to be achieved, where no national or regional DRLs are available, or simply to encourage further optimisation. These local DRL values would be set based on local patient surveys for use as comparators for the facility's QA programme in the future.

(48) A 'DRL value' is a selected numerical value of an 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, they 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.

(49) In nuclear medicine, the DRL represents what is regarded as the acceptable level of activity 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 Section 5.

(50) For a specific x-ray room within a radiology department or other section of a healthcare facility, median values of DRL quantities for diagnostic procedures performed in that room can be compared with DRL values to identify whether the median values in the room are higher or lower than might be anticipated. This 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 local practice should be performed.

(51) If the median value of a DRL quantity for a particular type of examination in a particular x-ray room exceeds the relevant DRL value (or is less than some specified percentile), an internal investigation should be performed by the facility without undue delay. 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.

(52) Compliance with DRL values does not necessarily indicate that image quality is appropriate or 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 with 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

(53) 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.

(54) In general, and for the majority of examination types, DRL values should be based on measurements made in surveys or registries 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 or registries 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.

(55) 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 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.

(56) The one exception to using data from patient examinations to set DRL values is dental radiography equipment (Section 3). As the same standard exposure settings linked to the teeth being imaged are used for the majority of adults, a measurement of output at the cone tip ($K_{a,i}$) with the appropriate settings can be considered as the median incident air kerma or patient dose for each intra-oral dental unit. DRL values can then be set based on the distribution of the measurements for different dental units.

(57) A summary of approaches recommended for different types of diagnostic imaging examination is given in Table 2.1. For examinations marked as lower priority, it is still recommended that DRL values are set, but these generally make a lower contribution to population dose or are more difficult to survey, so are not appropriate for inclusion in dose surveys undertaken in the early stages of setting DRL values.

Table 2.1. Examination selection and method of assessment.

Examination	DRL recommended	Method of assessment
Mammography	Yes	Patient survey to set DRL and phantom measurements as standard dose comparator
Intra-oral dental radiography	Yes	Output measurement on standard settings
Panoramic dental radiography	Yes	Measurement of air kerma-area product 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
Paediatric CT	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 or, preferably, activity per body weight
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

DRL, diagnostic reference level; CT, computed tomography.

(58) 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, DRL values 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.

As different technologies (including image reconstruction methods) may lead to very different doses being achievable for images of required diagnostic quality, it may sometimes be appropriate to link DRL values to technology.

(59) As 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. If there are two procedures for an examination with different values for the DRL quantity within a country or region, it is possible to set two DRL values and specify the examination and procedure. This is especially true when new techniques emerge with an influence on the doses to allow for a transition period.

(60) The best sources for DRL values are patient-based data for the country or region in which they will be used. Methods through which such DRL values can be derived are described later in this section. DRL values obtained from other sources can also provide useful information. These values can be used in the first instance for establishment of initial DRL values and for comparisons.

(61) DRL values published by other national or international organisations can be referred to when setting national DRL values. Examples are available from a number of sources, including the European Commission (EC, 1996a,b, 1999a,b, 2014), the UK Health Protection Agency (HPA) (now Public Health England) (HPA, 2012), and NCRP (2012).

(62) However, DRL values published by other national or international organisations will not necessarily be appropriate for many countries and states, as 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 differ.

2.3. Survey considerations

2.3.1. Responsibility for conducting surveys and establishing DRLs

(63) DRLs may be set based on the medians of the distributions of DRL quantities for individual patients for a variety of different geographical areas, and information on these is summarised in Table 2.2.

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

(65) 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 DRL values 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

Table 2.2. Types of diagnostic reference levels (DRLs), methods of derivation, and areas of application.

Term	Area and facilities surveyed	Value in distribution used to set DRL	Application
Typical values	Healthcare facility consisting of several x-ray rooms or a small number of facilities or single facility linked to a new technique	Median value of the distribution, as there are insufficient data to use the third quartile	Local use to identify x-ray units requiring further optimisation
Local	X-ray rooms within a few healthcare facilities (e.g. with at least 10–20 x-ray rooms) in a local area	Third quartile of median values for individual x-ray rooms	Local use to identify x-ray units requiring further optimisation
National	Representative selection of facilities covering an entire country	Third quartile of median values for individual x-ray rooms or of national values	Nationwide to identify x-ray facilities where optimisation is needed
Regional	Several countries within one continent	Median values of distributions of national values or 75th percentile of distribution for representative selection of healthcare facilities throughout the region	Countries within region without a relevant DRL or for which national DRL is higher than regional value

publication, and the methodology should be agreed upon among the competent authorities of all participating countries.

(66) The establishment of national or regional DRL values requires surveys or registries 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.

(67) 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.

(68) National or state legislation should clearly identify organisations that have responsibility for different components of the task. Collation of patient data and setting of national/regional DRL values needs to be done at a national/regional level. However, many different groups may perform the actual measurements and collection of patient data.

(69) 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 or x-ray technologists.

(70) 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.

(71) Local DRL values set by a group of radiology departments, or typical values set by 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 a 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. IPEM (2004) contains a comprehensive report on the implementation and use of local DRLs.

(72) A local DRL value can be derived for a group (e.g. 10–20) of x-ray rooms or healthcare facilities. For areas where 10–20 facilities are included in the survey, setting a local DRL value at the third quartile of the distribution may be helpful in identifying the x-ray units where more attention is required.

(73) For smaller numbers of x-ray rooms or a single facility, a typical value may be defined as the median of the distribution and used in a similar manner. Typical values can be useful 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, or to a paediatric hospital. In some cases, local DRLs may also be based on data from a large facility where large numbers of specialised examinations are performed for which there are no national DRL values.

(74) Local DRL values or typical values can 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) are used in parallel with computed radiography (CR) for general radiography or dental imaging.

(75) 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.

(76) In some countries, government departments or universities have undertaken surveys in the past (Martin et al., 2013). The experience of established groups should 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.

(77) In some countries, professional organisations have established ongoing registries for recording and disseminating radiation dose data. An example is the American College of Radiology's Dose Index Registry (http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry). Such registries allow for the collection of data on very large numbers of examinations (Bhargavan-Chatfield and Morin, 2013). For this reason, they can be especially useful for evaluating radiation dose data from infrequently performed examinations (Lukasiewicz et al., 2014).

(78) National registries offer an opportunity for automated collection of large amounts of data. The large number of healthcare facilities, large number of examination types, detail of the data, standardised reporting format, continuous updating, and ability to compare and analyse changes in dose over time are all substantial advantages over occasional surveys, but registries require a dedicated staff, continuous oversight, and the provision of necessary resources.

(79) As an understanding of the imaging and radiation performance of the equipment is required for optimisation, periodic quality control (QC) testing should be performed on the equipment, and the results should be evaluated by a qualified medical physicist. This may be mandated through regulations. In the UK, where DRLs have been employed successfully in the optimisation process for many years, medical physicists oversee performance tests on x-ray equipment and patient surveys.

(80) 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 perform the procedures and staff who perform QC 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

(81) The first step in setting DRLs is to perform 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. However, a random selection of a small proportion of all the healthcare facilities as a sample can provide a good starting point. 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 30–50% 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. A good option that can facilitate ongoing collection of patient dose data is to set up a registry to which data can be sent. This may allow automated data collection and, once established, can accept input from hundreds of facilities (Bhargavan-Chatfield and Morin, 2013).

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

(83) 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 large- or medium-sized hospitals as 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.

(84) The sample should also cover a representative selection of healthcare providers. In the majority of countries, these may be both public and private, hospital and freestanding, and priorities for optimisation may vary in different facilities. Some facilities, particularly those with more limited numbers of radiographers, may employ unusual practices that do not reflect those used widely across the country. It is important that, once a programme has been set up, dose surveys extend to all x-ray facilities to ensure that unusual practices giving rise to higher doses are identified through comparisons made with the DRL values that have been established. They will need to go through a survey process eventually in order to gain dose awareness.

(85) 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 perform QC testing, including measurement of x-ray equipment output, and to make arrangements for data collection.

(86) The UK 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 UK at the arbitrary level of the third quartile of the mean (not median) values of appropriate 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.

(87) The Commission now recommends use of the median of the local distribution of the DRL quantity for each x-ray facility as the value to be collated when compiling the national distribution from which the national DRL will be established. Local data should be obtained from a representative sample of typical patients in order to make this possible. The median is considered to be a more robust estimator than the mean, and with larger numbers of patient doses available from electronic data

collection methods, it is seen as providing a quantity that is more representative of the patient population.

(88) 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, or automated data collection. Alternatively, continuing participation in a national registry serves the same purpose.

(89) Once a DRL framework has been put in place, a suitable interval between national/regional data collection surveys may be 3–5 years (the interval used in the UK), but this will depend on the examination levels, the degree of variability of the survey results, the introduction of new technology or imaging postprocessing 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. Automated input of data into a national registry permits DRL values to be updated as often as every 6 months, if necessary (Bhargavan-Chatfield and Morin, 2013).

(90) Where there has been a drive to encourage healthcare facilities throughout a geographical area to perform their own patient surveys, 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

(91) The majority of the discussion in this section 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, apart from dental radiography, they should not replace data from patient examinations. Use of phantoms is discussed further in Section 3 in the subsections for each imaging modality.

(92) As attenuation of the x-ray beam depends on the amount of tissue that 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 50–90 kg can be used to achieve a 70-kg mean). A mean weight of

70 ± 5 kg was chosen as a reference weight in the UK as this represented the average in the UK at the time (IPSM/NRPB/CoR, 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 UK in the future. The mean weight chosen should be close to the average weight in the population being considered. A mean weight of 70 ± 10 kg may be appropriate for some countries.

(93) Where automated methods of recording values of appropriate 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). Automated registries permit collection of data on millions of examinations (Bhargavan-Chatfield and Morin, 2013). Where surveys are undertaken in this way, it may be possible to relax restrictions on weight. Results rely on the accuracy of data entry, and may not include patient weight. In order to eliminate outliers and data with gross errors from analysis, some form of exclusion method should be considered (e.g. removal of the highest and lowest 5%). However, care must be taken to ensure that results are not influenced by greater proportions of large patients in some areas. Specific considerations for development of DRL values for paediatric patients are discussed in Section 6.

(94) 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).

(95) 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/NRPB/CoR, 1992). However, data for more patients will be required when there is greater variation and a greater 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 and CT procedures (IPSM/NRPB/CoR, 1992). Even larger numbers of patients may be needed for interventional procedures (Section 4). For mammography, 50 patient measurements are recommended because of variation in compressed breast thickness. As the range in breast thicknesses is large, some standardisation through restriction of the range of breast thicknesses included in the analysis may be appropriate.

2.3.4. Examinations and DRL quantities

(96) The first priority in selecting examinations and imaging procedures for which DRL values should be set is to include 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. These should also be examinations for which dose assessment is practicable, and should encompass all groups of professionals involved in performing these examinations and procedures, namely

radiographers, radiologists, cardiologists, surgeons, and other medical staff allowed to use x-ray systems. 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. DRLs are not intended for use in radiation therapy, but they should be considered for imaging for treatment planning, treatment rehearsal, and patient set-up verification in radiotherapy.

(97) 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 performed frequently and results in relatively high patient radiation doses. For CT, it is particularly important that appropriately trained medical physicists and radiographers are involved in order to provide advice on the optimisation of protection.

(98) 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.

(99) Data collected for patient surveys should, when feasible, include the equipment manufacturer and model, examination name, patient weight, and P_{KA} and other DRL quantities (e.g. $CTDI_{vol}$, DLP, $K_{a,e}$, $K_{a,r}$) if appropriate and available for the examination types being surveyed. For the convenience of the reader, Table 2.3 lists the symbols for DRL quantities and their meaning. The quantities recommended by the Commission are given in Table 2.4. For fluoroscopy and CT,

Table 2.3. International Commission on Radiation Units and Measurements (ICRU) symbols for diagnostic reference level quantities.

ICRU symbol*	Meaning	Other common symbol
$CTDI_{vol}$	Computed tomography dose index (volume)	
DLP	Dose–length product	
$K_{a,i}$	Incident air kerma	IAK
$K_{a,e}$	Entrance-surface air kerma	ESAK, ESD
$K_{a,r}$	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 publication uses ICRU symbols. Other common symbols are shown for the convenience of the reader.

Table 2.4. Quantities suitable for setting diagnostic reference levels (DRLs).

Equipment	Recommended quantity	Recommended unit
Radiography	$K_{a,e}$	mGy
	P_{KA}	mGy cm^2
Mammography, breast tomosynthesis	$K_{a,e}$, $K_{a,i}$, or D_G*	mGy
Dental intra-oral	$K_{a,i}$	mGy
Dental panoramic	P_{KA} (or dose–width product)	mGy cm^2 (mGy cm)
Diagnostic fluoroscopy, interventional fluoroscopy	P_{KA}	Gy cm^2
	$K_{a,r}$	Gy
	Fluoroscopy time	s
	Number of images in cine or digital subtraction angiography runs	Number
CT, interventional CT	$CTDI_{vol}$	mGy
	DLP	mGy cm
Cone-beam CT (depending on availability of the quantity)	$K_{a,r}$	mGy
	P_{KA}	mGy cm^2
	$CTDI_{vol}$	mGy
	DLP	mGy cm
Nuclear medicine	Administered activity or activity per body weight†	MBq or MBq kg^{-1}

CT, computed tomography; $K_{a,e}$, entrance-surface air kerma; P_{KA}, air kerma-area product; $K_{a,i}$, incident air kerma; D_G, mean glandular dose; $K_{a,r}$, air kerma at the patient entrance reference point; $CTDI_{vol}$, computed tomography dose index (volume); DLP, dose–length product.

*For mammography and tomosynthesis, the recommended DRL quantity is one or more of $K_{a,e}$, $K_{a,i}$, or D_G, with the choice of quantity depending on local practices and regulatory requirements.

†For some nuclear medicine investigations for which the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid, sentinel node imaging, pulmonary ventilation, and perfusion studies), a standard activity could be administered for all adult patients. For other nuclear medicine examinations, the ideal would be for administered activities to be based on patient weights (MBq kg^{-1}). The Commission recommends that weight-based administered activities should be used for children, adolescents, and low-weight patients, and considered for other groups. Where only administered activities (MBq) in adults are available from a survey, DRL values in adult nuclear medicine are normally based on the administered activities used for average-sized patients (e.g. 70 ± 10 kg). A DRL value for administered activity per unit body weight (MBq kg^{-1}) can be calculated from this as required.

all of the quantities listed should be recorded if they are available. The quantities chosen should be easily measured or available, 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 or preferably activity per body weight for diagnostic nuclear medicine. The DRL quantity selected (e.g. $CTDI_{vol}$, DLP, administered activity, or activity per body weight) 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.

(100) Calibrations of meters and displays should be verified, preferably at intervals of no more than 1–2 years. Calibration of instruments used to confirm the accuracy of P_{KA} meters, CT scanner displays of $CTDI_{vol}$ and DLP, and thermoluminescent dosimeters 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 performed as part of standard QC programmes. QC tests should be performed at least annually on all medical equipment that emits x rays, except that a 3-year interval may be employed for dental radiography equipment. This exception does not include dental cone-beam CT units.

2.4. Procedure selection

(101) Procedure selection is important in ensuring that 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 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 regarding whether the DRL value would be based on all exposures or on a specific subset.

(102) Organisations that conduct surveys of appropriate DRL quantities or use automated data collection systems 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. An option for mobile radiography equipment is to measure $K_{a,i}$ for standard exposure factors used at the appropriate source to detector distance, and calculate values of $K_{a,e}$ for comparison with the appropriate DRL value.

2.5. Data collection methods

(103) 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 UK, other European countries, and the USA (FDA, 1984).

(104) The advent of HIS and RIS has allowed retrospective review of patient examination data. RIS data collection has the advantage that far greater numbers of patients can be included, but results may be for multiple views such as postero-anterior (PA) and lateral projections in radiography. Standard examination codes for the different types and variants of radiological procedures must be used to avoid introducing errors due to incorrect categorisation of examination types (Escalon et al., 2015). 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. As much larger numbers of patients can be included in data collected via an RIS, these problems can be overcome, to some extent, through the exclusion of outliers.

(105) The Digital Imaging and Communications in Medicine (DICOM) standard has defined the RDSR to handle the recording and storage of radiation dose information from imaging modalities. Collation of data in RDSRs can be used by the patient dose management system to notify clinical staff and medical physicists when dosimetric quantities exceed preset levels.

(106) Integrating the Healthcare Enterprise (IHE; https://www.ihe.net/) has established a standard workflow to ensure interoperability among modalities, Picture Archiving and Communication System (PACS), and dose report systems. The RDSR is used in the IHE Radiation Exposure Monitoring (REM; http://wiki.ihe.net/index.php/Radiation_Exposure_Monitoring) profile. Currently, data access is not straightforward, but patient dose management systems are now available and facilitate the establishment of databases as repositories of dosimetric data (Cook et al., 2011; Ikuta et al., 2012; Sodickson et al., 2012; Charnock et al., 2013; Vañó et al., 2013). Additionally, dosimetric data can be used by patient dose management systems to aid in radiation protection QA and quality improvement.

(107) The use of dose parameters from each DICOM image of CT examinations, when provided, allows the changing $CTDI_{vol}$ that results from dose modulation along the z-axis of a patient to be followed, which is not possible with RDSR data alone. The RDSR reports only an averaged $CTDI_{vol}$ of an entire series radiation event. For interventional procedures, the RDSR includes data for all radiation events, including fluoroscopy. If the dose from interventional fluoroscopy procedures is only extracted from acquired DICOM images, if available, the dose contribution from fluoroscopy is missing. For some of these procedures, the dose from fluoroscopy may exceed the dose from radiography. DICOM has also completed a radiopharmaceutical RDSR template (DICOM, 2014), and this is included in an updated IHE REM-NM Profile (http://wiki.ihe.net/index.php/Radiation_Exposure_Monitoring_for_Nuclear_Medicine). This will allow capture of the delivered dose from any nuclear medicine procedure, and also standardised recording of the radiopharmaceutical part of the dose of a PET-CT study.

(108) Modality performed procedure step (MPPS) service is still used in some systems to send x-ray procedure, patient, and image information from the modality

to the HIS/RIS server upon completion of the examination, but will be replaced by the DICOM RDSR (Vañó et al., 2008a, 2013; Ten et al., 2015). Secondary caption images are another widely used option to store dosimetric data as images in the PACS, and attach them to a study. For further analysis, these images have to be converted by optical character recognition (OCR) programmes to extract dose parameters (Cook et al., 2010; Li et al., 2011). Depending on the resolution and quality of these images, OCR conversion may produce errors. In addition, the content of information is usually much lower than with RSDR. However, MPPS has been withdrawn by the DICOM Committee and so its use is not recommended for new installations, but is necessary for existing ones.

(109) As patient dose management becomes more established, the number of examinations and number of patients included in databases can be expanded. This allows large dose registries to be built up. For example, the UK now has a system whereby dosimetric data collected by medical physicists in hospitals throughout the UK are sent to Public Health England for collation and analysis. The UK survey performed in 2010 collected data for 165,000 $K_{a,e}$ 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 as of 2013 (Bhargavan-Chatfield and Morin, 2013). Patient dose management systems will also be helpful in fulfilling legal requirements such as European Union requirements for reporting dose results to authorities for clinical audits, or for following the European Union's basic safety standards directive to identify unintended overexposures. Regardless of the data source used, the validity of the dosimetric indicators must be verified by medical physics experts, and corrected, if necessary, prior to their incorporation into patient dose management systems.

2.6. Determining DRL values

2.6.1. Distributions of DRL quantities

(110) Once a patient survey of appropriate DRL quantities is complete or a sufficient amount of data has been collected through an automated process, 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, 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.

(111) If large numbers of patients have been included from an electronic data collection system, 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

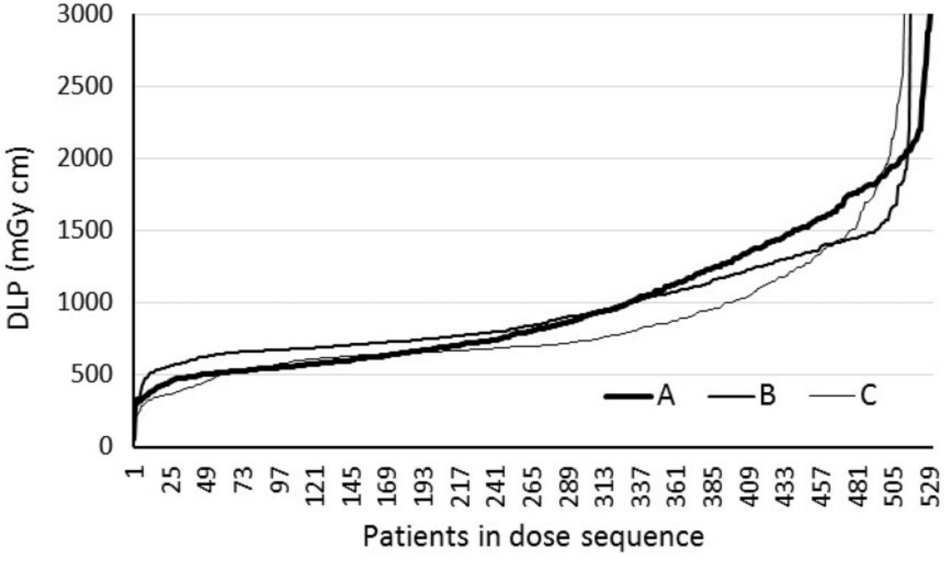

Fig. 2.1. Examples of data on dose–length product (DLP) for chest–abdomen–pelvis scans on three computed tomography (CT) scanners operating under automatic tube current modulation plotted sequentially in terms of increasing DLP (Martin, 2016). Outliers can be identified readily and omitted from the data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

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.

(112) 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 $K_{a,e}$ 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 $K_{a,e}$ values 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.

(113) 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., 2009), as there are inevitably always a few facilities where optimisation has not been fully implemented.

(114) DRL values for x-ray procedures have often been defined as the 75th percentile (third quartile) of the distribution. This can easily be understood at the

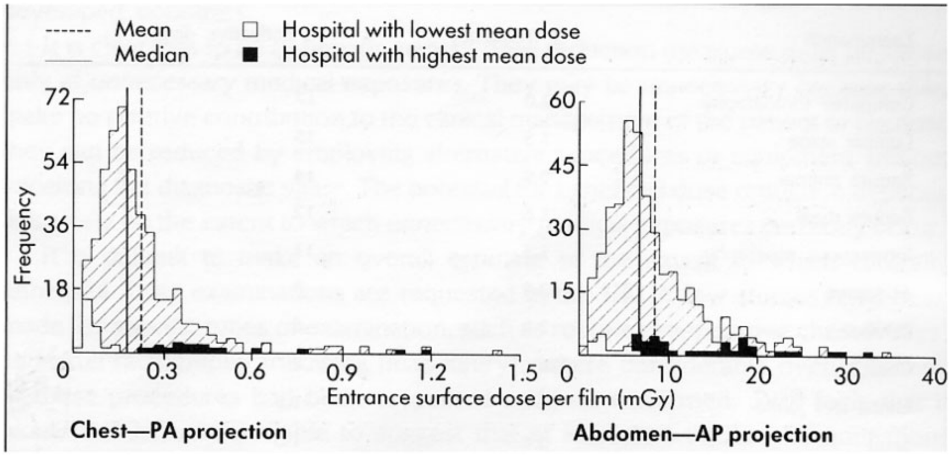

Fig. 2.2. Distributions of entrance-surface dose per image for patients from 20 English hospitals included in an early survey performed by the National Radiological Protection Board (now Public Health England) (reproduced from Shrimpton et al., 1986 with permission from Public Health England). Distributions for the hospitals with the highest and lowest mean values are highlighted. PA, postero-anterior; AP, antero-posterior.

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 scientific basis. However, the 75th percentile usually lies well below the high 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.

(115) 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 (Wall et al. 2005). This has been demonstrated in UK surveys of radiography (Fig. 2.3) and fluoroscopy (Hart et al., 2012). As optimisation occurs and practice improves, DRL values require periodic updating. Published DRL values should be accompanied by a statement of the local group, nation, or region from which the patient data were collected, the size of the 'standard' patient on whom the data are based, the details of the specific examination, as appropriate, and the date of the survey.

(116) Findings from a recent survey of CT doses for hospitals throughout Scotland have revealed a different pattern from the log-normal distributions of DRL 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 UK, there are more diagnostic radiology physicists engaged in optimisation of CT examinations. As 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

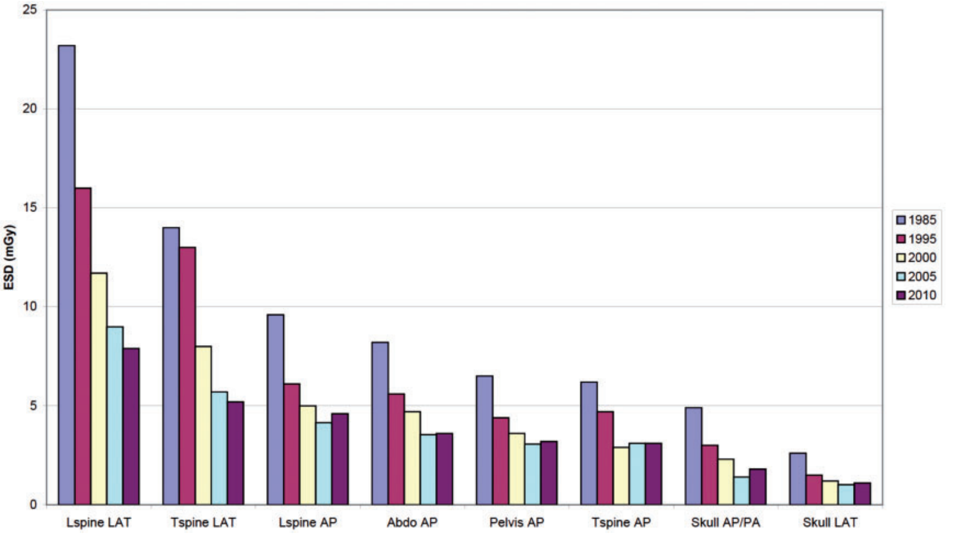

Fig. 2.3. Third quartile entrance-surface air kerma (ESD) ($K_{a,e}$) measurements for radiographic examinations derived from National Radiological Protection Board/Health Protection Agency surveys between 1985 and 2010 [reproduced from Hart et al. (2012) with permission from Public Health England]. LAT, lateral; AP, antero-posterior; PA, postero-anterior.

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 disappearance of the high tail of the distribution. 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

(117) The simple pooling of dosimetric data from surveys to derive DRL values is no longer completely satisfactory, and may result in the accumulation of values of dose survey results 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 radiation protection. The establishment of a second level, namely the median 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, as the DRL value is the third quartile of the distribution. This median value can be used, along with the DRL value, to assist in optimising image quality and patient dose.

(118) The purpose of a DRL is to identify facilities where investigation of practices is advisable because protection is not optimised (i.e. where the local median value of the DRL quantity is greater than the national or regional DRL value). However, at healthcare facilities where the local median 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 national median values (from the national DRL survey or automated data collection) provide an additional benchmark against which such healthcare facilities can evaluate their performance. As local median values of DRL quantities at most healthcare facilities will be below the national DRL value, the national median value provides a reasonable goal towards which to aim with standard techniques and technologies.

(119) Good practice with regard to patient doses would be to attempt to achieve and maintain a median value of DRL quantities at the healthcare facility 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.

(120) If the local median value of the DRL quantity is below the national median value, image quality, rather than dose, should be considered as a greater priority in additional optimisation efforts. 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 radiation that are below the national median value, further reduction in the amount of radiation used is not the principal concern. When local practices result in levels of radiation that are below the national median value, ensuring that image quality is adequate should be a priority. 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

(121) Some regions of the world, such as the European Union, are trying to harmonise the radiation safety aspects of their healthcare 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.

(122) 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 or registries. 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.

(123) 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. As the national values typically represent the 75th percentile values for the national distributions of DRL quantities for x-ray procedures, 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.

(124) 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 existing national DRL values into account, but should also consider that a median that is derived from a small number of national DRL values could be inappropriate.

(125) 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 relatively large numbers 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

(126) 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.

(127) The highest priority for any diagnostic imaging 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, of poor quality individually, may together provide the necessary clinical information.

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

(129) A focus on DRL quantities alone, without image quality criteria, could drive the value of the DRL ever downwards, so that image quality could be compromised at some stage. It is essential to ensure 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.

(130) Prior to collection of DRL data, surveyors should ensure that imaging equipment is functioning acceptably by means of a proper QC programme, paying particular attention to the accuracy of the dosimetric quantity of interest, and that it is providing clinical images 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; to date, only objective measures in the form of evaluations by radiologists are used. The European Commission has produced guidelines with criteria that can be used for scoring images when judging their diagnostic potential (EC, 1996a,b, 1999a). These or similar criteria can be used for assessing image quality whenever changes are made that could affect image quality. Involvement of radiologists is necessary to evaluate clinical images using clinical image criteria.

(131) Additional substantive data on appropriate image quality parameters for different examinations are needed. 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, the system transfer factor, and noise power spectra (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. These quantitative measurements provide a good description of the inherent performance of the imaging detector, but do not characterise the system in terms of clinical image quality (clinical task).

(132) Although research into objective measures of image assessment has been performed, no relationship has been established to date between physical measures and the radiologist's judgement (De Crop et al., 2015). To aid in this process, more

detailed analyses of acceptable levels of image quality for CT and other specialties are needed, so that the leading parameter is not just dose, but image quality per dose. There is an urgent need for further research in this area, and for additional data on the magnitude of objective image quality variables linked to clinical imaging tasks.

(133) 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 (ICRU, 1995).

(134) 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 or the exposure index (detector dose indicator) in digital radiography is essential. The balance between image quality and patient dose is essential. Appropriate postprocessing may permit the use of lower exposure levels.

(135) 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 imaging protocols are set up for a new scanner. The factors involved relate to: (1) low contrast detectability; and (2) spatial resolution of the displayed image. A report on image quality and dose assessment in CT has been prepared by ICRU (ICRU, 2012).

(136) Imaging equipment vendors promote and invest in improvement in image quality, and in dose-reduction techniques, but they tend to emphasise the dose reduction (e.g. of half-time imaging or iterative image reconstructions in CT) and pay less attention to the risk of reduced image quality by these techniques (Guimaraes et al., 2010; Ardenfors et al., 2015). The adequacy of the image quality should be assessed and dealt with at introduction of such techniques into clinical practice. Using protocols provided by the vendor to reduce dose is not optimisation if the results do not align with the clinical goals and image requirements of the procedure.

(137) So far, this publication has focused on imaging information for a single purpose (e.g. to answer one diagnostic question). However, for specific diagnoses (e.g. urinary tract stones), although considerable dose reduction might be available for that procedure by assessing the initial diagnostic question alone, if the diagnosis is positive, there are immediate follow-up questions such as the precise location of the problem, and its extent and severity (Niemann et al., 2008). If the initial diagnosis is negative, the immediate follow-up question would be, 'what is causing the patient's symptoms?' Both follow-up questions are foreseen and may justify extending the information requirements from the first imaging of the patient. This will lead to a higher patient dose from the procedure, but a reduction in total patient dose as no follow-up imaging is needed. Such variations should be recorded in the examination records, so that the procedures can be excluded from any comparison with the DRL for the simple procedure.

3. RADIOGRAPHY AND DIAGNOSTIC FLUOROSCOPY

- **DRL quantities should be easily assessed or available, preferably from a direct measurement for the examination. Either P_{KA} or $K_{a,e}$ may be used for radiography. P_{KA} also takes account of collimation.**
- **For mammography, the recommended DRL quantity is one or more of $K_{a,i}$, $K_{a,e}$, or D_G, with the choice of quantity depending on local practices and regulatory requirements.**
- **P_{KA} and $K_{a,r}$ 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 dose surveys.**
- **A convenient method for setting DRL values for dental radiography is to use measurements of $K_{a,i}$ 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

(138) Radiography and diagnostic fluoroscopy include a wide range of examinations, but obtaining reasonable and sufficient data is only practical for those examinations that are performed most often. 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.

(139) The examinations chosen for the DRL process should be those performed most often 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 10 European countries.

(140) In many countries, the most common radiographic examination is chest radiography (EC, 2008). As 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.

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 examinations (%)	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 (N.B. now often replaced by CT colonoscopy)	0.1–2.0	0.5–13
Cardiac angiography	0.2–1.3	2.8–9.4

CT, computed tomography.

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

(142) Although the upper and lower extremities are examined frequently, 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; as such, the estimated contribution to radiation risk is small. As a consequence, setting DRL values for these examinations is a lower priority, but optimisation is still necessary.

(143) Similar arguments can be applied to the choice of diagnostic fluoroscopy examinations to be studied. Interventional fluoroscopy is discussed separately in Section 4. More common procedures are included in Table 3.1, but as practices vary in different healthcare facilities as well as in different parts of the world, those appropriate for the country/region/facility where the DRL process is to be applied should be reviewed in making the selection.

3.2. DRL quantities for radiography

(144) The DRL quantity should be one that is easily assessed or available, preferably from a direct measurement for the examination. Either P_{KA} or $K_{a,e}$ may be used (Table 2.4), but assessment of both is preferable, when possible, in order to simplify evaluation of collimation.

Table 3.2. Radiographic outputs (μGy mAs^{-1}) at one meter from the x-ray tube focus, with 3.0–3.6 mm aluminium equivalent filtration.

kVp	Waveform Two pulse*	Six and 12 pulse*	Constant potential†
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: *Le Heron (1989), †Martin and Sutton (2014).

(145) 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). As P_{KA} is determined by both air kerma and the size of the radiation field, it takes all factors influencing patient radiation dose into account. 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 before it is incident on the patient.

(146) 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 should 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.

(147) When no P_{KA} value is available, $K_{a,e}$ (including backscatter) should be used as a tool for radiography. $K_{a,e}$ can be measured on the patient during the acquisition of the image using dosimeters such as radiolucent thermoluminescent dosimeters, as long as they do not interfere with the images. Alternatively, $K_{a,e}$ can be calculated from knowledge of the exposure factors (kVp, mAs) and source-to-skin distance, 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 as it involves less additional equipment, but it does require a measurement of x-ray unit output to be made.

(148) In countries where resources are very limited, it is possible to base a calculation of $K_{a,e}$ 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 (Le Heron, 1989; Martin and Sutton, 2014). Results that could be used are given in Table 3.2, but it is strongly recommended that measurements should be made wherever possible.

(149) The kV, mAs, and source-to-skin distance (or some method of deriving it) should be included to allow calculation of $K_{a,e}$. The exposure index 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/type of examination whenever possible to provide information for use in optimisation.

3.3. DRL quantities for diagnostic fluoroscopy

(150) P_{KA} should always be used as a DRL quantity for fluoroscopic examinations, if it is available (Table 2.4). Many fluoroscopy units display both $K_{a,r}$ (IEC, 2010) and P_{KA}. If $K_{a,r}$ is available, it should also be used as a DRL quantity for specific diagnostic imaging examinations, because comparison of $K_{a,r}$ and P_{KA} values is useful in judging the adequacy of beam collimation.

(151) For diagnostic fluoroscopy procedures, fluoroscopy time and numbers of cine or DSA images should also be recorded. 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.

3.4. Use of phantoms in radiography and fluoroscopy

(152) 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 DRL quantities employed in patient examinations. While these are not realistic surrogates for patients, they may be useful for estimating $K_{a,e}$ for different phantom thicknesses that equate to patients of different sizes, particularly when exposure factors are selected automatically. $K_{a,e}$ (including backscatter) can be measured with a flat plate ionisation chamber placed on the surface of such a slab phantom, and the postexposure mAs recorded.

(153) 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.

(154) Although phantoms can be helpful in assessing the 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.

(155) Slab phantoms can also be used to measure $K_{a,e}$ rates for different preset protocols on fluoroscopic equipment to provide information on the performance of the fluoroscope (Martin et al., 1998). The results can be compared with performance criteria, but these $K_{a,e}$ rates are not DRL quantities. These measurements can be performed during QA tests, and provide information valuable for QC testing (Balter et al., 2004) and for the interpretation of possible causes of high results found in patient surveys.

3.5. Mammography

(156) 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 38 kV with x-ray tube anodes and filters made from different materials (e.g. molybdenum, rhodium, and silver, as well as tungsten and aluminium) than the materials used in other x-ray systems. Specially designed meters are used for radiation output measurements for mammography 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.

(157) The radiation dose to the breast in mammography varies because of the range in breast thicknesses. However, rather than select a group of patients, it is recommended that all breast sizes should be included in the survey or automated data collection system, and that data should be collected for at least 50 patients in order to take account of the variation in breast size. This will also ensure that the sample is representative of the particular area or country where it is performed. It may be appropriate to restrict the analysis to data within a narrower range of compressed breast thickness in order to obtain results for a standard thickness representative of the local population.

(158) Three DRL quantities have been used for surveys of mammography: $K_{a,e}$, $K_{a,i}$, and D_G. For both mammography and breast tomosynthesis, the Commission recommends using one or more of $K_{a,e}$, $K_{a,i}$, or D_G as the DRL quantity, with the choice of quantity depending on local practices and regulatory requirements. 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 $K_{a,e}$ and $K_{a,i}$ with kV and with different anode/filter combinations, even for the same breast thickness.

(159) $K_{a,e}$ was used initially as the DRL quantity. Measurement of $K_{a,e}$ is straightforward, and no correction factors are required. It allows direct comparisons

between 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 $K_{a,e}$. These differences should be taken into consideration when comparing results.

(160) $K_{a,i}$ 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 $K_{a,i}$ for the examination. The $K_{a,i}$ will depend on the size of the breast; there are substantial variations between individuals. For this reason, the inclusion of more (e.g. 50) patients per facility is recommended for patient surveys.

(161) 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 $K_{a,i}$ and D_G is highly dependent on breast thickness and composition, as well as beam quality (Wu et al., 1994; Boone, 1999), so there is more variation in potential risk with the DRL quantities that are measured directly, such as $K_{a,i}$ and $K_{a,e}$, than for other examinations. This has been a persuasive argument for countries to use D_G to help in optimisation.

(162) D_G is calculated from the $K_{a,i}$ used for the examination for a specified thickness of compressed breast. The $K_{a,i}$ and D_G will depend on the size of the breast and its composition, which changes throughout a woman's life. The DRL value will also depend on the view, with a standard two-view mammogram consisting of craniocaudal and mediolateral oblique exposures.

(163) There is extensive published literature on the conversion from $K_{a,i}$ 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 thickness, anode/filter combination, breast thickness, and breast composition) (Dance et al., 2000; IPEM, 2005).

(164) When $K_{a,e}$ or $K_{a,i}$ 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, as 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.

(165) 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 UK, 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 $K_{a,i}$ measured at the surface of the phantom with a suitable calibrated detector using standard equations and conversion factors (Dance, 1990; Dance et al., 2000, 2009, 2011; IPEM, 2005; Dance and Young, 2014). The D_G DRL value adopted as a comparator for this standard breast by the UK Breast Screening Programme is 2.5 mGy.

(166) In the USA, 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. US 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 for film-screen mammography, and 1.6 mGy for digital mammography (Spelic et al., 2007).

(167) For the same views (i.e. craniocaudal, mediolateral), screening programmes for asymptomatic individuals should use the same DRL values as examinations performed to investigate patients with clinical symptoms.

3.6. Dental radiography

(168) There are some examinations that are relatively independent of patient size. Examples are dental intra-oral 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 provide the best option, rather than measurements on individual patients. Surveys may be performed by direct measurement with radiation detectors when QA checks are made on the x-ray units.

(169) A convenient method for setting DRL values and evaluating patient dose for dental radiography is to make measurements at standard settings. Intra-oral 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 $K_{a,i}$ can be made at standard settings with a suitable calibrated detector placed at the end of the spacer cone of the x-ray set (Gulson et al., 2007). This measurement relates to the air kerma incident on the skin surface.

(170) The measurements made must utilise the exposure settings that the dentist uses regularly. Information must be obtained to confirm the settings specified in the dental protocol. 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.

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

(172) 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, which 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.

(173) 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 performed. Periodic refresher training in radiographic techniques and the optimisation of radiation protection is recommended.

(174) 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 DWP (mean $K_{a,i}$ in the beam $\times$ beam width) and positioned at the receiving slit, can be used (Holroyd, 2012a; Mitchell and Martin, 2013). 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 DWP. However, as the air kerma varies across the beam, this method is subject to greater error.

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, should be tracked for interventional procedures. This will aid the optimisation process.**
- **The Commission recommends that the DRL process should be applied to both interventional fluoroscopy and interventional CT.**
- **For interventional procedures, complexity is a determinant of patient dose, and should ideally be evaluated individually for each case. A multiplying factor for the DRL may be appropriate for more complex cases of a procedure.**
- **An alternative method requires both a regional or national data set comprising dosimetric data for every case of a procedure from a large number of facilities, and a local data set of the dosimetric data for every case of the same procedure performed at the local facility.**
- **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

(175) DRLs were introduced for diagnostic radiology examinations in the 1980s and came into wide use in the 1990s (ICRP, 1991, 2001a; 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.

(176) DRLs are most useful for diagnostic imaging 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.

(177) For fluoroscopically guided interventional (FGI) procedures (e.g. interventional cardiology and interventional radiology procedures), the Commission has

stated that, in principle, DRLs could be used for dose management, but they 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 (Padovani and Quai, 2005; ICRP, 2007c). The amount of radiation used in FGI procedures is strongly affected by procedure complexity due to patient anatomy, lesion characteristics, and disease severity (Vehmas, 1997; Bernardi et al., 2000; Peterzol et al., 2005; IAEA, 2009). DRLs for interventional procedures must be developed differently from 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) should be used as the purpose is similar (i.e. providing a tool for optimisation), and the introduction of a different name is likely to cause confusion.

(178) In principle, for the most accurate comparisons of dosimetric data among populations undergoing FGI procedures, it would be desirable to normalise P_{KA} and $K_{a,r}$ 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 that are similar to those from an analysis limited to patients in the weight range of 65–85 kg (IAEA, 2009). This is consistent with previous studies which showed that the amount of radiation used for FGI procedures is affected much more by procedure complexity than by patient weight (IAEA, 2009; Miller et al., 2009).

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

4.2. Complexity analyses

(180) Procedure complexity varies for interventional procedures because of variability between patients and between the lesions being treated. Variability between patients 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 radiation used for individual cases due to patient, operator, type of materials (catheters, stents, etc.), and equipment factors (Wall, 2001; ICRP, 2001a; Miller et al., 2003, 2012a; Balter et al., 2004; IAEA, 2009; NCRP, 2010).

(181) A potential approach to compensating for variability due to patient factors is to incorporate a measure of the complexity of the procedure (ICRP, 2001a, 2007c).

Some studies have explored the feasibility of establishing DRL values for certain interventional cardiology 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 percutaneous coronary interventions (number of vessels treated, number of lesions with American College of Cardiology/American Heart Association 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 (Ryan et al., 1988; Bernardi et al., 2000; Balter et al., 2008; IAEA, 2009).

(182) Only preliminary examples of complexity analyses for other interventional cardiology and interventional radiology procedures are available. Padovani et al. (2008a) have proposed grouping radiofrequency 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. D'Ercole et al. (2012) have proposed local DRL values based on complexity for neuroangiographic diagnostic procedures and interventions, such as cerebral angiography and embolisation of intracranial aneurysms and arteriovenous malformations. A recent study has classified three levels of complexity for some common interventional radiology procedures (transjugular hepatic biopsies, biliary drainage, uterine fibroid embolisation, colon endoprosthesis placement, femoropopliteal revascularisation, iliac stent placement, and hepatic chemoembolization), and provides national DRL values for these procedures for Spain (Ruiz Cruces et al., 2016). However, these are only examples of how the problem of complexity may be tackled. This is an area requiring active participation in the development of appropriate methods.

(183) These examples show that it is possible to determine complexity factors for individual interventional radiology 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 UK HPA study on percutaneous coronary interventions, the number of implanted stents was identified as the determinant that adequately described the complexity of these procedures (Hart et al., 2007). However, as assessing procedure complexity requires substantial clinical data that are often not available, many recent published studies have presented DRL values for interventional procedures without consideration of procedure complexity (Neofotistou et al., 2003; Peterzol et al., 2005; Balter et al., 2008; Miller et al., 2009; Vañó et al., 2009a).

4.3. Data sets for interventional fluoroscopy procedures

(184) A different method can be applied to characterise and analyse the amount of radiation used for FGI procedures, without the need for the clinical data (pathology information, image analysis, and technical and clinical complexity factors) that are

usually difficult to collect (NCRP, 2010; Balter et al., 2011). 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 performed in each of a large number of facilities (Smans et al., 2008; IAEA, 2009; Vañó et al., 2009a; Balter et al., 2011; Sánchez et al., 2011, 2014). 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.

(185) 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' (NCRP, 2010; Balter et al., 2011). The method utilises data from every case of a procedure to create the distribution of the DRL quantity, rather than a limited sample of cases, in order to compensate for the large variability in the values of the DRL quantities for these procedures (Padovani and Quai, 2005).

(186) Determination of the need for an investigation is the same as with other data sets used for DRLs (i.e. the local median value is compared with the 75th percentile of the benchmark data, and an investigation is performed if the local median exceeds the 75th percentile of the benchmark data). The local mean value should not be used because it can be strongly influenced by the high 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 FGI 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

(187) The quantity used should be easily measurable (ICRP, 2007c) or available. Cumulative fluoroscopy time is readily available, but has been shown to correlate poorly with peak skin dose ($D_{skin,max}$) (Fletcher et al., 2002). For FGI procedures, $K_{a,r}$ and P_{KA} have been developed as estimators of the risk of radiation-related tissue effects and stochastic effects, respectively, due to radiation.

(188) P_{KA} is a surrogate measure of the amount of energy delivered to the patient, and thus is a reasonable indicator of the risk of stochastic effects (Miller et al., 2003, 2012b; Hirshfeld et al., 2004; NCRP, 2010; Chambers et al., 2011). $K_{a,r}$ is a useful

predictor of $D_{skin,max}$ and therefore of the risk of tissue effects, such as radiation-induced skin injury (Hirshfeld et al., 2004; NCRP, 2010; Chambers et al., 2011; Miller et al., 2012b; Jones et al., 2014).

(189) In Europe, P_{KA} is commonly used. In the USA, $K_{a,r}$ is more available, likely because the US Food and Drug Administration has required that all fluoroscopic units manufactured after mid-2006 display $K_{a,r}$ but has not required display of P_{KA}. Display of both $K_{a,r}$ 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 with DRLs, both quantities are acceptable (ICRP, 2007c; NCRP, 2010).

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

(191) While the literature contains data for $K_{a,r}$, P_{KA}, or fluoroscopy time at multiple healthcare facilities and nations for adult interventional fluoroscopic procedures, these data have only been published recently for paediatric examinations, and the numbers of cases in these paediatric studies are typically more limited (Strauss et al., 2015; Ubeda et al., 2015).

(192) 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 $K_{a,e}$ and air kerma rate. They can provide assessments of radiation levels from the different imaging programmes available on the fluoroscope; information that is essential for optimisation (Martin et al., 1998; Vañó et al., 2005; Padovani et al., 2008b; Ubeda et al., 2011). If the fluoroscopic equipment is functioning properly and within specification, procedure protocols and operator technique should be examined (NRPB/RCR, 1990; Vañó and Gonzalez, 2001; Wall, 2001; NCRP, 2010). This sequence has been recommended because equipment faults and incorrect set-up are the easiest to evaluate and correct, while operator performance is the most difficult process to analyse and influence (Vañó and Gonzalez, 2001; Balter et al., 2011).

(193) Cone-beam CT 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 $K_{a,r}$ for the cone-beam CT portion of interventional procedures, when this information is available, may be helpful in optimisation of this portion of interventional procedures (Section 5.3.3). The same is true for three-dimensional rotational angiography (Corredoira et al., 2015).

4.5. Interventional computed tomography

(194) Interventions can be performed with CT guidance. Relatively few 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 USA 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.

(195) 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.

(196) 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; Joemai et al., 2009; Hoang et al., 2011; 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; Saidatul et al., 2010; Kim et al., 2011).

(197) 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 should 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.

(198) DLP may not be a suitable DRL quantity for CT-guided interventional procedures because the CT imaging required typically takes place over a narrow range of scan lengths and may result in a DLP value that is unusually low in comparison with 'standard' CT acquisitions. The Commission recommends that DRLs should be established for $CTDI_{vol}$, the number of CT sequences obtained, and CT fluoroscopy time.

5. DIGITAL RADIOGRAPHY, COMPUTED TOMOGRAPHY, NUCLEAR MEDICINE, AND MULTI-MODALITY PROCEDURES

- **The general points mentioned in Section 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 also be helpful. Size-specific dose estimates (SSDE) (AAPM, 2011) 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 also be useful, and may be used in addition to the cumulative DLP.**
- **For nuclear medicine, the Commission recommends that DRL values should be established in terms of the administered activity or, preferably, activity per body weight.**
- **Weight-based administered activities may not be appropriate for examinations where the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid scans, 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.**
- **As 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

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

(200) Storage-phosphor techniques were the first available techniques for digital radiography. As 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. However, because of the different photon energy sensitivities of the phosphors, it is necessary to make adjustments to any AEC device used (Doyle and Martin, 2006). 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 after 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.

(201) Charge-coupled device systems represent a small share of the market in most countries. The image of a luminescent screen is recorded with charge-coupled device cameras and converted into digital images.

(202) 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.

(203) 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

(204) 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 that patient dose is optimised to the clinical task, and that 'dose creep' (use of unnecessarily high levels of radiation) (ICRP, 2004; Williams et al., 2007) does not occur. Application of the DRL process is an essential part of a QA system. Also, as digital detectors are often more sensitive than the film-based systems they are replacing, DRL values should be set explicitly for digital detectors (not copied from those for film techniques) whenever digital detectors are installed.

(205) In Section 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 DRL values should be developed. The pitfalls of dose creep are explained in greater detail.

(206) DRL values for digital radiography should be set taking into account the principles set out in this publication. 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

(207) 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 Section 2. The choice of quantity should also take into account the DRL quantity used in other literature and DRL values.

(208) The quantities used to define DRL values for digital radiography depend upon the digital detector system in question, but include P_{KA}, $K_{a,i}$, and $K_{a,e}$ (ACR, 2013). P_{KA} may be recorded automatically if the radiography system has the capability to measure or calculate it, so users can compare these data directly with DRL values. For projection radiography, the Commission recommends using two quantities to set DRLs – P_{KA} and either $K_{a,e}$ or $K_{a,i}$, if available – in order to simplify evaluation of the proper use of collimation.

(209) There is much historical data available for $K_{a,e}$, but assessment involves either calculation or labour-intensive measurements; as such, assessment may not always be possible. Where tube output data from routine QC or direct measurement capabilities are not available to calculate $K_{a,e}$, standard output data based on the mean output values from surveys of a large number of representative x-ray units have been used (Asada et al., 2014; Martin and Sutton, 2014) (e.g. Table 3.2). However, this method will not identify equipment with unusual exposure or filtration characteristics, and is only recommended as an initial step until surveys of all equipment can be performed.

5.2.2. Procedure selection

(210) 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 the 'multiple image' aspect into account, 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 (EU, 2006).

5.3. Computed tomography

5.3.1. DRLs in computed tomography

(211) There are many examples in the literature of DRL values established for CT (ICRP, 2007b; Foley et al., 2012; NCRP, 2012). For the purposes of this publication, the term 'CT' applies to both single- and multi-detector CT scanners, but not cone-beam CT. Cone-beam CT is considered in Section 5.3.3.

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

(213) All CT digital detector systems have a high dynamic range. Coupled with the direct relationship between dose to the detector (and patient dose) and image quality, this means that high doses will provide high image quality without the saturation seen in film-based imaging techniques. Consequently, 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.

(214) It is important that the data set in patient dose 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- vs multi-slice scanners, filtered back projection vs iterative reconstruction), even for the same procedure.

5.3.2. Considerations for DRL surveys in computed tomography

(215) When setting DRL values for CT, the principles outlined in this publication should be taken into account. There are specific issues that must be decided prior to surveying DRL quantities and setting DRL values for CT.

(216) 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 RIS or PACS systems. (The lateral or antero-posterior dimensions of

patients are easily determined by a radiological technologist equipped with standard calipers designed to measure patient thickness.) With a reduced range in patient size, variation in the values of DRL quantities is reduced substantially. As a result, data from fewer patients are required for the determination of DRL values (IPEM, 2004).

(217) Another important aspect of setting DRL values 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, 2007b). 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.

(218) 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 should be assessed in patient surveys performed for the purpose of setting DRL values, as is the practice in France and the UK (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 (Section 6).

(219) SSDE may be used as an additional source of information for optimisation. SSDE is not considered to be an appropriate quantity to adopt as a DRL at this time, as it is not as widely used as $CTDI_{vol}$. When scanner technology provides automatic calculation of SSDE, its use can provide valuable additional information for use in optimisation. SSDE may be a suitable DRL quantity for CT in the future, particularly when DRLs are established for patient sizes with attenuation characteristics that are not reasonably modelled by one of the two standard CTDI phantoms.

(220) 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 also be of value, and may be used in addition to the cumulative DLP.

(221) Use of tube current modulation can reduce patient dose by 30–40% per scan sequence, 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 one. However, users should check

that the $CTDI_{vol}$ value recorded corresponds to that expected, as 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 to explain differences in cumulative DLP.

(222) This approach has the advantage of simplifying certain aspects of the optimisation analysis. For example, if the median cumulative DLP exceeds the DRL value in local practice, 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.

(223) Procedure selection is also important in ensuring that DRL values are fit for purpose. There are two aspects to this. When developing DRL values, it is important that all of the dosimetric data collected come from similar procedures across all participating clinical facilities. This ensures that comparisons between facilities remain valid and useful. A common problem is that there typically 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).

(224) 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.

(225) 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 of the chest, abdomen, and pelvis. Protocols may also include a variety of imaging tasks (e.g. angiography, perfusion, renal stone identification).

(226) 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, 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.

(227) If data collection is via paper forms, the number of patients will be limited, but should be at least 20–30. With restricted numbers, information on patient sizes should be recorded, if possible, or at least the range of sizes should be restricted, with very large and very small patients being excluded. This is not a concern when an automated data collection system is used.

(228) For CT, as for radiography and fluoroscopy, the optimal radiation dose varies with patient size (Samei and Christianson, 2014). However, differences in the

operation of tube current modulation systems affect the relationship between patient dose and size in different ways, so that translating tube current modulation settings in scanning protocols between CT scanners is not straightforward (McKenney et al., 2014; Martin and Sookpeng, 2016). As systems for automatic adjustment of tube current on CT scanners from different vendors use different image quality parameters on which to base their adjustments, relationships between the DRL quantities and patient size vary on different CT scanners. Settings of automatic tube current systems on some CT scanners that use noise as the image quality reference may lead to unnecessarily high radiation doses for large patients. It is therefore necessary to ensure that the survey data reflect values for appropriate patient size ranges. In consequence, either setting DRL values for several adult size ranges (based on either dimension or weight) or comparisons of complete patient dose data sets between scanners (Fig. 2.1), as recommended for interventional radiology, is advantageous (Martin, 2016).

5.3.3. Cone-beam computed tomography

(229) Cone-beam CT typically includes dental and maxillofacial cone-beam CT systems, cone-beam CT 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 compared with conventional CT, whereas fluoroscopy and radiotherapy applications require visualisation of soft tissue structures and substantially higher exposures, comparable to conventional CT.

(230) Cone-beam CT is the subject of a recent ICRP publication (ICRP, 2015). The Commission recommends the use of P_{KA}, $K_{a,r}$, $CTDI_{vol}$, and DLP as DRL quantities, depending on availability (Table 2.4). P_{KA} and $K_{a,r}$ are more likely to be available and useful for fluoroscopes and dental cone-beam CT systems (HPA, 2010), while $CTDI_{vol}$ and DLP are used for radiotherapy imaging systems and some dental cone-beam CT systems.

(231) As of 2017, little progress has been made towards setting DRLs for cone-beam CT. Based on a preliminary audit of P_{KA} values on 41 dental and maxillofacial cone-beam CT units, HPA (2010) proposed a tentative DRL (although termed an 'achievable dose') of 250 mGy cm^2, normalised to an area corresponding to 4×4 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 cone-beam CT applications. This remark is also relevant for other cone-beam CT applications. Dental and maxillofacial cone-beam CT procedures should not exceed the dose of comparable CT procedures for high-contrast objects (typical $CTDI_{vol} < 10$ mGy).

(232) When used to guide biopsies, cone-beam CT can reduce patient dose and improve targeting accuracy compared with conventional CT (Abi-Jaoudeh et al.,

2016). Cone-beam CT 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 radiation used for the procedure that is due to cone-beam CT can be substantial. Corredoira et al. (2015) analysed the total P_{KA} measured in paediatric interventional cardiology procedures, and observed that cone-beam CT contributed 33% of the radiation used in therapeutic procedures and 16% of the radiation used in diagnostic procedures.

5.4. DRLs in planar and SPECT nuclear medicine imaging

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

(234) SPECT is a nuclear medicine tomographic functional imaging technique that uses gamma 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 information. This information is typically presented as cross-sectional images of the patient. These images can be freely reformatted and presented. Recently, gamma cameras based on solid-state detectors [e.g. cadmium-zinc-telluride (CZT)] have been developed and are now commercially available. Where cameras using more sensitive detectors are used, consideration should be given to reducing the activity of radiopharmaceutical administered and therefore the DRL.

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

(236) For planar nuclear medicine imaging, DRLs are surveyed and have been set either by administered activity (MBq) (EC, 1999b) or, preferably, by administered activity per body weight ($MBq\,kg^{-1}$). The latter approach is practical and simple to adopt (Roch and Aubert, 2013). For some nuclear medicine investigations for which the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid, sentinel node imaging, pulmonary ventilation and perfusion studies), a standard activity could be administered for all adult patients. For other nuclear medicine examinations, the ideal would be for administered activities to be based on patient weight ($MBq\,kg^{-1}$). The Commission recommends that weight-based administered activities should be used for children, adolescents, and low-weight patients, and

considered for other groups. Setting of a fixed maximum activity for very obese patients may also be considered. Appropriate administered activities for children are discussed in Section 6.

(237) For SPECT imaging procedures, DRL values should be set in the same way as for planar nuclear medicine procedures. Again, the ideal approach would be the establishment of weight-based administered activities ($MBq\,kg^{-1}$) set for each radiopharmaceutical where these are considered appropriate. Very limited data on DRL values for SPECT exist as of 2015 (Avramova-Cholakova et al., 2015). DRL values for SPECT studies are normally slightly higher than for the same radiopharmaceuticals used for planar imaging.

(238) Guidance documents produced by various countries have recommended maximum administered activities for established diagnostic procedures using specific radiopharmaceuticals including guidance on activities for overweight patients (CRCPD, 2003; ARSAC, 2006; NCRP, 2012; ACR-AAPM, 2015; J-RIME, 2015; Watanabe et al., 2016). In Europe, the administered activity must take into account the data and information given in the Summary of Product Characteristics that are part of the marketing authorisation for each radiopharmaceutical (e.g. EMA, 2013).

(239) The recommended administered activity provided by an authority or a national association of nuclear medicine (ARSAC, 2006; Alessio et al., 2015; EANM, 2015; SNMMI, 2015) for an average adult patient may not be entirely representative of the real situation in practice. However, in a UK survey (HPA, 2008), most nuclear medicine centres used administered activities that were very close to those recommended. As the majority of hospitals and clinics use recommended administered activity levels or lower levels, there is less interdepartmental variation in patient dose than in diagnostic radiology. Individual practitioners are encouraged to use lower administered activities if their equipment or software permits, and the resultant image quality is adequate for diagnosis.

(240) The administered activity for individual patients may be adjusted upwards where there are sound clinical reasons to justify the change. Examples include a patient who is in extreme pain and cannot endure the normal investigation time, in order to allow the examination to be performed in a shorter time, or a patient who is obese. If the DRL will be adjusted routinely [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.)

(241) 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. On the other hand, it is not desirable, from a radiological protection point of view, to administer more activity to patients in order to achieve greater patient throughput.

5.5. Considerations for DRL surveys for nuclear medicine

(242) DRL values for nuclear medicine imaging should be set taking into account the principles outlined in this publication, and surveys should be performed in accordance with the guidelines given in Section 2. Useful data can also be obtained from QA and accreditation processes (Becker et al., 2016). It can be expected that DRL values will decrease with advances in technology, such as iterative reconstruction and CZT solid-state detectors (Gunalp, 2015; Piccinelli and Garcia, 2015).

(243) There are specific issues that must be decided prior to setting DRL values for nuclear medicine imaging. For most planar nuclear medicine procedures, except for specific devices such as CZT cameras, 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 1-day and 2-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 in some countries are based on the whole protocol with two injections, while in other countries, DRL values are provided separately for stress and rest imaging.

(244) Patient selection is an important aspect of establishing and using 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 (e.g. 70 ± 10 kg), and then a DRL value for administered activity per body weight ($MBq\,kg^{-1}$) can be calculated. DRL values for paediatric nuclear medicine are discussed in Section 6.

(245) Work is ongoing to establish a radiopharmaceutical radiation dose structured report template, similar in concept to the radiation dose structured report for imaging using x rays (ftp://medical.nema.org/medical/dicom/final/sup159_ft.pdf; https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_Suppl_REM-NM.pdf). This will allow efficient registration of administered activity, patient weight, etc. from any nuclear medicine procedure, and simplify inclusion of these procedures when an automated data collection system is used.

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

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

(247) 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.

(248) For the purposes of this publication, 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 radiation protection point of view, PET-MRI can be considered to be a PET scan.

(249) As 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 identified correctly. Considerations for PET, SPECT, and CT in hybrid imaging are considered below.

(250) Often a diagnostic-quality CT may not be needed for the nuclear medicine scan being performed, and a low-dose CT examination is adequate for attenuation correction and localisation. However, in some cases, the CT images from the PET-CT or SPECT-CT examination can be used to replace a diagnostic CT later, therefore reducing the exposure to the patient and providing additional information to aid in the interpretation of the nuclear medicine scan. This should be taken into account when setting DRLs.

5.6.1. Positron emission tomography

(251) 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 gamma photons emitted at almost 180° to each other. These pairs of annihilation photons are detected in a stationary detector ring around the patient. Three-dimensional images of the activity concentration within the body are then constructed.

(252) Different radiopharmaceuticals may be used for PET imaging, depending on the purpose of the study. ^{18}F-fluorodeoxiglucose (^{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-chloride are used to assess myocardial perfusion. ^{68}Ga-DOTATATE and DOTA-TOC reflect the status of somatostatin receptors in various neuroendocrine tumours. As the physical half-lives of radionuclides and biological half-times of radiopharmaceuticals are different, DRL values have to be set for each

radiopharmaceutical. As a majority of current PET examinations use ^{18}FDG, this section discusses ^{18}FDG PET and PET-CT alone.

(253) The ideal is for the administered activity to be adjusted for patient weight; this should be considered. Less activity is sufficient to generate good image quality for thin people, as attenuation and scatter effects of gamma photons in these individuals are less than those in obese individuals. US 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 (two- or three-dimensional), scan speed (min/table position), and table overlap during consecutive PET acquisitions ($\leq$30% or >30%) (Boellaard et al., 2015).

(254) As 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 <530 MBq (Boellaard et al., 2015) for PET systems equipped with LYSO scintillation detectors so as not to affect the image quality.

(255) Acquisition sensitivities vary, depending on the individual PET system. Older PET systems had a two-dimensional acquisition mode that used axial collimators. As computation power and electronics improved, a three-dimensional acquisition mode was developed. All collimator septa were removed, resulting in four to eight times higher sensitivity. In three-dimensional acquisition mode, the administered activity can be reduced without affecting image quality. The European Association of Nuclear Medicine recommends using administered activities of 380 MBq for the two-dimensional acquisition mode and 190 MBq for the three-dimensional acquisition mode for a 'standard' adult patient (75 ± 5 kg) (Boellaard et al., 2015).

(256) Newer PET-CT scanners offer time-of-flight (TOF) technology, which can help to overcome poor signal from large patients. TOF devices 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 to 3.5 MBq kg^{-1}) without loss of image quality (Etard et al., 2012).

(257) 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^{-1}, in agreement with contemporary European recommendations (Boellaard et al., 2015).

5.6.2. Computer tomography in PET-CT and SPECT-CT

(258) 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 localiser radiograph 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 for attenuation correction and anatomical localisation alone. 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 (Jallow et al., 2016).

(259) For a diagnostic contrast-enhanced CT, standard protocols should be used. It is preferable to perform a diagnostic CT alone for limited portions of the body. For the rest of the body, a low-dose CT is sufficient for attenuation correction and anatomic localisation. Current DRL values for diagnostic CT of the trunk are too high for the CT component of PET-CT if the CT is performed for attenuation correction and localisation alone. Despite wide variations between PET-CT systems (four-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).

6. PAEDIATRICS

- **Establishing DRL values for children is more challenging than for adults, due to the broad range of sizes 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 DRL values for paediatric imaging.**
- **The amounts of radiation used 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, compared with adults, means that more organs are likely to be within or near the primary beam in x-ray examinations in children, so precise collimation is both more important and more difficult. For projection radiography, fluoroscopy, and interventional fluoroscopy, the relevance of appropriate collimation is higher in children than in adults.**
- **Patient age categories have been used in the past to define groups of children for the purpose of establishing paediatric DRL values. It has become apparent that age alone is not a good indicator. Weight categories are preferred, and should be used whenever possible.**
- **Weight bands are recommended for establishing paediatric DRL values; this approach should be promoted. The European Guidelines recommend: <5 kg, 5–<15 kg, 15 –<30 kg, 30 –<50 kg, and 50–$<$ 80 kg. Age bands grouped around the ages of 0, 1, 5, 10, and 15 years can be used if age is the only available measure.**
- **For examinations involving the head, age groupings (instead of weight) are recommended for establishing DRL values.**
- **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-diameter phantom for body examinations and a 16-cm-diameter 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. SSDE may be used in addition to the recommended DRL quantities as an additional source of information for optimisation.**
- **For nuclear medicine imaging, the DRL quantities and DRL values are set as administered activity (MBq) or administered activity per body weight (MBq kg^{-1}) as 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 with appropriate available published data. This is especially relevant for paediatrics due to the scarcity of national or regional DRL values.**

6.1. Considerations relevant to paediatric DRLs

(260) Optimisation of paediatric imaging is of particular importance because the risk of 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 compared with adults means that more organs are likely to be within or near the primary beam in children, so precise collimation is both more important and more difficult (ICRP, 2013b). The geometry and spacing of the three sensors of AEC systems are designed for an adult-sized body, which limits the application of AEC-controlled exposures for paediatric patients. The small size of the trunk of the smallest patients and of the limbs of most paediatric patients require manual as opposed to AEC-controlled exposures because small bodies cannot adequately cover the entire area of an individual AEC sensor.

(261) The amount of radiation used 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, variation in patient radiation dose is not appropriate for two paediatric patients who are the same size when the area of anatomy that is irradiated is the same for the same clinical indication. This may be due to poor technique or failure to adapt imaging protocols to account for both paediatric diseases and paediatric patient sizes. Weight- or size-adjusted paediatric DRL values 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.

(262) A number of factors need to be considered when discussing the development of DRL values 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 collect data from patient examinations or from measurements with phantoms. For other factors, particularly patient weight and size, specific considerations apply for children that must recognise the unique design characteristics, for example, of a given manufacturer's fluoroscopic unit, so that the unit is configured in a manner to take advantage of its strengths while minimising the effects of its design weaknesses.

(263) DRL values for adults are defined for a patient of standard size. 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 (<1 kg) to that of an obese adolescent (>100 kg). Within the first 6 months of life, a typical baby's body weight doubles, and during the first year, it increases three-fold. AAPM uses several different standard paediatric

phantoms to help in optimisation for paediatric imaging (AAPM, 2011). Ideally, five or more size ranges should be established between premature infants (<5 kg) and teenagers (~60 kg) who are smaller than standard-size adults.

(264) 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, 2007b, 2013b), 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). Four age groups (<1, >1–5, >5–10, and >10–15 years) have frequently been used in the past (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. Independent of variation in patient size, establishment of DRL values should involve a broad scope of practice types. Routine patient doses in academic centres may be different from typical patient doses in non-academic practices due to differences in confidence levels, familiarity with paediatric diseases, and body sizes.

(265) Weight is a more reliable factor to link with the DRL quantity than age (Watson and Coakley, 2010; Järvinen et al., 2015). Use of weight bands should be promoted. A number of different grouping schemes for patient size and patient weight have been described in the published literature. The European Commission (EC, 2016) has proposed the weight bands in Table 6.1, with an indication of the age bands to which they correspond. However, this equivalence will vary substantially in different parts of the world.

Table 6.1. Weight grouping for paediatric diagnostic reference levels (DRLs) recommended by the European Guidelines on DRLs for Paediatric Imaging and approximate equivalent ages (EC, 2016), and age groups used for earlier surveys.

Description	Weight group (kg)	Age group based on weight-for-age charts	Most common age groups used for the previous national DRLs (years)
Neonate	<5	<1 month	0
Infant, toddler, and early childhood	5–<15	1 month to <4 years	1
Middle childhood	15–<30	4–<10 years	5
Early adolescence	30–<50	10–<14 years	10
Late adolescence	50–<80	14–<18 years	15

(266) Age bands can be used if age is the only available measure. The most commonly used age bands for age groups up to 15 years of age are centred around the ages: 0, 1, 5, 10, and 15 years. If weight is available, this parameter should be collected so that DRL values can be presented in weight bands.

(267) 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).

(268) For comparison with national or regional DRL values, the weight ranges should be the same as those of the sample on which the DRL values were based. Comparison of results from different surveys should always be performed with caution, taking into consideration the method of grouping paediatric patients.

(269) 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 AEC 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 (i.e. small ranges of patient thickness that result in a small change of the total attenuation of the x rays between the smallest and largest patients within a given group of patient sizes).

(270) For CT, precise prescription of the scan length, in order to exclude primary irradiation of unnecessary regions of the paediatric body, is extremely important in optimising patient dose.

(271) For radiography and fluoroscopy, grouping paediatric patients into size groups for the purpose of determining DRL values and evaluating local practice can be performed accurately by measuring the thickness of the patient anatomy that will be directly irradiated with a set of calipers. This is particularly applicable to radiography performed with digital detectors, where numerous variables make it a challenge to deliver the correct entrance air kerma to the image receptor as a function of the wide variation of paediatric patient size. Any variable that can be eliminated by a simple measurement, such as measurement of patient thickness with calipers, helps to standardise the dose used for a patient of a given size, and allows more accurate development of DRL values as a function of patient size.

(272) Head size changes less with age than body size, so use of body weight for grouping paediatric patients is not appropriate. The European Commission recommendation for establishing DRL values for examinations involving the head is the use of age bands (<3 months, 3 months–<1 year, 1–<6 years and ≥6 years) (EC, 2017).

(273) Updating of existing paediatric DRL values has been very slow in comparison with the rapid development of imaging technology. In most countries, current paediatric DRL values are the first to be implemented, and were established many

years ago. Only a few countries have data on dose trends for paediatric procedures based on successive surveys of DRL quantities.

(274) As paediatric imaging in many hospitals is performed less frequently than adult examinations, data collection is a particular problem. There are likely to be only a few examinations in any paediatric 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 hospitals that provide paediatric imaging. An alternative to surveys is the establishment of an automated data collection system to which healthcare facilities submit dose data.

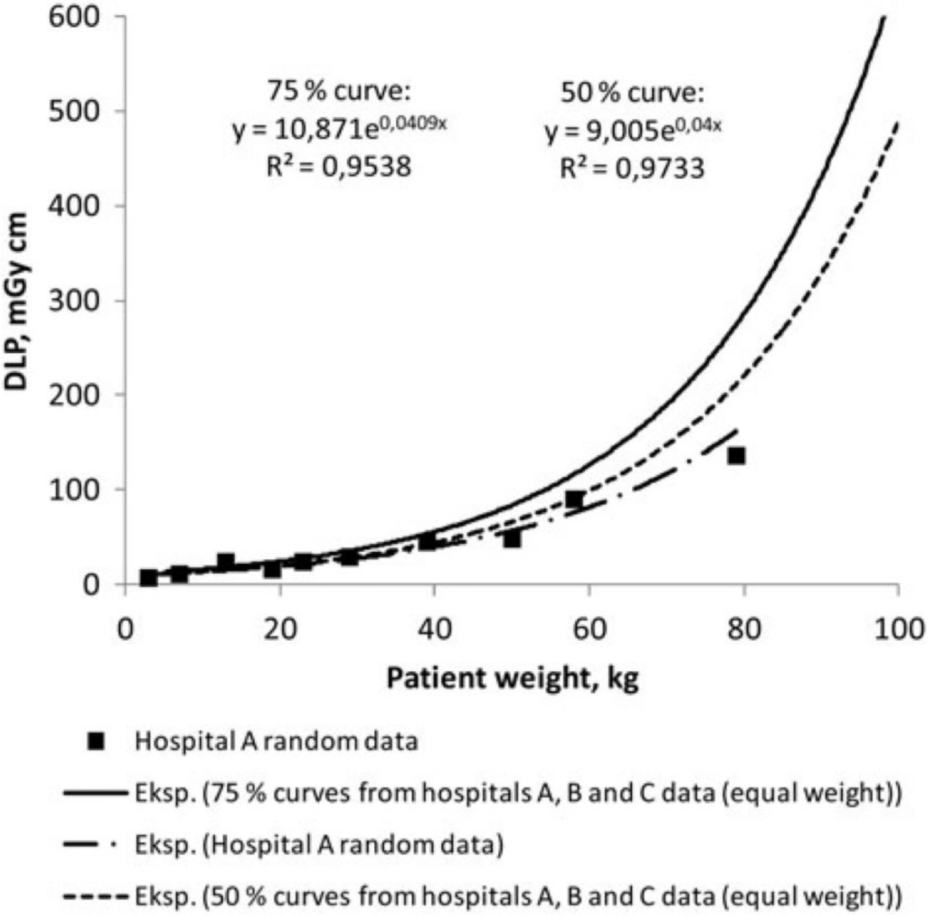

Fig. 6.1. An example of diagnostic reference level (DRL) quantity–weight curves for computed tomography (CT) of the chest, with dose–length product (DLP) as the DRL quantity. The DLP values relate to the 32-cm-diameter CT dosimetry phantom. The lowest curve shows an example of using this methodology to provide comparison for a limited data set from an individual hospital (Järvinen et al., 2015).

(275) 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, 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 (Järvinen et al., 2015). To compare local patient data with this curve, the user obtains data for a limited number of patients (e.g. 10 consecutive patients) regardless of their age, size, or weight, and overlays these data points on the DRL quantity–weight curve. If the majority of the points are beneath the DRL quantity–weight curve, or if a curve fitted to the data lies below the DRL curve, the DRL value has not been exceeded. The same principle has been applied to presenting DRL values for paediatric chest radiography, using patient thickness as a parameter (Kiljunen et al., 2007). This alternative has been used with some success in Scandinavia, but experience is limited to date.

6.2. Paediatric DRL values for computed tomography

(276) $CTDI_{vol}$ 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 some used the 32-cm-diameter phantom as the reference when calculating $CTDI_{vol}$ and DLP for paediatric body CT protocols. In 2012, 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).

(277) To compare $CTDI_{vol}$ or DLP values for patient examinations on a specific CT scanner with 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 $CTDl_{vol}$ 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 cases.

(278) Patient size has a large effect on the amount of radiation applied for a procedure, but phantom size does not address the variability in size of children or adults. AAPM Report 204 introduced a parameter known as SSDE to allow estimation of patient dose based on $CTDI_{vol}$ and patient size (AAPM, 2011). SSDE is $CTDI_{vol}$ adjusted for patient equivalent thickness based on a set of standard coefficients. This work has been extended in AAPM Report 220, which proposes a water equivalent diameter as the preferred patient size metric (AAPM, 2014; Gabusi et al., 2016).

(279) While the thickness of the body region imaged (the lateral dimension is easily measured with standard calipers) provides the most accurate classification of paediatric patient size, the current weight of the patient is the next best substitute if available. In the future, the equivalent thickness of the patient based on both the physical thickness of the patient and attenuation characteristics of the anatomy as determined by the CT scanner may result in the automated calculation and display of SSDE on the display of the CT scanner.

(280) Some caution is required in interpreting $CTDI_{vol}$ and DLP data for smaller paediatric patients. If a 16-cm-diameter phantom is used to determine the reference $CTDI_{vol}$, rather than a 32-cm-diameter phantom, patient dose could be overestimated by a factor of two to three. 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 could be accounted for.

(281) In the USA, the very large number of patients in the ACR registry has permitted median and 75th (and other) percentile values to be detemined for a number of paediatric CT examinations (http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/NRDR/DIR/DIR%20Percentiles%20Report.pdf) using age bands (weight data are not collected in the registry). Outside the USA, DRLs for paediatric CT are available for very limited types of examinations, and were included in earlier ICRP publications (ICRP, 2007b, 2013b; 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-diameter 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. Likewise, if iterative reconstruction is available and used by the operator at a given strength, the properly revised CT scan protocols may reduce patient dose.

(282) 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 antero-posterior and lateral dimensions (effective diameter = square root of the product of the antero-posterior and lateral dimensions). When both these dimensions are known, the product of the two dimensions can be used to estimate effective diameter.

(283) Use of patient equivalent thickness for grouping patients for the purpose of determining DRLs may be considered as an alternative to weight or as an 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.

(284) 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 to be more accurate and should be used when size information is available (AAPM, 2011).

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

(285) There is a need to establish DRL values for radiography, nuclear medicine, and interventional procedures. The DRL quantities recommended for adults apply equally to paediatric DRL values. 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 DRL values.

(286) During the last three decades, the UK has demonstrated the widest experience in periodically reviewing and revising DRL values for paediatric imaging. Even in the UK, 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 with any available published data.

(287) For diagnostic fluoroscopy, current national DRL values in European countries are given for micturating cystourography alone, except in the UK, 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 DRL values for paediatric interventional radiology or interventional cardiology. Attempts at establishing local paediatric DRL values for interventional procedures have been made in a number of countries, mainly in Europe but also in Asia and Latin America (Tsapaki et al., 2008; IAEA, 2009; Vitta et al., 2009; Kloeckner et al., 2012; Ubeda et al., 2015).

(288) For nuclear medicine imaging, examinations are surveyed and DRL values set using administered activity (MBq) or administered activity per body weight ($MBq\,kg^{-1}$) as the DRL quantity as 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; Lassmann and Treves, 2014). Standardisation of administered activities and the use of administered activity/weight charts is important for all paediatric nuclear medicine procedures, as sizable variations in administered activity have been shown to occur when they are not used.

(289) Weight-based radiopharmaceutical consensus values have been developed by the European Association of Nuclear Medicine (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 (Fahey et al., 2015, 2016; Grant et al., 2015; Lassmann and Treves, 2014). These have been tested in children's hospitals to ensure that adequate image quality is maintained with optimised radiation 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 result in a procedure that does not permit a clinical diagnosis.

7. APPLICATION OF DRLS IN CLINICAL PRACTICE

- DRLs should never be applied to individual patients, as some patients will require higher amounts of radiation for a given imaging examination or procedure than others due to their size, a particular diagnosis, or the complexity of the procedure.
- Local surveys of DRL quantities should normally be performed for diagnostic radiography and diagnostic fluoroscopy. A representative selection of examinations for each x-ray unit should be surveyed at intervals of about 3 years, and when substantial changes in technology or software have been introduced. This forms part of the regular review and optimisation process that is part of the QA programme (referred to in Europe as a 'clinical audit').
- Local surveys of DRL quantities, as part of the QA programme, should be more frequent (annual) for CT and interventional procedures. Annual surveys are also appropriate as part of the QA programme for SPECT-CT and PET-CT.
- If continuous collection of data on DRL quantities is possible through registries or automated collation of data from electronic databases, the dose management process may take the form of a regular review of all these data.
- 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 radiation protection or image quality can be reviewed and optimised if necessary.
- A DRL value is considered to be 'consistently exceeded' whenever the local median value of a DRL quantity for a representative sample of patients within an agreed range of weights or sizes is greater than the DRL value.
- If an audit or review of registry or database data reveals that a local or national DRL value is consistently exceeded, an investigation should be undertaken without undue delay and, where appropriate, a corrective action plan should be implemented and documented.
- The investigation 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.
- 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. The highest priority for any diagnostic imaging examination is achieving image quality sufficient for the clinical purpose.
- The median (the 50th percentile) of the national DRL 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 facility value of a DRL quantity is very much lower than the median value of the benchmark national DRL survey distribution, image quality (or diagnostic information, when multiple images are used) should be examined as a priority in the review.**
- **The DRL process does not stop after a single assessment. Repeat surveys are required following any optimisation, and the whole process should be repeated after an appropriate time interval.**

7.1. Quality assurance review of DRL quantities for x-ray examinations

(290) Local surveys of DRL quantities should be undertaken routinely in healthcare facilities where imaging examinations are performed with ionising radiation. These are part of the QA programme, 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 reviews are normally performed for a representative selection of examinations for each x-ray unit. In regions with limited infrastructure for data collection, intervals of about 3 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 doses of radiation. As automated systems for patient data collection and management become more widely available, the frequencies for review of all examinations should be reduced to annual. If continual collection of data on DRL quantities is possible through registries or automated collation of data from electronic databases, the dose management process may take the form of a regular review of all the data to identify any adverse trends at the earliest possible stage.

(291) When new imaging equipment is introduced, or changes are made to imaging 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.

(292) The DRL process provides a tool through which x-ray examinations, equipment, and facilities using higher amounts of radiation can be identified. However, this is just the start of the patient dose evaluation 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 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.

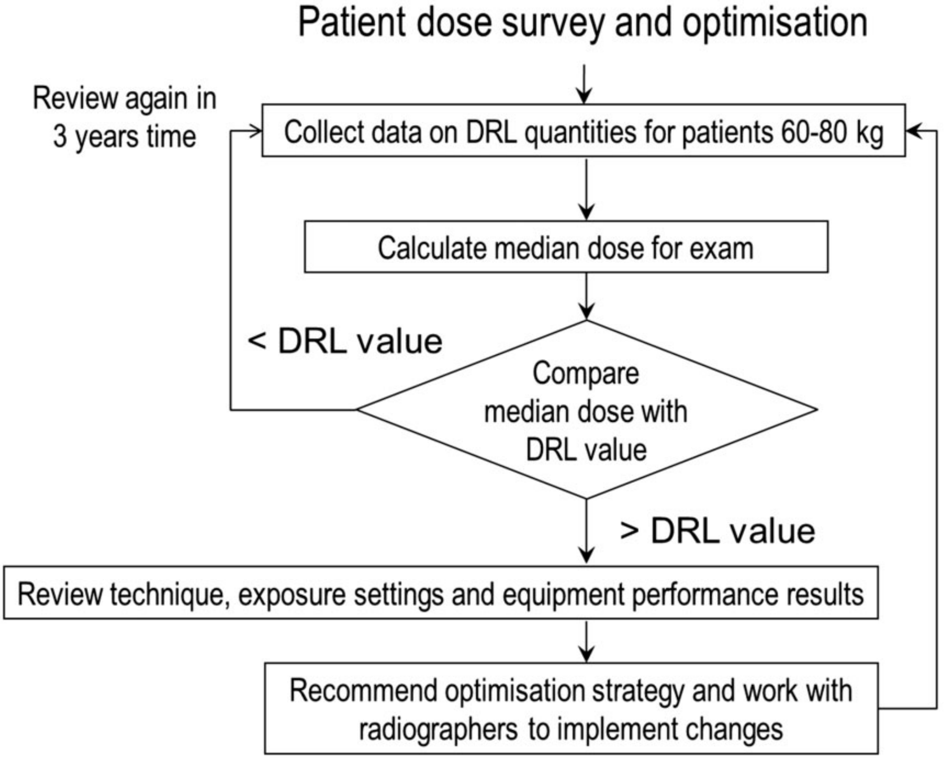

Fig. 7.1. Example of audit cycle and optimisation flow chart. DRL, diagnostic reference level.

7.1.1. Setting up a review programme in healthcare facilities

(293) Each facility should review carefully which examinations ought to be included in local reviews. 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) Reviews 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.

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

(a) Examinations should cover the work of all groups of operators who perform 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 value or other comparator available, although this is not essential.
(c) 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 or typical values.

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

(296) As discussed in Section 2.3.3, surveys for a particular examination should generally include at least 20 patients, and preferably ≥ 30 for diagnostic fluoroscopy examinations (IPSM/NRPB/CoR, 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 for a patient of standard size, 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. A weight criterion appropriate to the local, national, or regional population should be used. The weight inclusion criterion can be relaxed if data from an RIS or PACS for a large number of examinations are analysed.

(297) Surveys of DRL quantities for paediatric examinations (see Section 6) are more difficult to perform 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 the standard technique factors recorded on radiology department exposure charts for imaging children of different weights/ages. This can still be useful, as it helps to 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.

(298) 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. 7.1).

(299) Ideally, for interventional procedures, data should be collected for all cases of the procedure at the facility. 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 with the corresponding percentile values of the national ADS (see Section 4).

(300) Where collection of data is only possible for small numbers of patients, the uncertainty in the median or mean could be large. As 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. 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 = standard deviation/$\sqrt{n}$, 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. With regard to making judgements about whether a DRL has been exceeded from comparisons between the median for a patient group and the DRL, it is reasonable to assume a 10% uncertainty when analysing data from small numbers of patients.

7.1.2. Quality assurance review for dental radiography

(301) The application of the DRL process 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 frequently not made when new techniques are introduced (e.g. use of faster E- or F-speed film instead of D-speed film, or digital radiography image receptors). Establishment of national or regional DRL values for adult and paediatric examinations is recommended in terms of single values, but because of the substantial increase in sensitivity of digital radiography using imaging plates over film and computed radiography, the introduction of separate local DRLs or typical values for digital radiography systems can prove useful (Martin, 2016).

(302) The method for managing and achieving optimisation for dental radiography differs from the method for other x-ray applications, as 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 digital radiography image receptors (Gulson et al., 2007; Holroyd, 2012b; Farris and Spelic, 2015).

(303) All dental facilities should measure the dose and imaging performance of x-ray equipment at installation and at intervals thereafter, typically of 3 years. Dental DRL values are set for specific examinations using $K_{a,i}$ as the DRL quantity. The radiation dose for intra-oral 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 dentist.

(304) 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) described an example of the reductions in dental doses achieved in the West of Scotland through this approach. If there is no planned patient dose review 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

(305) If the review reveals that a DRL for any procedure is consistently exceeded, an investigation should be undertaken without undue delay, and appropriate corrective action should be performed (EC, 2013). 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 the examination protocols, and finally evaluate how the operators use the examination protocols.

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

(307) The QA review 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 3 years, and also when substantial changes in technology or software have been introduced. Local reviews of DRL quantities should be more frequent (annual) for CT and interventional procedures. Annual reviews are also appropriate for SPECT-CT and PET-CT.

(308) It is important that all QA programme dose reviews are documented and records 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

(309) QA programme reviews are quality improvement processes that seek to enhance patient care through systematic review and evaluation against explicit criteria, and implementation of change when indicated. Surveys of appropriate DRL

quantities and comparisons with DRL values can help identify where optimisation should be targeted.

(310) 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 review cycle. The factors that are most likely to 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; and
(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.

(311) Each of the preceding factors is discussed in more detail below. It is important to remember that the DRL process 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

(312) The first thing to be considered if the facility's median value of the DRL quantity exceeds the DRL value is whether the survey was performed 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 thermoluminescent dosimeters that were used calibrated appropriately and 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? Such meters will normally be calibrated in situ with the patient table and mattress in place. However, in some countries, this may not be the case, and then the proper patient table attenuation factor should be applied to the P_{KA} readings. For CT scanners, were the $CTDI_{vol}$ or mAs values representative of the true values or (for tube current modulation) the average mAs set?

(d) Were the displayed CT technique factors (e.g. kVp, slice thickness, $CTDI_{vol}$) calibrated correctly?
(e) Were all calculations performed using appropriate correction and calibration factors and based on output measurements?
(f) 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

(313) 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.

(314) 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 below.

7.4.1. Radiography and fluoroscopy

(315) 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 focused 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.

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

(317) Computed radiography or flat-panel digital radiography
(a) AEC not set up correctly.
(b) Use of a combination of computed radiography/digital radiography and film techniques in the same facility.
(c) Differences in grid usage.
(d) Inappropriate digital image processing.

(318) 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.

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

(320) 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. Computed tomography

(321) 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).

(322) 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.

(323) 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 the dose and decreasing the pitch will increase the dose. Other manufacturers (many Siemens and Philips models) adjust the tube current when the pitch is changed to maintain a similar dose level.

(324) 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. This is especially true when imaging the small trunk or head of the young paediatric patient or the extremities of any patient, paediatric or adult sized. A qualified medical physicist should be involved when changes in tube potential are considered.

(325) 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 use a measure of image quality based on the noise level in the image (many GE and Toshiba models). 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; Martin and Sookpeng, 2016).

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

(327) Selection of other parameters, such as filter options, can affect the function of the tube current modulation on Toshiba CT scanners. 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).

(328) 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, and the associated scanning protocol adapted. These techniques should be employed wherever available and practicable, and setting of lower DRL values linked to the reconstruction technique should be considered.

(329) 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.

(330) As 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 (see Sections 5.3.2 and 6.1). This may be done by taking data for different weight groupings or through the fit of an exponential equation to DLP vs 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 in an RIS or other patient dose management system, so that results for large numbers of patients are available, then the first and third quartiles may be recorded as well as the median value (Martin, 2016). If data collection and patient size assessment are automated, 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 with DRL values, can be useful in the evaluation.

7.4.3. Nuclear medicine

(331) As 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 publication.

(332) 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.

(333) 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, the purpose of the imaging task (i.e. whether it is primarily a diagnostic test or performed for attenuation correction or positioning) should be considered.

7.5. Procedure protocols

(334) 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

(335) 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).

(336) 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.

(337) A review of technique may identify a need to improve a clinical protocol to further optimise protection, especially for paediatric examinations. For the majority of procedures (adult or paediatric), 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 or typical 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. Computed tomography protocols

(338) 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. This may be more of a problem for manufacturer-suggested protocols for paediatric examinations than for adult examinations. 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; Cody et al., 2013). As CT scanner models are so different, clinical protocols must never be transferred between CT scanners without adjustment, unless the CT scanners are identical models running identical versions of system software.

(339) First, check whether the clinical imaging task for which the DRL value has been determined is similar to one for which the scan is used. Next, check whether DLP and $CTDI_{vol}$ are both too high. If DLP is high but $CTDI_{vol}$ is within the normal range, 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 initially performed without contrast material, followed by ones enhanced with contrast material. Consideration should be given to whether these sequences are all necessary for the clinical task in hand.

(340) If both DLP and $CTDI_{vol}$ are too high, the following scan parameters should be reviewed.

(a) Slice thickness.
(b) Beam collimation and geometric efficiency.
(c) Tube voltage.
(d) Beam-shaping filter.
(e) Is the helical pitch appropriate for the selected mAs?
(f) Is the relationship of helical pitch and the mAs indicator understood?
(g) Is the selected tube current modulation image noise indicator appropriate for the slice thickness?

(341) 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 parameters that can be set interact with other parameters. Tube current modulation systems that use noise as an image quality indicator may require that higher noise levels be set for larger patients. One should not assume that acceptable noise levels for CT images of small- and average-sized adults will be acceptable for small paediatric patients. Typically, lower levels of quantum mottle are required in paediatric imaging, especially of the smallest patients, which requires unique settings of image quality indicators as a function of patient size.

(342) 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.

(343) If the scanner manufacturer's application specialists do not have recommendations for changes to adult protocols to make them suitable for imaging of paediatric patients performed on their scanner, universal protocols for paediatric patients based on the protocols recommended on the Image Gently website should be helpful in establishing reference $CTDI_{vol}$, DLP, or SSDE values as a function of patient size (Strauss, 2014). Once reference dose indices as a function of patient size are determined by a particular site, the radiologists, technologists, and medical physicist(s) at

the site should work in collaboration with application specialists and other resource individuals from the manufacturer to ensure that the necessary modifications to paediatric protocols have been made to deliver the desired image quality and patient radiation dose.

(344) 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

(345) If the survey results exceed the local or national DRL value, but the imaging equipment performance is adequate according to QA tests, 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

(346) 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.

(347) Variations in operator skill can result in large variations in values of DRL quantities (e.g. P_{KA}, $K_{a,r}$, $CTDI_{vol}$, 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 radiographic images (e.g. digital subtraction angiography) can provide an obvious comparator, while review of relative values for $K_{a,r}$ 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.

(348) 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 in their performance.

(349) 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.

(350) 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

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

(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 performing 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.

(352) 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 or typical 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

(353) Comparisons of local data with 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.

(354) 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, a critical review of QA and maintenance programmes might be required. For example:

(a) High values of DRL quantities for computed radiography or digital radiography 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, 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 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 setting a higher local DRL or typical value.

(355) 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, appropriate testing to confirm that this is not the case must be completed and analysed prior to first clinical use of the changes.

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

7.9. National collation of patient dose survey results

(357) The results from dose surveys performed in local areas have the potential to provide valuable results for updating national patient dose records from which future DRL values may be derived. National dose registries should be established with mechanisms whereby dose survey results from radiology departments can be sent, so that patient dose levels can be continually updated. This will facilitate the revision of DRLs and ensure that the optimisation process continues to evolve and develop within the country.

8. SUMMARY OF MAIN POINTS

8.1. General

(358) The DRL process 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 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.

(359) A DRL value is considered to be consistently exceeded when the local median value of the appropriate DRL quantity for a representative sample of patients within an agreed weight range is greater than the local, national, or regional DRL value. Here, 'consistently' means 'in a majority of cases' and not 'over a period of time'.

(360) 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.

(361) 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.

(362) DRL values shall not be used for individual patients or as trigger (alert or alarm) levels for individual patients or individual examinations.

(363) Comparison of local practices with DRL values is not sufficient, by itself, for optimisation of protection. Action is required to identify and address any deficiencies. The highest priority for any diagnostic imaging examination is achieving image quality sufficient for the clinical purpose. Image quality or, more generally, the diagnostic information provided by the examination (including the effects of post-processing), must be evaluated as part of the DRL process, and methods to achieve optimisation should be implemented.

(364) All individuals who have a role in subjecting a patient to a medical imaging procedure should be familiar with the DRL process as a tool for optimisation of protection.

(365) 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

(366) 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 D_G may be used.

(367) DRL quantities should be appropriate to the imaging modality being evaluated, to the specific study being performed, and to the specific size of the patient.

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

(369) For projection radiography, two DRL quantities are recommended – $K_{a,e}$ (or $K_{a,i}$) and P_{KA} – in order to simplify assessment of proper use of collimation, especially in paediatrics.

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

(371) For mammography, the recommended DRL quantity is one or more of $K_{a,i}$, $K_{a,e}$, and D_G, with the choice of quantity depending on local practices and regulatory requirements.

(372) For mammography, a simple approach could be setting DRL values for breasts of 5.0 ± 0.5 cm thickness. Establishing DRL values for different breast thicknesses is a more complex but better approach to refine the DRL process for mammography.

(373) For interventional radiology, all of the following DRL quantities are recommended (if available): P_{KA}, cumulative air kerma at $K_{a,r}$, fluoroscopy time, and the number of radiographic images (e.g. cine images in cardiology and digital subtraction angiography images in vascular procedures).

(374) The recommended DRL quantities for CT are $CTDI_{vol}$ and DLP. The number of scan sequences in the examination may be helpful as well. SSDE provide more accurate estimates of paediatric patient doses than $CTDI_{vol}$ or DLP, which are both indices of the dose to standardised phantoms and may be used as an additional aid in optimisation.

(375) The recommended $CTDI_{vol}$ value to be used 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 also be useful, and may be used in addition to the cumulative DLP.

(376) For nuclear medicine, the ideal DRL quantity would be the administered activity per body weight of a specific radionuclide for a specific clinical task and, if relevant, the radiopharmaceutical used. The Commission recommends that weight-based administered activities should be used for children, adolescents, and low-weight patients, and considered for other groups. 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.

(377) 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).

(378) As DRL values for nuclear medicine procedures and CT procedures apply to radiation from very different modalities, and use different DRL quantities, for hybrid imaging procedures (SPECT-CT, PET-CT), it is appropriate to set and present DRL values for each modality independently.

8.3. Use of median values of the national survey distribution

(379) Compliance with DRL values 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 DRL value.

(380) This median value of the national distribution can serve as an additional tool to aid in optimisation, may be a desirable goal at which to aim using standard techniques and technologies, and represents a situation closer to the optimum use of the applied radiation.

(381) When the facility's median value of a DRL quantity is lower than the median value of the national distribution, image quality (or diagnostic information, when multiple images are used) might be affected adversely. Image quality should be considered as a greater priority in the review if additional optimisation efforts are undertaken.

8.4. DRL surveys and registries

(382) The Commission recommends setting local and national DRL values based on DRL quantities for imaging examinations and procedures performed on 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.

(383) 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.

(384) Data on DRL quantities may be collected using surveys, registries, or other automated data collection methods.

(385) 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.

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

(387) 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.

(388) DRLs are not intended for use in radiation therapy, but they should be considered for imaging for treatment planning, treatment rehearsal, and patient set-up verification in radiotherapy.

(389) National surveys and registries for setting DRL values 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.

(390) 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 DRL values, if no national registry or method for automated data collection exists. Results from 20–30 facilities are likely to be sufficient in the first instance. In a smaller country with fewer than 50 healthcare facilities, an initial survey of 30–50% of them may suffice.

(391) A survey for a particular examination in a facility should normally involve collection of data on DRL quantities for at least 20 patients, and preferably 30 patients for diagnostic fluoroscopy and CT examinations, and 50 patients for mammography. For paediatrics, these figures may need to be decreased for facilities where relatively few children are examined. For registries, all available and appropriate data should be used.

(392) 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 and 80 kg for a mean weight of 70 ± 5 kg).

(393) HIS and RIS can provide data for large numbers of patients, but may not include patient weight. As with all DRL surveys, the results rely on the accuracy of data entry.

(394) RIS and associated software may permit data on DRL quantities to be obtained in an automated fashion, either locally or through a national registry. 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

(395) The DRL value should be tied to defined clinical and technical requirements for the selected medical imaging task.

(396) The appropriate image quality or diagnostic information needed for the clinical task should be a priority when setting DRL values. DRL values may differ for different clinical tasks, especially for CT where visualisation of differences in the internal structure of tissues or identification of nodules is often important. Different tasks may require use of different image filters with varying exposure levels.

(397) It is important when developing DRL values that all data collected come from similar procedures across all participating facilities. This ensures that comparisons among facilities remain valid and useful.

(398) 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.

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

(400) DRL values are dependent on the state of practice and the available technology (including postprocessing software) at a particular point in time.

(401) Median values (not mean values) of the distributions of data collected from a representative sample of patients within an agreed weight range should be used for comparison with DRL values. The mean can be affected substantially by a few high or low values.

(402) National DRL values should be set as the 75th percentile of median values obtained in a sample of representative centres.

(403) If regional (multi-national) DRL values are created, they should be set as the median value of the national DRL values (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.

(404) The process to set and to update DRL values 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 DRL values to be derived from these data while waiting for a wider survey to be conducted.

(405) 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).

(406) Local DRL values set by a group of radiology departments 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. Where the number of facilities or x-ray rooms is small, the median of the distribution of values of the DRL quantity is recommended as a 'typical value'. Typical values can also be set for newer technologies that enable decreased amounts of radiation to be used in achieving a similar level of image quality.

(407) Published DRL values should be accompanied by a statement of the local group, nation, or region from which the patient data were collected, the size of the 'standard' patient on whom the data are based, the details of the specific examination, as appropriate, and the date of the survey.

8.6. DRLs for interventional procedures

(408) The Commission recommends retaining the term 'diagnostic reference level' for the DRL process as applied to interventional procedures.

(409) For interventional procedures, complexity of the procedure may be considered in setting DRL values, and a multiplying factor for the DRL value may be appropriate for more complex cases of a procedure.

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

8.7. Paediatric DRLs

(411) A single 'representative patient' should not be used to define DRLs for paediatric imaging, as weight in children can vary by a factor of more than 100 from a premature infant to an obese adolescent.

(412) The amount of radiation used 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.

(413) Weight bands are recommended for establishing paediatric DRL values for examinations of the trunk and should be promoted for paediatrics. Age bands can be used if age is the only available measure.

(414) Age groupings are recommended for establishing DRL values for examinations involving the head.

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

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

(417) For nuclear medicine imaging, consideration should be given to adjusting administered activities based on agreed factors linked to weight. Adjustments should be made for paediatric examinations.

8.8. Application of DRLs in clinical practice

(418) 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 postprocessing of images become available.

(419) Median values of the DRL quantity for medical imaging procedures in a representative sample of patients within an agreed weight range 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.

(420) If a local or national DRL value for any procedure is consistently exceeded, an investigation should be performed without undue delay, and, if appropriate, corrective action should be taken.

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

(422) 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.

(423) 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 and the actual size of the patient irradiated.

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

(425) The DRL audit process does not stop after a single assessment. Repeat evaluations are required following any optimisation, and the whole process should be repeated after an appropriate time interval.

(426) Local surveys of DRL quantities should normally be performed as part of the QA programme unless these data are continuously submitted to a registry, in which case, review of the registry data should be performed. A representative selection of examinations for each x-ray unit should be surveyed at intervals of about 3 years, and whenever substantial changes in technology or software have been introduced.

(427) Local surveys of DRL quantities, as part of the QA programme, should be performed annually for CT and interventional procedures, unless these data are continuously submitted to a registry, in which case review of the registry data should be performed at least annually. Annual surveys or review of registry data are also appropriate as part of the QA programme for SPECT-CT and PET-CT.

(428) If continuous collection of data on DRL quantities is possible through registries or automated collation of data from electronic databases, the dose

management process may take the form of a regular review of all the data to identify any adverse trends.

(429) 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 protocols (equipment settings) and adjustments. The investigator should work with the dentist to optimise protection. Improvement in protection linked to new technology can be realised which otherwise might not be achieved.

REFERENCES

AAPM, 2011a. Size-specific Dose Estimates (SSDE) in Pediatric and Adult Body CT Examinations. AAPM Report No. 204. American Association of Physicists in Medicine, College Park, MD.

AAPM, 2011b. AAPM Recommendations Regarding Notification and Alert Values for CT Scanners: Guidelines for Use of the NEMA XR 25 CT Dose-Check Standard. AAPM Dose Check Guidelines Version 1. American Association of Physicists in Medicine, Alexandra, VA, USA.

AAPM, 2014. Use of Water Equivalent Diameter for Calculating Patient Size and Size-Specific Dose Estimates (SSDE) in CT. Report of AAPM Task Group 220. American Association of Physicists in Medicine, College Park, MD.

Abi-Jaoudeh, N., Fisher, T., Jacobus, J., et al., 2016. Prospective randomized trial for imageguided biopsy using cone-beam CT navigation compared with conventional CT. J. Vasc. Interv. Radiol. 27, 1342–1349.

ACR-SPR, 2014. ACR-SPR Practice Parameter for Performing FDG-PET/CT in Oncology. American College of Radiology, Reston, VA. Available at: http://www.acr.org/_/media/ACR/Documents/PGTS/guidelines/FDG_PET_CT.pdf (last accessed 29 June 2017).

ACR, 2013. ACR-AAPM Practice Parameter for Diagnostic Reference Levels and Achievable Doses in Medical X-ray Imaging. American College of Radiology, Reston, VA. Available at: http://www.acr.org/_/media/ACR/Documents/PGTS/guidelines/Reference_Levels_Diagnostic_Xray.pdf (last accessed 29 June 2017).

ACR-AAPM, 2015. ACR-AAPM Practice Parameter for Reference Levels and Achievable Administered Activity for Nuclear Medicine and Molecular Imaging. American College of Radiology, Reston, VA. Available at: http://www.acr.org/_/media/ACR/Documents/PGTS/guidelines/Reference_Levels.pdf (last accessed 29 June 2017).

Alessio, A.M., Farrell, M.B., Fahey, F.H., 2015. Role of reference levels in nuclear medicine: a report of the SNMMI Dose Optimization Task Force. J. Nucl. Med. 56, 1960–1964.

Ardenfors, O., Svanholm, U., Jacobsson, H., et al., 2015. Reduced acquisition times in whole body bone scintigraphy using a noise-reducing Pixon-algorithm – a qualitative evaluation study. EJNMMI Res. 5, 48.

ARSAC, 2006. Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources. Administration of Radioactive Substances Advisory Committee, Health Protection Agency, Chilton.

ARSAC, 2014. Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources. Department of Health, Public Health England, and Administration of Radioactive Substances Advisory Committee, Chilton. Available at: https://www.gov.uk/government/publications/arsac-notes-for-guidance (last accessed 10 August 2017).

Asada, Y., Suzuki, S., Minami, K., Shirakawa, S., 2014. Results of a 2011 national questionnaire for investigation of mean glandular dose from mammography in Japan. J. Radiol. Prot. 34, 125–132.

Avramova-Cholakova, S., Dimcheva, M., Petrova, E., et al., 2015. Patient doses from hybrid SPECT-CT procedures. Radiat. Prot. Dosim. 165, 424–429.

Balter, S., Schueler, B.A., Miller, D.L., et al., 2004. Radiation doses in interventional radiology procedures: the RAD-IR Study. Part III: dosimetric performance of the interventional fluoroscopy units. J. Vasc. Interv. Radiol. 15, 919–926.

Balter, S., Miller, D.L., Vañó, E., et al., 2008. A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures. Med. Phys. 35, 673–680.

Balter, S., Rosenstein, M., Miller, D.L., Schueler, B., Spelic, D., 2011. Patient radiation dose audits for fluoroscopically guided interventional proedures. Med. Phys. 38, 1611–1618.

Becker, M.D., Butler, P.F., Bhargavan-Chatfield, M., et al., 2016. Adult gamma camera myocardial perfusion imaging: diagnostic reference levels and achievable administered activities derived from ACR accreditation data. J. Am. Coll. Radiol. 13, 688–695.

Bernardi, G., Padovani, R., Morocutti, G., et al., 2000. Clinical and technical determinants of the complexity of percutaneous transluminal coronary angioplasty procedures: analysis in relation to radiation exposure parameters. Catheter. Cardiovasc. Interv. 51, 1–9 discussion 10.

Bhargavan-Chatfield, M., Morin, R.L., 2013. The ACR computed tomography dose index registry: The 5 million examination update. J. Am. Coll. Radiol. 10, 980–983.

Boellaard, R., Delgado-Bolton, R., Oyen, W.J.G., et al., 2015. FDG PET/CT: EANM procedure guidelines for tumour imaging: version 2.0. Eur. J. Nucl. Med. Mol. Imag. 42, 328–354.

Boone, J.M., 1999. Glandular breast dose for monoenergetic and high-energy x-ray beams: Monte Carlo Assessment. Radiology. 213, 23–37.

Botros, G.M., Smart, R.C., Towson, J.E., 2009. Diagnostic reference activities for nuclear medicine procedures in Australia and New Zealand derived from the 2008 survey. ANZ Nucl. Med. 40, 2–11.

Buls, N., Pagés, J., de Mey, J., Osteaux, M., 2003. Evaluation of patient and staff doses during various CT fluoroscopy guided interventions. Health Phys. 85, 165–173.

Chambers, C.E., Fetterly, K.A., Holzer, R., et al., 2011. Radiation safety program for the cardiac catheterization laboratory. Catheter. Cardiovasc. Interv. 77, 546–556.

Charnock, P., Moores, B.M., Wilde, R., 2013. Establishing local and regional DRLs by means of electronic radiographical x-ray examination records. Radiat. Prot. Dosim. 157, 62–72.

Cody, D.D., Fisher, T.S., Gress, D.A., et al., 2013. AAPM Medical Physics Practice Guideline 1.a: CT protocol management and review practice guideline. J. Appl. Clin. Med. Phys. 14, 3–12.

Conway, B.J., Suleiman, O.H., Rueter, F.G., McCrohan, J.L., 1992. Patient equivalent attenuation phantoms. Radiat. Prot. Dosim. 43, 123–125.

Cook, T.S., Zimmerman, S., Maidment, A.D.A., Kim, W., Boonn, W.W., 2010. Automated extraction of radiation dose information for CT examinations. J. Am. Coll. Radiol. 7, 871–877.

Cook, T.S., Zimmerman, S.L., Steingall, S.R., et al., 2011. Informatics in radiology: RADIANCE: an automated, enterprise-wide solution for archiving and reporting CT radiation dose estimates. Radiographics. 31, 1833–1846.

Corredoira, E., Vañó, E., Ubeda, C., Gutiérrez-Larraya, F., 2015. Patient doses in paediatric interventional cardiology: impact of 3D rotational angiography. J. Radiol. Prot. 35, 179–195 Erratum in: J. Radiol. Prot. 35, 491.

CRCPD/CDRH, 1992. Average Patient Exposure Guides – 1992. CRCPD Pub. 92–4. Conference of Radiation Control Program Directors, Frankfort, KY, USA.

CRCPD, 2003. Use of radionuclides in the healing arts. In: Suggested State Regulations for Control of Radiation, Volume I (Ionising Radiation), Part G, CRCPD dynamic document. Conference of Radiation Control Program Directors, Frankfort, KY, USA. Available at: http://www.crcpd.org/SSRCRs/gpart.pdf (last accessed 29 June 2017).

Daly, B., Templeton, P.A., 1999. Real-time CT fluoroscopy: evolution of an interventional tool. Radiology. 211, 309–315.

Dance, D.R., 1990. Monte Carlo calculation of conversion factors for the estimation of mean glandular breast dose. Phys. Med. Biol. 351211–351219.

Dance, D.R., Skinner, C.L., Young, K.C., Beckett, J.R., Kotre, C.J., 2000. Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol. Phys. Med. Biol. 45, 3225–3240.

Dance, D.R., Young, K.C., van Engen, R.E., 2009. Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA dosimetry protocols. Phys. Med. Biol. 54, 4361–4372.

Dance, D.R., Young, K.C., van Engen, R.E., 2011. Estimation of mean glandular dose for breast tomosynthesis: factors for use with the UK, European and IAEA dosimetry protocols. Phys. Med. Biol. 56, 453–471.

Dance, D.R., Young, K.C., 2014. Estimation of mean glandular dose for contrast enhanced digital mammography: factors for use with the UK, European and IAEA breast dosimetry protocols. Phys. Med. Biol. 59, 2127–2137.

De Crop, A., Smeets, P., Hoof, T.V., et al., 2015. Correlation of clinical and physical-technical image quality in chest CT: a human cadaver study applied on iterative reconstruction. BMC Med. Imag. 15, 32.

D'Ercole, L., Thyrion, F.Z., Bocchiola, M., et al., 2012. Proposed local diagnostic reference levels in angiography and interventional neuroradiology and a preliminary analysis according to the complexity of the procedures. Physica. Medica. 28, 61–70.

DICOM, 2014. Supplement 159. Radiopharmaceutical Radiation Dose Reporting. DICOM Standards Committee, Rosslyn, VA, USA. Available at: ftp://medical.nema.org/medical/dicom/final/sup159_ft.pdf (last accessed 10 August 2017).

DIMOND, 2006. European Programme. Digital Imaging: Measures for Optimization of Radiological Information Content and Dose, Luxembourg. Available at: http://cordis.europa.eu/project/rcn/52375_en.html (last accessed 15 August 2017).

Doyle, P., Martin, C.J., 2006. Calibrating automatic exposure control devices for digital radiography. Phys. Med. Biol. 51, 5475–5485.

EANM, 2015. Guidelines. European Association of Nuclear Medicine, Vienna. Available at: http://www.eanm.org/publications/guidelines/index.php?navId¼37&PHPSESSID¼okn9uumdi20mmfjuop6edr7j87 (last accessed 29 June 2017).

EC, 1996a. European Guidelines on Quality Criteria for Diagnostic Radiographic Images. Report EUR 16260. Office for Official Publications of the European Communities, Luxembourg.

EC, 1996b. European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics. EUR 16261. Office for Official Publications of the European Communities, Luxembourg.

EC, 1997. Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Off. J. Eur. Commun. L180, 22–27.

EC, 1999a. European Guidelines on Quality Criteria for Computed Tomography. Report EUR 16262 EN. Official Publications of the European Communities, Luxembourg.

EC, 1999b. Guidance on Diagnostic Reference Levels for Medical Exposures. Radiation Protection 109. European Commission, Brussels. Available at: https://ec.europa.eu/energy/sites/ener/files/documents/109_en.pdf (last accessed 14 March 2015).

EC, 2008. European Guidance on Estimating Population Doses from Medical X-ray Procedures. Radiation Protection No. 154 . European Commission, Directorate-General for Energy and Transport, Luxembourg. Available at: https://ec.europa.eu/energy/sites/ener/files/documents/154.zip (last accessed 10 August 2017).

EC, 2012. Radiation Protection No. 172. Cone Beam CT for Dental and Maxillofacial Radiology – Evidence Based Guidelines. European Commission, Luxembourg. Available at: http://www.sedentexct.eu/content/guidelines-cbct-dental-and-maxillofacial-radiology (last accessed 29 June 2017).

EC, 2013. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/.

Euratom and 2003/122/Euratom. Off. J. Eur. Union L13, 1–73. Available at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri¼OJ:L:2014:013:0001:0073:EN:PDF (last accessed 30 June 2017).

EC, 2014. (Part 1) Medical Radiation Exposure of the European Population. (Part 2) Diagnostic Reference Levels in Thirty-six European Countries. Radiation Protection No. 180. European Commission, Luxembourg. Available at: https://ec.europa.eu/energy/en/radiation-protection-publications (last accessed 29 June 2017).

EC, 2016. European Guidelines on Diagnostic Reference Levels for Paediatric Imaging. Radiation Protection 185. European Union, Luxembourg.

EC, 2017. European Guidelines on DRLs for paediatric imaging (in press). European Commission, Luxembourg.

Escalon, J.G., Chatfield, M.B., Sengupta, D., Loftus, M.L., 2015. Dose length products for the 10 most commonly ordered CT examinations in adults: analysis of three years of the ACR Dose Index Registry. J. Am. Coll. Radiol. 12, 815–823.

EMA, 2013. Guideline on Core SmPC and Package Leaflet for Technetium (99mTc) Sestamibi. European Medicines Agency, London. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/12/WC500158406.pdf (last accessed 29 June 2017).

Etard, C., Celier, D., Roch, P., Aubert, B., 2012. National survey of patient doses from wholebody FDG PET-CT examinations in France in 2011. Radiat. Prot. Dosim. 152, 334–338.

EU, 2006. European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, fourth ed. Office for Official Publications of the European Communities, Luxembourg. Available at: http://www.euref.org/downloads?download¼24:europeanguidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pdf (last accessed 29 June 2017).

EU, 2013. European Directive 2013/59/EURATOM. Off. J. Eur. Union L13, 1–73. Available at: https://ec.europa.eu/energy/sites/ener/files/documents/CELEX-32013L0059-ENTXT.pdf (last accessed 28 June 2017).

Fahey, F.H., Bom, H.H., Chiti, A., et al., 2015. Standardization of administered activities in pediatric nuclear medicine: a report of the first Nuclear Medicine Global Initiative Project, Part 1. Statement of the issue and a review of available resources. J. Nucl. Med. 56, 646–651.

Fahey, F.H., Bom, H.H., Chiti, A., et al., 2016. Standardization of administered activities in pediatric nuclear medicine: a report of the first Nuclear Medicine Global Initiative Project, Part 2. Current standards and the path toward global standardization. J. Nucl. Med. 57, 1148–1157.

Farris, K., Spelic, D., 2015. Nationwide evaluation of x-ray trends: highlights of the 2014–15 NEXT Dental Survey. In: Proceedings of 47th National Conference on Radiation Control, August 2015. CRCPD Publication E-15-4, Frankfort, KY, USA.

FDA, 1984. Nationwide Evaluation of X-ray Trends (NEXT) Eight Years of Data (1974–1981). US Department of Health and Human Services, Public Health Service, Food and Drug Administration, Silver Spring, MD.

Fletcher, D.W., Miller, D.L., Balter, S., Taylor, M.A., 2002. Comparison of four techniques to estimate radiation dose to skin during angiographic and interventional radiology procedures. J. Vasc. Interv. Radiol. 13, 391–397.

Foley, S.J., McEntee, M.F., Rainford, L.A., 2012. Establishment of CT diagnostic reference levels in Ireland. Br. J. Radiol. 85, 1390–1397.

Fuchs, T., Kachelriess, M., Kalendar, W.A., 2000. Direct comparison of a xenon and a solidstate CT detector system: measurements under working conditions. IEEE Trans. Med. Imag. 19, 941–948.

Gabusi, M., Riccardi, L., Aliberti, C., Vito, S., Paiusco, M., 2016. Radiation dose in chest CT: assessment of size-specific dose estimates based on water equivalent correction. Phys. Med. Eur. J. Med. Phys. 32, 393–397.

Gianfelice, D., Lepanto, L., Perreault, P., Chartrand-Lefebvre, C., Milette, P.C., 2000a. Effect of the learning process on procedure times and radiation exposure for CT fluoroscopy-guided percutaneous biopsy procedures. J. Vasc. Interv. Radiol. 11, 1217–1221.

Gianfelice, D., Lepanto, L., Perreault, P., Chartrand-Lefebvre, C., Milette, P.C., 2000b. Value of CT fluoroscopy for percutaneous biopsy procedures. J. Vasc. Interv. Radiol. 11, 879–884.

Goenka, A.H., Dong, F., Wildman, B., et al., 2015. CT radiation dose optimization and tracking program at a large quaternary-care health care system. J. Am. Coll. Radiol. 12, 703–710.

Grant, F.D., Gelfand, M.J., Drubach, L.A., Treves, S.T., Fahey, F.H., 2015. Radiation doses for pediatric nuclear medicine studies: comparing the North American consensus guidelines and the pediatric dosage card of the European Association of Nuclear Medicine. Pediatr. Radiol. 45, 706–713.

Guimaraes, L.S., Fletcher, J.G., Harmsen, W.S., et al., 2010. Appropriate patient selection at abdominal dual-energy CT using 80 kV: relationship between patient size, image noise, and image quality. Radiology. 257, 732–742.

Gulson, A.D., Knapp, T.A., Ramsden, P.G., 2007. Doses to Patient Arising from Dental Xray Examinations in the UK 2002–2004. A Review of X-ray Protection Service Data. HPARPD-022. Health Protection Agency, Chilton.

Gunalp, B., 2015. Role of cardiac ultrafast cameras with CZT solid-state detectors and software developments on radiation absorbed dose reduction to the patients. Radiat. Prot. Dosim. 165, 461–463.

Gulson, A.D., Knapp, T.A., Ramsden, P.G., 2007. Doses to Patients Arising from Dental Xray Examinations in the UK 2002–2004. A Review of X-ray Protection Service Data. HPARPD-022. Health Protection Agency, Chilton.

Hart, D., Hillier, M.C., Wall, B.F., Shrimpton, P.C., Bungay, D., 1996a. Doses to Patients from Medical X-ray Examinations in the UK – 1995 Review. NRPB-R289. National Radiological Protection Board, Chilton.

Hart, D., Jones, D.G., Wall, B.F., 1996b. Coefficients for Estimating Effective Doses from Paediatric X-ray Examinations. NRPB-R279. National Radiological Protection Board, Chilton.

Hart, D., Hillier, M.C., Wall, B.F., 2007. Doses to Patients from Common Radiographic, and Fluoroscopic X-ray Imaging Procedures in the UK – 2005 Review. Report HPA-RPD-029. Health Protection Agency, Chilton.

Hart, D., Hillier, M.C., Wall, B.F., 2009. National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK. Br. J. Radiol. 82, 1–12.

Hart, D., Hillier, M.C., Shrimpton, P.C., 2012. Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK – 2010 Review Report. HPA-CRCE-034. Health Protection Agency, Chilton. Available at: https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls (last accessed 28 June 2017).

Hesse, B., Tagil, K., Cuocolo, A., et al., 2005. EANM/ESC procedural guidelines for myocardial perfusion imaging in nuclear cardiology. Eur. J. Nucl. Med. Mol. Imag. 32, 855–897.

Hirshfeld, J.W., Jr., Balter, S., Brinker, J.A., et al., 2004. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. J. Am. Coll. Cardiol. 44, 2259–2282.

Hoang, J.K., Yoshizumi, T.T., Toncheva, G., et al., 2011. Radiation dose exposure for lumbar spine epidural steroid injections: a comparison of conventional fluoroscopy data and CT fluoroscopy techniques. AJR. Am. J. Roentgenol. 197, 778–782.

Holroyd, J.R., 2012a. The Measurement of X-ray Beam Size from Dental Panoramic Radiography Equipment. HPA-CRCE-032. Health Protection Agency, Chilton.

Holroyd, J.R., 2012b. Trends in Dental Radiography Equipment and Patient Dose in the UK and Ireland. HPA-CRCE-043. Health Protection Agency, Chilton.

HPA, 2008. Frequency and Collective Dose for Medical and Dental X-ray Examinations in the UK. Report HPA-CRCE-012. Health Protection Agency, Chilton.

HPA, 2010. Recommendations for the Design of X-ray Facilities and the Quality Assurance of Dental Cone Beam CT (Computed Tomography) Systems. Report HPA-RPD-065. Health Protection Agency, Chilton.

IAEA, 1996. International Basic Safety Standards for Protection Against Ionizing Radiation and the Safety of Radiation Sources. Safety Series No. 115. International Atomic Energy Agency, Vienna.

IAEA, 2009. Establishing Guidance Levels in X-ray Guided Medical Interventional Procedures: a Pilot Study. Safety Reports Series No. 59. International Atomic Energy Agency, Vienna.

ICRP, 1987a. Protection of the patient in nuclear medicine. ICRP Publication 52. Ann. ICRP 17(4).

ICRP, 1987b. Radiation dose to patients from radiopharmaceuticals. ICRP Publication 53. Ann. ICRP 18(1–4).

ICRP, 1991. 1990 Recommendations of the International Commission on Radiological Protection. Publication 60. Ann. ICRP 21(1–3).

ICRP, 1996. Radiological protection and safety in medicine. ICRP Publication 73. Ann. ICRP 26(2).

ICRP, 1998. Radiation dose to patients from radiopharmaceuticals. Addendum 2 to ICRP Publication 53. ICRP Publication 80. Ann. ICRP 28(3).

ICRP, 2000. Avoidance of radiation injuries from interventional procedures. ICRP Publication 85. Ann. ICRP 30(2).

ICRP, 2001a. Diagnostic reference levels in medical imaging: review and additional advice. ICRP Supporting Guidance 2. Ann. ICRP 31(4).

ICRP, 2001b. Radiation and your patient: a guide for medical practitioners. Supporting Guidance 2. Ann. ICRP 31(4).

ICRP, 2004. Managing patient dose in digital radiology. ICRP Publication 93. Ann. ICRP 34(1).

ICRP, 2007a. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37(2–4).

ICRP, 2007b. Managing patient dose in multi-detector computed tomography (MDCT).

ICRP Publication 102. Ann ICRP 37(1).

ICRP, 2007c. Radiation protection in medicine. ICRP Publication 105. Ann ICRP 37(6).

ICRP, 2008. Radiation dose to patients from radiopharmaceuticals. Addendum 3 to ICRP Publication 53. ICRP Publication 106. Ann. ICRP 38(1/2).

ICRP, 2009. Education and training in radiological protection for diagnostic and interventional procedures. Publication 113. Ann. ICRP 39(5).

ICRP, 2013a. Radiological protection in cardiology. ICRP Publication 120. Ann ICRP 42(1).

ICRP, 2013b. Radiological protection in paediatric diagnostic and interventional radiology.

ICRP Publication 121. Ann. ICRP 42(2).

ICRP, 2015. Radiation dose to patients from radiopharmaceuticals. A compendium of current information related to frequently used substances. ICRP Publication 128. Ann. ICRP 44(2S).

ICRU, 1995. Medical imaging – the assessment of image quality. Report 54. International Commission on Radiation Units and Measurements, Bethesda, MD.

ICRU, 2005. Patient dosimetry for x-rays used in medical imaging. Report 74. J. ICRU 5, 1–113.

ICRU, 2012. Radiation dose and image quality and image-quality assessment in computed tomography. Report 87. J. ICRU 12, 1–149.

IEC, 2000. Medical Electrical Equipment – Part 2-43. Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures. Report 60601. International.

Electrotechnical Commission, Geneva.

IEC, 2010. Medical Electrical Equipment – Part 2-43. Particular requirements for the safety of X-ray equipment for interventional procedures, 2nd ed. Report 60601. International Electrotechnical Commission, Geneva.

IEC, 2012. Medical Electrical Equipment – Part 2-44: Particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Computed Tomography. IEC 60601-2-44, ed 3.1. IEC, Geneva.

ICRU, 1995. Medical Imaging – the Assessment of Image Quality. Report 54. International Commission on Radiation Units and Measurements, Bethesda, MD.

ICRU, 2005. Patient dosimetry for x rays used in medical imaging. ICRU Report 74. J. ICRU 5, 1–113.

ICRU, 2012. Radiation dose and image-quality assessment in computed tomography. ICRU Report 87. J. ICRU 1, 1–164.

IEC, 2010. Medical Electrical Equipment – Part 2-43. Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures, second ed. Report 60601. International Electrotechnical Commission, Geneva.

Ikuta, I., Sodickson, A., Wasser, E.J., et al., 2012. Exposing exposure: enhancing patient safety through automated data mining of nuclear medicine reports for quality assurance and organ dose monitoring. Radiology 264, 406–413.

IPEM, 2004. Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations. IPEM Report 88. Institute of Physics and Engineering in Medicine, York.

IPEM, 2005. Commissioning and Routine Testing of Mammographic X-ray Systems. Report No. 89. Institute of Physics and Engineering in Medicine, York.

IPSM/NRPB/CoR, 1992. National Protocol for Patient Dose Measurements in Diagnostic Radiology. National Radiological Protection Board, Chilton.

J-RIME, 2015. Diagnostic Reference Levels Based on Latest Surveys in Japan – Japan DRLs 2015. Japan Network for Research and Information on Medical Exposures, Gojodori, Shimogyo-ku, Kyoto. Available at: http://www.radher.jp/J-RIME/report/DRLhoukokusyoEng.pdf (last accessed 29 June 2017).

Jallow, N., Christian, P., Sunderland, J., et al., 2016. Diagnostic reference levels of CT radiation dose in whole-body PET/CT. J. Nucl. Med. 57, 238–241.

Ja?rvinen, H., Seuri, R., Kortesniemi, M., et al., 2015. Indication based national diagnostic reference levels for paediatric CT: a new approach with proposed values. Radiat. Prot. Dosim. 165, 86–90.

Jensen, J.E., Butler, P.F., 1978. Breast exposure: nationwide trends; a mammographic quality assurance program – results to date. Radiol. Technol. 50, 251–257.

Jones, A.K., Ensor, J.E., Pasciak, A.S., 2014. How accurately can the peak skin dose in fluoroscopy be determined using indirect dose metrics? Med. Phys. 41, 071913.

Joemai, R.M., Zweers, D., Obermann, W.R., Geleijns, J., 2009. Assessment of patient and occupational dose in established and new applications of MDCT fluoroscopy. AJR. Am. J. Roentgenol. 192, 881–886.

Kiljunen, T., Ja?rvinen, H., Savolainen, S., 2007. Diagnostic reference levels for thorax X-ray examinations of paediatric patients. Br. J. Radiol. 80, 452–459.

Kim, G.R., Hur, J., Lee, S.M., et al., 2011. CT fluoroscopy-guided lung biopsy versus conventional CT-guided lung biopsy: a prospective controlled study to assess radiation doses and diagnostic performance. Eur. Radiol. 21, 232–239.

Kleinman, P.L., Strauss, K.J., Zurakowski, D., Buckley, K.S., Taylor, G.A., 2010. Patient size measured on CT images as a function of age at a tertiary care children's hospital. AJR. Am. J. Roentgenol. 194, 1611–1619.

Kloeckner, R., Bersch, A., dos Santos, D.P., et al., 2012. Radiation exposure in nonvascular fluoroscopy-guided interventional procedures. Cardiovasc. Intervent. Radiol. 35, 613–620.

Kwon, D., Little, M.P., Miller, D.L., 2011. Reference air kerma and kerma-area product as estimators of peak skin dose for fluoroscopically guided interventions. Med. Phys. 38, 4196–4204.

Lassmann, M., Biassoni, L., Monsieurs, M., Franzius, C., Jacobs, F., European Association of Nuclear Medicine (EANM) Dosimetry and Paediatrics Committees, 2007. The new EANM paediatric dosage card. Eur. J. Nucl. Med. Mol. Imag. 34, 796–798.

Lassmann, M., Treves, S.T., EANM/SNMMI Paediatric Dosage Harmonization Working Group, 2014. Paediatric radiopharmaceutical administration: harmonization of the 2007 EANM paediatric dosage card (version 1.5.2008) and the 2010 North American consensus guidelines. Eur. J. Nucl. Med. Mol. Imag. 41, 1036–1041.

Lee, S.M., Park, C.M., Lee, K.H., et al., 2014. C-arm cone-beam CT-guided percutaneous transthoracic needle biopsy of lung nodules: clinical experience in 1108 patients. Radiology. 271, 291–300.

Le Heron, J., 1989. Variability of Medical Diagnostic X-ray Machine Parameters as Determined from a National Survey. National Radiation Laboratory Report 1989/1. National Radiation Laboratory, Christchurch.

Li, X., Zhang, D., Liu, B., 2011. Automated extraction of radiation dose information from CT dose report images. Am. J. Roentgenol. 196, W781–W783.

Lightfoot, C.B., Ju, Y., Dubois, J., et al., 2013. Cone-beam CT: an additional imaging tool in the interventional treatment and management of low-flow vascular malformations. J. Vasc. Interv. Radiol. 24, 981–988, e982.

Lukasiewicz, A., Bhargavan-Chatfield, M., Coombs, L., et al., 2014. Radiation dose index of renal colic protocol CT studies in the United States: a report from the American College of Radiology National Radiology Data Registry. Radiology. 271, 445–451.

MacGregor, K., Li, I., Dowdell, T., Gray, B.G., 2015. Identifying institutional diagnostic reference levels for CT with radiation dose monitoring software. Radiology. 276, 507–517.

Marshall, N.W., Chapple, C.L., Kotre, C.J., 2000. Diagnostic reference levels in interventional radiology. Phys. Med. Biol. 45, 3833–3846.

Martin, C.J., 2011. Management of patient dose in radiology in the UK. Radiat. Prot. Dosim. 147, 355–372.

Martin, C.J., 2016. The application of diagnostic reference levels for optimisation of x-ray imaging in the UK. Radiat. Prot. Dosim. 169, 211–216.

Martin, C.J., Darragh, C.L., McKenzie, G., Bayliss, A.P., 1993. Implementation of a programme for reduction of radiographic doses and results achieved through increases in tube potential. Br. J. Radiol. 66, 228–233.

Martin, C.J., Hunter, S., 1994. Reduction of patient doses from barium meal and barium enema examinations through charges in equipment factors. Br. J. Radiol. 67, 1196–1205.

Martin, C.J., Sutton, D.G., Workmann, A., Shaw, A., Temperton, D., 1998. Protocol for measurement of patient entrance surface dose rates for fluoroscopic equipment. Br. J. Radiol. 71, 1283–1287.

Martin, C.J., Sutton, D.G., Martin, C.J., Sutton, D.G., 2014. Diagnostic radiology – 3 patient dosimetry. Practical Radiation Protection in Healthcare, second ed.. Oxford University Press. Oxford.

Martin, C.J., Le Heron, J., Borrás, C., Sookpeng, S., Ramirez, G., 2013. Approaches to aspects of optimisation of protection in diagnostic radiology in six continents. J. Radiol. Prot. 33, 711–734.

Martin, C.J., Sookpeng, S., 2016. Setting up computed tomography automatic tube current modulation systems. J. Radiol. Prot. 36, R74–R95.

McKenney, S.E., Seibert, J.A., Lamba, R., Boone, J.M., 2014. Methods for CT automatic exposure control protocol translation between scanner platforms. J. Am. Coll. Radiol. 11, 285–291.

Miller, D.L., Balter, S., Cole, P.E., et al., RAD-IR study, 2003. Radiation doses in interventional radiology procedures: the RAD-IR study. Part I. Overall measures of dose. J. Vasc. Interv. Radiol. 14, 711–727.

Miller, D.L., Kwon, D., Bonavia, G.H., 2009. Reference levels for patient radiation doses in interventional radiology: proposed initial values for U.S. practice. Radiology. 253, 753–764.

Miller, D.L., Hilohi, C.M., Spelic, D.C., 2012a. Patient radiation doses in interventional cardiology in the U.S.: advisory data sets and possible initial values for U.S. reference levels. Med. Phys. 39, 6276–6286.

Miller, D.L., Balter, S., Dixon, R.G., et al., 2012a. Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures. J. Vasc. Interv. Radiol. 23, 11–18.

Minot, D.M., Jaben, E., Aubry, M.C., et al., 2012. Evolution of transthoracic fine needle aspiration and core needle biopsy practice: a comparison of two time periods, 1996–1998 and 2003–2005. Diagn. Cytopathol. 40, 876–881.

Mitchell, S.A., Martin, C.J., 2013. Comparison of ionisation and semiconductor detector devices for measurement of the dose–width product for panoramic dental. J. Radiol. Prot. 33, 321–325.

Morin, R.L., Coombs, L.P., Chatfield, M.B., 2011. ACR Dose Index Registry. J. Am. Coll. Radiol. 8, 288–291.

NCRP, 2009. Ionizing Radiation Exposure of the Population of the United States. NCRP Report 160. National Council on Radiation Protection and Measurements, Bethesda, MD.

NCRP, 2010. Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures. NCRP Report No. 168. National Council on Radiation Protection and Measurements, Bethesda, MD.

NCRP, 2012. Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States. NCRP Report No. 172. National Council on Radiation Protection and Measurements, Bethesda, MD.

NEMA, 2010. Computed Tomography Dose Check. NEMA Standards Publication XR 25-2010. National Electrical Manufacturers Association, Rosslyn, VA.

Neofotistou, V., Vañó, E., Padovani, R., et al., 2003. Preliminary reference levels in interventional cardiology. Eur. Radiol. 13, 2259–2263.

Niemann, T., Kollmann, T., Bongartz, G., 2008. Diagnostic performance of low-dose CT for the detection of urolithiasis: a meta-analysis. Am. J. Roentgenol. 191, 396–401.

Notghi, A., Williams, N., Smith, N., Goyle, S., Harding, L.K., 2003. Relationship between myocardial counts and patient weight: adjusting the injected activity in myocardial perfusion scans. Nucl. Med. Commun. 24, 55–59.

NRPB, 1999. Guidelines on Patient Dose to Promote the Optimisation of Protection for Diagnostic Medical Exposures. Documents of the NRPB 10(1). National Radiological Protection Board, Chilton.

NRPB/RCR, 1990. Patient Dose Reduction in Diagnostic Radiology. Documents of the NRPB 1(3). HMSO, London.

Padovani, R., Quai, E., 2005. Patient dosimetry approaches in interventional cardiology and literature dose data review. Radiat. Prot. Dosim. 117, 217–221.

Padovani, R., Vañó, E., Trianni, A., et al., 2008a. Reference levels at European level for cardiac interventional procedures. Radiat. Prot. Dosim. 129, 104–107.

Padovani, R., Trianni, A., Bokou, C., et al., 2008b. Survey on performance assessment of cardiac angiography systems. Radiat. Prot Dosim. 129, 108–111.

Peterzol, A., Quai, E., Padovani, R., et al., 2005. Reference levels in PTCA as a function of procedure complexity. Radiat. Prot. Dosim. 117, 54–58.

Piccinelli, M., Garcia, E.V., 2015. Advances in software for faster procedure and lower radiotracer dose myocardial perfusion imaging. Prog. Cardiovasc. Dis. 57, 579–587.

Roch, P., Aubert, B., 2013. French diagnostic reference levels in diagnostic radiology, computed tomography and nuclear medicine: 2004–2008 review. Radiat. Prot. Dosim. 154, 52–75.

Ruiz Cruces, R., Vañó, E., Carrera-Magarinõ, F., et al., 2016. Diagnostic reference levels and complexity indices in interventional radiology: a national programme. Eur. Radiol. 26, 4268–4276.

Ryan, T.J., Faxon, D.P., Gunnar, R.M., et al., 1988. Guidelines for percutaneous transluminal coronary angioplasty. A report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Percutaneous Transluminal Coronary Angioplasty). Circulation. 78, 486–502.

Saidatul, A., Azlan, C., Megat Amin, M., et al., 2010. A survey of radiation dose to patients and operators during radiofrequency ablation using computed tomography. Biomed. Imaging Interv. J. 6, e1.

Samara, E.T., Aroua, A., De, P.R., et al., 2012. An audit of diagnostic reference levels in interventional cardiology and radiology: are there differences between academic and non-academic centres? Radiat. Prot. Dosim. 148, 74–82.

Samei, E., Christianson, O., 2014. Dose index analytics: more than a low number. J. Am. Coll. Radiol. 11, 832–834.

Sánchez, R., Vañó, E., Fernández, J.M., et al., 2011. A national programme for patient and staff dose monitoring in interventional cardiology. Radiat. Prot. Dosim. 147, 57–61.

Sánchez, R.M., Vañó, E., Fernández, J.M., et al., 2014. Initial results from a national followup program to monitor radiation doses for patients in interventional cardiology. Rev. Esp. Cardiol. (Engl. Ed.). 67, 63–65.

Seidenbusch, M.C., Schneider, K., 2014. Conversion coefficients for determining organ doses in paediatric pelvis and hip joint radiography. Pediatr. Radiol. 44, 1110–1123.

SENTINEL, 2007. European Programme. Safety and Efficacy for New Techniques and Imaging Using New Equipment to Support European Legislation: Supporting Digital Medicine. Available at: http://cordis.europa.eu/pub/fp6-euratom/docs/sentinel_projrep_en.pdf (last accessed 15 August 2017).

Shrimpton, P.C., Wall, B.F., Jones, D.G., et al., 1986. A National Survey of Doses to Patients Undergoing a Selection of Routine X-ray Examinations in English Hospitals. NRPB-R200. HMSO, London.

Shrimpton, P.C., Wall, B.F., Hillier, M.C., 1989. Suggested guideline doses for medical examinations. In: Radiation Protection – Theory and Practice. Proceedings of the 4th International Symposium of the Society of Radiological Protection 1989. Institute of Physics, Bristol, pp. 85–88.

Shrimpton, P.C., Hillier, M.C., Meeson, S., Golding, S.J., 2014. Doses from Computed Tomography (CT) Examinations in the UK – 2011 Review. PHE-CRCE-013. Public Health England, Chilton.

Smans, K., Vañó, E., Sanchez, R., et al., 2008. Results of a European survey on patient doses in paediatric radiology. Radiat. Prot. Dosim. 129, 204–210.

SNMMI, 2015. Procedure Standards. Society of Nuclear Medicine and Molecular Imaging, Reston, VA. Available at: https://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber¼6414 (last accessed 29 June 2017).

Sodickson, A., Warden, G.I., Farkas, C.E., et al., 2012. Exposing exposure: automated anatomy-specific CT radiation exposure extraction for quality assurance and radiation monitoring. Radiology. 264, 397–405.

Sookpeng, S., Martin, C.J., Gentle, D.J., Lopez-Gonzalez, M.R., 2014. Relationships between patient size, dose and image noise under automatic tube current modulation systems. J. Radiol. Prot. 34, 103–123.

Sookpeng, S., Martin, C.J., Gentle, D.J., 2015. Investigation of the influence of image reconstruction filter and scan parameters on operation of automatic tube current modulation systems for different CT scanners. Radiat. Prot. Dosim. 163, 521–531.

Spelic, D.C., Kaczmarek, R.V., Hilohi, M., Belella, S., 2007. United States radiological health activities: inspection results of mammography facilities. Biomed. Imag. Interv. J. 3, e35.

Strauss, K.J., 2014. Dose indices: everybody wants a number. Pediatr. Radiol. 44 (Suppl. 3), 450–459.

Strauss, K.J., Racadio, J.M., Johnson, N., et al., 2015. Estimates of diagnostic reference levels for pediatric peripheral and abdominal fluoroscopically guided procedures. AJR. Am. J. Roentgenol. 204, W713–W719.

Sutton, D.G., McVey, S., Gentle, D., et al., 2014. CT chest abdomen pelvis doses in Scotland: has the DRL had its day? Br. J. Radiol. 87, 20140157.

Ten, J.I., Vañó, E., Sánchez, R., Fernandez-Soto, J.M., 2015. Automatic patient dose registry and clinical audit on line for mammography. Radiat. Prot. Dosim. 165, 346–349.

Trumm, C.G., Jakobs, T.F., Stahl, R., et al., 2013. CT fluoroscopy-guided vertebral augmentation with a radio frequency-induced, high-viscosity bone cement (StabiliT): technical results and polymethylmethacrylate leakages in 25 patients. Skeletal Radiol. 42, 113–120.

Tsapaki, V., Kottou, S., Korniotis, S., et al., 2008. Radiation doses in paediatric interventional cardiology procedures. Radiat. Prot. Dosim. 132, 390–394.

Ubeda, C., Vañó, E., Miranda, P., et al., 2011. Radiation dose and image quality for paediatric interventional cardiology systems. A national survey in Chile. Radiat. Prot. Dosim. 14, 429–4387, .

Ubeda, C., Miranda, P., Vañó, E., 2015. Local patient dose diagnostic reference levels in pediatric interventional cardiology in Chile using age bands and patient weight values. Med. Phys. 42, 615–622.

Vañó, E., Gonzalez, L., 2001. Approaches to establishing reference levels in interventional radiology. Radiat. Prot. Dosim. 94, 109–112.

Vañó, E., Geiger, B., Schreiner, A., Back, C., Beissel, J., 2005. Dynamic flat panel detector versus image intensifier in cardiac imaging: dose and image quality. Phys. Med. Biol. 50, 5731–5742.

Vañó, E., Fernandez, J.M., Ten, J.I., et al., 2007. Transition from screen-film to digital radiography: evolution of patient radiation doses at projection radiography. Radiology. 243, 461–466.

Vañó, E., Ten, J.I., Fernandez, J.M., et al., 2008a. Quality control and patient dosimetry in digital radiology. On line system: new features and transportability. Radiat. Prot. Dosim. 12, 144–146.

Vañó, E., Ubeda, C., Leyton, F., Miranda, P., 2008b. Radiation dose and image quality for paediatric interventional cardiology. Phys. Med. Biol. 53, 4049–4062.

Vañó, E., Sanchez, R., Fernandez, J.M., et al., 2009a. Patient dose reference levels for interventional radiology: a national approach. Cardiovasc. Intervent. Radiol. 32, 19–24.

Vañó, E., Sanchez, R., Fernandez, J.M., et al., 2009b. Importance of dose settings in the x-ray systems used for interventional radiology: a national survey. Cardiovasc. Intervent. Radiol. 32, 121–126.

Vañó, E., Ten, J.I., Fernandez-Soto, J.M., Sanchez-Casanueva, R.M., 2013. Experience with patient dosimetry and quality control online for diagnostic and interventional radiology using DICOM services. Am. J. Roentgenol. 200, 783–790.

Vassileva, J., Rehani, M.M., 2015. Patient grouping for dosimetry studies and establishment of diagnostic reference levels in paediatric CT. Radiat. Prot. Dosim. 165, 81–85.

Vassileva, J., Rehani, M., Kostova-Lefterova, D., et al., 2015. A study to establish international diagnostic reference levels for paediatric computed tomography. Radiat. Prot. Dosim. 165, 70–80.

Vehmas, T., 1997. Radiation exposure during standard and complex interventional procedures. Br. J. Radiol. 70, 296–298.

Vitta, L., Raghavan, A., Morrell, R., Sprigg, A., 2009. Fluoroscopy-guided insertion of nasojejunal tubes in children – setting local diagnostic reference levels. Pediatr. Radiol. 39, 1203–1208.

Wall, B.F., 2001. Diagnostic reference levels – the way forward. Br. J. Radiol. 74, 785–788.

Wall, B.F., Shrimpton, P.C., 1998. The historical development of reference doses in diagnostic radiology. Radiat. Prot. Dosim. 80, 15–19.

Wall, B.F., 2005. Implementation of DRLs in the UK. Radiat. Prot. Dosim. 114, 183–187.

Wallace, M.J., Kuo, M.D., Glaiberman, C., et al., 2008. Three-dimensional C-arm cone-beam CT: applications in the interventional suite. J. Vasc. Interv. Radiol. 19, 799–813.

Watanabe, H., Ishii, K., Hosono, M., et al., 2016. Report of a nationwide survey on actual administered radioactivities of radiopharmaceuticals for diagnostic reference levels in Japan. Ann. Nucl. Med. 30, 435–444.

Watson, D.J., Coakley, K.S., 2010. Paediatric CT reference doses based on weight and CT dosimetry phantom size: local experience using a 64-slice CT scanner. Pediatr. Radiol. 40, 693–703.

Williams, M.B., Krupinski, E.A., Strauss, K.J., et al., 2007. Digital radiography image quality: image acquisition. J. Am. Coll. Radiol. 4, 371–388.

Wu, X., Gingold, E.L., Barns, G., et al., 1994. Normalized average glandular dose in molybdenum target-rhodium filter and rhodium target-rhodium filter mammography. Radiology. 193, 83–89.

ANNEX A. PREVIOUS ICRP RECOMMENDATIONS ON DRLS

- **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

(430) 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, 2001a). Achieving acceptable image quality or adequate diagnostic information, consistent with the medical imaging task, is the over-riding clinical objective. DRLs are then used to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose.

(431) 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.

(432) 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 is given here.

A.2. Existing ICRP guidance

(433) *Publication 60* (ICRP, 1991) provided the following recommendation in the section on optimisation of protection in medical exposure in Para. 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.'

(434) *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 Para. S34 in more detail [Paras 99–106 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 be a lower level also (i.e. below which there is insufficient radiation dose to achieve a suitable medical image).
(c) DRLs are supplements to professional judgement 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 examinations 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

(435) 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.

(436) 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 had usually 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).

(437) 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.

(438) 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.

(439) 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 *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

(440) 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, 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 cognisant of these considerations.

A.5. Advice on DRLs provided in *Supporting Guidance 2* (ICRP, 2001)

A.5.1. Objective of a DRL

(441) The objective of a DRL is to help avoid delivery of excess radiation in the form of a 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 was 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

(442) 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.

A 'general imaging task' is an imaging task performed for a general clinical purpose, with minimum specification of other factors (e.g. a postero-anterior 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 postero-anterior 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 postero-anterior 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.

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

A.5.3. Definitions and examples

(444) 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 provide a general illustration of the advice. More focused discussions of desirable quantities for various medical imaging modalities are found in the relevant sections of this publication.

(445) 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) $K_{a,i}$ or $K_{a,e}$, in mGy, for a given radiographic projection (e.g. postero-anterior chest);
(b) 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, in MBq, for a given nuclear medicine imaging task using a given radiopharmaceutical (e.g. lung perfusion with Tc-99m macro-aggregated albumin).

(446) 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) $K_{a,i}$ or $K_{a,e}$, 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) P_{KA}, in mGy cm^2, for a given type of 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) 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.

(447) 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, in kVp, for a specific CT protocol. The clinical purpose, type of equipment, technique factors, and patient characteristics are defined; and
(b) administered activity, 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

(448) 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 is 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.

(449) 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, 2013a).

A.5.5. Local flexibility in setting DRLs

(450) 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.

(451) 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.

(452) 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.

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