European Guidelines on DRLs for Paediatric Imaging

Final complete draft

Contents

PREFACE

[*To be written by the EC; Approx. no of pages: 1. A proposal on the contents, to account for some feedback of the Workshop, is provided separately by the consortium.*]

EXECUTIVE SUMMARY

The establishment and use of diagnostic reference levels (DRLs) have been recommended by the International Commission on Radiological Protection (ICRP) and required in the European Council Directive 2013/59/Euratom Basic Safety Standards (BSS). DRLs are a useful tool in the quest to optimise patient doses in diagnostic radiology and interventional radiology (IR). Particular attention should be paid to establishing and using DRLs in paediatric radiology because children have a higher risk (for some organs and body areas) compared to adults from the detrimental effects of radiation.

A comprehensive European and worldwide review of DRLs for paediatric examinations (Section 5 and Annex C) has indicated that only a few countries have set DRLs for paediatric examinations and there is a complete lack of national DRLs for many examinations, in particular for all paediatric interventional procedures. Furthermore, the existing DRLs are often adopted from the old European Commission (EC) recommendations or from other countries, and only a few countries have based their DRLs on their own national patient dose surveys. In many countries, the initial DRLs have never been updated. Due to the huge variation of patient sizes among the paediatric population, several age, size or weight groups are needed to establish the DRLs, and there has been little consistency in grouping of the patients. Extensive patient dose surveys are needed to establish DRLs but there has been no detailed guidance on how to carry out and report such surveys in order to ensure consistent methods and comparability of the DRLs, in particular for reliable evaluation of DRLs for use at a European level.

In these Guidelines, basic recommendations on how to establish and to use DRLs for paediatric x-ray examinations and procedures have been given. DRLs for the paediatric examinations and procedures given in Section 6 should be established and used in accordance with the recommendations given in Sections 7-9.

The main recommendations of Section 6 are summarized as follows:

- All examinations resulting in high collective doses should have DRLs. This can include both the most common low dose examinations and the less common high dose examinations It is acknowledged that other common very low dose procedures (e.g. dental) should also be optimised.
- The application of DRLs should be the responsibility of all providers of X-ray imaging. This means that DRLs should also be applied to imaging performed outside the radiology department, including cardiology, orthopaedic surgery, gastroenterology, intensive care (line placement), neurology, vascular surgery, etc. Specific considerations may also be appropriate for imaging associated with radiation therapy where the purpose and scope of imaging can be different.
- The list of radiography, fluoroscopy and CT examinations where DRLs are recommended are given in Tables 6.2 and 6.3. DRLs should be defined separately for different indications if these require different image quality.

- For IR procedures, the development of LDRLs should be encouraged and the feasibility of NDRLs and EDRLs should be studied. The main focus should initially be to establish LDRLs for local guidance where the number of variabilities a priori is smaller. LDRLs between centres should then be compared and the reasons for the large differences should be studied, to be able to decide if NDRLs and EDRLs are appropriate. In Section 6.3, a few IR procedures have been specified where DRLs (at least LDRLs) could be established:
- As a note for emerging or increasing new practices, DRLs established for conventional CT should be applied to the CT part of hybrid imaging when the CT is used for diagnostic purposes. There is also a need to develop DRLs for paediatric cone beam CT (CBCT) examinations.

The main recommendations of Section 7-9 are summarized as follows:

- The physical *quantity* used to establish DRLs should be an easily measurable quantity, usually directly obtainable from the x-ray equipment console, obtained either by manual recording or preferably by automatic recording and analysis. Organ doses and effective dose are not considered feasible as a DRL quantity because these cannot be easily determined. The following quantities are recommended (see the list of symbols and abbreviations in Annex H):
  - Radiography: P_{KA} (primary quantity) and $K_{a,e}$ (useful additional quantity)
  - Fluoroscopy: P_{KA} (primary quantity), $K_{a,r}$, fluoroscopy time and number of images (useful additional quantities)
  - Computed tomography: $CTDI_{vol}$ and DLP, determined for a 32 cm phantom (all body CT examinations: chest, abdomen, trunk and spine) and for a 16 cm phantom (head CT examinations); besides $CTDI_{vol}$, when available, SSDE can be used for all body CT examinations
  - IR: P_{KA} (primary quantity), $K_{a,r}$, fluoroscopy time and number of images (useful additional quantities)
- The values used for patient dose monitoring, at the display unit and in the DICOM header should be *regularly calibrated or checked* for all beam qualities used in clinical practice. In particular, such calibrations or checks should be made prior to comparison with NDRLs and also prior to submission of data as part of national dose collection.
- The *parameters to group the patients* should be patient weights for all body examinations and patient ages for all head examinations (this recommendation might not be valid for some examinations where little experience on DRLs exist, e.g. for IR, IC and dental procedures). For body examinations, in the transition period until data from weight-based patient dose surveys becomes available, age can be used as an additional grouping parameter and for the purpose of comparing proposed new weight-based DRLs with earlier age-based DRLs (trend analysis). For the comparison purposes, an approximate equivalence of the average weight and age groups can be deduced from the weight-for-age charts as shown in Table 7.2.
- Grouping of patients should be carried out with *intervals* as follows (Table 7.1):
  - Weight groups for body exams: < 5 kg, 5 - < 15 kg, 15 - < 30 kg, 30 - < 50 kg, 50 - < 80 kg. The recommended first weight group (< 5 kg or neonates) applies to newborn babies but does not apply to those in incubators.
  - Age groups for head exams: 0 - < 3 months, 3 months - < 1 y, 1 - < 6 y, ≥ 6 y
- The DRLs can also be given as a *DRL curve* by expressing the DRL quantity as a continuous function of the grouping parameter (e.g. DLP as a function of patient weight) provided the collected data for setting of the DRLs indicates a clear relationship between patient doses and the grouping parameter. This approach can help to overcome the problem

of poor statistics when it is difficult to find adequate patient dose data for each discrete group.

- The DRLs should be based on sufficient *patient dose data* determined or collected from the records of individual paediatric patients. Using data obtained only from typical protocol data or from measurements in phantoms is not recommended.
- National DRLs (NDRLs) should be based on national patient dose surveys with *a representative sample* of all radiological institutions and all types of equipment and practices in the country when practical. DRLs based on very limited surveys or on measurements only in phantoms, as well as DRLs adopted from international recommendations, such as these Guidelines (EDRLs) or from other countries, should only be used as preliminary values until data from the relevant patient dose surveys is available. For local DRLs (LDRLs), the sample should include data from all types of equipment used in the hospital or a group of hospitals.
- For NDRLs, by definition, the 3rd quartile or the *75th percentile* value of the median (the 50th percentile) values of the distributions of patient doses obtained from a representative sample of radiology departments in the country should be determined, for a defined clinical imaging task (i.e., common indication based protocol) surveyed for standardised patient groupings. To provide a better goal of optimisation for those institutions with new technology using advanced dose reduction techniques, the median or 50th percentile from the same distribution of patient doses should be provided as an additional tool for optimisation.
- For the setting of DRLs, statistically relevant numbers of patient dose data should be collected. From each hospital or radiology department a representative sample of at least 10 patients per procedure type and per patient group is recommended for non-complex examinations such as radiography and CT, and at least 20 patients per procedure type and per patient group for complex procedures such as fluoroscopy and fluoroscopically guided procedures.
- In collecting the patient dose data for the DRLs, likewise in daily imaging practices, there should always be a system in place to judge whether *image quality* is adequate for the diagnosis according to the indication of the examination. This could be based, e.g., on image quality assessment of typical test cases by several radiologists. The image quality requirement should be based on clinical grounds only.
- Due to the generally large amount of data needed and the large amount of potential errors when these data are to be collected during routine practice, *automatic data collection* is recommended wherever possible.
- Besides the actual patient dose data according to the recommended patient grouping, *other data from the examination characteristics* (e.g. x-ray equipment type, exposure parameters, use of AEC) should be collected for the evaluation and decision making when DRLs are to be established.
- Patient dose surveys for the basis of setting the NDRLs, should be *conducted by* the authoritative body which sets the DRLs or by another competent institution, with the *collaboration* of national professional/scientific societies or at least having recognized clinical experts as consultants in the process.
- The complete *history of the patient dose surveys* for the setting of DRLs, including all essential dosimetric and statistical information (e.g. quantities and their collected values, coverage of institutions and practices, sample sizes) should be *documented* and preferably reported.
- NDRLs should be *set by an authoritative body*, i.e. competent national authorities such as national radiation protection or health authorities, or specific institutions established and authorized by competent national authorities.

- *Instructions* on how to make use of the NDRLs or LDRLs (the purpose of the DRLs, recommended frequencies for comparison of the local dose levels with DRLs, the sample sizes recommended for comparison etc.) should always be provided with the DRLs.
- The *comparison* of patient dose levels of a hospital or a group of hospitals with LDRLs or NDRLs should be carried out at the minimum frequency of once per year. A median value of the patient dose distribution should be used to compare against the DRL, determined from a sample of at least 10 patients per patient group from each hospital. In cases where a DRL curve is used, a sample of at least 10 patients per DRL curve is recommended, distributed throughout the range of the patient grouping parameter. Automatic dose management/monitoring systems can enable frequent comparisons.
- Whenever the DRLs are consistently exceeded, appropriate *investigations* to identify the reasons, and *corrective actions* to improve the clinical practice, if necessary and feasible, should be taken without undue delay.
- The use of the DRLs, including all findings and subsequent corrective actions should be *documented* and made available for clinical audits (internal or external audits) and for regulatory inspections by competent authorities.
- DRLs should be *updated regularly*. NDRLs should be reviewed and updated at least every 5 years. LDRLs should be reviewed and updated at least every 3 years and when there are changes of equipment or practices which have a potential impact on patient dose levels.
- The NDRLs should be compared with available EDRLs whenever either of the values have been established or updated and consideration given to the need for further optimisation if the NDRLs are higher than the EDRLs.

It is strongly recommended that DRLs should be based on patient dose surveys and should sufficiently cover all types of the most common high dose (or where the collective dose to the population is significant) paediatric radiology practices in a healthcare facility or group of healthcare facilities (for LDRLs) or in the country (for NDRLs). As discussed in Section 6, different image quality requirements should be taken care of by using indication based DRLs where appropriate. To facilitate the establishment of DRLs and their frequent updating, the use of automatic dose collection systems is highly recommended whenever possible. The implementation and the results of patient dose surveys, and the subsequent procedures to establish DRLs, should be documented in a way that enables reliable comparison of DRLs. This will allow trends in their development to be followed-up and possibly established as European-wide preliminary levels where national DRLs have not yet been established.

Based on the critical review of all paediatric national DRLs set by authoritative bodies in European countries, including proposed national values not yet accepted by an authoritative body and also some relevant data from published nationwide patient dose surveys, a few European DRLs have been suggested for radiography, fluoroscopy and CT (Section 10). For fluoroscopy-guided paediatric interventional procedures, it has not been possible to propose EDRLs due to the lack of published NDRLs (paediatric cardiac procedures) or any DRLs (paediatric non-cardiac procedures). However, information on published studies on LDRLs and on the limited patient dose collection in the context of the PiDRL project has been presented in Annex G.

It is concluded (Section 10) that all the given EDRLs should be considered only as the preliminary choice for the NDRLs, until appropriate national patient dose surveys have been carried out and NDRLs based on these surveys have been established by an authoritative body. In particular, patient dose surveys and further research in coming years is needed for IR procedures, to study the feasibility of NDRLs and EDRLs for interventional procedures and to establish such DRLs when possible.

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1. Background

Tremendous growth in the use of computed tomography (CT) and interventional radiology (IR) procedures has taken place over the last 15 years. Radiological imaging of children, some organs of whose are particularly sensitive to radiation, has been shown to be among the fastest growing areas in the last few years. In 1999, the European Commission issued Radiation Protection 109 (RP 109), 'Guidance on diagnostic reference levels (DRLs) for medical exposure'. This document highlights the importance of establishing DRLs for high-dose medical examinations, in particular CT and IR, of patients sensitive to radiation, especially children. The approach most commonly used for adults has been that of average sized adult phantom or standard phantom. The same approach has not been considered appropriate for children in view of the wide variation in body habitus.

Despite a large number of studies available from European countries, European DRLs for paediatric patients are only available for some common radiological examinations. Hence, there was a need to consolidate what is available and to provide guidance on what actions are needed in using DRLs to further enhance radiation protection of children. The European Commission recognised this need and launched the PiDRL project on the establishment of European DRLs for paediatric patients in December 2013.

This 27-month tender project was awarded to a consortium, which is headed by the European Society of Radiology (ESR). Other participating organisations are key European stakeholders and professional groups with relevance to radiation protection of paediatric patients:

- European Society of Paediatric Radiology (ESPR)
- European Federation of Radiographer Societies (EFRS)
- European Federation of Organisations for Medical Physics (EFOMP)
- Finnish Radiation and Nuclear Safety Authority (STUK) with Luxembourg Institute of Science and Technology (LIST) as subcontractor

The PiDRL project aimed at:

- Agreeing on a methodology for establishing and using DRLs for paediatric imaging.
- Updating and extending the European DRLs to cover more procedures and a wider patient age/weight-range based on current knowledge.

The project's work was coordinated with the parallel work of the International Commission on Radiological Protection (ICRP) on DRLs in medical imaging, with an attempt to ensure consistent use of the concepts.

The project's work included three major tasks:

1. Developing European Guidelines on DRLs for paediatric imaging covering plain radiography, fluoroscopy, CT and IR procedures (Work Package 1)
2. Deciding on European DRLs for the main paediatric imaging procedures, involving plain radiography, fluoroscopy, CT, IR and as far as possible, examinations using mobile equipment, e.g. on neonates (Work Package 2)
3. Organising a European workshop to discuss the results of the first two tasks and the need for further action on DRLs and the optimisation of radiation protection of paediatric patients (Work Package 3). This workshop was held at the Lisbon School of Health Technology in Portugal on October 15-17, 2015.

2. Introduction

Diagnostic reference levels (DRLs) have been recommended by the International Commission on Radiological Protection (ICRP) (ICRP, 1991; 1996; 2001; 2007a; 2007b; 2013) as an advisory measure to improve optimisation of patient protection, by identifying high patient dose levels which might not be justified on the basis of image quality requirements. DRLs should be set for common examinations using easily measurable dose quantities. National DRLs are usually set by a collaboration of authorities and professional societies, typically using a percentile point (most commonly 75% or the 3rd quartile) of the observed distribution of patient doses in the country. ICRP has also stated (ICRP 2001) that DRLs specific to clinical indications (clinical protocols) are desirable. Consequently, in several groups of examinations, mainly of the adult population, DRLs have become a valuable tool in the optimisation of the procedures.

The European Council Directive 2013/59/Euratom Basic Safety Standards (BSS) (EC, 2013; repealing five earlier directives including 97/43/EURATOM, 1997), Article 56, requires that "Member States shall ensure the establishment, regular review and use of DRLs for radiodiagnostic examinations, having regard to the recommended European DRLs where available, and when appropriate, for interventional radiology (IR) procedures, and the availability of guidance for this purpose". In 1999 the Commission issued Radiation Protection 109 (RP 109; EC, 1999), "Guidance on diagnostic reference levels DRLs for medical exposure". RP 109 document highlighted the importance of establishing DRLs for high-dose medical examinations, in particular computed tomography (CT) and IR procedures and for patients groups that are more sensitive to radiation, especially children. However, RP 109 quoted paediatric DRLs only for several plain radiography examinations of standard sized five-year old patients.

Accumulating evidence from the last decade shows a tremendous growth in the use of CT examinations and IR procedures i.e. fluoroscopy-guided interventional procedures including cardiac procedures. A further significant change has been the transition from conventional film-screen to digital radiology. The importance of the need for DRLs in CT is also highlighted by the fact that exposures from CT examinations contribute a major part of the population dose from all diagnostic uses of radiation (EC, 2014). Radiological imaging of children is among the fastest growing in the last decade (UNSCEAR, 2013). Paediatric examinations and procedures are of special concern because, compared to adults, children have a higher risk from the detrimental effects of radiation. Increased incidence of cancer after CT examinations in childhood has been reported in recent years (Pearce et al, 2012, Matthews et al, 2013, UNSCEAR, 2013, Krill et al., 2015). Because of the limitations of the epidemiological studies so far, there is no indisputable evidence to determine the risk of cancer related to radiation received from diagnostic and interventional procedures (Journy et al. 2014, Harvey et al. 2015, Boice 2015). However, our present knowledge emphasises the significance of justification and dose optimisation in paediatric radiology (see e.g. IAEA, 2012).

Despite the recommendations and the clear need for DRLs for paediatric examinations, few paediatric DRL data are available and they are only set in a small number of countries within Europe. The reasons for this are many-fold: the number of paediatric examinations is lower than adults; patient dose levels vary considerably as a function of age, size or weight of the patients and therefore, DRLs for several age, size or weight groups need to be defined; due to the lack of standardisation of these groups, the comparison of DRLs or patient dose data with other countries is not straightforward; due to the general paucity of patient dose data for paediatric examinations, it is often difficult to collect sufficient data to establish DRLs, or to compare local values with established DRLs, for each age or weight sub-group. Patient dose surveys are needed to establish DRLs, and there is little guidance on the statistical requirements for such surveys and on how to

derive the DRL values. Special challenges may be introduced by different institutions, e.g. the procedures in a specialty cancer centre might require different DRLs compared to those in a more general institution. Further, the rapidly evolving technology may complicate the establishment of DRLs.

There are continuing efforts to develop DRLs throughout Europe as will be shown in Section 5. For example, DRLs for paediatric CT examinations have been established or studied in several European countries including Germany, France, the UK, Switzerland, Greece, Belgium, Finland, Lithuania, Estonia, Portugal, Ireland, Spain, the Netherlands and Italy. In some countries, patient dose surveys and proposals for national paediatric DRLs have been made but the proposed values have not been confirmed or officially set by an authoritative body. Furthermore, no guidelines are available on how to measure, collect and process the data needed for establishing paediatric DRLs.

It is clear that studies designed to establish DRLs should follow a methodology that allows meaningful comparison of DRL values. Unfortunately, this is not the case. For example, some studies on paediatric CT DRLs express results in Computed Tomography Dose Index (CTDI) using the 16 cm standard dosimetry phantom for both head and trunk paediatric examinations and some other studies use the 16 cm dosimetry phantom for head and neck and the 32 cm dosimetry phantom for trunk paediatric examinations. Protocols and patient groupings also differ considerably amongst CT DRL studies. Studies on radiographic and fluoroscopic DRLs have similar issues. All studies designed to establish DRLs should follow a methodology that allows meaningful comparison of DRL values, and of local dose values, to these national DRLs.

3. Purpose and scope

The purpose of these Guidelines is trifold:

- to recommend a methodology for establishing and using DRLs for paediatric radiodiagnostic imaging and IR practices,
- to update and extend the European DRLs for these examinations where sufficient experience and data are available for a consensus on DRL values,
- to promote the establishment and use of DRLs in paediatric radiodiagnostic imaging and IR practices so as to advance optimisation of radiation protection of paediatric patients.

The Guidelines cover all types of examinations and procedures in paediatric radiodiagnostic x-ray imaging: plain radiography, fluoroscopy, CT and IR practices. The focus of the Guidelines is on CT, IR and digital projection imaging.

The Guidelines do not deal with paediatric imaging in nuclear medicine to avoid duplicating and potentially disrupting the work that has already been extensively undertaken by national and European societies and organisations.

4. Definitions

In this document, *patient dose* means the value of the dosimetric quantity indicated by, or determined from the display of the X-ray equipment.

The concept of DRLs was first introduced by the ICRP (ICRP, 1991), and later on further elaborated in other recommendations by the ICRP (ICRP, 1991; 1996; 2001; 2007a; 2007b). According to the ICRP (ICRP 103), a DRL is a form of investigational level, applied to an easily measured quantity, and intended for use as a simple test for identifying situations where the levels of patient dose are unusually high or low. The objective of DRLs is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task (ICRP 105). Collection of patient dose data for the purpose of setting DRLs should include an assessment of image quality to ensure relevance of the data; the image quality should be the minimum that meets the need of the clinical question. Image quality that exceeds the clinical requirement leads to unnecessary high patient dose levels.

In the EU Basic Safety Standard (BSS), DRLs are defined as:

> "dose levels in medical radiodiagnostic or IR practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment".

In principle, different generations of given imaging equipment (e.g. CT scanner) may affect the patient dose level significantly and thus, different DRLs for different generations might be suggested. However, this can be too complicated in practice and DRLs usually cover all generations of given equipment ("broadly defined types of equipment"). Due to the possible effect of equipment development on patient doses, it would be important to ensure frequent update of the DRLs.

For IR, the term "diagnostic reference level" is used in these Guidelines in accordance with the terminology adopted by the ICRP and the EU BSS, even though IR encompasses both diagnostic and therapeutic procedures.

According to the ICRP recommendations (ICRP 2001, 2007a) a DRL is not to be used to implement constraints on individual patient doses, and it is not for regulatory or commercial purposes.

DRLs help ensure that the doses delivered to patients are in accordance with the ALARA principle (as low as reasonable achievable). Examination-specific DRLs can provide the stimulus for practices to monitor and promote improvements in patient protection. It can therefore be expected that, within the paediatric radiology community, paediatric DRLs will increase dose awareness and will make paediatric practices more actively manage the required imaging quality that patients need.

For the purpose of these Guidelines, DRLs are further categorized in three sub-types as follows:

Local DRL

> A local DRL (LDRL) is based on the 3rd quartile (the 75th percentile) value of the distribution of patient doses obtained from radiology departments in a single large healthcare facility or a group of healthcare facilities, for a defined clinical imaging task (i.e., common indication based protocol) surveyed for standardised patient groupings.

Note 1: If a large group of healthcare facilities are involved, it would be appropriate to use the 75th percentile of the distribution of median values obtained from the facilities, but if just a small group (2-4) of healthcare facilities are involved or one large healthcare facility, then it would be appropriate to use the 75th percentile value of the patient dose distribution (pooled distribution).
Note 2: The 75th percentile has been chosen to be consistent with the definition of National DRLs.
Note 3: The 50th percentile value of patient dose distributions obtained from each radiology department should regularly be compared with LDRLs (Section 9.1.1).

National DRL

A national DRL (NDRL) is based on the 3rd quartile (the 75th percentile) value of the median (the 50th percentile) values of the distributions of patient doses obtained from a representative sample of radiology departments in the country, for a defined clinical imaging task (i.e., common indication based protocol) surveyed for standardised patient groupings.

European DRL

A European DRL (EDRL) is based on the median (the 50th percentile) value of the distribution of the NDRLs for a defined clinical imaging task (i.e., common indication based protocol) surveyed for standardised patient groupings.

Note 1: The median value of the NDRLs has been chosen to represent the EDRLs as opposed to taking the 75th percentile values because the NDRLs already represent 75th percentile dose values.
Note 2: This definition for the EDRL has been adopted because of the scarceness of data for EDRL evaluation. It was not possible to establish the EDRLs on single surveys of a representative sample of facilities drawn from European countries. Further, there was no sufficient basis to calculate the EDRLs by weighting national DRL values according to the population of each participating country.

If the NDRLs exceed the proposed EDRLs, the reasons for the differences should be considered. In particular, if the NDRLs are not based on recent national patient dose surveys, the need for new surveys to update the NDRLs should be considered. This can lead to greater improvements with further reductions in patient doses.

Further information on the use of these three DRLs is given in Section 9.

5. Review of existing paediatric DRLs

5.1 Introduction

A review of existing paediatric DRLs has been carried out by a follow-up questionnaire to European countries and by a comprehensive literature review. The information gained has been used to identify the existing status of paediatric DRLs with an emphasis on their application in European countries. Data from this review has also been the basis for the recommendations in Sections 6-10.

A short summary of the review is presented in this section. Details of the review and the results are presented in Annex C.

5.2 Methods of review

National DRLs set by an authoritative body in European countries were reviewed in 2010-11 in the Dose Datamed 2 (DDM2) project (EC, 2014), including DRLs for paediatric examinations. For the present Guidelines, the data on paediatric DRLs stored in the DDM2 database was verified (confirmed and supplemented) by use of a questionnaire, sent to the contact persons of 36 European countries according to the list of contacts established in the DDM2 project and updated for the present purpose.

Furthermore, a worldwide review of literature on patient doses and DRLs for children of different age groups, or other distributions, and for different examinations was carried out with an emphasis on peer reviewed papers, and reports from authoritative bodies, within Europe. For the output of this review, a database of literature was created, classified in suitable headings, using the Mendeley (www.mendeley.com) platform. The resulting database [consolidated on 25 February 2015] contains 215 articles. For articles reporting on DRLs in European countries, the correspondence of this data with the results of the above questionnaire was checked and the information from the two sources combined.

5.3 National DRLs for paediatric exams set in the European countries

The summary of the national DRLs for paediatric exams set by an authoritative body in the European countries is shown in Table 5.1, and the values of these national DRLs are given in Annex A. A more detailed summary, including available information on patient dose surveys and on the setting of the national paediatric DRLs in European countries is compiled in Annex C.

National paediatric DRLs are provided for some groups of examinations (radiography, fluoroscopy or CT) in 17 countries, i.e. in 47 % of the European countries. In Lithuania and Belgium, the DRLs had been set very recently and were not included in the DDM2 database. In 9 countries (AT, BE, DE, DK, ES, FI, LT, NL and UK) all available national DRLs are based on own patient dose surveys covering several radiology institutions. In 6 countries (CY, LU, PL, RO, CH, IT), the available national DRLs are adopted from published values; in 5 countries (CY, LU, PL, RO, IT) from the EC guidance (EC, 1999) and in Switzerland from published values in another country (DE). In Ireland national DRLs are based on own survey for some CT and radiography examinations, other values are adopted from the UK. In France, the national DRLs are based on collected data, protocol data or adopted from literature. A general observation from the review is that it is difficult to keep the DRLs up-to-date.

For IR, no national paediatric DRLs have been set for any procedures in any European country.

For national DRLs in radiography, fluoroscopy and CT, there seems to be reasonable agreement on the examinations for which DRLs have been needed: skull, chest, abdomen and pelvis in radiography, urinary tract (micturating/voiding cystourethrography, MCU/VCU) in fluoroscopy, and head, chest and abdomen in CT.

A reasonable agreement prevails also on the quantities used: air kerma-area product or dose-area product and/or entrance-surface air kerma, entrance-surface dose or incident air kerma in radiography, air kerma-area product or dose-area product in fluoroscopy, and dose-length product or air kerma-length product and volume CT air-kerma index in CT. The DRL quantities and their symbols are summarized in Table 5.2. Air kerma at the patient entrance reference point is a possible additional quantity for DRLs in fluoroscopy and IR but has not been applied so far.

Table 5.1. Summary of existing national DRLs in European countries, set or accepted by an authoritative body, based on the results of the questionnaire and the literature review. Coloured cells: data accepted for EDRL calculation (c.f. Table 10.1).

Country	Source of DRL values	Radiography		Fluoroscopy	CT		References
		$K_{a,e}$ **(ESD, ESAK),** $K_{a,i}$ **(IAK)**	P_{KA} **(KAP, DAP)**	P_{KA} **(KAP, DAP)**	**DLP (P_{KL})**	**CTDI$_{vol}$ (C_{vol})**	
AT	Own survey		Skull (AP/ PA, LAT) Thorax (AP/PA) Abdomen (AP/PA)	MCU	Brain Chest		Questionaire (all). Billiger et al. 2010 (radiography)
BE	Own survey		Thorax (PA, PA+LAT) Abdomen		Brain Sinus Thorax Abdomen	Brain Sinus Thorax Abdomen	www.fanc.fgov.be
DE	Own survey		Head (AP, PA, LAT) Thorax (AP, PA, LAT) Abdomen (AP) Pelvis	MCU	Head Facial bones Thorax Abdomen	Head Facial bones Thorax Abdomen	Questionaire. Bundesamt fur Strahlenschutz, 2010.
DK	Own survey	Thorax (AP, PA, LAT) Pelvis (AP) Overview of abdomen		MCU			Questionnaire.
ES	Own survey		Head (AP) Thorax (PA) Abdomen (AP) Pelvis (PA)	MCU	Head Chest Abdomen		Ruiz-Cruces, 2015
FI	Own survey	Sinuses (Waters projection) (discrete values) Thorax (AP, PA, LAT) (DRL-curve)	Sinuses (Waters projection) (discrete values) Thorax (AP, PA, LAT) (DRL-curve)	MCU	Head (discrete values) Thorax, abdomen (abd. + pelvis), WB (chest+abd. +pelvis) (DRL-curve)	Head (discrete values) Thorax, abdomen (abd. + pelvis), WB (chest+abd. +pelvis) (DRL-curve)	Questionnaire. Kiljunen et al., 2007. Järvinen et al. 2015.
LT	Own survey	Chest (PA) Skull (AP/PA, LAT) Abdomen	Chest (PA) Skull (AP/PA, LAT) Abdomen		Head		Questionnaire.
NL	Own survey		Thorax (AP, PA) Abdomen (AP)	MCU	Head	Head	Questionnaire.
UK	Own survey			MCU Barium meal Barium swallow	Head Chest	Head Chest	Hart et al. 2012 (F). Shrimpton et al., 2006, 2014 (CT).
IE	Own survey for some radiography and CT examinations. Other values adopted from other countries.	Skull (AP, LAT) Chest (AP/PA) Abdomen (AP) Pelvis (AP)		MCU Barium meal Barium swallow	Brain Abdomen/Pelvis		Questionnaire. Medical council, 2004. HSE Medical Exposures Radiation Unit, 2013.
FR	Own survey for radiography, CT data based on protocol data or literature	Thorax (AP, LAT) Pelvis	Thorax (AP, PA, LAT) Abdomen (AP) Pelvis		Brain Facial Bone Petrous Bone Chest Abdomen+Pelvis	Brain Facial Bone Petrous Bone Chest Abdomen+Pelvis	Questionnaire. Roch et al., 2012.
CY	Adopted (EC)	Head (AP, PA, LAT) Thorax (AP, PA, LAT) Abdomen Pelvis (AP)					Questionnaire.
IT	Adopted (EC)	"					Questionnaire
LU	Adopted (EC)	"					Questionnaire.
PL	Adopted (EC)	"					Questionnaire.
RO	Adopted (EC)	"					Questionnaire.
CH	Adopted (DE)				Brain Face, nasal cavity Thorax Abdomen Lumbar spine	Brain Face, nasal cavity	Questionnaire.. Galanski and Nagel, 2005

Table 5.2. Quantities used for DRLs and their symbols. The symbols used in these guidelines (the second column) are in accordance with the latest publications of the ICRP (2016) and the ICRU (2012). See also ICRU (2006) and IAEA (2007).

Quantity	**Symbol used in these guidelines**	**Other symbols used in literature**	**Closely similar quantity***
Incident air kerma	$K_{a,i}$	IAK	
Entrance-surface air kerma	$K_{a,e}$	ESAK	Entrance-surface dose (ESD)
Air kerma at the patient entrance reference point**	$K_{a,r}$	CAK	
Air kerma-area product	P_{KA}	KAP	Dose-area product (DAP)
Volume computed tomography dose index	$CTDI_{vol}$	C_{vol}	
Dose-length product	DLP	-	Air kerma-length product (P_{KL})

*Because "air kerma" and "dose in air" are numerically equal in diagnostic radiology energy range.
**Also names "cumulative dose", "reference air kerma" and "reference point air kerma" have been used in the literature

Most of the current national DRLs are based on the 3rd quartile method. In one case for CT, a 50 % level is given as supplementary information (FI) and in another case, a metric referred to as "achievable dose levels" was also given (NL). For patient grouping, a set of age groups up to 15 years of age (0, 1, 5, 10, 15 y) is the most common practice. In one country (FI), a DRL curve with patient thickness (radiography) or weight (CT) as the parameter is used to overcome the problems of poor statistics with discrete groups. Most of the current national DRLs have been set by national authorities, based on patient dose data which is from 2 years to more than 10 years old. In one case (NL), the DRLs have been set by a national committee, which consists of members of several professional organisations. There is a large variation between countries on the number of institutions and patients included in the patient dose surveys. For user guidelines, typically, patient dose data is required from a minimum of 10 patients for each patient grouping with a comparison frequency between 1-5 years.

It is evident that a rough consensus on the examinations for the DRLs and the DRL parameters (quantities, percentile of dose distribution, patient grouping) already exists or is closely achievable. However, better standardisation and guidelines would be of benefit, in particular for the patient dose surveys as the basis of setting DRLs.

5.4 Studies and proposals on paediatric DRLs

Besides the NDRLs set by authoritative bodies for paediatric examinations and procedures, several studies have been published to propose NDRLs or to develop LDRLs for paediatric examinations, or to compare patient dose distributions between several countries. These studies are summarized in Annex C. The actual values of the proposed NDRLs, or of *selected* other DRLs, are presented in Annex B.

For radiography and fluoroscopy, except for the few studies for NDRLs, the other published studies on paediatric DRLs are either dated or limited to a few centres so that they do not provide high quality input to the setting of European paediatric DRLs. Also the few studies outside European

countries had major limitations and could not be considered as the basis for European paediatric DRL determination.

For CT, a small number of European publications have collected paediatric CT data, mostly to propose NDRL values, using a range of different methodologies. In particular, studies varied according to whether patient or phantom/protocol data was collected and how patients were categorized into specific age ranges. The majority of studies outside European countries reported local paediatric DRLs for a small number of centres and not national values. Age was the most commonly used method to categorise paediatric patients but there was little consistency in terms of the age categories used.

For paediatric interventional cardiology procedures, data concerning patient doses and DRLs are still very scarce in Europe, and even scarcer outside Europe. Neither national nor regional DRLs are available, only LDRLs are provided. The studies greatly differ in their methodology and information provided, making comparisons very difficult.

For paediatric non-cardiologic interventional procedures, no studies are available on DRLs from European countries. Data published outside Europe are extremely scarce and limited to common vascular and enteric procedures. No data are available for embolization or sclerotherapy of vascular malformations, neuroradiology procedures, arteriography, CT guided biopsies, and biliary IR. Although relatively rare, these procedures can cause very high doses.

5.5 Strengths and limitations of the available DRLs and systems for their establishment

5.5.1 Strengths of the available systems

Review of the existing systems of paediatric DRLs (both NDRLs set by authoritative bodies and published other proposals of NDRLs or LDRLs) has shown some strengths and benefits of their establishment and use. There has been consistent understanding on what DRLs are needed: mainly skull, thorax, abdomen and pelvis exams of radiography, MCU in fluoroscopy, and brain, chest and abdomen in CT. The use of DRLs has helped to identify non-optimised practices and thus improve optimisation. The observed reductions on DRLs over time (Shrimpton et al., 2014) may partly be due to improved techniques. On the other hand, there are also cases where successive DRLs have shown an increasing trend due to changes of technology and practices (Shrimpton et al., 2014), thus indicating their capability to detect negative influences of technology changes on patient dose optimisation and to trigger further studies and efforts for improved optimisation. As for the technical details of DRLs, there has been relatively good consensus on the DRL quantities used, and their values have been easily available from the equipment consoles.

5.5.2 Shortcomings and limitations

While there are clear benefits of establishing and using DRLs in paediatric radiology, these have not been implemented in an optimal way, and there have been several shortcomings and limitations justifying additional considerations and guidance to be given.

In general, despite the comprehensive review (questionnaire and literature search) the retrievable data has not been sufficient e.g. for detailed analysis of the representativeness of the collected patient dose data and consequently, for their reliability. While the physical quantity and the patient grouping (mainly by age) selected for the DRL settings have usually been reported exactly, the background information on the patient dose collection is often only briefly reported or not described at all. Few reports provide exact information on the practical methods of data collection, and the

coverage of the imaging institutions (types, percentage of total) and the imaging practices have been reported in only a few countries. Most probably, data was collected manually, occasionally not well controlled, and possibly hampered by human errors. Few notes are available on the application of automatic data management systems for data collection or how the use of the DRLs has been specified. Published information is rarely available on the experiences of using paediatric DRLs and on their feasibility in practice.

Despite the recognized importance and need for DRLs, less than half of the EU countries have set DRLs for paediatric examinations, and there is a complete lack of paediatric DRLs in many countries (it is noted that the new BSS (2013) which should be implemented by February 2018 requires Member States to ensure that DRLs are established). Only in about one fifth of the countries are the existing DRLs based on own national patient dose surveys (less than half of the countries with established DRLs). Furthermore, there has been a very slow updating of the existing DRLs, in comparison with the rapid development of imaging technology. In most countries, the established DRLs are the first ones ever implemented, and only in a few countries does information exist on the trends with several successive DRLs. For the high dose procedures in IR, including cardiac procedures, there is a complete lack of NDRLs; only some local efforts have been published.

The patient dose surveys required for setting DRLs are resource demanding and time consuming, in particular because the main methods of data collection still rely on manual or semi-manual due to the lack, or non-compatibility, of automatic data management systems. Data analysis is also difficult because there is often a lack of standardisation in the specification of a given examination. This makes comparisons of DRLs difficult and sometimes not relevant. In some countries, the infrastructure is not capable of estimating the frequencies of examinations or the proportion of paediatric examinations from all (including adult) examinations, which would be useful supplementary information when planning to establish paediatric DRLs. Patient dose surveys may suffer from a low response rate unless good cooperation between authorities and professional societies exists to promote the participation of healthcare institutions.

As discussed above, the review of current systems of DRLs has shown that there is an insufficient recording of the procedures used to establish the DRLs, and the available information also reveals large differences in approaches. There is a lack of consistency in patient groupings (age, weight or other groups with a variety of options) and lack of clear recommendations on the dose quantities to be used. Detailed guidelines are needed on how to organise patient dose surveys and how to establish DRLs, e.g.:

- What sort of institutions should be included in the data collection/survey (public, private, general or devoted paediatric)?
- What information is needed besides the actual patient dose data?
- What dosimetric quantities are to be used (e.g. should one use P_{KA} vs $K_{a,e}$ in radiography, should one use effective dose, what is the role of Size Specific Dose Estimate (SSDE))?
- Should patients be grouped together by age, size or weight?
- What should be the granularity of such grouping?
- How are DRLs to be derived from the patient dose distribution (percentile point) etc.?
- How are DRLs used to review and improve clinical practice?

In more advanced setting of DRLs other questions arise such as how to deal with different equipment generations and technologies and the different levels of implementation of automatic dose saving systems.

The problem associated with the much lower frequency of paediatric examinations, compared with adult examinations, and the subsequent problems of poor statistics because of the need to collect data for several patient age, size or weight groups can be addressed by introducing the "DRL curve" (Kiljunen et al., 2007; Järvinen et al. 2015). This approach can be particularly useful for small institutions with a very low number of paediatric patients.

An easy and effective follow-up of patient doses and their comparison with DRLs still suffers from the slow development or non-compatibility of automatic data management systems. The availability of more compatible systems regardless of the type of x-ray equipment and the development of institutions' overall data management systems in the future could provide valuable support for the implementation of DRLs, not only for occasional comparisons but for continuous patient dose monitoring and comparisons, with appropriate practices to alert staff on any unusually high or low dose levels.

5.5.3 Accuracy and comparability of DRLs

For the comparability of NDRLs between countries, in particular when trying to establish joint DRLs for several countries (e.g., for European wide DRLs), the following points need to be considered:

(1) *The accuracy of the dose values.* For the comparison and follow-up of patient dose levels as a quality control measure, whatever patient dose quantity is selected, the equipment used has to display appropriate values of this quantity to a known (calibrated) accuracy. For example, experience has shown (e.g., Vano et al., 2008) that P_{KA} displays can easily have more than 50% error.

(2) *The representativeness of the collected patient dose data.* It is important that the samples of data collected include data from various levels of institutions; small and big, public and private, so that the established DRL is representative of all radiology practices in the country. However, attention should be paid to exceptionally high differences of data from some centres compared with the average data, in order to avoid the inclusion of biased data from very old equipment or suboptimal practice.

(3) *The adequacy of collected patient dose data.* It is important that a sufficiently representative number of institutions (compared with the total number) and reasonable samples of patients per age/weight group from each institution are collected.

(4) *The data collection period.* The DRLs should be updated at regular intervals, based on new patient dose surveys (see Section 8.2), because both the development of technology and the imaging practices can change rapidly and have a large impact on the patient dose levels. There is also both an expectation and practical evidence (e.g. Shrimpton et al., 2014) that DRLs will tend to decrease over time during the course of their application, even though the changes in technology or practices can sometimes have an opposite effect. Therefore, it would not be appropriate to include in the evaluation, patient dose studies and DRLs which are more than 5-10 years old.

Further, significant differences in the level of technology in the country, e.g. due to the differences in the national income and available economic resources, may affect the patient dose level. However, such differences are difficult to assess and cannot usually be taken into account.

The uncertainties caused by item (1) may be a relatively small factor in the overall comparability of the DRLs, in particular because such errors can compensate each other in the nationwide evaluation of data from several centres.

If the above conditions (1)-(3) can be ensured and (4) considered homogenous enough for the evaluation of the median value of the national DRLs, e.g. to determine the European DRL (see Section 4), the interquartile value (i.e., the ratio of 3rd and 1st quartiles) of the DRLs gives an indication of their variability. High interquartile values indicates significant variation of the practices which may be associated with different levels of optimisation. A high interquartile value can also be used as a measure of the possible weakness in adopting the European DRL instead of a DRL based on own national patient dose survey (see Annex F). The distributions of the NDRLs in European countries and their impact on the feasibility of the European DRL are discussed in further detail in Annex F.

6. Need for modality specific paediatric DRLs

In this section, the paediatric examinations and procedures with the greatest need for DRLs will be presented separately for each imaging modality (radiography and fluoroscopy, CT and IR). The information is derived from the data on existing DRLs (Section 5 and Annexes A-C), from the results of specific questionnaires sent to selected paediatric institutions in European countries (Annex D) and from literature on examination frequencies. The need for further studies to establish DRLs is highlighted, based on the identified lack of patient dose surveys, together with the need for DRLs on important present or emerging new imaging practices.

The need for a DRL is judged on the basis of collective dose to the paediatric population: all examinations resulting in high collective doses should have DRLs. This can include both the most common low dose examinations and the less common high dose examinations. Due to the observed difficulties in setting paediatric DRLs, this has been used as the main criterion, but it is acknowledged that other common very low dose procedures (e.g. dental) should also be optimised.

The lists of procedures given in this section are neither exhaustive nor prescriptive – countries or local healthcare facilities may choose to establish DRLs for their practices that may be important contributors to patient dose in their jurisdiction. Further, it should be stressed that the application of DRLs should be the responsibility of all providers of X-ray imaging. This means that DRLs should also be applied to imaging performed outside the radiology department, including cardiology, orthopaedic surgery, gastroenterology, intensive care (line placement), neurology, vascular surgery, etc. Specific considerations may also be appropriate for imaging associated with radiation therapy where the purpose and scope of imaging can be different.

6.1 Radiography and fluoroscopy

Table 6.1 provides the list of radiography and fluoroscopy examinations where DRLs are recommended. Only examinations that have an important contribution to the collective effective dose have been included. Conventional chest examination is included, even though it is a relatively low dose examination, because it is by far the most frequent paediatric radiography examination in all countries and produces a significant contribution to the collective effective dose. No examinations of extremities, even though these are the most frequent of all radiography examinations, are included in Table 6.1 because of their very low dose and low contribution to the collective effective dose.

There has been no attempt to define paediatric DRLs according to detailed indications, or the complexity of the procedure.

Table 6.1 Radiography and fluoroscopic examinations where DRLs should be set (AP/PA means that the same DRL applies to both AP and PA projections).

Anatomical region	Projection(s) or procedure
Radiography	
Head (skull)	AP/PA
	LAT
Thorax (chest)	AP/PA
Abdomen	Abdomen-pelvis AP
Pelvis	Pelvis/hip AP
Cervical spine	AP/PA
	LAT
Thoracic spine	AP/PA
	LAT
Lumbar spine	AP/PA
	LAT
Whole spine/Scoliosis	AP/PA
	LAT
Fluoroscopy	
Urinary tract	Micturating/Voiding cystourethrography (MCU/VCU)
Gastro-intestinal tract	Upper GE-examinations
	Contrast enema

6.2 Computed tomography

Table 6.2 gives the list of CT examinations for which DRLs are recommended. CT provides the highest contribution (typically up to 60 %) of the total collective effective dose from all paediatric medical imaging, and all the CT examinations of Table 6.2. are potentially high dose examinations. CT examinations of extremities are excluded from Table 6.2, because of their relatively low dose and low contribution to the collective effective dose.

The CT examinations in Table 6.2 correspond to complete routine CT examinations. Multi-phase scanning is only used for special purposes, and a need for a DRL for such purposes should be considered separately. Pre-contrast scans are not needed in paediatrics (except bolus-tracking).

Different image quality requirements should use indication based DRLs, e.g. defining the DRL for CT Head, indication: ventricular size.

There is no attempt to define DRLs according to the complexity of the CT procedure.

Table 6.2. CT examinations where the DRLs should be set

Anatomical region	Procedure
Head	Routine Paranasal sinuses Inner ear/internal auditory meatus Ventricular size (shunt)
Neck	Neck
Chest	Chest
	Cardiovascular CT angiography
Abdomen	Abdomen (upper abdomen)
	Abdomen+pelvis
Trunk	Whole body CT in trauma
Spine	Cervical spine
	Thoracic spine
	Lumbar spine

6.3 Interventional radiology (incl. cardiology)

Interventional radiology (IR) covers a wide range of procedures – from several types of cardiac interventions and procedures to non-cardiac procedures (fluoroscopy and CT guided) to vascular access, treatment of thrombosed dialysis shunts, and embolization of tumours (e.g. central nervous system) without any other treatment option. The questionnaire reported in Annex D did not address paediatric IR, cardiac and non-cardiac, image guided procedures, and there are no similar statistics available. However, there has been a significant increase in IR procedures during the last decade, and although these procedures are less common in the paediatric population, they deliver high radiation doses (see also Annex G). Radiation protection issues in interventional cardiology has recently been addressed by the ICRP (ICRP, 2013), including the need for DRLs.

As shown in Section 5, no NDRLs exist for paediatric IR procedures, and LDRLs have been published only for paediatric interventional cardiology (IC) procedures. The development of LDRLs for these procedures should be encouraged and the feasibility of NDRLs and EDRLs should be studied. For IR procedures, patient dose depends on several factors, including the maturity of the patient (preterm, baby, child), the complexity of the specific situation, and the experience of the medical staff. There will always be case based decisions and in these situations the use of DRLs is not appropriate. DRLs may therefore only be feasible for a few standard procedures like diagnostic cardiac catheterization (morphology, pressure measurements, oximetry, biplane guided cardiac function assessment), interventional closure of cardiac septal defects or stent placements (e.g. coarctation), and peripheral insertion of central catheters (PICC) or nephrostomy from non-cardiac procedures. In Annex G, some information is presented on patient doses and published LDRLs for IC procedures, and on the results of a limited survey within the PiDRL project for non-cardiac procedures.

For IC procedures, the experiences presented in Annex G suggest that the establishment of a generic DRL for all diagnostic procedures or for all therapeutic procedures might not be appropriate. In particular, for therapeutic procedures, the observed variation of patient doses between different types of procedures suggests the need for procedure-specific DRLs. This is further complicated by

the fact that several techniques may have been developed for the same procedure and there would be a need to establish a DRL for each technique.

For non-cardiac IR, catheter placement and diagnostic procedures are usually completed with just a single procedure with defined steps. For most of the other non-cardiac procedures, such as embolization and sclerotherapy, it may be necessary to perform two, three or more procedures within a few weeks, the steps of the procedure are not clearly defined, and the duration of a single procedure can be very different according to the severity of the condition requiring the procedure. Ultrasonic guidance in paediatrics is more often combined with fluoroscopy than in adults, and the relative contribution of the two techniques widely varies with the clinical task and the experience of the interventionalist. Consequently, setting DRLs for non-cardiac IR procedures might only be possible for catheter placement and diagnostic procedures.

Due to the observed high variation of dose levels between various centres (see Annex G), the feasibility of NDRLs (or EDRLs) is questionable. The main focus should therefore initially be to establish LDRLs for local guidance where the number of variabilities a priori is smaller. LDRLs between centres should then be compared and the reasons for the large differences should be studied, to be able to decide if NDRLs and EDRLs are appropriate.

Based on the limited information available from the few published articles and the small-scale extra surveys carried out within the PiDRL project, a few IR procedures have been specified where DRLs (at least LDRLs) could be established:

- Cardiac procedures
  - Patent Ductus Arteriosus (PDA) occlusion
  - Atrial Septal Defect (ASD) occlusion
  - Pulmonary valve dilatation
  - Diagnostic cardiac catheterization
- Non-cardiac procedures
  - Peripherally inserted central catheter (PICC)

For the following non-cardiac procedures, further studies should be carried out to confirm the feasibility of LDRLs:

- Embolization (arterio-venus malformation, trauma, iatrogenic, portal); there is probably a need for anatomical separation (all excluding head+neck+spine); the DRL should include the whole treatment in case of multiple sessions
- Embolization (arterio-venus malformation, trauma, iatrogenic) head/brain+neck+spine
- Sclerotherapy (vascular malformations, cysts); the DRL should include the whole treatment in case of multiple sessions
- Arteriography (anatomical separation needed: head/neck, trunk, extremities)

The present very low or partially non-existing experience on DRLs in IR procedures does not allow the determination of specific complexity levels of the procedures (to establish DRLs). However, this aspect should be taken into consideration when patient dose surveys are conducted to study the feasibility of establishing DRLs for specific complexity levels in IR procedures.

6.4 Prospective need of DRLs for emerging or increasing new practices

Emerging new or increasing practices for which the establishment of DRLs should be considered include hybrid imaging (currently PET-CT and SPECT-CT) as well as cone beam CT (CBCT). Besides these examples of practices, a challenge for the future development of DRLs could be to

distinguish and establish DRLs, within a given examination for a given anatomical region, for different indications if these require considerably different image qualities.

Concerning the use of CT in hybrid imaging, limited effort has been taken to establish DRLs and there is currently only one guideline available (Segall et al., 2010). It should be emphasized that the DRLs established for conventional CT should be applied to the CT part of hybrid imaging when the CT is used for diagnostic purposes (this is not relevant if CT is only used for the determination of attenuation correction). This is important because the users in some nuclear medicine departments might not be adequately aware of CT doses and their optimisation, and the use of DRLs could thus improve their awareness and the overall optimisation of hybrid imaging.

Cone Beam CT (CBCT) represents an imaging modality introduced in recent years, and is used especially in paediatric dental procedures (Ludlow and Walker, 2013, Noffke et al., 2011, Prins et al., 2011, Schulze, 2013, Vassileva et al., 2013, EC, 2012). An effective dose of 0.05 mSv to paediatric patients has been reported (Vassileva and Stoyanov, 2010), and doses in paediatric procedures can be 36% higher than those for adults, mainly due to the higher relative position of the thyroid gland (Ludlow and Walker, 2013). EC publication RP172 (SEDENTEX-CT report; EC, 2012) contains a strong recommendation on the need to establish DRLs for CBCT. Establishing DRLs is also supported by the recent ICRP publication on CBCT (ICRP, 2015). These observations suggest a need to develop DRLs for paediatric CBCT examinations.

6.5 Need for further patient dose surveys

To decide the need for further paediatric patient dose surveys to provide paediatric DRLs, the following questions should be addressed:

- Which examinations or procedures (examination or procedure protocols) should have DRLs?
- Which examinations or procedures have DRLs that are no longer relevant and need updating?
- Which emerging new practices might need DRLs in the future?

The first question is discussed in Sections 6.1 -6.3 and the second question partly in Section 5 and Annexes A-D. As evident from Section 5, most European countries have never established paediatric DRLs or the DRLs have been established only for a few paediatric examinations. Patient dose surveys are therefore needed to provide data for many examinations. Further, there is an evident need for new patient dose surveys to update many of the existing NDRLs. The last question is discussed in Section 6.4.

7. Basic approach to paediatric DRLs

The dose quantities and the grouping of patients recommended in this section are based on the analysis of the present status and experiences on paediatric DRLs (Section 5), the identified need for the DRLs (Section 6) and the discussions and consultations during the PiDRL project. The general principles are presented followed by separate considerations for each modality (radiography and fluoroscopy, CT, IR).

The recommended statistics and methods for the setting of the DRLs, i.e. the minimum data and the selection of institutions for patient dose surveys, representativeness of samples, methods of data collection and the percentile point selected at patient dose distribution, are discussed in Section 8. The recommended methods of using DRLs, i.e. the minimum number of patient dose data for comparison with DRLs, frequency of comparisons etc., are discussed in Section 9.

7.1 General

The DRL quantity should be an easily measurable quantity (ICRP 1996, 2007b), usually directly obtainable from the x-ray equipment console, obtained either by manual recording or preferably by automatic recording and analysis (Section 8.4). The quantity should reflect the changes in the patient dose level with different selections of the imaging parameters and imaging practices, thus enabling follow-up of the patient dose level when using similar equipment, and also enabling comparisons with other equipment, rooms or institutions for the same examination or procedure. It is however well known that different beam qualities or acquisition geometries in radiography and fluoroscopy can result in very different organ doses even when the P_{KA} values are the same. The same applies for CT if tube voltage or bow tie filter is adjusted. It would be advantageous if the quantity is closely related to the real patient dose: organ doses or whole body doses approximated by effective dose. However, organ doses and effective dose are not considered feasible as a DRL quantity because these are not measurable and their use also introduces extraneous factors that are not needed or pertinent for the purpose of DRLs.

The DRLs should be based on sufficient patient dose data determined or collected from the records of individual paediatric patients (for more details of the recommended patient dose surveys, see Section 8). Using data obtained from typical protocol data or from phantom measurements to determine DRLs are not recommended because the data should take into account the technical settings and characteristics of the equipment, *and* the clinical practice (data based on individual patient characteristics, imaging area, scan length, differences in the use and effect of the automatic exposure control and other dose saving systems etc.). Simple geometrical phantoms, such as polymethyl methacrylate (PMMA) plates can however be used to verify doses under various conditions. They should be an integral part of the acceptability and quality control tests by the medical physicist / medical physics expert. Also, anthropomorphic phantoms can be used to predict or explain low or high patient dose settings. Phantoms can therefore provide complementary information to patient dose surveys and valuable inputs for optimisation studies.

Particular consideration is needed in the grouping of patients for paediatric DRLs because the size of children, and hence the dose levels, significantly varies not only by age but also at a given age. Adults usually vary in size by a factor of 4 (40 – 160 kg bodyweight), whereas paediatric patients vary in size from premature babies (e.g., 300-400 g) to obese adolescents (> 80 kg body weight) representing a factor of more than 200. Classification of DRLs should also take into account the steep growth pattern of a baby: within the first six months of life a baby's body weight doubles and during the first year its weight trebles.

More radiation is needed for bigger patients to obtain the same image quality compared to smaller patients. Due to the large variation of patient size (e.g. patient trunk thickness or effective diameter) at a given age, the *weight* or *size* (e.g. girth or patient diameter) is generally a more relevant parameter for patient grouping for DRLs in body examinations (see e.g. Järvinen et al., 2015, Watson and Coakley, 2010). Patient weight is recommended because it is currently more easily available than the size parameters. Accordingly, patients' weights should be used, at least for prospective collection of data, for all body examinations. If age has been used for previous DRLs and the aim is to make comparisons and trend analysis, it could continue be used as an additional parameter (in association with weight or size) during the transition phase to weight groupings. The recommended grouping parameters might not be valid for some examinations where little experience on DRLs exist, e.g. for IR, IC and dental procedures.

Except for the first two years of life, the size of a patient's head does not show the same high variation as that of a patient's trunk; therefore, age should be used as a grouping parameter for all head examinations (see Section 7.3).

Some X-ray systems can now acquire data on the X-ray attenuation of the patient. This data would be a more valuable patient dose metric than patient trunk thickness or effective diameter. Digital imaging and communication in medicine (DICOM) working groups are proposing to incorporate the 'patient equivalent thickness', as obtained from pre-exposure or exposure, into the extended radiation dose structured report (RDSR) of the patient (IEC 2007; 2010). Once the "patient equivalent thickness" becomes generally available in dose management systems, it could also be used as a grouping parameter for NDRLs.

The groupings for *DRLs (weight, size or age)* should be defined unambiguously using intervals; e.g. weight intervals < 5 kg, 5 - <15 kg, etc. The number of groups should be restricted because of the practical difficulty in collecting a sufficient number of patient dose data in each group (both for setting of the DRLs and for the use of the DRLs).

To overcome the problem caused by the need for several patient groups and the general paucity of patient dose data in paediatric imaging, instead of using discrete patient groups, the dosimetric quantity can be presented as a function of the parameter used for patient grouping, i.e. to define a *DRL-curve;* an example is shown in Fig. 7.1. For the comparison of local patient dose data with the DRL-curve, the user can obtain data e.g. for ten consecutive patients, regardless of their age/size/weight, and insert these data points in the graph with the DRL-curve. If the majority of the points are below the curve, or if a similar curve fitted to the points (provided these cover a sufficient range of the patient grouping parameters) runs mostly below the DRL-curve, then the DRL has not been exceeded, and vice versa. For comparison of the DRL curve with the DRLs given for discrete patient groups, average data from the DRL curve can be derived for each discrete weight or size group (interval).

The DRL-curve approach can be applied when the data from the patient dose surveys indicates a clear relationship between the dosimetric quantity and the patient grouping parameter. For appropriate comparison of local patient doses with the DRL-curve, data points should cover the range of parameter values as completely as possible. The DRL-curve method provides an easy and comprehensive visual indication of the local dose level compared with the DRL in cases where no other analysis is possible due to the scarceness of data. It is recognised that this comparison might not give an assurance with the same confidence as would be possible if the sample of patients had been much higher.

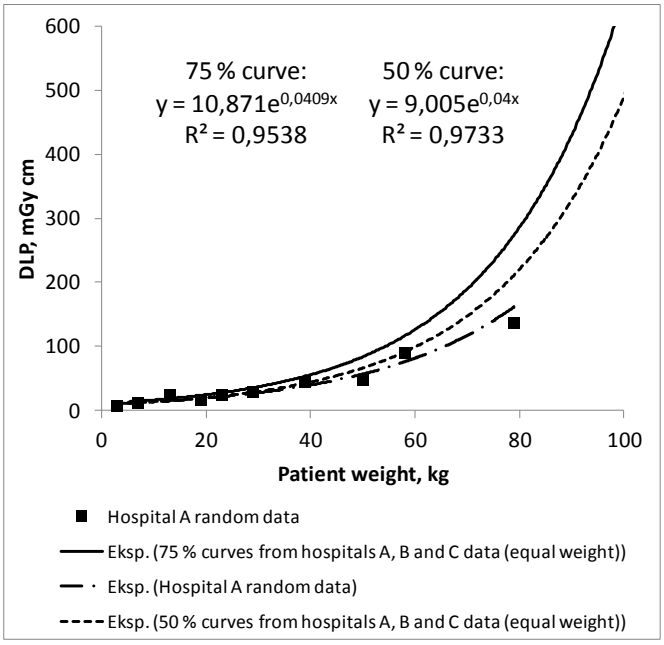

Fig. 7.1. An example of DRL-curves for DLP in chest CT.
The DLP values relate to the 32 cm diameter CT dosimetry phantom.
The lowest dotted curve shows an example of using the DRL curve.
(Järvinen et al. 2015)

Instead of using patient size or age groups with defined intervals (e.g. 1-2 y, 2-5 y,…), another approach is to specify certain standard sizes (patient widths, with a correlation to age) and to define a method to convert the dosimetric parameter for a patient of any width to that for the closest standard patient width (Hart et al., 2000). The conversion factor can be based on the average change of absorption as a function of width for different patient widths compared to the standard patient width. While this method is more exact for grouping data, the conversion might not be appropriate for each patient if additional conversions from age to width are required, and it may be difficult to obtain sufficient patient dose data for each standard size.

7.2 Recommended DRL quantities

7.2.1 Radiography and fluoroscopy

Air kerma-area product (P_{KA}) is the recommended primary DRL quantity for radiography and fluoroscopy. It is commonly available in radiography and fluoroscopy equipment of the present technology and takes into account the full radiation exposure of the patient. This quantity can be easily recorded in daily practice and there are possibilities for automatic recording and comparison with the DRLs (See section 8.4).

For radiography, entrance-surface air kerma ($K_{a,e}$) is recommended as an additional DRL quantity. The $K_{a,e}$ provides added value for the follow up of patient dose, and enables comparisons and trend analysis with earlier DRLs because the majority of the present DRLs have been given in terms of $K_{a,e}$.

For fluoroscopy, air kerma at patient entrance reference point ($K_{a,r}$), fluoroscopy time and number of images are recommended as useful additional DRL quantities (a multiple DRL). For example, the

3rd quartile or median value of the fluoroscopy time distribution for a sample of patients in standard procedures can provide an indication of the achieved optimisation/ quality of the practice.

The P_{KA} is determined either by built-in or removable P_{KA} meters, or by computational systems in x-ray units that calculate the P_{KA} value from the imaging parameters. The $K_{a,r}$ is determined by computational systems in x-ray units and is indicated at the equipment console. In all cases, it is important to ensure accurate values of the dosimetric quantity by regular calibration, or checks, that are typically performed by the medical physicist during the acceptance and quality control tests. In particular, such checks should be made prior to comparison with NDRLs and also prior to submission as part of a national dose collection. The dose values shown at the display unit and in the DICOM header should be verified for all beam qualities used in clinical practice (IAEA, 2007; 2013).

The $K_{a,e}$ can be calculated by dividing the P_{KA} by the entrance surface area measured at the patient skin (delineated by the light beam), and multiplying by the appropriate backscatter factor (IAEA, 2006; 2013). When the P_{KA} is not available, $K_{a,e}$ can be calculated from the measured beam output (air kerma/current time product; mGy/mAs) and the associated backscatter factor, or from the detailed acquisition parameter by using indirect calculation (IAEA, 2015).

7.2.2 Computed tomography

7.2.2.1 Present recommendations

Both volume computed tomography dose index ($CTDI_{vol}$) and dose length product (DLP) are recommended quantities for setting DRLs. The former is relevant for the patient dose burden per slice while the latter is relevant for the patient dose burden for the complete CT procedure. Both quantities together enable analysis of the scan length e.g. for studying the reasons for exceeding a DRL. In modern CT scanners, both $CTDI_{vol}$ and DLP are available from the console and can also be automatically retrieved from the radiation dose structured reports for automatic dose management (see Section 8.4). Besides $CTDI_{vol}$, a Size-Specific Dose Estimate (SSDE; see Section 7.2.2.2), when available, can be used as a DRL metric for body CT examinations.

An important consideration for the determination of $CTDI_{vol}$ and DLP, as well as for the setting of DRLs in terms of these quantities, is the calibration of the CT console readings. The calibration uses standard cylindrical CT phantoms, with either 16 cm or 32 cm diameters ("head" and "body" phantoms; IEC, 2002, IAEA, 2013). In some scanners the calibration phantom size used is different in paediatric body CT protocols. In recording and reporting patient dose values, it is therefore essential to state the phantom size (diameter either 16 or 32 cm) used in the calibration of the console value. Consequently, the $CTDI_{vol}$ and DLP values should also always be specified together with the size of the calibration phantom. It is recommended that $CTDI_{vol}$ and DLP are determined for a 32 cm phantom for all paediatric body CT examinations (chest, abdomen, trunk and spine) and for a 16 cm phantom for paediatric head CT examinations.

It is important to ensure that correct $CTDI_{vol}$ and DLP values are obtained from CT consoles by regular re-calibration, or check of the calibration, using the above standard CT phantoms (IAEA, 2006; 2013). This test is included in the acceptance and quality control tests performed by the medical physicist, and in particular, should be made prior to comparison with NDRLs and also prior to submission as part of national dose collection. It is recommended that verification of the dose displays is performed for all parameters with possible influences from: large and small phantom, tube voltage, collimation, bowtie filter and tube current modulation activated.

7.2.2.2 Future developments: SSDE

The data from a number of investigators have shown that for the same CT technique factors, the average absorbed dose is higher for smaller patients (ICRU, 2013). A Size-Specific Dose Estimate (SSDE) is a quantity recently introduced by the AAPM (AAPM, 2011; 2014) and the ICRU (ICRU, 2013) aimed at taking into consideration the size of the patient so that the dose metrics would better correspond to the actual dose to the patient.

The SSDE can be calculated from $CTDI_{vol}$ by using published conversion factors as a function of effective diameter (d_{eff}) or water-equivalent patient diameter (d_w). The latter quantity is more appropriate for CT images of the chest region where an appreciable amount of internal air is contained within the body dimensions. The calculation is straightforward when the tube current modulation (TCM) is not utilized and when the patient diameter is relatively uniform over the scan length. However, TCM is being widely applied in clinical practice and therefore, tube current and hence the absorbed dose in the patient can vary appreciably along the z axis of the patient. The exact calculation of the SSDE would then require the use of CT-image-by-image data instead of using the above "global" correction factors (ICRU, 2013). In practice, such calculation requires automated software which is not available in the current stage of technology.

Due to its closer relationship to the actual patient dose for varying sizes of paediatric patients, SSDE is, in principle, a more suitable parameter than $CTDI_{vol}$ as a DRL quantity. However, when the global conversion factor is used for its calculation from $CTDI_{vol}$, it has the same weakness as $CTDI_{vol}$. For the same water-equivalent diameter, there will be variation from patient to patient due to the TCM operation and varying anatomies of the patients. Furthermore, SSDE is not yet in such general use as $CTDI_{vol}$, and its value cannot be used to calculate DLP which remains another important DRL quantity. When the scanner technology develops to provide automatic calculation of the more advanced SSDE, it will be a valuable addition to overall dose management.

7.2.3 Interventional radiology

7.2.3.1 Present recommendations

Air kerma-area product (P_{KA}) is the recommended primary DRL quantity for IR procedures. Air kerma at patient entrance reference point ($K_{a,r}$), fluoroscopy time and number of images are recommended as useful secondary DRL quantities (a multiple DRL) (Stecker et al. 2009). All these quantities are usually available in IR x-ray equipment of the present technology. They can be easily recorded in daily practice and there are possibilities for automatic recording and comparison with the DRLs (See section 8.4).

For the determination of the DRL quantities and the requirements of calibration, see Section 7.2.1.

7.2.3.2 Future developments

For cardiac interventional procedures, a practical alternative, P_{KA} normalized to body weight (P_{KA}/BW) has been proposed as a DRL quantity (Onnasch et al., 2007; Chida et al. 2010; see Annex G). This was based on the observation that P_{KA}/BW remains reasonably constant making it unnecessary to specify any patient grouping. Another new parameter has also been proposed: product of fluoroscopy time and weight (Chida et al., 2010). These parameters can become useful options in the future if more experience is gained about their general applicability.

7.3 Recommended patient grouping

For all body examinations, and for DRLs based on prospective patient dose surveys, weight should be used as the parameter for patient grouping in accordance with the general recommendations in Section 7.1. The recommended weight groups (intervals) are shown in Table 7.1. For head examinations, age is recommended as the grouping parameter. The recommended age groups (intervals) are shown in Table 7.1. When the DRL-curve approach is adopted as described above, patient (trunk) thickness can also be used as the grouping parameter for radiography (Kiljunen et al., 2007).

The recommended first weight group (< 5 kg) applies to newborn babies but does not apply to those in incubators. The optimisation of the dose for babies in incubators is important but it might not be appropriate to establish DRLs for these very specific and varying cases, where, e.g., different types of incubators affect dose differently.

The basic definition of the DRLs refers to "standard-sized patients" (Section 4). It is important, therefore, to realize that very obese or severely underweight patients should be excluded from the sample of patients used in patient dose surveys to establish DRLs, or to compare the local median patient dose value with the LDRLs or NDRLs. The effect of including very obese or severely underweight patients can be significant in very small samples and becomes less important or insignificant in very large samples. Published tables of weight-for-age charts (Centers for Disease, 2015) can be used to judge the acceptability of the weight of a patient of a given age for inclusion in the survey, e.g. by excluding patients below the 5^{th} percentile and above 95^{th} percentile of weight; see also Table 7.2.

Because most of the current NDRLs have been given in terms of patient age, it is acknowledged that age will still be used in a transition period until data from the recommended weight based patient dose surveys become available. In the transition period, age can be used as an additional parameter for patient grouping and for the purpose of comparison of proposed new, weight-based DRLs with earlier values (trend analysis).

There is a rough correlation between the average weight and age groups, as can be deduced from the published weight-for-age charts (Centers for Disease, 2015). Using the 25^{th} to 75^{th} percentiles of weight, i.e. by excluding the relatively low or high weights for a given age, an approximate equivalence shown in Table 7.2 can be obtained. There are also some published studies on empirical equivalencies (AAPM, 2011; Seidenbusch and Schneider, 2008).

The weights to age range equivalence shown in Table 7.2 should only be used as a rough approximation when comparing the weight-based DRLs with previous age-based DRLs. It should also be noted that several differing sets of age groups have been used for the NDRLs (or equivalent); the most common grouping found is approximated in the last column of Table 7.2. When calculating the EDRLs (Section 10), the age groupings in the last two columns of Table 7.2 have been used to roughly derive the EDRLs based on weight.

Every effort should be taken to group patients according to the above recommendations. However, less groupings can be considered if it can be justified nationally by clear reasoning, e.g., if the range of patient weights for a given examination in a country is narrower than those described in Table 7.1.

Table 7.1. Recommended grouping of patients for paediatric DRLs

Recommended weight groups (intervals) for *body* examinations	**Recommended age groups (intervals) for *head* examinations**
< 5 kg	0 - < 3 months
5 - < 15 kg	3 months - < 1 y
15 - < 30 kg	1- < 6 y
30 - < 50 kg	≥ 6 y
50 - < 80 kg	

Table 7.2. Approximate equivalence of weight and age groups for the purpose of comparing weight-based DRLs with age-based DRLs.

Description	**Weight group**	**Age group based on weight-for-age charts**	**Most common age groups used for the NDRLs (or equivalent)**
Neonate	< 5 kg	< 1 m	0 y
Infant, toddler and early childhood	5 - < 15 kg	1 m - < 4 y	1 y
Middle childhood	15 - < 30 kg	4 - < 10 y	5 y
Early adolescence	30 - < 50 kg	10 – < 14 y	10 y
Late adolescence	50 - < 80 kg	14 - < 18 y	15 y

8. Practical methods to establish paediatric DRLs

8.1 General

DRLs should be established primarily for paediatric examinations that significantly contribute to the collective effective dose of the paediatric patient population (as discussed and introduced in Section 6). This can include both the most common examinations and less common high dose examinations.

DRLs should be based on appropriate patient dose surveys. These surveys should have sufficient coverage of all institutions for which the DRLs are intended (i.e., the geographical area concerned), whenever possible. In particular, NRLs should be based on national patient dose surveys with a representative sample of all radiological institutions in the country when available. DRLs based on very limited surveys or on measurements only in phantoms, as well as DRLs adopted from international recommendations or from other countries, should only be used as preliminary values until data from the relevant national patient dose surveys are available.

Patient dose data can be collected manually or by making use of automatic data recording and collection systems (see Section 8.4). Due to the generally large amount of data needed and the large amount of potential errors when these data are to be collected during routine practice, automatic data collection is recommended wherever possible. However, a manual approach is needed until automatic systems become generally available, validated for accuracy of collected data and are sufficiently harmonised.

There is a need to update the DRLs at regular intervals, based on new patient dose surveys. National DRLs should be reviewed and updated at a minimum frequency (maximum interval) of 5 years. Once automatic dose management systems become more generally available, the frequency could be 3 years or even lower. Local DRLs should be reviewed and updated at least every 3 years and when there are changes of the equipment or practices which have a potential impact on patient dose levels.

8.2 Patient dose surveys

To carry out patient dose surveys, the following parameters should be carefully determined:

- procedures for which DRLs are needed
- dose and other quantities (DRL quantities)
- patient grouping (according to weight, age, body size)
- technical equipment parameters
- number and distribution of X-ray departments participating in the survey
- percentile point for the DRL selection

8.2.1 DRL quantities and patient grouping

Patient dose data should be collected consistently with the DRL quantities and patient grouping (discrete groups or continuous DRL curve) recommended for DRLs in Section 7.

8.2.2 Technical equipment parameters

Besides the actual patient dose data according to the recommended patient grouping, there are other data (Table 8.1) which are useful for the evaluation and decision making when DRLs are to be established.

Table 8.1. Supplementary data to support the patient dose surveys for establishing DRLs.

Radiography	**Fluoroscopy**	**CT**	**IR**
Equipment data: manufacturer and type	Equipment data: manufacturer and type	Equipment data: manufacturer and type	Equipment data: manufacturer and type
Detector system (screen/film, including speed class (S/F); computed radiography, including phosphor used (CR); digital radiography; type of detector (DR)	Type of detector (DR)	Detector configuration (number of detector rows)	Type of detector (DR)
Source detector distance (SDD)	Source detector distance (SDD)		Source detector distance (SDD)
Added filtration	Added filtration		Added filtration
Grid (used/not used/not removable)	Grid (used/not used/not removable)		Grid (used/not used/not removable)
Exposure parameters: kV, mA, mAs	Exposure parameters: kV, mA, mAs	Exposure parameters: kV, mA, mAs	Exposure parameters: kV, mA, mAs
		Automatic tube voltage selection tool used/ not used	
		Rotation time, mode (sequential/helical), pitch (helical) or table increment (sequential), Field of View (FOV), collimation thickness, beam shaping filters, scanning length	Field of View (FOV)
Automatic exposure control (AEC) (activated/ deactivated)	AEC mode	Tube-current modulation	AEC mode
		Image quality level: Quality Reference mAs/noise index/reference image	
		Standard deviation of CT numbers or equivalent	
		Image handling: reconstruction slice thickness, iterative reconstruction	
		Number of phases and scan sequences	
		Size of the calibration phantom	

8.2.3 Recommended sample size and composition

Patient dose data should be collected from a representative sample of various types of equipment and practices in the geographical area concerned. For LDRLs, data should be collected from all rooms and all types of x-ray equipment used. For NDRLs, the institutions providing patient dose data should include dedicated paediatric healthcare facilities and departments (i.e. children hospitals or departments/units specialising in paediatric imaging), and general healthcare facilities and departments where paediatric practices are part of the overall radiology services. Among the healthcare facilities and departments, big, medium size and small units as well as private and public units should be selected.

Statistically relevant numbers of patient dose data should be collected. In general, the number of subjects used to estimate DRLs, the confidence level, the confidence interval and the variability observed in patient doses for the same type of x-ray examination are interrelated variables. Confidence intervals from small sample sizes may produce unacceptably imprecise results. It is common practice to consider a 95% level of confidence. For a given confidence level, the larger the sample size the smaller the confidence interval. To obtain a 10% confidence interval at a 95% level of confidence requires a sample size of about 100 patients and a 20% confidence interval requires a sample size of about 25 patients. Therefore, for a given confidence level, the larger the variability in patient doses for the same type of examination the larger the sample size needed to obtain a given confidence interval.

In IR procedures, a very wide distribution of doses for the same type of procedures has been observed. This variability may be attributed to many factors including technique variations between interventionalists and complications arising during the interventional procedure. Investigators should balance the benefits of increased sample size and increased precision against the cost of increased time of data collection.

It is recommended that from each institution a representative sample of at least 10 patients per procedure type and per patient group is needed for non-complex examinations such as radiography and CT and at least 20 patients per procedure type and per patient group for complex procedures such as fluoroscopy and fluoroscopically guided procedures. If the DRL- curve approach can be used, a total of 10 (non-complex examinations) and 20 (complex procedures) patients per DRL curve are required and consequently, much less patients are needed per procedure type. For cardiac catheterization and interventional cardiology in paediatric patients, even more patients may be needed because of large differences in complexity and duration of the procedures; however, to recommend the minimum number for these procedures, further studies are needed.

8.2.4 Percentile point for DRL

For setting the values of NDRLs and LDRLs, according to the definition, the 3rd quartile (the 75thpercentile) should be used. This will ensure effective recognition of the "outliers", i.e., the institutions and practices which have unusually high patient dose levels compared with most of the other institutions, possibly because of old x-ray units or the lack of adequate optimisation. However, the full dose distribution should be exploited for optimisation in addition to DRLs: the median (2nd quartile (the 50th percentile)) value should also be determined and retained for the purpose of follow up of optimisation, trend analysis and comparisons in the future updates of the DRLs. The comparison of the relative changes in the 75% and 50% levels can provide useful information on the development of the optimisation.

When the DRLs are being updated, in particular if the dose distribution is less peaked and the variation between the median values collected from institutions is less prominent than during the first introduction of the DRLs, the 50th percentile of the dose distribution could be used as a supplementary metric to the DRL (the 75th percentile). This provides a better goal for optimisation in those institutions with advanced level of technology and optimisation of practices.

In consideration of the patient dose needed, the overriding criterion is an acceptable image quality: the image quality should be adequate for the diagnosis according to the indication of the examination. In the patient dose surveys for setting DRLs, likewise in daily imaging practices, there should always be a system in place to judge whether the image quality is adequate. Patient doses associated with rejected images should not be included in the sample for setting DRLs. The image quality requirement should be based on clinical grounds only. Therefore no limit or warning level for low image quality based solely on the dose level is recommended. If specific actions are taken to reduce a LDRL, it is advisable to establish a dose management team, consisting of a radiologist, radiographer and a medical physicist.

8.3 Setting of DRLs

8.3.1 Organisations to set the DRLs

The organisation which should set the DRLs depends on whether the DRL is local, national, or European (see the definitions in Section 4).

LDRLs are set by a given hospital or group of hospitals within a defined district for their own use, as an aid to improve optimisation of imaging practices in all rooms and with all radiology equipment used in the radiology departments of the hospital or group of hospitals. These can be set to correspond to the level of technology and local achievements of optimisation, to ensure continuous vigilance on the optimum procedures and to provide an alert when any unjustified changes in the local patient dose levels occur.

NDRLs are set by an authoritative body, i.e. competent national authorities such as national radiation protection or health authorities (e.g. ministry of health; e.g., in AT, FI, DE), or specific institutions established and authorized by competent national authorities (e.g. in FR) (see Tables C.2 and C.4 in Annex C). The purpose of the NDRLs is to provide a tool for each hospital or radiology department in the country to check their local median patient dose levels or LDRLs against the national 75th percentile levels for standard radiological practices and to undertake appropriate actions when the NDRLs are exceeded (see also section 9.1.2).

The organisation conducting the patient dose surveys, for the basis of setting the NDRLs, can be either the same authoritative body, which sets the NDRLs, or another institution capable of coordinating such an effort. Good practice is to undertake these surveys and to analyse the results with the collaboration of national professional/scientific societies or at least having recognized clinical experts as consultants in the process.

EDRLs are given by European Commission (this publication). EDRLs are recommendations, and can be adopted by the countries as NDRLs only as long as NDRLs based on national patient dose surveys are not available (see Section 10.3).

8.3.2 Role of authorities and professional societies

The competent national authorities should be responsible for guaranteeing the establishment, implementation and use of DRLs. The authorities should take the lead in bringing together the professional societies representing medical doctors, radiographers and medical physicists to implement patient dose surveys and to establish NDRLs according to the methodology defined in these guidelines. The strong involvement of all professional societies in the establishment of NDRLs is the best vehicle to promote the effective use of the DRL concept.

In practice, the professional societies and their clinical experts should advise on the examinations and procedures where DRLs should be set, advise on organising or coordinate the patient dose surveys (institutions included, practical methods), and advise on the analysis and conclusions on the results to establish the NDRLs.

8.4 Automatic dose management

8.4.1 General review

Dose management solutions can play an important role in the establishment and use of NDRLs or LDRLs. These systems facilitate data collection for patient dose surveys, enable the comparison of patient dose data with DRLs and harvest electronic dose data.

The general development for automatic dose management systems is reviewed in Annex E. A list of currently available dose management systems is also presented in Annex E. Besides the commercial systems shown in Annex E, the dose management system with the largest CT database in the world is the ACR Dose Index Registry (Bhargavan-Chatfield and Morin, 2013). Currently it has captured data from over 800 facilities and 16 million examinations and is available to facilities both within the US and outside of the US.

Most products on the market already support the control and review of paediatric DRLs. The most important parameters are collected and export functions exist in most products, so the systems are becoming very useful tools to establish LDRLs and NDRLs and to make comparisons of local patient dose data with these DRLs. Specific paediatric models currently in development will further facilitate these tasks.

It is important that the desired features (Section 8.4.2) and the local needs should be considered from the beginning and discussed in collaboration with the chosen system manufacturer. For example, in CT imaging, the most critical point in the systems currently is the availability of weight, effective diameter and/or SSDE values. The efficient implementation and use of the systems in daily practice should be ensured by appropriate personnel resources, including training on their use and how to interpret the results and when to undertake further investigations and remedial actions.

8.4.2 Recommendations for the dose management systems to support paediatric DRLs

To establish and use paediatric DRLs for the different imaging modalities, the dose management system should be able to provide the following features:

General features:

- Access patient age
- Access patient weight
- Access to required patient dose quantities (see below)
- Access to technical equipment parameters (exposure parameters, image handling algorithms etc.; see the list in Section 8.2.2)
- Export of a filtered set of data for further analysis e.g. examination type, patient grouping with age or weight, etc.)

Radiography

- P_{KA}
- $K_{a,e}$

CT

- CTDIvol (calibration phantom size indicated)
- DLP
- Patient width or water equivalent diameter
- SSDE (AAPM, 2011)

Interventional procedures

- P_{KA}
- Ka,r
- Fluoroscopy time
- Number of cine, digital, and frontal versus lateral images

It is desirable that these features are easily accessible in any selected product. To allow non-standard evaluations of the collected data, a flexible export feature should be available to export a selected dataset for further analysis.

9. Methods of using DRLs

9.1 Use of different types of DRLs

The use of different DRLs should be in accordance with their definitions (Section 4) and therefore, three different levels are distinguished in the following:

(1) DRLs available at the level of the healthcare facility or group of healthcare facilities (LDRL)
(2) DRLs available at national level (NDRL)
(3) DRLs available at European level (EDRL)

The comparison of patient doses with DRLs should always be based on data from a sample of patients, as described below, and should not be used on an individual patient basis.

9.1.1 LDRLs – for optimisation within a healthcare facility or group of healthcare facilities

The median (the 50th percentile) values of patient dose distributions from a wide representative sample of examinations, obtained from within the healthcare facility or group of healthcare facilities, should regularly be compared with any existing LDRLs. The objectives of these comparisons is to identify and improve shortcomings in the optimisation of the patient doses within the healthcare facility or group of healthcare facilities, to follow up the patient dose levels and to find out if there are any unexpected changes in the levels, e.g. due to equipment malfunction, unauthorized change of the imaging practice or lack of sufficient training of new users. The LDRLs will enable more systematic studies of patient dose levels and the achievement of optimisation within the healthcare facility or group of healthcare facilities, e.g., comparisons between radiology departments, effect of selected local parameters such as week-end versus working days, day time versus night shift, dedicated paediatric versus general radiology staff, or performance of selected teams of radiographers.

9.1.2 NDRLs – for both local and nationwide optimisation

NDRLs should be set by an authoritative body, based on national patient dose surveys and according to the other principles laid down in Section 8. The NDRLs, when not adopted from the EDRLs, should be compared with the EDRLs (see Section 10.3).

Institutions that have their own LDRLs must carry out regular comparison of the LDRLs with NRDLs to ensure they are not higher. Where it is found that an LDRL is higher than a newer reported NDRL, increased attention must be paid to optimisation and new patient dose surveys should be conducted to check whether updating the LDRL is needed. If the LDRL or its update remains higher than the relevant NDRL, it should be replaced by the NDRL.

Where no LDRLs have been set, the median (the 50th percentile) values of patient dose distributions from representative samples of examinations, obtained from the healthcare facility or group of healthcare facilities, should regularly be compared with the NDRLs for all types of examinations where NDRLs have been set. The objectives of these comparisons are to identify and improve shortcomings of local practices in the optimisation of the patient doses, to follow up the patient dose levels in various hospitals and to find out if there have been any changes in the levels, e.g. due to change of imaging technology or imaging practices, or lack of sufficient training of users. Cases should be investigated where the median values of the local patient dose distributions are above the NDRLs and reduced through appropriate changes in practice in order to improve patient protection.

The authoritative body issuing the NDRLs should complement them with detailed guidance on how to compare the values with local patient dose levels. The implementation of such comparisons should be a component in the regulatory inspection program and it is highly recommended that the correct implementation and the results of comparisons are among the key topics of regular clinical auditing (EC, 2009). Results of the comparisons should also be collected and summarized from time to time, to enable trend analysis and to check the need for updating the NDRLs, and to focus training efforts on practices and areas where the need is most evident.

9.1.3 EDRL – for support of national efforts

How individual countries can use EDRLs is discussed in Section 10.3.

The use of EDRLs provides an interim solution for countries with no national patient dose surveys, until such surveys are made. The established EDRLs, together with the recommendations of Section 6, will indicate the examinations where the establishment of NDRLs is feasible and recommended. The analysis and development of EDRLs also indicates the examinations where harmonisation of DRLs could be achievable, as well as the types of examinations where DRLs would be needed but are not currently available, and consequently, where patient dose surveys and research on DRLs should be directed.

Regular updates of EDRLs will provide data for trend analysis and development of the optimisation of paediatric patient doses in Europe. The patient dose surveys used for the basis of paediatric DRLs can also be exploited in studies on the collective doses to the paediatric population from medical imaging.

9.2 Methods of comparison

When comparing the local patient dose data with DRLs, it is clear that the same quantities and patient groupings have to be applied as those used for the DRLs. In the cases where the same patient groupings are not available, conversions (e.g. from age to weight) can be applied but this will add uncertainty to the comparison.

The median value of a patient dose distribution, for a minimum of 10 patients for each patient group (weight, age), should be calculated and compared with the DRL. If the DRL curve method is used, a minimum of 10 (non-complex examinations) or 20 (complex procedures) patients is sufficient for the whole comparison provided these cover reasonably well the whole range of patient weight or size parameter.

As the main purpose of using DRLs is to find where patient doses are significantly higher than those generally achievable, a simple observation that the local median dose level exceeds the DRL, or a visual observation that the local dose data points or the curve fitted through them exceeds the DRL-curve generally suffice. However, the significance of the difference can be more exactly studied and confirmed by statistical means e.g. the Student's t-test can be applied.

The development of automatic dose management systems with integrated dose monitoring programs will enable frequent or even on-line comparisons of the median (the 50^{th} percentile) values of patient dose distributions with the DRL (LDRL or NDRL), and can include an automatic indication when the DRL is exceeded. Such automatic systems can provide continuous follow-up of patient dose levels and ensure a rapid communication between the radiographers (operators) and the medical physicist / medical physics expert to identify the reasons for the unusual dose levels.

9.3 Comparison frequency

The local patient dose levels should be compared with LDRLs or NDRLs at least once per year. LDRLs should be compared with NDRLs and NDRLs with EDRLs whenever any DRLs have been established or updated.

9.4 Local reviews and actions when DRLs are exceeded

All radiological departments should apply the available NDRLs, unless lower (more strict) LDRLs have been defined. Whenever the DRLs applied are consistently exceeded, appropriate investigations to identify the reasons, and corrective actions to improve the clinical practice, if necessary and feasible, should be undertaken without undue delay (EC, 2014). The investigation should include review of equipment performance, the settings used, and the examination protocols (Martin, 2011). The factors most likely to be involved are dose survey methodology, equipment performance, procedure protocol and operator skill. A typical reason maybe related to a failure to adapt the imaging protocol to account for paediatric diseases and paediatric patient sizes.

Findings of deficiencies in equipment performance might require a critical review of QA and maintenance programmes or initiate the replacement of equipment, Other corrective actions may include for example adjustment of the AEC, review and adjustment of standard operating procedures and protocols, and setting of equipment controls,

The responsibility for investigations and corrective actions must be given to appropriate staff who have the necessary expertise. The groups of staff involved will depend on arrangements in each country or region, and may be medical physicists, radiographers, medical physics technologists, or paediatric radiologists, who may be employed by the healthcare provider or under contract to the provider (Martin et al., 2013).

The use of the DRLs, including all findings and subsequent corrective actions should be documented and made available for clinical audits (internal or external audits) and for regulatory inspections by competent authorities. Several international recommendations (EC, 2009; ICRP, 2007; IAEA, 1996) point out that the patient dose should be addressed in clinical audits in comparison with the given DRLs. As a minimum, assessing the local practice of comparisons of patient doses with the DRLs should be part of the clinical audit procedure.

As highlighted in the introduction (Section 2), optimization of paediatric x-ray examinations and procedures is of particular importance due to the children's higher radiation risk. The application of DRLs is an important part of this but not sufficient, by itself, for optimisation of protection. Optimisation is generally concerned with maintaining the quality of the diagnostic information 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. Methods to achieve optimisation that encompass both DRLs and image quality evaluation should therefore be implemented.

10. European DRLs (EDRLs)

10.1 Methods to establish EDRLs

For these guidelines there has been no possibility to establish new large scale patient dose surveys, either nationally or European wide. Therefore, the proposed European DRLs (EDRLs) had to be based on national DRLs (NDRLs) existing in European countries. EDRLs have been derived as the median values of the relevant NDRLs, in accordance with the definitions adopted in Section 4. However, due to the scarceness of official NDRLs, i.e. NDRLs set by an authoritative body, a few recent publications presenting proposed NDRLs or relevant results (the 75th percentiles) of nationwide patient dose surveys, have also been taken into consideration. The DRL data (the official and proposed NDRLs and the published 75th percentile values) were accepted for the calculation if these met the following criteria (see also Section 5.5.3):

- Data had to be based on own national patient dose surveys i.e. no phantom or protocol based evaluations, no DRLs adopted from other countries or from the out-of-date European recommendations.
- Patient dose surveys had to cover a representative sample of national practices (number and types of institutions).
- DRL quantities must be in accordance with the recommendations (Section 7 and Executive summary).
- Patient groupings for DRLs must be adaptable to the recommended groupings (Section 7 and Executive summary), i.e. if different groups have been used, their equivalence with the recommended groups has to be specified.
- The percentile point for the DRL selection had to be 75%.
- Patient dose surveys must not be more than 6 years older than the most recent survey for the DRL quantity in question.
- DRLs from at least 3 countries must be available for the calculation.
- DRLs for CT must refer to a complete routine CT examination (one scan series).

With the above criteria, EDRLs could only be derived for a few examinations in radiography, fluoroscopy and CT.

For IR, no EDRL can be proposed because neither official nor proposed NDRLs exist. As shown in Section 5, for paediatric cardiac procedures, only LDRLs have been published, and for paediatric non-cardiac procedures, no DRL data is available. In the context of the PiDRL project, a limited number of patient dose data for both cardiac and non-cardiac procedures was collected from a few paediatric centres. In Annex G, a summary of the most recent publications on patient doses and LDRLs for cardiac procedures, including some notes of the limited PiDRL survey, has been presented, as well as a brief summary of the PiDRL patient data collection for paediatric non-cardiac procedures. The need for DRLs for paediatric IC and other IR procedures was stated in Section 6.3 and is further highlighted in the summaries of Annex G. It is concluded that further research and data collection from several cardiac centres has to be conducted to assess the feasibility of paediatric NDRLs or EDRLs and to obtain a sufficient and reliable basis for suggesting these DRLs when feasible.

The DRL data or publications used for the evaluation of the EDRLs for radiography, fluoroscopy and CT are shown in Table 10.1. More details of the selection of the data are given in Annex F.

Table 10.1. Data on DRLs accepted for consideration of the European DRLs.

	Radiography	**Fluoroscopy**	**Computed tomography**	**Interventional radiology**
NDRLs set by an authoritative body (Annex 1)	AT- Billiger et al., 2010 BE DE DK ES- Ruiz-Cruces, 2015 FI- Kiljunen et al., 2007 FR- Roch et al., 2012 LT NL	AT DE DK ES- Ruiz-Cruces, 2015 FI NL UK- Hart et al. 2012	AT BE DE ES- Ruiz-Cruces, 2015 FI- Järvinen et al. 2014 IE- HSE Medical Exposures Radiation Unit , 2013 LT NL UK- Shrimpton et al. 2006, Shrimpton et al. 2014	No NDRLs exist
Other published/ available data			PT- Santos et al. 2013 IT- Granata et. al. 2015	No acceptable data.

10.2. EDRL values

The resulting EDRLs are presented in Table 10.2 a, b. In these tables, the recommended age groups for head examinations and weight groups for body examinations have been used (see Table 7.1).

In Annex F, the mean values and the interquartile values of the DRL-data used in the calculations are also given. These data can give some understanding of the possible uncertainties when adopting an EDRL as an NDRL (see also Section 10.3).

Table 10.2a. European DRLs for radiography and fluoroscopy

Radiography and fluoroscopy			
Examination	Age or weight group	**EDRL**	
		$K_{a,e}$, mGy	**P_{KA}, mGy cm^2**
Head AP/PA	3 months-<1 y		215
	1-<6 y		295
	≥6 y		350
Head LAT	3 months-<1 y		200
	1-<6 y		250
Thorax AP/PA**	<5 kg		15
	5-<15 kg	0,06	22
	15-<30 kg	0,08	50
	30-<50 kg	0,11	70
	50-<80 kg		87
Abdomen AP	<5 kg		45
	5-<15 kg		150
	15-<30 kg	0,40	250
	30-<50 kg	0,75	475
	50-<80 kg		700
Pelvis AP	15-<30 kg		180
	30-<50 kg		310
MCU	<5 kg		300
	5-<15 kg		700
	15-<30 kg		800
	30-<50 kg		750*
*Based on 4 NDRLs, range 400-2000 mGy cm^2; **AP/PA: DRL applies to both AP and PA projections			

Table 10.2b. European DRLs for computed tomography. EDRLs for head CT refer to 16 cm phantom and EDRLs for thorax and abdomen for 32 cm phantom. DRLs refer to a complete routine CT examination (one scan series).

Computed tomography			
Exam	Age or weight group	**EDRL**	
		$CTDI_{vol}$, mGy	**DLP, mGy cm**
Head	0-<3 months	24	300
	3 months-<1 y	28	385
	1-<6 y	40	505
	≥6 y	50	650
Thorax	<5 kg	1,4	35
	5-<15 kg	1,8	50
	15-<30 kg	2,7	70
	30-<50 kg	3,7	115
	50-<80 kg	5,4	200
Abdomen	<5 kg		45
	5-<15 kg	3,5	120
	15-<30 kg	5,4	150
	30-<50 kg	7,3	210
	50-<80 kg	13	480

10.3 Use of the EDRLs

It is strongly recommended that NDRLs, based on adequate national patient dose surveys, are established in each country instead of adopting the above EDRLs. Therefore, all the EDRLs presented in these Guidelines (Tables 10.2a,b) should be considered only as the preliminary choice for the NDRLs until appropriate national patient dose surveys have been carried out and NDRLs based on these surveys have been established by an authoritative body.

If the NDRLs exceed the EDRLs, the reasons for these differences should be considered. In particular, if the NDRLs are not based on recent national patient dose surveys, the need for new surveys to update the NDRLs should be considered.

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ANNEX A. NATIONAL DRL VALUES FOR PAEDIATRIC EXAMINATIONS AND PROCEDURES IN EUROPEAN COUNTRIES

The NDRL data in this Annex is based on DDM2 database, an update by PIDRL questionnaire (Annex C, Section C.2.1), and a literature review (Annex C, Section C.2.2). Only NDRLs accepted by an authoritative body have been presented.

Table A.1. DRLs for paediatric x-ray procedures: head, skull and sinuses.

Country	**Procedure & quantity**					
	Head, skull AP/PA		**Head, skull LAT**		**Waters projection**	
	$K_{a,e}$ or $K_{a,i}$, mGy	P_{KA}, mGy*cm^2	$K_{a,e}$ or $K_{a,i}$, mGy	P_{KA}, mGy*cm^2	$K_{a,e}$, mGy	P_{KA}, mGy*cm^2
AT	$K_{a,i}$, Ref[2] 0.35 (0y) 0.60 (1y) 0.75 (5y) 0.90 (10y) 1.00 (15y)	Ref[1,2] 150(0y) 250 (1y) 350 (5y) 450(10y) 500(15y)	$K_{a,i}$, Ref[2] 0.30 (0y) 0.,40 (1y) 0.50 (5y) 0.55 (10y) 0.60 (15y)	Ref[1,2] 100(0y) 200 (1y) 250 (5y) 300(10y) 350(15y))		
CY	$K_{a,e}$, Ref[1,3] 1.5 (5y)		$K_{a,e}$, Ref[1,3] 1.0 (5y)			
DE		AP, Ref[1,4] 200(10±2mo) 300 (5±2y)		Ref[1,4] 200 (10±2mo) 250 (5±2y)		
ES		AP, Ref[5] 130 (0y) 230 (1y-5y) 350 (6y-10y) 430 (11y-15y)				
FI					Ref[1,6] 2 (7-15 y)	Ref[1,6] 250 (7-15 y)
IE	$K_{a,e}$, Ref[7,8] 1.37 (5y)		$K_{a,e}$, Ref[7,8] 0.82 (5y)			
IT	$K_{a,e}$, Ref[1,3] 1.5 (5y)		$K_{a,e}$, Ref[1,3] 1.0 (5y)			
LT	$K_{a,e}$, Ref[1] 0.8 (1y) 1.0 (5y) 1.3 (10y) 1.5 (15y)	Ref[1] 200 (1y) 290 (5y) 350 (10y) 410 (15y)	$K_{a,e}$, Ref[1] 0.4 (1y) 0.5 (5y) 0.6 (10y) 0.65 (15y)	Ref[1] 160 (1y) 260 (5y) 270 (10y) 380 (15y)		
LU	$K_{a,e}$, Ref[1,3] 1.5 (5y)		$K_{a,e}$, Ref[1,3] 1.0 (5y)			
PL	$K_{a,e}$, Ref[1,3] 1.5 (5y)		$K_{a,e}$, Ref[1,3] 1.0 (5y)			
RO	$K_{a,e}$, Ref[1,3] 1.5 (5y)		$K_{a,e}$, Ref[1,3] 1.0 (5y)			

[1]Questionnaire,[2]Billiger et al., 2010, [3]EC 1999 (Radiation Protection 109), [4]Veit et al., 2010, [5]Ruiz-Cruces, 2015, [6]STUK resolution 1 Jan 2006 (www.stuk.fi), [7]Ireland Medical Council, 2004, [8]HSE Medical Exposures Radiation Unit, 2013.

Table A.2. DRLs for paediatric x-ray procedures: thorax. (AP/PA: the same DRL for both AP and PA projections)

Country	Procedure & quantity				
	Thorax AP/PA		**Thorax LAT**		**Thorax PA+LAT**
	$K_{a,e}$ or $K_{a,i}$, mGy	P_{KA}, mGy*cm^2	$K_{a,e}$, mGy	P_{KA}, mGy*cm^2	P_{KA}, mGy*cm^2
AT	$K_{a,i}$, Ref[2] 0.05 (0y) 0.06 (1y) 0.07 (5y) 0.09 (10y) 0.11 (15y)	PA, Ref[1]; AP/PA, Ref[2] 17 (0y) 23 (1y) 26 (5y) 37 (10y) 73 (15y)			
BE		PA, Ref[3] 20 (<1y) 35 (1-<5y) 50 (5-<10y) 120 (10-<15y)			Ref[3] 60 (<1y) 105 (1-<5y) 150 (5-<10y) 350 (10-<15y)
CY	$K_{a,e}$, Ref[1,4] 0,08 (newborn)(AP) 0.1(5y)		Ref [1,4] 0.2 (5y)		
DE		AP/PA, Ref[5] 3 (about 1000 g) 5 (about 3000 g) 15 (10±2mo) 25 (5±2y) 35 (10±2y)		Ref[5] 40 (5±2y) 60 (10±2y)	
DK	$K_{a,e}$, Ref[1] 0.080 (5y; exp scaling with equiv.diam. for other ages)		Ref[1] 0.095 (5y; exp scaling with eq.diam. for other ages)		
ES		PA, Ref[6] 40 (0y) 50 (1y-5y) 85 (6y-10y) 100 (11y-15y)			
FI	$K_{a,e}$, Ref[1,7,8] DRL-curve as a function of patient width	Ref[1,7,8] DRL-curve as a function of patient width	Ref [1,7,8] DRL-curve as a function of patient width	Ref[1,7,8] DRL-curve as a function of patient width	
FR	$K_{a,e}$, Ref [1,9] 0.08 (3,5 kg/ newborn) (AP) 0.08 (10 kg/1y) (AP) 0.1 (20 kg/5y) (PA) 0.2 (30 kg/10y) (PA)	Ref [1,9] 10 (3.5 kg/ newborn) (AP) 20 (10 kg/1 y) (AP) 50 (20 kg/5y) (PA) 70 (30kg/10y) (PA)	Ref [1,9] 0.2 (20 kg/5y) 0.3 (30kg/10y)	Ref [1,9] 60 (20 kg/5y) 80 (30 kg/10y)	

Country	Procedure & quantity				
	Thorax AP/PA		**Thorax LAT**		**Thorax PA+LAT**
	$K_{a,e}$ or $K_{a,i}$, mGy	P_{KA}, mGy*cm^2	$K_{a,e}$, mGy	P_{KA}, mGy*cm^2	P_{KA}, mGy*cm^2
IE	$K_{a,e}$, Ref[10, 11] 0.057 (1y) 0.053 (5y) 0,066 (10y) 0.088 (15y)				
IT	$K_{a,e}$, Ref [1,4] 0.08 (newborn)(AP) 0.1 (5y)		Ref [1,4] 0.2 (5y)		
LT	$K_{a,e}$, PA, Ref[1] 0.06 (1y) 0.07 (5y) 0,08 (10y) 0.09 (15y)	PA, Ref[1] 50 (1y) 60 (5y) 80 (10y) 100 (15y)			
LU	$K_{a,e}$, Ref [1,4] 0.08 (newborn)(AP) 0.1 (5y)		Ref [1,4] 0.2 (5y)		
NL		Ref [1] 15 (4 kg/0y), 20 (11 kg/1y) 50 (21 kg/5y)			
PL	$K_{a,e}$, Ref [1,4] 0.08 (newborn)(AP) 0.1 (5y)		Ref [1,4] 0.2 (5y)		
RO	$K_{a,e}$, Ref [1,4] 0.08 (newborn)(AP) 0.1 (5y)		Ref [1,4] 0.2 (5y)		

[1]Questionnaire, [2]Billiger et al., 2010, [3]www.fanc.fgov.be, [4]EC 1999 (Radiation Protection 109), [5]Veit et al., 2010, [6]Ruiz-Cruces, 2015, [7]STUK resolution 1 Jan 2006 (www.stuk.fi), [8]Kiljunen et al. 2007, [9]Roch and Aubert, 2012, [10]Ireland Medical Council, 2004, [11]HSE Medical Exposures Radiation Unit, 2013.

Table A.3. DRLs for paediatric x-ray procedures: abdomen, pelvis, micturating cystourethrography, barium meal and barium swallow.

Country	Procedure & quantity						
	Abdomen, common technique		**Pelvis**		**Micturating cystourethrography (MCU)**	**Barium meal**	**Barium swallow**
	$K_{a,e}$ or $K_{a,i}$, mGy	P_{KA}, mGy*cm^2	$K_{a,e}$, mGy	P_{KA}, mGy*cm^2	P_{KA}, Gy*cm^2	P_{KA}, Gy*cm^2	P_{KA}, Gy*cm^2
AT	$K_{a,i}$, AP/PA, Ref[2] 0.20 (0y) 0.30 (1y) 0.40 (5y) 0.75 (10y) 1.00(15y)	AP, Ref[1]; AP/PA, Ref[2] 60 (0y) 90 (1y) 200 (5y) 500 (10y) 700 (15y)			Ref[1] 0.5 (0y) 0.7 (1y) 1.2 (5y) 2.0 (10y)		
BE		Ref[3] 30 (<1y) 100 (1-<5y) 250 (5-<10y) 450 (10-<15y)					
CY	$K_{a,e}$, AP/PA, Ref[1,4] 1.0 (5y)		AP, Ref[1,4] 0.2 (infants) 0.9 (5y)				
DE		AP/PA, Ref[5] 200 (10±2mo) 250 (5±2y) 350 (10±2y)		AP, Ref[5] 150 (5±2y) 250 (10±2y)	Ref[5] 0.1 (ab. 3000g) 0.2 (10±2mo) 0.3 (5±2y) 0.6 (10±2y)		
DK	$K_{a,e}$, Ref [1] 0.075 (< 1y)		AP, Ref[1] 0.375 (5y)		Ref[1] 0.3 (<1y) 0.9 (1-5y)		
ES		AP, Ref[6] 150 (0y) 200 (1y-5y) 225 (6y-10y) 300 (11y-15y)		PA, Ref[6] 60 (0y) 180 (1y-5y) 310 (6y-10y) 400 (11y-15y)	Ref[6] 0,50 (0y) 0,75 (1y-5y) 0,90 (6y-10y) 1,45 (11y-15y)		
FI					Ref[1,7] 0.3 (<1y) 0.9 (1-5y)		
FR	$K_{a,e}$, Ref[1,8] 1.0 (20 kg/5y) 1.5 (30 kg/10y)	Ref[1,8] 300 (20 kg/5y)[1] 700 (30 kg/10y)[1,8]	Ref[1,8] 0.2 (10 kg/1y) 0.9 (20 kg/5y) 1.5 (30 kg/10y)	Ref[1,8] 30 (10 kg/1y)[1] 200 (20 kg/5y)[1,8] 400 (30 kg/10y)[1,8]			

Country	Procedure & quantity						
	Abdomen, common technique		**Pelvis**		**Micturating cystourethrography (MCU)**	**Barium meal**	**Barium swallow**
	$K_{a,e}$ or $K_{a,i}$, mGy	P_{KA}, mGy*cm^2	$K_{a,e}$, mGy	P_{KA}, mGy*cm^2	P_{KA}, Gy*cm^2	P_{KA}, Gy*cm^2	P_{KA}, Gy*cm^2
IE	$K_{a,e}$, AP, Ref[9,10] 0.330 (1y) 0.752 (5y)		AP, Ref[9, 10] 0.265 (1y) 0.475 (5y) 0.807 (10y) 0.892 (15y)		Ref[9,10, 11] 0.4 (0y) 0.9 (1y) 1.1(5y) 2.1 (10y) 4.7(15y)	Ref[9,10,11] 0.7 (0y) 2 (1y) 2 (5y) 4.5 (10y) 7.2 (15y)	Ref[9,10,11] 0.8 (0y) 1.6 (1y) 1.3(5y) 2.7 (10y) 4.6(15y)
IT	$K_{a,e}$, AP/PA, Ref[1,4] 1.0 (5y)		AP, Ref[1,4] 0.2 (infants) 0.9 (5y)				
LT	$K_{a,e}$, Ref[1] 0.3 (1y) 0.4 (5y) 0,6 (10y) 0.7 (15y)	Ref[1] 300 (1y) 800 (5y) 1000 (10y) 1200 (15y)					
LU	$K_{a,e}$, AP/PA, Ref[1,4] 1.0 (5y)		AP, Ref[1,4] 0.2 (infants) 0.9 (5y)				
NL		Ref[1] 15 (4 kg/0y) 100 (11 kg/1y) 250 (21 kg/5y)			Ref [1] 0.3 (4 kg/0y) 0.7 (11 kg/1y) 0.8 (21 kg/5y)		
PL	$K_{a,e}$, AP/PA, Ref[1,4] 1.0 (5y)		AP, Ref[1,4] 0.2 (infants) 0.9 (5y)				
RO	$K_{a,e}$, AP/PA, Ref[1,4] 1.0 (5y)		AP, Ref[1,4] 0.2 (infants) 0.9 (5y)				
UK					Ref[12] 0.1 (0y) 0.3 (1y) 0.3 (5y) 0.4 (10y) 0.9 (15y)	Ref [12] 0.1 (0y) 0.2 (1y) 0.2 (5y) 0.7 (10y) 2.0 (15y)	Ref [12] 0.2 (0y) 0.4 (1y) 0.5 (5y) 1.8 (10y) 3.0 (15y)

[1]Questionnaire, [2]Billiger et al., 2010, [3]www.fanc.fgov.be, [4]EC 1999 (Radiation Protection 109), [5]Veit et al., 2010, [6]Ruiz-Cruces, 2015, [7]STUK resolution 1 Jan 2006 (www.stuk.fi), [8]Roch and Aubert, 2012, [9]Ireland Medical Council, 2004, [10]HSE Medical Exposures Radiation Unit, 2013, [11]Hart et al., 2002, [12]Hart et al., 2012.

Table A.4. DRLs for paediatric CT procedures: head. DRLs refer to a complete routine CT examination (one scan series) and the use of 16 cm phantom, except for (1) BE, where DLP is an average of plain scans and contrast enhanced scans, and (2) IE, where DLP is the average of routine CT examination which include both single phase and multi phase scans.

Country	**Procedure & quantity**						
	CT Head, brain, cranial, skull		**CT Face and sinuses, nasal cavity**	**CT Facial bones**		**CT Petrous bone**	
	DLP, mGy*cm	$CTDI_{VOL}$, mGy	DLP, mGy*cm	DLP, mGy*cm	$CTDI_{VOL}$, mGy	DLP, mGy*cm	$CTDI_{VOL}$, mGy
AT	Ref[1] 300 (0y) 400 (1y) 600 (5y) 750 (10y) 900 (15y)						
BE	Ref[2] 420 (<1y) 540 (1-<5y) 660 (5-<10y) 780 (10-<15y)	Ref[2] 22 (<1y) 30 (1-<5y) 40 (5-<10y) 45 (10-<15y)	DLP (mGy cm), sinus[2] 50 (1-<5y) 65 (5-<10y) 80 (10-<15y) $CTDI_{vol}$ (mGy), sinus[2] 4 (5-<10y) 6 (10-<15y)				
CH	Ref[1,3] 290 (newborn) 390 (0-1y) 520 (1-5y) 710 (6-10y) 920 (11-15y)	Ref[1,3] 27 (newborn) 33 (0-1y) 40 (1-5y) 50 (6-10y) 50 (11-15y)	Face, nasal cavity, Ref[1,3] 70 (newborn) 95 (0-1 y) 125 (1-5 y) 180 (6-10 y) 230 (11-15y)				
DE	Ref[1,4] 300 (newborn) 400 (< 1y) 500 (2-5y) 650 (6-10y) 850 (11-15y) 950 (>15y)	Ref[1,4] 27 (newborn) 33 (< 1y) 40 (2-5y) 50 (6-10y) 60 (11-15y) 65 (>15y)		Facial bones, Ref[1,4] 70 (newborn) 95 (< 1y) 125 (2-5y) 180 (6-10y) 230 (11-15y) 250 (>15y)	Facial bones, Ref[1,4] 9 (newborn) 11 (< 1y) 13 (2-5y) 17 (6-10y) 20 (11-15y) 22 (>15y)		
ES	Ref[5] 250 (0y) 340 (1y-5y) 450 (6y-10y) 650 (11y-15y)						

Country	Procedure & quantity						
	CT Head, brain, cranial, skull		**CT Face and sinuses, nasal cavity**	**CT Facial bones**		**CT Petrous bone**	
	DLP, mGy*cm	$CTDI_{VOL}$, mGy	DLP, mGy*cm	DLP, mGy*cm	$CTDI_{VOL}$, mGy	DLP, mGy*cm	$CTDI_{VOL}$, mGy
FI	Routine head, Ref[6] 330 (<1y) 370 (1-<5y) 460 (5-<10y) 560 (10-15y) Ventricular size, Ref[6] 35 (<1-15y)	Routine head, Ref[6] 23 (<1y) 25 (1-<5y) 29 (5-<10y) 35 (10-15y) Ventricular size, Ref[6] 4 (<1-15y)					
FR	Ref[1,7] 420 (10 kg/1y) 600 (20 kg/5y) 900 (30 kg/10y)	Ref[1,7] 30 (10 kg/1y) 40 (20 kg/5y) 50 (30 kg/10y)		Ref[1,7] 200 (10 kg/1y) 275 (20 kg/5y) 300 (30 kg/10y)	Ref[1,7] 25 (10 kg/1y) 25 (20 kg/5y) 25 (30 kg/10y)	Ref[1,7] 160 (10 kg/1y) 280 (20 kg/5y) 340 (30 kg/10y)	Ref[1,7] 45 (10 kg/1y) 70 (20 kg/5y) 85 (30 kg/10y)
IE	Ref[8] 340 (newborn) 470 (1-4y) 620 (5-9y) 850 (10-15y)						
LT	Ref[1] 570 (1y) 630 (5y) 650 (10y) 830 (15y)						
NL	Ref[1] 240 (4 kg/0 y) 300 (11kg/1y) 420 (21 kg/5y) 600 (36 kg/10y)	Ref[1] 20 (4 kg/0 y) 25 (11kg/1y) 35 (21 kg/5y) 50 (36 kg/10y)					
UK	Head (trauma), Ref[9] 350 (0-1y) 650 (>1-5y) 860 (>5y)	Head (trauma), Ref[9] 25 (0-1y) 40 (>1-5y) 60 (>5y)					

[1]Questionnaire, [2]www.fanc.fgov.be, [3]Galanski and Nagel, 2006, [4]Veit et al., 2010, [5]Ruiz-Cruces, 2015, [6]Järvinen et al., 2015, [7]Roch and Aubert, 2012, [8]HSE Medical Exposures Radiation Unit, 2013, [9]Shrimpton et. al., 2014.

Table A.5. DRLs for paediatric CT procedures: chest, abdomen. DRLs refer to a complete routine CT examination (one scan series) and the use of 32 cm phantom, except for (1) BE, where DLP is an average of plain scans and contrast enhanced scans, and (2) IE, where DLP is the average of routine CT examination which include both single phase and multi phase scans.

Country	**Procedure & quantity**			
	CT chest, thorax		**CT abdomen**	
	DLP, mGy*cm	$CTDI_{VOL}$, mGy	DLP, mGy*cm	$CTDI_{VOL}$, mGy
AT	Ref.[1] 80 (0y) 100 (1y) 150 (5y) 180 (10y) 200 (15y)			
BE	Ref[2] 35 (1-<5y) 55 (5-<10y) 130 (10-<15y)	Ref[2] 1,5 (1-<5y) 2,0 (5-<10y) 3,5 (10-<15y)	Ref[2] 110 (1-<5y) 220 (5-<10y) 330 (10-<15y)	Ref[2] 5,0 (5-<10y) 7,5 (10-<15y)
CH	Ref[1,9] 12 (newborn) 28 (0-1y) 55 (1-5y) 105 (6-10y) 205 (11-15y)		Ref[1,9] 27 (newborn) 70 (0-1y) 125 (1-5y) 240 (6-10y) 500 (11-15y)	
DE	Ref[3] 20 (newborn) 30 (< 1y) 65 (2-5y) 115 (6-10y) 230 (11-15y) 400 (>15y)	Ref[3] 1,5 (newborn) 2 (< 1y) 3,5 (2-5y) 5 (6-10y) 8 (11-15y) 12 (>15y)	Ref[3] 45 (newborn) 85 (< 1y) 165 (2-5y) 250 (6-10y) 500 (11-15y) 900 (>15y)	Ref[3] 2,5 (newborn) 3,5 (< 1y) 6 (2-5y) 8 (6-10y) 13 (11-15y) 20 (>15y)
ES	Ref[4] 46 (0y) 82 (1y-5y) 125 (6y-10y) 200 (11y-15y)		Ref[4] 95 (0y) 150 (1y-5y) 190 (6y-10y) 340 (11y-15y)	
FI	Ref[5] DRL curve as a function of patient weight	Ref[5] DRL curve as a function of patient weight	Ref[5] DRL curve as a function of patient weight	Ref[5] DRL curve as a function of patient weight
FR	Ref[1,6] 30 (10 kg/1y) 65 (20 kg/5y) 140 (30 kg/10y)	Ref[1,6] 3 (10 kg/1y) 4 (20 kg/5y) 5 (30 kg/10y)	Abdomen-pelvis, Ref[1,6] 80 (10 kg/1y) 120 (20 kg/5y) 245 (30 kg/10y)	Abdomen-pelvis, Ref[1,6] 4 (10 kg/1y) 5 (20 kg/5y) 7 (30 kg/10y)
IE			Abdomen/ Pelvis, Ref[7] 130 (newborn) 160 (1-4y) 230 (5-9y) 400 (10-15y)	

Country	Procedure & quantity			
	CT chest, thorax		CT abdomen	
	DLP, mGy*cm	$CTDI_{VOL}$, mGy	DLP, mGy*cm	$CTDI_{VOL}$, mGy
UK	Chest, detect. of malignancy, Ref[8] 100 (0-1y) 115 (5y) 185 (10y)	Chest, detect. of malignancy, Ref[8] 6 (0-1y) 6,5 (5y) 10 (10y)		

[1]Questionnaire, [2]www.fanc.fgov.be, [3]Veit et al., 2010, [4]Ruiz-Cruces, 2015, [5]Järvinen et al., 2015, [6]Roch and Aubert, 2012, [7]HSE Medical Exposures Radiation Unit, 2013, [8]Shrimpton et al., 2006, [9]Galanski and Nagel, 2006.

Table A.6. DRLs for paediatric CT procedures: lumbar spine, whole body (thorax+abdomen+pelvis). DRLs refer to a complete routine CT examination (one scan series) and the use of 16 cm phantom.

Country	Procedure & quantity	Procedure & quantity	Procedure & quantity
	CT lumbar spine	CT whole body	CT whole body
	DLP, mGy*cm	DLP, mGy*cm	$CTDI_{VOL}$, mGy
CH	Ref[1,2] 42 (newborn) 85 (0-1y) 135 (1-5y) 215 (6-10y) 380 (11-15)		
FI		Whole body (WB; thorax + abdomen), Ref[3] DRL curve as a function of patient weight	Whole body (WB; thorax + abdomen), Ref[3] DRL curve as a function of patient weight

[1]Questionnaire, [2]Galanski and Nagel, 2006, [3]Järvinen et al., 2015

1 Table A.7. DRL curves (FI). Data for CT corresponds to 32 cm phantom.
2

Examination	Quantity and unit	DRL curve	x-value and unit	Reference
Chest radiography AP/PA	$K_{a,e}$, mGy	$y=0.036e^{0.067x}$	patient thickness, cm	STUK resolution 1, January 2006 (www.stuk.fi) Kiljunen et al., 2007
	P_{KA}, mGy cm^2	$y=3.556e^{0.132x}$		
Chest radiography LAT	$K_{a,e}$, mGy	$y=0.040e^{0.080x}$		
	P_{KA}, mGy cm^2	$y=7.469e^{0.083x}$		
Chest CT	$CTDI_{VOL}$, mGy	$y=0.726\ e^{0.026x}$	patient weight, kg	STUK resolution 1, June 2015 (www.stuk.fi) Järvinen et. al, 2015
	DLP, mGy cm	$y=10.871e^{0.0409x}$		
Abdomen CT	$CTDI_{VOL}$, mGy	$y=1.314\ e^{0.0282x}$		
	DLP, mGy cm	$y=38.75e^{0.0358x}$		
WB (thorax + abdomen) CT	$CTDI_{VOL}$, mGy	$y=1.8486\ e^{0.0234x}$		
	DLP, mGy cm	$y=62.129e^{0.0373x}$		

ANNEX B. DRL VALUES FOR PAEDIATRIC EXAMINATIONS AND PROCEDURES: SUMMARY OF SELECTED DRL DATA PUBLISHED IN EUROPEAN COUNTRIES.

Table B1. Summary of selected DRL data from published in European countries, for paediatric radiography examinations.

Country or region	Examination	Patient grouping	$K_{a,e}$ mGy	P_{KA} mGy cm^2	Reference
ES (existing NDRL)	Head AP	0y		130	Ruiz-Cruces (2015) (DOPOES project)
		1-5y		230	
		6-10y		350	
		11-15y		430	
	Thorax PA	0y		40	
		1-5y		50	
		6-10y		85	
		11-15y		100	
	Abdomen AP	0y		150	
		1-5y		200	
		6-10y		225	
		11-15y		300	
	Pelvis PA	0y		60	
		1-5y		180	
		6-10y		310	
		11-15y		400	
Europe	Chest	<1 y	0.131	88	Smans et al., 2008
		1-2 y	0.240	136	
		2-3 y	0.143	189	
		3-8 y	0.228	233	
		8-12 y	0.434	395	
		>12 y	0.455		

Table B2. Summary of selected DRL data from published in European countries, for paediatric fluoroscopy examinations.

Country or region	Examination	Patient grouping	P_{KA} mGy cm^2	Reference
ES (Existing NDRL)	MCU (VCUG)	0 y	500	Ruiz-Cruces (2015) (DOPOES project)
		1-5 y	750	
		6-10 y	900	
		11-15 y	1450	
Europe	VCUG	<1 y	187	Smans et al. (2008)
		2-3 y	533	
		8-12 y	1322	
		>12 y	3165	

Table B3. Summary of selected DRL data from selected publication in European countries, for paediatric CT examinations.

Country	CT Protocol	Category	$CTDI_{VOL}$ (mGy)	DLP (mGy cm)	Dosimetry Phantom size	Reference
LT	Head (epilepsy)	0-9kg / 1.1y		350	16 cm	Jarvinen et al (2011)
		9-19kg / 2.4y		500		
		>19kg / 9.6y		650		
EE, LT, FI	Chest (cancer follow up)	0-10kg		52		
		11-25kg		146		
		26-40kg		216		
		41-60kg		282		
		61-75kg		341		
		>75kg (75-100)		398		
ES (Existing NDRL)	Head	0y		250	16 cm	Ruiz-Cruces (2015) (DOPOES project)
		1-5y		340		
		6-10y		450		
		11-15y		650		
	Chest	0y		46	32 cm	
		1-5y		82		
		6-10y		125		
		11-15y		200		
	Abdomen	0y		95	32 cm	
		1-5y		150		
		6-10y		190		
		11-15y		340		
FR (existing NDRL)	Brain	10kg / 1y	30	420	16cm	Roch et al (2013)
		20kg / 5y	40	600		
		30kg / 10y	50	900		
	Facial bones	10kg / 1y	25	200		
		20kg / 5y	25	275		
		30kg / 10y	25	300		
	Petrosal bone	10kg / 1y	45	160		
		20kg / 5y	70	280		
		30kg / 10y	85	340		
	Chest	10kg / 1y	3	30	32cm	
		20kg / 5y	4	65		
		30kg / 10y	5	140		
	Abdomen / Pelvis	10kg / 1y	4	80		
		20kg / 5y	5	120		
		30kg / 10y	7	245		
IT	Head	1-5y	30.6	504	16 cm	Granata et al (2015)
		6-10y	56.4	852		
		11-15y	58.2	985		
	Chest	1-5y	2.5	49	32 cm	
		6-10y	3.8	108		
		11-15y	6.6	195		
	Abdomen	1-5y	5.7	151	32 cm	
		6-10y	7	227		
		11-15y	14	602		

Country	CT Protocol	Category	$CTDI_{VOL}$ (mGy)	DLP (mGy cm)	Dosimetry Phantom size	Reference
PT	Head	<1y	48	630	16 cm	Santos et al (2013)
		5y	50	770		
		10y	70	1100		
		15y	72	1120		
	Chest	<1y	2.4	45	32 cm	
		5y	5.6	140		
		10y	5.7	185		
		15y	7.1	195		
UK (existing NDRL)	Chest (malignancy)	0-1y	12	200	16cm	Shrimpton et al (2006)
		5y	13	230		
		10	20	370		
UK (existing NDRL)	Head (trauma)	0-1y	25	350	16cm	Shrimpton et al (2014)
		>1-5y	40	650		
		>5-10y	60	860		

1

ANNEX C. REVIEW OF EXISTING PAEDIATRIC DRLS

C.1 Introduction

A follow-up questionnaire (Section C.2.1) on paediatric DRLs has been issued to 36 European countries and a comprehensive literature review has been made of all published information on paediatric DRLs (Section C.2.2). The information gained has been reviewed to identify the existing status of paediatric DRLs with an emphasis on their application in European countries. Data from this review have been used to form the basis of recommendations in Sections 6-10. The DRLs in European countries which have been set by authoritative national institutions are presented and discussed separately (Section C.3) from DRLs which are either new proposals or published for local use only (Section C.4). The DRLs proposed internationally or published in other countries (outside Europe) are also briefly summarized (Section C.5).

C.2 Methods of review

C.2.1 Questionnaire on paediatric DRLs

National DRLs set by an authoritative body in European countries were reviewed in 2010-11 in the Dose Datamed 2 (DDM2) project (EC, 2014), including DRLs for paediatric examinations. For the present Guidelines, the data on paediatric DRLs stored in the DDM2 database was verified (confirmed and supplemented) by use of a questionnaire, sent to the contact persons of 36 European countries according to the list of contacts established in the DDM2 project and updated for the present purpose.

Two different approaches were adopted in the questionnaire: countries with no reported paediatric DRLs were asked to verify the situation, and countries with reported paediatric DRLs were asked to check and confirm the reported values. In both cases, if new paediatric DRLs had been set or if the DDM2 data was no longer up-to-date, values of the new or updated DRLs were requested. Furthermore, for all reported DRLs, details on how the DRLs had been established (own patient dose surveys or published other data, years of data collection, sample sizes etc.) were requested, because such details had not been collected in the DDM2 project.

C.2.2 Literature review and database

A worldwide review of literature on patient doses and DRLs for children of different age groups, or other distributions and for different examinations was carried out with an emphasis on European literature. Several different search engines were used: PubMed, Google Scholar and Science Direct, using various terms to locate pertinent articles.

For the output of this review, a database of literature was created, classified in suitable headings, using the Mendeley (www.mendeley.com) platform. The articles selected included studies on DRLs in general but also in dose optimisation. Subgroups were created to help facilitate the process of the literature review. The resulting database contains 215 articles [*until 25 Feb 2015*].

To evaluate the data found in the literature, the information was further grouped to help identify the advantages and/or limitations of each study and to more easily draw conclusions on the methodology used in the DRL determinations.

For articles reporting on DRLs in the European countries, the correspondence of this data with the results of the questionnaire (Section C.3) was checked and the information from the two sources combined.

C.3 National DRLs for paediatric exams set in the European countries

The summary of the national DRLs for paediatric exams set by an authoritative body in the European countries is shown in Table C.1 (the same as Table 5.1), and the detailed data of the DRLs are given in Annex A. National paediatric DRLs are provided for some groups of examinations (radiography, fluoroscopy or CT) in 17 countries, i.e. in 47 % of the European countries. In Lithuania and Belgium, the DRLs had been set very recently and had not been included in the DDM2 database.

In 9 countries (AT, BE, DE, DK, ES, FI, LT, NL and UK) all available national DRLs are based on own patient dose surveys covering several radiology institutions. In 6 countries (CY, LU, PL, RO, CH, IT), the available national DRLs are adopted from published values; in 5 countries (CY, LU, PL, RO, IT) from the EC guidance (EC, 1999) and in Switzerland from published values in another country (DE). In Ireland, DRLs are based on own survey only for some radiography and CT examinations, other values are adopted from the UK. In France, the national DRLs are based on collected data, protocol data or adopted from literature.

Table C.1. Summary of existing national DRLs in European countries, set or accepted by an authoritative body, based on the results of the questionnaire and the literature review. Coloured cells: data accepted for EDRL calculation.

Country	Source of DRL values	Radiography		Fluoroscopy	CT		References
		$K_{a,e}$ **(ESD, ESAK),** $K_{a,i}$ **(IAK)**	P_{KA} **(KAP, DAP)**	P_{KA} **(KAP, DAP)**	**DLP (P_{KL})**	**CTDI$_{vol}$ (C_{vol})**	
AT	Own survey		Skull (AP/ PA, LAT) Thorax (AP/PA) Abdomen (AP/PA)	MCU	Brain Chest		Questionaire (all). Billiger et al. 2010 (radiography)
BE	Own survey		Thorax (PA, PA+LAT) Abdomen		Brain Sinus Thorax Abdomen	Brain Sinus Thorax Abdomen	www.fanc.fgov.be
DE	Own survey		Head (AP, PA, LAT) Thorax (AP, PA, LAT) Abdomen (AP) Pelvis	MCU	Head Facial bones Thorax Abdomen	Head Facial bones Thorax Abdomen	Questionaire. Bundesamt fur Strahlenschutz, 2010.
DK	Own survey	Thorax (AP, PA, LAT) Pelvis (AP) Overview of abdomen		MCU			Questionnaire.
ES	Own survey		Head (AP) Thorax (PA) Abdomen (AP) Pelvis (PA)	MCU	Head Chest Abdomen		Ruiz-Cruces, 2015
FI	Own survey	Sinuses (Waters projection) (discrete values) Thorax (AP, PA, LAT) (DRL-curve)	Sinuses (Waters projection) (discrete values) Thorax (AP, PA, LAT) (DRL-curve)	MCU	Head (discrete values) Thorax, abdomen (abd. + pelvis), WB (chest+abd. +pelvis) (DRL-curve)	Head (discrete values) Thorax, abdomen (abd. + pelvis), WB (chest+abd. +pelvis) (DRL-curve)	Questionnaire. Kiljunen et al., 2007. Järvinen et al. 2015.
LT	Own survey	Chest (PA) Skull (AP/PA, LAT) Abdomen	Chest (PA) Skull (AP/PA, LAT) Abdomen		Head		Questionnaire.
NL	Own survey		Thorax (AP, PA) Abdomen (AP)	MCU	Head	Head	Questionnaire.
UK	Own survey			MCU Barium meal Barium swallow	Head Chest	Head Chest	Hart et al. 2012 (F). Shrimpton et al., 2006, 2014 (CT).
IE	Own survey for some radiography and CT examinations. Other values adopted from other countries.	Skull (AP, LAT) Chest (AP/PA) Abdomen (AP) Pelvis (AP)		MCU Barium meal Barium swallow	Brain Abdomen/Pelvis		Questionnaire. Medical council, 2004. HSE Medical Exposures Radiation Unit, 2013.
FR	Own survey for radiography, CT data based on protocol data or literature	Thorax (AP, LAT) Pelvis	Thorax (AP, PA, LAT) Abdomen (AP) Pelvis		Brain Facial Bone Petrous Bone Chest Abdomen+Pelvis	Brain Facial Bone Petrous Bone Chest Abdomen+Pelvis	Questionnaire. Roch et al., 2012.
CY	Adopted (EC)	Head (AP, PA, LAT) Thorax (AP, PA, LAT) Abdomen Pelvis (AP)					Questionnaire.
IT	Adopted (EC)	"					Questionnaire
LU	Adopted (EC)	"					Questionnaire.
PL	Adopted (EC)	"					Questionnaire.
RO	Adopted (EC)	"					Questionnaire.
CH	Adopted (DE)				Brain Face, nasal cavity Thorax Abdomen Lumbar spine	Brain Face, nasal cavity	Questionnaire.. Galanski and Nagel, 2005

C.3.1 Radiography

In 9 countries (AT, BE, DE, DK, ES, FI, FR, LT and NL; see Table C.1), the paediatric DRLs for radiography are based on own national patient dose survey covering several radiology institutions. In France, the DRLs for radiography are based on both collected data and literature data. In 5 countries (CY, LU, PL, RO. IT) the paediatric DRLs for radiography had been adopted from the EC guidelines (EC, 1999). In Ireland national DRLs for radiography are based on own survey for some radiography examinations, other values are adopted from the UK.

In Tables C.2 and C.3 details of DRLs, for both radiography and fluoroscopy (see Section C.3.2), are given for those countries, which have their DRLs based on own national patient dose surveys. All these DRLs correspond to complete routine CT examination (one scan series). When comparing NDRLs it is important to ensure that the DRLs correspond to one scan series and not to a complete procedure of all series (multi-phase examinations)-

Table C.2. Patient dose survey and setting of the national paediatric DRLs in European countries for radiography (R) and fluoroscopy (F): organisational and practical details.

Country	Years of data collection	Organizer of dose survey	Organization to set the DRL	Professional societies/ clinical experts consulted	Number of institutions/ installations/ patients; coverage of total (%)	Practical method, limitations, comments	User guidance given (recommended sample size, frequency of comparison with DRLs)	References
AT	2006-2007	Center for Biomedical Engineering and Physics, Medical			14 hospitalls/ 25 installations/ 41-1187 patients	Standard forms for data collection, data sending by mail.		Billiger et al. 2010
BE		Federal Agency of Nuclear Control (FANC)	Federal Agency of Nuclear Control (FANC)					www.fanc.fgov.be
DE	2006-2009		Bundesamt für Strahlenschutz	Yes	All German institutions (100 %)			Questionnaire
DK	2004-2005		NIRP		4-5 (about 10 % (R))		Yes (10 patients, 2 years) (R) Yes (10 patients, 1 year) (F)	Questionnaire. Report in NIRP website.
ES	2011-2013	DOPOES project	Ministry of Health		5-10 % of paediatric institutions			Ruiz-Cruces, 2015
FI	2004-2005	STUK	STUK	Yes	8-20 (3-6 %) (R) 11 (about 50 %) (F)	Both grid and non-grid techniues (R)	Yes (10 patients, 3 years)	Questionnaire. Kiljunen et al. 2007. STUK Resolution 1Jan 2006 (www.stuk.fi)
LT	2009-2012	Radiation Protection Centre of Lithuania	Ministry of Health of the Republic of Lithuania		5 institutions/ 260-1474 patients		(at least 10 patients, 5 years)	Questionnaire
NL		The Netherlands Commission on Radiation Dosimetry	The Netherlands Commission on Radiation Dosimetry	Yes (Commission members include representatives of professional societies)	Restricted survey			Questionnaire
UK	2010	Health Protection Agency	Health Protection Agency		12-61 rooms	DAP for children of known size adjusted to the values for the nearest standard size.		Hart et al. 2012 (F).
FR	2004-2008	Nuclear Safety and Radiation Protection French Institute (IRSN)	Ministry of Health and ASN					Roch and Aubert, 2012

Table C.3. Patient dose survey and setting of the national paediatric DRLs in European countries for radiography (R) and fluoroscopy (F): technical details.

Country	DRL quantities*	Source/verification of dosimeric value	Patient grouping	DRL method: Percentile of dose distribution	Reference
AT	$K_{a,e}$, $K_{a,i}$, P_{KA}	Local audits to ensure correct values: Dose output measurements and in situ calibration of P_{KA} meters. Conversion of $K_{a,i}$ to $K_{a,e}$ by mean of backscatter factor.	Age: 0, 1, 5, 10, 15 y (R) 0, 1, 5, 10 y (F)	75 %	Questionnaire. Billiger et al. 2010
BE	P_{KA}		Age: <1 y, 1-<5 y, 5-<10 y, 10-<15 y	75 %	www.fanc.fgov.be
DE	P_{KA}		Weight: 1000 g, 3000 g (R), 3000 g (F) (premature babies and newborns) Age: 10±2mo, 5±2y, 10±2y (R,F)		Questionnaire
DK	$K_{a,e}$, P_{KA}	Calculated based on exposure parameters, calibration 2005 (R) for P_{KA} meters, calibration unknown (F)	Age: 5 y (= thickness 14,7 cm) (thorax, pelvis) < 1 y (overview of abdomen) <1, 1-5 y (MCU)	75 %	Questionnaire
ES	P_{KA}		Age: 0, 1-5, 6-10, 11-15 y	75 %	Ruez-Cruices, 2015
FI	$K_{a,e}$, P_{KA}	$K_{a,e}$ calculated from both P_{KA} and x-ray tube output (R). Calibrated P_{KA} meters (R, F)	DRL-curve as a functiion of patient thickness (thorax) One age group 7-15 y (Sinuses tilted projection) Age groups < 1 y, 1-5 y (MCU)	75 %	Questionnaire. Kiljunen et al. 2007. STUK Resolution 1Jan 2006 (www.stuk.fi)
LT	$K_{a,e}$, P_{KA}	$K_{a,e}$ calculated from x-ray tube output (R). Calibration of P_{KA} meters checked (R, F)	Age: 1, 5, 10, 15 y (R)	75 %	Questionnaire
NL	P_{KA}		Weight/age groups: 4 kg/ 0 y, 11 kg/ 1 y, 21 kg/ 5 y	Expert judgement guided by the results of a restricted dose survey	Questionnaire
UK	P_{KA}		Age: 0, 1, 5, 10, 15 y		Hart et al. 2012 (F).
FR	$K_{a,e}$, P_{KA}		Weight: 3.5, 10, 20, 30 kg, Age: 0, 1, 5, 10 y	75 %	Roch and Aubert, 2012

All the DRLs are specified on the basis of the anatomical region imaged. The most common radiography examinations are:

- Skull (head) AP, PA and LAT (in 4 countries with own patient dose survey)
- Chest (thorax) AP, PA, LAT (in 9 countries with own patient dose survey)
- Abdomen AP/PA (in 7 countries with own patient dose survey)
- Pelvis AP (in 6 countries with own patient dose survey)

These are the same groups of examinations that had been earlier recommended by the European Commission (EC, 1999). Consequently, DRLs for these groups have been set in the 5 countries adopting the DRL values from the EC.

Most of the DRLs (in 8 of the 9 countries having their own patient dose surveys) are given in terms of dose-area product (P_{KA}). Entrance-surface air kerma ($K_{a,e}$) has also been used in 4 of these countries, and solely in one country (see Table C.3). $K_{a,e}$ has been calculated from the x-ray tube output values and the examination parameters and in one case also from the P_{KA} values. P_{KA} values have been obtained from P_{KA} meters; in four countries it has been reported that the P_{KA} meter calibration has been checked in connection with the data collection. In the other countries (having only adopted values) only the $K_{a,e}$ has been used, in accordance with the EC recommendations (EC, 1999).

In 7 out of 9 countries it was noted that DRLs were estimated using the traditional approach, i.e. using the 3rd quartile or 75 % point of the dose distribution, In the Netherlands, the setting of DRLs was based on expert judgement guided by the results of a restricted dose survey; a metric called "achievable dose level" has been given together with the DRL. The earlier recommendation by the EC (EC, 1999) was based on the 3rd quartile approach.

For patient groupings in the 9 countries with their own patient dose surveys, age alone has been used in 6 countries, both age and weight in three countries and patient thickness in one country (Table C.3). In Germany, for premature babies and newborns, two weight groups (1000 g and 3000 g) have been defined while age groups with limits have been defined for older children (10±2 months, 5±2 y and 10±2 y). The most common age groups are 0, 1, 5, 10 and 15 years; the whole set (0-15) in two countries and 1-15 years in one country. In the other countries, slightly different sets of groups exist, but one or more of the ages 0, 1, 5 and 10 years appear in these groupings. In the Netherlands, with both age and weight groups specified, the equivalence of weight and age are defined as: 4 kg – 0 y, 11 kg – 1 y and 21 kg – 5 y. In the UK, P_{KA} values for children with known sizes (ages) were adjusted for the values of the nearest standard size (age). In France, several age and weight groups have been defined, with their equivalence being close to that used in the Netherlands, i.e. 3,5 kg – newborn, 10 kg – 1y, 20 kg – 5 y and 30 kg – 10y.

One study deserves specific attention, especially when there is limited data for statistical analysis. According to the study of Kiljunen et al (2007), a DRL curve produced using $K_{a,e}$ and P_{KA} as a function of patient projection thickness could be a practical method for determining a DRL. The study was limited to chest examinations but could be potentially applied to other types of examinations as well.

The majority of patient dose surveys were carried out during 2004-2009, while the most recent ones (three countries) are from 2010-2013. The organiser of the patient dose survey was reported to be an authority in 5 countries, and in most countries the DRLs were set by an authority (radiation protection or health authority). Professional societies or clinical experts were consulted in at least two countries. In one case (NL), the DRLs have been set by a national committee, which consists of members of several professional organisations.

The number of institutions surveyed in different countries ranged from a few to all of their imaging institutions, 5% – 100 %, with the total number of patients ranging from less than 100 to more than 1000. No automatic data collection and management has been reported. User guidance for the comparison of local patient doses with the national DRLs has been issued in three countries,

requesting a minimum of 10 patients for each age group, or 10 patients in total in the case of the DRL curve approach, and the comparison frequency ranged from 2 to 5 years.

In one national study (Kiljunen et al., 2007), attention was paid to the use of anti-scatter grids and additional filtration in paediatric examinations which should be taken into account for the calculation of DRLs as they influence the patients' dose. The national DRLs in this study were provided for common grid and non-grid techniques because the use of removable grid techniques in paediatric examinations was not always possible.

In conclusion, there seems to be reasonable agreement on the radiography examinations for which DRLs have been needed (skull, chest, abdomen, pelvis) and on the quantities used (P_{KA} and/or $K_{a,e}$). All the current national DRLs seem to be based on the 3rd quartile method. For patient grouping, a set of age groups up to 15y of age (0, 1, 5, 10, 15 y) seems to be the practice while in one country, a DRL curve with patient thickness as the parameter has been proposed to overcome the problems of poor statistics with discrete groups. All current DRLs have been set by authorities, based on patient dose data collected about 5-10 years ago. There is a large variation between countries on the number of institutions and patients included in the patient dose surveys. For user guidelines, consistent systems exist (minimum of 10 patients in each group, data collection frequency 2-5 years). It is evident that a rough consensus on the examinations for the DRLs and the DRL parameters (quantities, percentile of dose distribution, patient grouping) already exists or is close to being achieved. However, better standardisation and guidelines are needed, in particular for the patient dose surveys as the basis of setting the DRLs.

C.3.2 Fluoroscopy

In 7 countries, the paediatric DRLs for fluoroscopy examinations are based on own national patient dose survey covering several radiology institutions (AT, DE, DK, ES, FI, NL and UK) (Table C.1). In Ireland (IE), the DRL was adopted from UK data (Hart et al. 2002).

In Tables C.2 and C.3 details of DRLs are given for the countries, that have their DRLs based on own national patient dose surveys.

The current national DRLs in European countries are given only for micturating cystourethrography (MCU), except in the UK and Ireland, where DRLs have been set also for barium swallow and barium meal.

All the DRLs for fluoroscopy are given in terms of P_{KA}. P_{KA} values have been obtained from P_{KA} meters; in four countries it has been reported that the P_{KA} meter calibration had been checked in connection with the data collection.

In 4 out of 6 countries the DRLs were estimated using the traditional approach, i.e. using the 3rd quartile or 75 % point of the dose distribution. In the Netherlands, the setting of DRLs was based on expert judgement guided by the results of a restricted dose survey; a metric called "achievable dose level" has been given together with the DRL.

For patient grouping in the 7 countries with own patient dose surveys, age has been used in 6 countries, and both age and weight in one country (Table C.3). In Germany, a weight group (3000 g) has been defined for newborns, while age groups with limits have been defined for older children (10±2 months, 5±2 y and 10±2 y). Age groups 0, 1, 5, 10 years have been used in 2 countries, with an additional 15 years used in one of these countries. In two countries, only two age groups have

been defined: < 1 y and 1-5 y. In one country (NL) both age and weight groups are used, the equivalence of weight and age are defined as: 4 kg – 0 y, 11 kg – 1 y and 21 kg – 5 y (the same as for radiography examinations). In the UK, P_{KA} values for children with known sizes (ages) were adjusted for the values of the nearest standard size (age): the adjustment was based on the relationship between the thickness of the body part being x-rayed in the patient and the corresponding thickness in the nearest standard-sized child. This could either be measured directly or if more convenient, could be calculated from the height and weight of the patient (Hart et al., 2000).

The majority of patient dose surveys for fluoroscopy were carried out during 2004-2009, while the most recent ones are from 2010 (in UK) and 2013 (ES). The organiser of the patient dose survey was reported to be an authority (radiation protection or health) in 2 countries, and in most countries the DRLs were set by an authority. Professional societies or clinical experts were consulted in at least in two countries. In one case (NL), the DRLs have been set by a national committee, which consists of members of several professional organisations. The institutions involved in the patient dose surveys ranged from around half to all in the country. User guidance for the comparison of local patient doses with the national DRLs has been issued in two countries, requesting a minimum of 10 patients for each age group and the comparison frequency of 1 or 3 years.

In conclusion, there seems to be reasonable agreement on the fluoroscopy examinations for which DRLs have been needed (mainly MCU) and on the quantities used (P_{KA}). All the current national DRLs seem to be based on the 3rd quartile method. For patient grouping, a set of age groups up to 15y of age (0, 1, 5, 10, 15 y) have been identified although in some cases only children up to 5y of age (< 1 y and 1-5 y) have been considered. All current DRLs have been set by authorities, based on patient dose data for children of about 5-10 years old. For user guidelines, consistent systems exist (minimum of 10 patients for comparison in each group, comparison frequency 1 or 3 years). It is evident that a rough consensus on the examinations for the DRLs and the DRL parameters (quantities, percentile of dose distribution, patient grouping) already exists or is closely achievable. However, better standardisation and guidelines are needed, in particular for the patient dose surveys as the basis of setting the DRLs.

C.3.3 Computed tomography

In 9 countries (AT, BE, DE, ES, FI, IE, LT, NL and UK), the paediatric DRLs for CT examinations are based on own national patient dose survey covering several radiology institutions (see Table C.1). In Ireland, the DRLs are based on a combination of local survey (HSE Medical Exposures Radiation Unit, 2013) and on the initial European values (Shrimpton and Wall, 2000). In France, the DRLs are not based on collection of individual patient doses but on typical dose values for given imaging protocols, or on published other data. In Switzerland, the existing DRLs have been adopted from old German DRLs (Galanski and Nagel, 2005), while a proposal on new national DRLs has been published (Verdun et al. 2008). In Portugal and Italy, proposals on national DRLs have been published (Santos et al. 2013, Granata et al. 2015) although this has not yet been accepted by an authoritative body.

In Tables C.4 and C.5 details of DRLs are given for those countries that have their DRLs based on own national patient dose surveys. When comparing NDRLs it is important to ensure that the DRLs correspond to a complete routine CT examination (one scan series) and not to a complete procedure of all series (multi-phase examinations)-

Table C.4. Patient dose survey and setting of the national paediatric DRLs in European countries for computed tomography: organisational and practical details

Country	Years of data collection	Organizer of dose survey	Organization to set the DRL	Professional societies/ clinical experts consulted	Number of institutions/ installations/ patients; coverage of total (%)	Practical method, limitations, comments	User guidance given (recommended sample size, frequency of comparison with DRLs)	References
AT	No details reported							
BE	2012	Federal Agency of Nuclear Control (FANC)	Federal Agency of Nuclear Control (FANC)	No			Website	Questionnaire. www.fanc.fgov.be
DE	2005-2006	Medizinische Hochschule Hannover	Bundesamt für Strahlenschutz	Yes	656 institutions, incl. 72 devoted paediatric institutions, 6-1634 patients			Questionnaire
DK	No DRLs for CT							
ES	2011-2013	DOPOES project	Ministry of Health		5-10 % of paediatric institutions			Ruiz-Cruces, 2015
FI	2011-2013	STUK	STUK	Yes	4 institutions (about 30 %)/ 1049 patients	Indication based	Yes	Questionnaire Järvinen et al. 2015
IE	2009		HSE Medical Exposures Radiation Unit, 2013.	Yes	27 institutions (about 20 %), 3200 patients.			Medical council, 2004. HSE Medical Exposures Radiation Unit, 2013.
LT	2009-2012	Radiation Protection Centre of Lithuania	Ministry of Health of the Republic of Lithuania		3 institutions/ 51-234 patients		(at least 10 patients, 5 years)	Questionnaire
NL	No details reported	The Netherlands Commission on Radiation Dosimetry	The Netherlands Commission on Radiation Dosimetry	Yes (Commission members include representatives of professional societies)	Restricted survey			Questionnaire
UK	2003	Health Protection Agency (HPA)	Department of Health (Public Health England)	Yes	118 hospitals/ 126 scanners; about 25 % of total	Scan protocols + scan sequence data for min. 10 patients		Shrimpton et al., 2006, 2014

Table C.5. Patient dose survey and setting of the national paediatric DRLs in European countries for computed tomography: technical details

Country	DRL quantities	Source/verification of dosimeric value	Patient grouping	DRL method: Percentile of dose distribution	Reference
AT	DLP		Age: 0, 1, 5, 10, 15 y		Questionnaire
BE	DLP, $CTDI_{VOL}$	Federal Agency of Nuclear Control (FANC)	Age: <1 y, 1-<5 y, 5-<10 y, 10-<15 y	75 %	Questionnaire. www.fanc.fgov.be
DE	DLP, $CTDI_{VOL}$		Age: Newborn, < 1 y, 2-5 y, 6-10 y, 11-15 y, > 15 y		Questionnaire
DK					
ES	DLP		Age: 0, 1-5, 6-10, 11-15 y	75 %	Ruez-Cruices, 2015
FI	DLP, $CTDI_{VOL}$	Calibration of CT console values checked	DRL-curve as a functiion of patient weight (chest, abdomen, trunk) Ages: <1, 1-5, 5-10, 10-15 (head, routine); all ages (head, ventricular size)	75%, 50 %	Questionnaire Järvinen et al. 2015
IE	DLP		Age: Newborn, 1-4 y, 5-9 y, 10-15 y	75 %	Medical council, 2004. HSE Medical Exposures Radiation Unit, 2013.
LT	DLP	Calibration of CT console values checked	Age: 1, 5, 10, 15 y	75 %	Questionnaire
NL	DLP, $CTDI_{VOL}$		Weight/age groups: 4 kg/ 0 y, 11 kg/ 1 y, 21 kg/ 5 y, 36 kg/10y	Expert judgement guided by the results of a restricted dose survey	Questionnaire
UK	DLP, $CTDI_{VOL}$	Calcilations based on protocol and sequence data	Age: 0-1 y, 5 y, 10 y	75 %	Shrimpton et al., 2006, 2014.

At present the DRLs are specified mainly on the basis of the anatomical region imaged. DRLs for CT head (brain) have been set in all 9 countries that have national DRLs for CT examinations, for both CT chest (thorax) and CT abdomen in 5 countries, and for either CT chest or CT abdomen/pelvis in 2 countries. In Germany, DRLs for CT facial bones have also been set. In UK, the DRLs for CT are based on anatomical region and clinical indication, e.g. paediatric head (trauma) (Shrimpton et al., 2014). The new DRLs for CT examinations in Finland (Järvinen et al., 2015) are based on clinical indications, while in the case of examinations of the thorax, abdomen and trunk (=thorax+abdomen) the DRLs are the same for all indications studied, and in case of head, the DRLs have been given for two indications (routine head and ventricular size).

In 4 of the 9 countries, DRLs are given in terms of both air kerma-length product (DLP) and volume computed tomography dose index ($CTDI_{VOL}$) (Table C.5). DRLs have been set in terms of DLP alone in four countries and in terms of $CTDI_{VOL}$ alone in one country. In two countries it has been reported that the calibration of the CT scanner console values have been checked in connection with the data collection.

In 5 out of 8 countries the DRLs were estimated using the traditional approach, i.e. using the 3rd quartile or 75 % point of the dose distribution. In the Netherlands, the setting of DRLs was based on expert judgement guided by the results of a restricted dose survey; an “achievable dose level” has

been given together with the DRL. In Finland, in addition to the use of the 75 % DRL curve, a 50 % level curve is provided as supplementary information to enable varying levels of technology to be taken into account (Järvinen et al., 2014) (the 75 % DRL curve was obtained by making an exponential fitting to the points above the 50 % level curve).

For patient groupings, in 6 of the 8 countries with own patient dose surveys (DE, ES, FI, IE, LT, UK), age has been used, in one country both age and weight has been used (NL), and in one country patient weight for body CT and age for head CT (Table C.5) has been used (FI). Similar sets of age groups, 1, 5, 10 and 15 years have been used by 5 countries and additionally 0 years have been used in one country (AT) and 0-1 years in one country (UK). In some countries (DE, ES, FI, IE) the age groups are defined by ranges, e.g. newborn, < 1y, 2-5, 6-10 y, 11-15 y and >15y (DE). In one country with both age and weight groups (NL), the equivalence of weight and age are defined as: 4 kg – 0 y, 11 kg – 1 y, 21 kg – 5 y and 36 kg – 10 y (similarly with radiography). In Finland, the dosimetric quantities (DLP and $CTDI_{VOL}$) are presented as a function of patient weight (the DRL curve approach) which has been considered to be a better parameter than age (Järvinen et al., 2014).

In four countries (ES, FI, IE, LT) the patient dose surveys for CT examinations is quite recent and were carried out during 2009-2013, while in the other cases surveys were carried out during 2003-2006. The organiser of the patient dose survey was reported to be an authority (radiation protection or health) in 3 countries, and in most countries the DRLs were set by an authority. Professional societies or clinical experts were consulted at least in two countries. In one case (NL), the DRLs have been set by a national committee, which consists of members of several professional organisations. The patient dose surveys ranged from a few to hundreds of institutions, with the number of patients ranging from less than 100 to more than 1000. User guidance for comparison of local patient doses with the national DRLs has been issued in two countries, requesting a minimum of 10 patients for each age group, or 10 patients in total in case of the DRL curve approach, and the comparison frequency of 3or 5 years.

In conclusion, there seems to be reasonable agreement on the CT examinations for which DRLs have been needed (head, chest, abdomen) and on the quantities used (DLP and $CTDI_{VOL}$). All the current national DRLs seem to be based on the 3rd quartile method, while in one case a 50% level is planned to be given as supplementary information. For patient grouping, a set of age groups (e.g. 0, 1, 5, 10, 15 y) seems to be the practice while in one country, a DRL curve with patient weight as the parameter has been proposed to overcome the problems of poor statistics with discrete groups. All current DRLs have been set by authorities, based in part on recent patient dose data, about 2-5 years old, and partly on data that is more than 10 years old. For user guidelines, the reported systems are similar to that of radiography (minimum of 10 patients for comparison in each group or per DRL curve, comparison frequency 3 or 5 years). It is evident that a rough consensus on the examinations for the DRLs and the DRL parameters (quantities, percentile of dose distribution, patient grouping) already exist or is closely achievable. However, better standardisation and guidelines are needed, in particular for the patient dose surveys as the basis of setting the DRLs. A consensus in the definition of DLP (one series or all series) is also needed.

C.3.4 Interventional radiology

No national paediatric DRLs have been set for IR procedures in any European country.

C.4 Studies on paediatric DRLs in European countries

Besides the national DRLs set by authoritative bodies for paediatric examinations and procedures (Section C.3.), several studies have been published in European countries, to propose national

DRLs or to develop practice or local DRLs for paediatric examinations, or to compare patient dose distributions between several countries. These articles are summarized in the following sections, with a note on those studies which have already led to the establishment of national DRLs by authoritative bodies.

C.4.1 Radiography

The summary of the literature survey for DRLs in paediatric radiography in European countries is compiled in Table C.6. The actual values of NDRLs are shown in Annex A and for *selected* other DRLs in Annex B.

Nine European publications plus one personal communication (Ruiz-Cruces, 2015) were identified which reported dose values for paediatric radiography examinations, six of which were based on data collected from single countries/regions (Billiger et al., 2010; Kiljunen et al., 2007; Roch et al. 2012; Ireland Medical council, 2004; Montgomery et al., 2000, Ruiz-Cruces, 2015) and three dealing with European wide establishment for DRLs (Schneider et al., 1998; Hart, 1996; Smans et al., 2008). Five of these publications have already resulted in national DRLs (Billiger et al., 2010 - AT; Kiljunen et al., 2007- FI; Roch et al. 2012- FR, Ireland Medical council, 2004-IE, Ruiz-Cruces, 2015-ES) and have been included in the discussion in Section 5.3.1. Dabin et al (Dabin et al. 2013) published data on a national survey with proposal of NDRL for chest X-ray and combined chest-abdomen X-ray in neonatology.

In one paper (Montgomery et al., 2000) the aim was to investigate if the use of a single value as a DRL for all ages (DRL for 5-year old child) is appropriate or if age group classification is needed. $K_{a,e}$ values, for only non-grid examinations, were collected for chest, abdomen and pelvis examinations from three hospitals. The relationship between age, weight and calculated EPD (equivalent patient diameter) was discussed and weight was found to be as reliable a factor as EPD, and better than age. Adjustment factors have been defined for doses to be compared to a standard 5 years old child. The main limitation of the results is that examinations with a grid, which generally leads to a higher patient dose, have not been considered.

From the three European wide studies, Schneider et al. (1998) re-analysed the data from four European surveys for chest X-rays examinations, which had formed the basis for the DRLs proposed by the European Guidelines (EC, 1996). They re-grouped the data according to the patient's age and in addition sorted the data into the "optimised" and "un-optimised" techniques proposing that the data from an optimised technique could be considered as a DRL. The study had several limitations (differences in the use of grid, differences in focus-to-film distance/focus-to-detector distance) and the results are dated. Hart (1996) also re-analysed the data from the survey presented in the European guidelines (EC, 1996). The purpose of this study was to normalize the doses to those of the nearest standard-sized patient and define new DRLs for each group. A new method was suggested for the estimation of the patient thickness according to the patient height and weight. The main limitation of this study was that there were not enough data for children older than 5 years old, and the results are also dated. Smans et al. (2008) collected patient dose data for 6 age groups (<1, 1-2, 2-3, 3-8, 8-12, >12y) from 11 EU Member States: $K_{a,e}$ and/or P_{KA} for chest (12 centres), abdomen (4 centres) and pelvis (5 centres) radiography. The main limitation with the study was the relative small number of centres included.

Table C.6. Published studies on paediatric DRLs for radiography in European countries.

Reference	Region	Data source	Exams	Patient grouping	Dose value	No. patients	No. centres	NDRLs proposed
Billiger et al., 2010	AT	Patients	Skull, thorax, abdomen	0y, 1y, 5y, 10y, 15y	3rd quartile $K_{a,e}$, $K_{a,i}$, P_{KA}	41-1187	14	YES (existing NDRL, see C.3.1)
Dabin et al, 2013	BE	Patients	Chest PA and combined chest-abdomen in neonatology	<1000 g,, 1000 g<. . .<2000 g, , >2000 g,	3rd quartile $K_{a,e}$	721	17	YES
Rafael Ruiz-Cruces, 2015 (DOPOES-project)	ES	Patients	Head AP, thorax PA, abdomen AP, pelvis PA	0y, 1-5y, 6-10y, 11-15y	3rd quartile P_{KA}	135-1025	5-10 % of total	YES (existing NDRL, see C.3.1)
Kiljunen et al., 2007	FI	Patients	Thorax, sinuses waters	7-15 y DRL – curve for thorax	3rd quartile values $K_{a,e}$, P_{KA}	N/a	8-20	YES (existing NDRL, see C.3.1)
Roch et al., 2012	FR	A mixture of patient data, EC guidelines, literature and PCXMC calcul-ations	Thorax, abdomen, pelvis	Newborn 1y, 5y, 10y / 3,5 kg, 10 kg, 20 kg, 30 kg	3rd quartile $K_{a,e}$, P_{KA}			YES (existing NDRL, see C.3.1)
HSE Medical Exposures Radiation Unit, 2013	IE	Patients	Chest, abdomen, pelvis, skull	0y, 1y, 5y, 10y, 15y	3rd quartile $K_{a,e}$		1	YES (existing NDRL, see C.3.1)
Mont-gomery et al., 2000	UK	Patients	Chest, abdomen, pelvis	5y	3rd quartile $K_{a,e}$		3	No
Schneider et al., 1998	Europe	Patients	Chest	5 y, 10 y	3rd quartile $K_{a,e}$		12	No
Hart, 1996	Europe	Patients	Chest, abdomen, pelvis, skull	1y, 5y, 10y, 15y	3rd quartile $K_{a,e}$		12	No
Smans et al., 2008	Europe	Patients	Chest, abdomen, pelvis	<1, 1-2, 2-3, 3-8, 8-12, >12y	3rd quartile $K_{a,e}$		12	No

As a conclusion, except for the few studies for national DRLs, the other published studies, including the European wide studies, are either dated or limited to a few centres so that they do not provide high quality input to the setting of European paediatric DRLs.

C.4.2 Fluoroscopy

The summary of the literature survey for DRLs in paediatric conventional fluoroscopy in European countries is compiled in Table C.7. The actual values of NDRLs are shown in Annex A and for *selected* other DRLs in Annex B.

Four European publications plus one personal communication (Ruiz-Cruces, 2015) were identified which reported dose values for paediatric fluoroscopy examinations, four of which were based on data collected from single countries/regions (Hart et al., 2012; Hiorns et al. 2014; Yakoumakis et al., 2014, Ruiz-Cruces, 2015) and one considers a European wide establishment for DRLs (Smans et al., 2008). Two of these publications has resulted in a national DRL (Hart et al., 2012 –UK, Ruiz-Cruces, 2015 - ES) and has been included in the discussion in Section C.3.2.

Table C.7. Published studies on paediatric DRLs for fluoroscopy in European countries.

Reference	Region	Data source	Exams	Patient grouping	Dose value	No. patients	No. centres	NDRLs proposed
Rafael Ruiz-Cruces, 2015 (DOPOES-project)	ES	Patients	MCU	0y, 1-5y, 6-10y, 11-15y	3rd quartile P_{KA}	200-1050	5-10 % of total	YES (existing NDRL, see C.3.2)
Hart et al., 2012	UK	Patients	MCU (MCUG), barium meal, barium swallow	0y, 1y, 5y, 10y, 15y	3rd quartile P_{KA}	335-2020		YES (existing NDRL, see C.3.2)
Hiorns et al., 2014	UK	Patients	MCU (MCUG) + 7 other exams	0y, 1y, 5y, 10y, 15y	3rd quartile P_{KA}		1	No
Smans et al., 2008	Europe	Patients	Lower GI tract, upper GI tract, voiding cystourethro-gram (VCUG)	<1y, 1-2y, 2-3y, 3-8y, 8-12y, <12y	3rd quartile P_{KA}		12	No
Yakoumakis et al, 2014	EL?	Patients	Barium meal	Newborn 1y, 5y	Mean P_{KA}	51	1	No

Hiorns et al. (2014) reported LDRLs for paediatric fluoroscopy at a tertiary referral centre (GOSH, London, UK) and compared them with the current national DRLs. The authors' conclusions are that only strict attention to technique and critical review of LDRLs can ensure best practice. They also underscore that, if the DRLs are used as a sole guide, many institutions can be falsely reassured and may be using greater doses than necessary.

In conclusion, data concerning paediatric DRLs in fluoroscopy procedures are extremely scarce. Just a single study reports national DRLs (Hart e al., 2012).

C.4.3 Computed tomography

The summary of the literature survey for DRLs in paediatric computed tomography in European countries is compiled in Table C.8. The actual values of NDRLs are shown in Annex A and for *selected* other DRLs are given in tables in Annex B.

Thirteen European publications plus one personal communication (Ruiz-Cruces, 2015) were identified which reported dose values for paediatric CT examinations, eleven of which were based on data collected from single countries, while three collected data from multiple jurisdictions (Brisse & Aubert, 2009; Järvinen et al., 2011; Shrimpton & Wall, 2000). Many of these publications (N=7) proposed national DRL values based on their data; three of them (Roch and Aubert, 2013;Shrimpton et al., 2006, Ruiz-Cruces, 2015) have resulted in currently existing NDRLs (see also Table 4.1), one (Galanski et al., 2005) has resulted in NDRLs which are already obsolete, two (Santos et al., 2013; Shrimpton et al., 2014) proposed NDRLs, and one (Verdun et al., 2008) proposed DRLs to be used only provisionally until more robust data became available. Two studies (Buls et al., 2010, Granata et al. 2015) are national multi-centre studies but do not propose national DRLs, and one (Yakoumakis et al., 2009) presents local DRLs and derives from these a suggestion for national DRLs.

In terms of the examinations for which DRLs were calculated, the most common were for brain/head (N=14), chest (N=13) and abdomen (/pelvis) (N=10), although others were included by some, facial bones / sinuses (N=4), temporal bones / inner ear (N=2), HRCT (N=1), low dose chest (N=1) and lumbar spine (N=1)). Most studies, where the patient data was not collected from the displayed CT dose metrics for each patient, do not report the scan length per examination which can have a large effect on the study DLP. Regarding the abdomen (/pelvis) examination, six studies reported the extent of the scan range used, as being the full abdomen (from the diaphragm to the symphysis pubis), but one study (Verdun et al., 2008) did not provide this detail, making comparison between studies difficult. Similarly only half of publications (Brisse & Aubert, 2009; Buls et al., 2010; Järvinen et al., 2011,2014; Shrimpton et al., 2006, 2014; Verdun et al., 2008) incorporated clinical indications (e.g. trauma) in the setting of DRLs. To allow comparison between published values, it is essential that clinical indications for CT protocols (e.g. Head CT: trauma) are reported, as protocols and doses for specific clinical indications within a single CT examination category (e.g. Head) can differ significantly.

Table C.8. Published studies on paediatric DRLs for CT in European countries.

Reference	**Region**	**Data source**	**Exams**	**Patient grouping**	**Dose value**	**No. patients**	**No. centres**	**NDRLs proposed**
Brisse et al, 2009	FR data + 1 Belgian hosp. and 1 Dutch hosp.	Sample protocols	Head, Facial bones, Sinus, Temporal bones, Chest, Low dose chest, Abdomen-Pelvis Bone	1y, 5y, 10y	3rd quartile $CTDI_{VOL}$	N/a	20	Yes
Buls et al, 2010	BE	Phantoms	Head, Sinus, Inner Ear, Chest, Abdomen	<1y 1-5y 5-10 y 10-15y	3rd quartile values from standard protocols	N/a	18	No
Verdun et al, 2008	CH	Sample protocols	Brain, Chest, Abdomen	<1y, 1-5y, 5-10y, 10-15y	Mean $CTDI_{VOL}$, DLP	N/a	8	Yes

Reference	Region	Data source	Exams	Patient grouping	Dose value	No. patients	No. centres	NDRLs proposed
Galanski et al, 2005	DE	Sample protocols	Brain, Facial bones/Sinus Chest, Abdomen/ Pelvis, L-spine	Newborn <1y 1-5y 6-10y 11-15y >15y	3rd quartile $CTDI_{VOL}$, DLP	N/a	63	Yes
Yakoumakis et al, 2009	EL	Phantoms	Brain, Chest, Abdomen	5y, 10y	3rd quartile $CTDI_{VOL}$, DLP	N/a	12	No. PDRL for 12 sites
Rafael Ruiz-Cruces, 2015 (DOPOES-project)	ES	Patients	Head, Chest, Abdomen	0y, 1-5y, 6-10y, 11-15y	3rd quartile DLP	80-750	5-10 % of total	YES
Jarvinen et al., 2011	FI (EE, LI)	Patients	Brain, Chest	0-9kg, 9-19kg, >19kg, 0-10kg, 11-25kg, 26-40kg, 41-60kg, 61-75kg, >75kg	3rd quartile DLP	286	9	No
Jarvinen et al., 2015	FI	Patients	Head Chest, Abdomen, Chest + Abdomen	< 1y, 1-<5y, 5-<10y, 10-15y DRL curve with weight	3rd quartile $CTDI_{VOL}$, DLP	1049	4	Yes (Existing NDRL, see C.3.3)
Roch & Aubert, 2013	FR	Sample protocols	Brain, Facial bones, Chest, Abdomen/ Pelvis	1y /10kg 5y /20kg 10y/30kg	3rd quartile $CTDI_{VOL}$, DLP	Not given	Not given	Yes (Existing NDRL, see C.3.3)
Granata et al. , 2015	IT	Patients	Head, Chest, Abdomen	1-5y, 6-10y, 11-15y	3rd quartile $CTDI_{VOL}$, DLP	993	25	No but reports 3rd quartile values
Santos et al, 2013	PT	Patients	Head, Chest	0y, 5y, 10y, 15y	3rd quartile $CTDI_{VOL}$, DLP	330	3	Yes
Shrimpton & Wall, 2000	7 countries	Phantoms	Brain, Chest, HRCT, Upper Abdomen, Lower abdomen	<1y, 5y, 10y	3rd quartile $CTDI_{VOL}$, DLP	N/a	40	No. Regional Europe
Shrimpton et al, 2006	UK	Sample protocols	Head, Chest	0-1y, 5y, 10y	3rd quartile $CTDI_{VOL}$, DLP	Not given	126	Yes (Existing NDRL, see C.3.3)
Shrimpton et al, 2014	UK	Patients	Head	0-1y, >1-5y, >5-10y	3rd quartile $CTDI_{VOL}$, DLP	838	19	Yes (Existing NDRL, see C.3.3)

1

All methodologies used the standard CT dose metrics of either $CTDI_{VOL}$ and/or DLP, with the majority (N=12) basing their calculations on the 3rd quartile of dose distribution recorded. Just one study used the adjusted mean value as a DRL (Verdun et al., 2008), as no dose distribution was available here, while Galanski et al (2005) used a modified 3rd quartile value.

Three distinct methods of data collection were noted across all publications, with six collecting the displayed CT dose metrics from patient studies (Järvinen et al., 2011, 2014; Santos et al., 2013; Shrimpton et al. 2014; Ruiz-Cruces, 2015; Granata et al., 2015), while another three (Shrimpton & Wall, 2000; Yakoumakis et al., 2009; Buls et al., 2010) used phantom data and the remaining five collected CT dose metrics from standard protocols (Galanski et al., 2005;Shrimpton et al., 2006, Verdun et al., 2008; Brisse & Aubert, 2009; Roch & Aubert, 2013). The number of CT scanners from which data was collected varied from as little as three scanners (Santos et al., 2013) to as many as 126 (Shrimpton & Wall, 2000), while the reported patient numbers ranged from 51 to 1049, divided amongst all the various examination and patient categories.

Regarding patient groupings, the majority of publications used patient age (N=11) with just two using patient weight (Järvinen et al., 2011, 2014), and one quoting both patient age and weight (Roch & Aubert, 2013). Of note a variety of patient age categories were used, although the most common appears to be derivations of the following <1, 1-5, 5-10, 10-15 years of age.

Most studies (N=11) detailed the calibration phantom size (16 cm or 32cm) used for reporting paediatric CT dose metrics, or else reported values based on both phantom sizes (e.g., Galanski et al., 2005). This involved applying a correction factor for some examinations, in particular trunk examinations to adjust for this difference, which exists with some manufacturer's settings. However two studies (Santos et al., 2013; Verdun et al., 2008) did not specify or detail such adjustment, so it is unclear which values are reported. Only one study (Santos et al., 2013) reported calibrating / checking the displayed dose metrics to ensure accuracy prior to reporting patient values, although two others did refer to routine quality assurance being performed (Shrimpton et al., 2014; Verdun et al., 2008).

In conclusion, a small number of European publications have collected paediatric CT data with most of these doing so to propose national DRL values, although a range of methodologies were used. In particular, studies varied according to whether patient or phantom/protocol data was collected and also in how patients were categorized into specific age ranges.

C.4.4 Interventional radiology

C.4.4.1 Paediatric interventional cardiology

Data concerning dose exposures in paediatric interventional cardiology are very scarce. All of the 8 European articles located (Barnaoui et al., 2014; Dragusin et al., 2008; Martinez et al., 2007; McFadden et al., 2013; Onnasch et al., 2007; Tsapaki et al., 2008; Papadopoulou et al., 2005, Corredoira et al., 2015) considered data from a single institution. The main aim of all studies was to determine Local Diagnostic Reference Levels (LDRL). In a recent article (Corredoira et al., 2015) the impact of 3D rotational angiography, or Cone beam CT, on the patient dose level was studied. Of 7 Institutions from 6 countries (BE, DE, EL, ES, FR, IE), 7 were specialized paediatric cardiology interventional units and 1 general cardiology unit (EL; Tsapaki et al, 2008).

The number of interventional procedures undertaken in a single institution ranged from 137 to 2140, performed mostly from 1998 to 2011. Examples of the procedures studied are: PDA closure,

atrial septal defect closure, balloon angioplasty, balloon valvuloplasty, and electrophysiology for different body weight ranges.

Patient grouping was done according to age in 4 studies (Dragusin et al., 2008; Martinez et al., 2007; McFadden et al., 2013; Tsapaki et al., 2008) and to weight in 2 studies (Barnaoui et al., 2014, Corredoira et al, 2015). In 1 study (Onnasch et al., 2007) grouping was not done but P_{KA} was normalized to body weight, whereas grouping was not done at all in 1 study (Papadopoulou et al., 2005).

In all studies dose exposures were differentiated between diagnostic and interventional procedures. In 2 studies (Barnaoui et al., 2014; Onnasch et al., 2007) exposure data were provided concerning respectively 5 and 7 different common interventional procedures.

In all studies the source of dosimetric values was the patient. LDRLs were reported as the mean (Barnaoui et al., 2014;Dragusin et al., 2008; Martinez et al., 2007; McFadden et al., 2013; Onnasch et al., 2007, Corredoira et al., 2015) or median (Tsapaki et al., 2008; Papadopoulou et al., 200530-32) value of the distribution of the dose observed. Corredoira et al., 2015 reported also 75^{th} percentile values. Dosimetric values were expressed in terms of P_{KA} in 7 studies, whereas in 1 study these were reported as P_{KA} per body weight (Onnasch et al., 2007). Effective dose was also reported in 1 study (Onnasch et al., 2007) and calculated in detail by Dragusin et al, 2008. Mean fluoroscopy time and number of images was reported in 4 studies (Barnaoui et al., 2014;Dragusin et al., 2008; McFadden et al., 2013; Tsapaki et al., 2008). Dose data were quite dispersed among institutions.

More details from some of these studies are compiled in Annex G.

In conclusion, dose data concerning exposures from paediatric interventional cardiology procedures are still very scarce. Neither national nor regional DRLs are available, only LDRLs are provided by each study. The studies greatly differ in their methodology and information provided, making the comparison very difficult. Furthermore, sometimes the conclusions are contradictory. Better standardisation and guidelines are needed, in particular for the patient dose surveys as the basis of setting the DRLs (see also the conclusions in Annex G).

C.4.4.2 Paediatric non-cardiologic interventional procedures

There are no studies available from European countries on DRLs for paediatric non-cardiologic interventional procedures.

C.5 Other studies on paediatric DRLs

In this section, DRLs published or studied outside Europe are briefly reviewed.

C.5.1 Radiography

A total of 5 publications were identified from outside Europe which reported DRL values for paediatric radiography, with 2 from America (Freitas, 2009; ACR, 1998; 2013), 2 from Asia (Sonawane, 2011; Kim, 2012) and 1 from Africa (Wambani, 2013). All studies but one (Wambani, 2013) determined national DRLs.

The most common examination for which DRL values were calculated was for the Chest (N=5). Other examinations were: skull (N=3) (Wambani, Sonawane, Freitas), abdomen (N=2) (Wambani, Sonawane), pelvis (N=2) (Wambani and Sonawane) and spine (N=2) (Wambani, Sonawane).

All studies but one (Wambani, 2013) based their DRL calculations on the 3rd quartile value. Wambani (2013) calculated the mean value of measurements for setting local DRLs.

The dose quantity applied was $K_{a,e}$ (N=5) (ESD with Wambani, Kim, and Freitas and ESAK with Wambani and Sonawane). One study used air-kerma without backscatter (ACR). Two out of 5 studies based their calculations on patient data (Wambani, Freitas) and the rest on air-kerma or phantom measurements. Patients in these 2 studies were grouped according to age.

All 5 studies have major limitations and could not be considered for DRL determination. These limitations are listed below:

- The Wambani study is limited to only one hospital.
- The Sonawane study defines DRLs for only one age group 5-9 yrs old.
- The Freitas study considers all children under 15 years old as one group and there is no division of the sample into groups.
- The Kim study found the 3rd quartile value was too high and it was finally concluded that it could not be used as a DRL
- The ACR study is based on data from 1998.

In conclusion, none of the above studies could be considered when trying to set up DRLs in radiography.

C.5.2 Fluoroscopy

Only three articles on DRLs have been found from countries outside Europe (NCRP, 2012; Emigh et al., 2013; Lee et al., 2009). The NCRP report (NCRP, 2012) does not recommend DRLs in terms of P_{KA} but in terms of $K_{a,i}$ at a specified location. The measurements were made using a geometry representative of clinical conditions which includes some backscatter due to the phantom-dosimeter geometry. The other two articles (Emigh et al., 2013; Lee et al., 2009) report P_{KA} and effective dose estimations for patients in single institutions, for upper GI examinations and MCU, respectively; these studies can be considered to yield data for local DRLs only.

C.5.3 Computed tomography

A total of thirteen publications were identified from outside Europe which reported DRL values for paediatric CT, with four from USA (NCRP, 2012; CRCPD, 2012; Goske et al., 2013; McCollough et al., 2011) and three from Australia (Brady, Ramanauskas, Cain, & Johnston, 2012; Hayton et al., 2013; Watson & Coakley, 2010), one from Syria (Kharita & Khazzam, 2010), Thailand (Kritsaneepaiboon, Trinavarat, & Visrutaratna, 2012) and Japan (Fukushima et al., 2012), one with data from both Saudi Arabia and Australia (Mohiy et al., 2012) and finally two international studies performed by the IAEA across 40 countries (Vassileva et al., 2015; Vassileva and Rehani 2015).

Most publications did not report national DRL values. Two of the Australian studies reported local DRLs for single institutions, each with a single CT scanner (Brady et al., 2012; Watson & Coakley, 2010), while the other (Hayton et al., 2013) was unable to collect sufficient data from a nationwide study to propose DRLs. Fukushima et al (2011) calculated regional DRL values, while Kristaneepaiboon et al (2010) and Goske et al (2013) calculated local DRLs for just three and six selected centres respectively. The Nationwide Evaluation of X-ray Trends survey in the US (CRCPD, 2012) did not set DRLs, but rather reported 75th percentile values for the data collected to allow comparison with other published DRL figures. McCollough et al (2011) did report national

DRL values, based on phantom measurements using standard protocols, although this used data from 2002. The recent IAEA study (Vassileva et al., 2015) proposes international DRLs for paediatric CT examinations in 4 age groups, based on data from 32 countries worldwide.

The most common examinations for which DRL values were calculated was for the abdomen (or abdomen/pelvis) (N=10), Head (N=9), and Chest (N=6), although one single centre study also reported values for temporal bones, sinuses and HRCT examinations (Watson & Coakley, 2010). Eleven of the twelve studies based their DRL calculations on the 3rd quartile value, using either or both $CTDI_{VOL}$ and DLP, with only one reporting the mean value (Brady et al., 2012) and another also reported the SSDE (Goske et al., 2013).

Six of the twelve studies based their calculations on patient data (Brady et al., 2012; Fukushima et al., 2012; Goske et al., 2013; Hayton et al., 2013; Kritsaneepaiboon et al., 2012; Watson & Coakley, 2010) using relatively small numbers (range 220-1382), with the other studies using either phantom data or standard protocols. Patients were mainly grouped according to age (N=8), although the age categories varied significantly between studies. One study categorized according to weight (Watson & Coakley, 2010), while another according to body width (Goske et al., 2013).

Of interest, one study proposed a range of dose values for CT, termed a diagnostic reference range (Goske et al., 2013), which included a lower 25th percentile value, below which it advised that image quality may not be diagnostic and was based on a subjective image quality analysis, while the upper 75th percentile value gave an indication of when doses may be excessive. This study also reported the SSDE based on body size as a better indicator of patient dose.

Regarding limitations, only seven studies reported the phantom size used, with just two reporting performing any calibration / checking of the displayed dose metrics to ensure accuracy prior to reporting patient values. Of the ten studies reporting values for the abdomen examination again in four it was unclear whether this referred to the entire abdomen/pelvis or just to the upper abdomen.

In conclusion, the majority of international publications reported local DRLs for a small number of centres and not national values. Although age was the most commonly used method to categorise patients there was no consistency in terms of the categories used between studies.

C.5.4 Interventional radiology

C.5.4.1 Paediatric interventional cardiology

Only four articles on paediatric DRL studies outside European countries have been found (Chida et al, 2010; Ubeda et al., 2011; Ubeda et al. 2015; Vano et al., 2011). Three of these articles considered data just from a single institution, and one (Vano et al., 2011) dealt with 10 centres in 9 different South American countries. The main aim of the first three studies was to determine local DRLs, while Vano et al. (2011) aimed at determining the quality of radiation protection in paediatric cardiologic IR procedures in Latin America; patient radiation doses were collected from only 70 procedures. Of 12 institutions from 11 countries (Japan, Chile and nine South American countries) 1 (Ubeda et al., 2011; 2015) was a specialized paediatric cardiology interventional unit and 11 others general cardiology units. The number of interventional procedures executed in the two single institutions (Chida et al, 2010; Ubeda et al., 2011; 2015) was 239 and 517 and respectively.

Patient grouping was according to age except in the study by Chida et al. (2010), where grouping was not done at all. Patient doses were differentiated between diagnostic and interventional procedures except in the study by Vano et al. (2011).

In all studies the source of dosimetric values was the patient. Local DRLs were reported as the mean (Chida et al, 2010) or median (Ubeda et al., 2011; 2015) value of the distribution of the doses observed. The dosimetric data reported in the multicentre study by Vano et al. (2011) cannot be considered as DRL data, as the sample was too small. Dosimetric values were expressed in terms of P_{KA} in all studies. Mean fluoroscopy time was reported only by Chida et al. (2010), while none of these publications reported the number of images. Dose data were quite dispersed among institutions.

More details of the first three publications are compiled in Annex G.

In conclusion, data published outside European countries, concerning patient doses and DRLs from paediatric interventional cardiology procedures, is even scarcer than in Europe. Only local DRLs are provided by the existing few studies. Similarly to European studies, these studies greatly differ in their methodology and information provided, making comparisons very difficult.

C.5.4.2 Paediatric non-cardiologic interventional procedures

Data concerning dose exposures in paediatric non-cardiologic interventional procedures are extremely scarce and limited to common vascular and enteric procedures. Just one non-European article concerning paediatric non-cardiologic interventional procedures from a single paediatric institution was found (Govia et al., 2012). The aim of this study was to determine the effective dose in children for enteric (insertion of gastrostomy tube, gastro-jejunal tube, cecostomy tube and their maintenance) and venous access procedures (central venous catheter, PICC, Port). Patient grouping was according to age. The number of procedures performed from 2004 to 2008 was 7074.

No data are available about embolization or sclerotherapy of vascular malformations, neuroradiology procedures, arteriography, CT guided biopsies, and biliary IR. Although relatively rare, these procedures can cause very high individual dose exposures. Therefore, further studies and guidelines are needed, as the basis to setting DRLs.

ANNEX D. NEED FOR PAEDIATRIC DRLs

For the basis of the recommendations given in Section 6, on the paediatric examinations and procedures with highest need for DRLs, statistical information on the frequency of paediatric examinations was collected. Further, the relative importance of the examinations in Tables 6.1 and 6.2, on point of view of their contribution to the overall collective effective dose to population (population dose) was analysed by rough estimation of the population doses.

D.1 Frequencies of paediatric examinations

Information about the distributions of different types of procedures in paediatric imaging is sparse; the paper by Seidenbusch depicts such data over 30 years but gives no information on the proportion of paediatric examinations compared to adult examinations (Seidenbusch & Schneider, 2008). The UNSCEAR 2013 Report, Volume II, Scientific Annex B (UNSCEAR, 2013) summarizes the percentages of various types of medical examinations on infants and children (0-15 years old) in well-developed countries. This indicated that approximately 3-10 % of all x-ray procedures are performed on children. The UNSCEAR report also gives some data on the age and sex distributions of various radiographic examinations, and summarizes methods to estimate effective doses from the measurable patient dose metrics for various examinations. In an IAEA survey of paediatric CT practice in 40 countries in Asia, Europe, Latin America, and Africa (Vassileva et al., 2012, 2013), the average frequency of paediatric CT examinations for all departments was 7.5% in 2007 and 9.0%, in 2009. The lowest mean frequency was in European facilities (4.6% in 2007 and 4.3% in 2009). In Finland, complete statistics of all paediatric examinations has been published every three years (STUK, 2013).

Because of the general sparseness of data, the specific questionnaire on the most common paediatric examinations was conducted to support the information available from the other sources. The questionnaire was sent to key persons of the European Society of Paediatric Radiology (ESPR – www.espr.org) and to medical partners of Central European Exchange Program for University Studies (CEEPUS; www.ceepus.info). Altogether 33 centres were contacted and responses were received from 18 centres (54.5%; Table D.1); from one centre information was received only for frequencies for Interventional Radiology.

Table D.1. Responses per country (without Interventional Radiology and Cardiac Catherization).

Country	Responses
AT	3
CH	1
CZ	1
DE	1
IE	1
IT	2
PT	2
RO	2
SI	1
RS	2
UK	1
Total	**17**

The detailed results of the questionnaire are presented in Tables D.2 to D.4. The calculated relative frequencies of examinations, for radiography, fluoroscopy and CT, based on the total annual frequencies obtained from the 16 centres that replied to the questionnaire, are shown in Fig. D.1 to Fig. D.3, respectively.

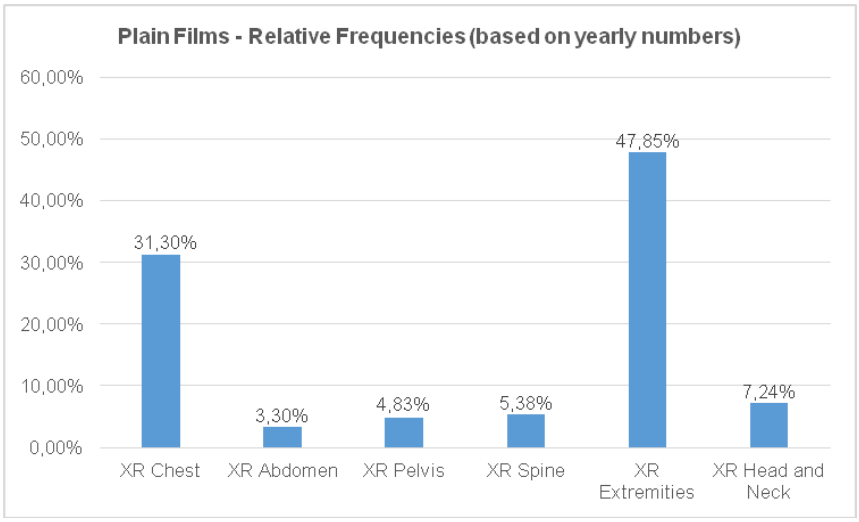

Fig. D.1. Relative frequencies of plain radiography examinations.

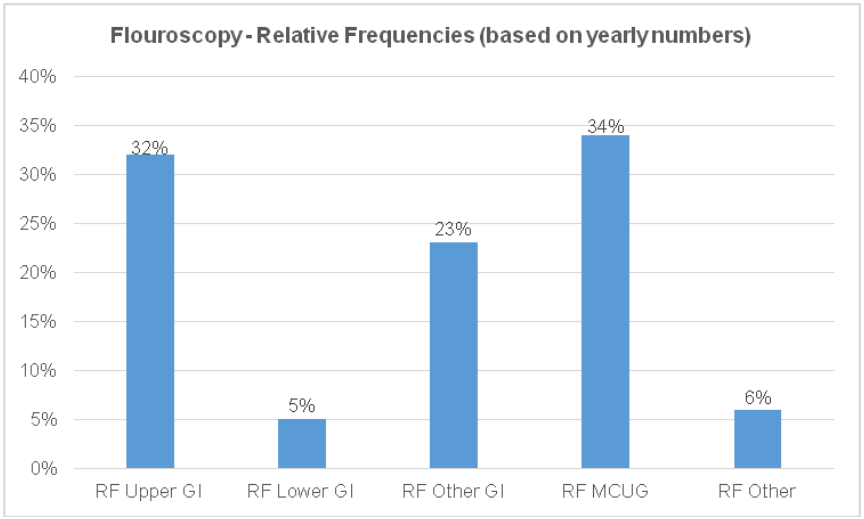

Fig. D.2. Relative frequencies of fluoroscopy examinations

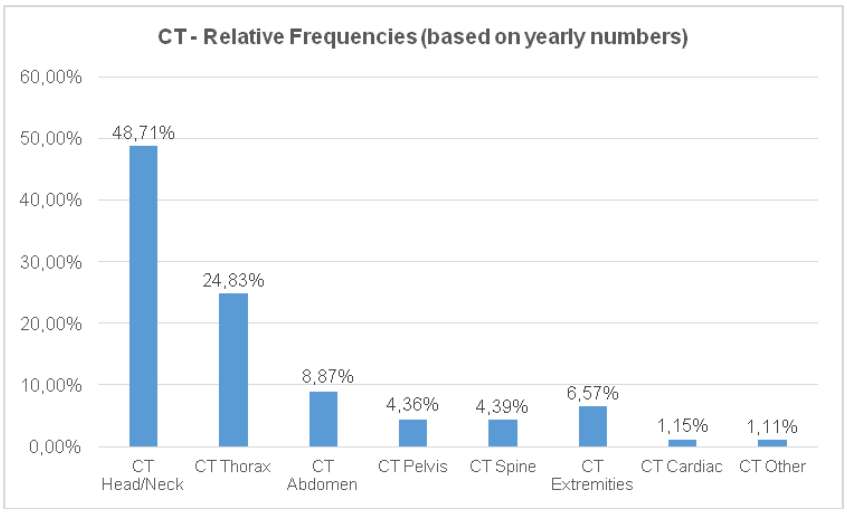

Fig. D.3. Relative frequencies of computed tomography examinations.

These result for radiography, fluoroscopy and CT are reasonably consistent with the data obtained from the others sources of information, i.e. the literature survey and information collected through the PiDRL contacts.

Table D.2. Radiography examinations.

Country	XR Chest	XR Abdomen	XR Pelvis	XR Spine	XR Extremities	XR Head & Neck
Austria	12800	2398	2069	3211	43799	5751
Czech	9903	664	0	0	13658	2478
Germany	1989	0	943	547	2205	0
Ireland	6581	1187	4714	863	2348	0
Italy	34589	5303	3523	4897	42947	1408
Portugal	1447	0	540	662	279	318
Romania	7933	250	827	1881	20377	4056
Serbia	12260	1998	1490	3100	33687	6350
Slovenia	2194	61	60	136	1307	51
Swiss	3452	356	710	0	3692	0
UK	13897	1859	1324	2472	857	0
Total	**107045**	**14076**	**16200**	**17769**	**165156**	**20411**
Mean	**9731,32**	**1279,64**	**1472,68**	**1615,40**	**15014,17**	**1855,58**
Stand. Dev.	**9429,09**	**1592,17**	**1462,95**	**1623,23**	**17453,45**	**2453,47**
%	**31,42**	**4,13**	**4,76**	**5,22**	**48,48**	**5,99**

Table D.3. Fluoroscopy (Upper GI: upper gastro-intestinal tract, lower GI: lower gastro-intestinal tract, MCU: micturating-cysto-urethrography)

Country	RF Upper GI	RF lower GI	RF Other GI	RF MCU	RF Other
Austria	82	50	371	509	2
Czech	283	149		296	
Germany	62	54		114	15
Ireland	456		131	119	
Italy	868			1149	
NL	90	82	9	37	48
Portugal	266			276	156
Romania	451		164	35	157
Serbia			104	377	
Slovenia	70	7	59	50	45
Swiss	47	35	23	146	8
UK	333		866	179	
Total	**3007**	**377**	**1727**	**3287**	**431**
Mean	**273,39**	**62,75**	**215,91**	**273,92**	**61,60**
Stand. Dev.	**251,00**	**48,90**	**286,26**	**311,96**	**67,14**
%	**34,06**	**4,26**	**19,56**	**37,23**	**4,88**

Table D.4. Computed tomography.

Country	CT Head/Neck	CT Thorax	CT Abdomen	CT Pelvis	CT Extremities	CT Cardiac
Austria	1370	568	395	154	429	18
Czech						
Germany	79	30			20	
Ireland	83	90				
Italy	2617	2632	1420	88	300	182
NL	334	199	21	7	173	5
Portugal	1018	851	603	423	192	
Romania						
Serbia	2068	281	203	18	105	
Slovenia						
Swiss	370	141	45	21	19	32
UK	1244	656				109
Total	**9183**	**5448**	**2687**	**711**	**1238**	**346**
Mean	**1020,36**	**605,31**	**447,82**	**118,45**	**176,81**	**69,14**
Stand. Dev.	**899,87**	**810,42**	**524,74**	**159,41**	**149,40**	**74,92**
%	**46,82**	**27,78**	**13,70**	**3,62**	**6,31**	**1,76**

D.2 Population dose from paediatric examinations

As discussed in Section 6, the need for a DRL is judged mainly on the basis of collective effective dose to population: all examinations resulting in high collective effective doses should have DRLs.

For the estimation of population dose, the frequencies of paediatric examinations for several age (or weight) groups should be known as well as the typical effective doses for each examination and each age (weight) group. Such information is not comprehensively and conveniently available, and can have high differences from country to country. Therefore, it has neither been possible nor considered feasible to provide an exact analysis on the population dose caused by the paediatric examinations recommended for DRLs in Section 6.

However, a very rough estimate of the population dose was done for some of the radiography and CT examinations, making use of (1) relative distributions of frequencies for various age groups based on comprehensive frequency data available from one country, (2) the total frequency data from the DDM2 project (EC, 2014), and (3) published values of typical effective doses of paediatric examinations (mean values were calculated from several published values). Due to the roughness of the results or associated high uncertainties, only relative values of this estimation are shown in Table D.5.

Table D.5. Relative collective effective doses to population, for a few paediatric radiography and CT examinations where setting DRLs has been recommended

Anatomical region	Description (PiDRL)	Relative collective effective dose to population, normalized to thorax radiography.
Radiography		
Head (skull)	AP/PA and LAT	0,01
Thorax	Thorax AP/PA	1,0
Abdomen	Abdomen-pelvis AP	0,1
Pelvis	Pelvis/hip AP	na
Spine	Cervical spine AP/PA and LAT	na
	Thoracic spine AP/PA and LAT	na
	Lumbar spine AP/PA and LAT	na
	Whole spine/Scoliosis AP/PA and LAT	na
Computed Tomography (CT)		
Head	Routine	2,6
	Paranasal sinuses	na
	Inner ear/ Internal auditory means	na
	Ventricular size (shunt)	na
Neck	Neck	na
Chest	Chest	10,2
	Cardiovascular CT angiography	na
Abdomen	Abdomen (upper abdomen)	4,5
	Abdomen+pelvis	na
Trunk	Whole body CT in trauma	na
Spine	Cervical+thoracic+lumbar	na

na: not available (sufficient data for calculations have not been available)

It can be seen that, despite of being a very low dose examination, conventional thorax radiography is of top importance among radiography because of its commonness. On the other hand, all CT examinations result in higher population dose than any of the radiography examinations, thus highlighting the importance of establishing DRLs also for paediatric CT examinations.

The proportion of the collective effective dose of the paediatric examinations shown in Table D.5 from the total population dose (adults + children) varied from less than 1 % to more than 3 %. For spine CT, this proportion seemed to be much higher and also the collective effective dose seemed to be very high; no value has been recorded in Table D.5., because of the very poor statistics of this case. This observation however supports paediatric spine CT to be in the list of examinations where DRL should be established.

ANNEX E. DEVELOPMENT OF DOSE MANAGEMENT SYSTEMS

E.1 General development

Dose management systems are an extremely helpful tool for radiation protection, dose monitoring, quality control, detection and reporting of unintended overexposures (EU-BSS, Art. 63; EC, 2013) and collection of data for national authorities for update of NDRLs.

The first step towards automatic dose management systems was the DICOM standard which has specified that the radiation dose to the patient (or more specifically, the doses reported by the x-ray unit) may be stored in the DICOM header of each image. However, at that time, the data was only stored in the Picture Archiving and Communication System (PACS). In many cases it is therefore impossible to deduce the dose from the procedure. Moreover, the DICOM standard does not give requirements on necessary fields to be filled, e.g., which field (place of information) should be used for a given parameter. The dose reporting was completed independently by various vendors and the comparison of different dose reports is not straightforward. In CT examinations, an advantage of dosimetric data in the DICOM header of each CT slice is, that it allows monitoring the dose distribution along the z-axis of a patient, if dose modulation is used.

The above shortcomings were identified and a DICOM supplement 94 was published in 2005 (DICOM, 2005). In this supplement a new type of dose report was described (Radiation Dose Structure Report, RDSR) that was intended to be used independently of the image data and be stored in "an appropriate Radiation Safety Reporting System". An advantage of RDSR is that dosimetric data stored at the end of a procedure include exposures of non stored images like rejected exposures. Furthermore RDSR in fluoroscopy also include the dose contribution of fluoroscopy times without taking images. In 2007, the RDSR was promoted when the IEC published a Publicly Available Specification (PAS) (IEC, 2007) that applies to medical electrical equipment and medical electrical systems including fluoroscopy systems. It gives the means for measuring or calculating dose-related quantities and for producing DICOM compatible images and/or reports, i.e. RDSR's. The implementation of the RDSRs was requested in the update of IEC 60601-2-43, published in 2010 (IEC, 2010). Currently, work is underway to publish IEC/PAS (IEC, 2007) as an IEC standard. Today nearly all modalities on the market allow generating and storing DICOM images but a significant number of modalities are still not able to generate a RDSR report.

To overcome technical problems in inter-system communication, healthcare professionals and industry have established a community (Integrating the Healthcare Enterprise, IHE) that aims to improve the way computer systems in health care share information (IHE, 2014a). IHE publishes Integration Profiles that describe solutions to particular problems by introducing case examples and the use of standards. One profile is devoted to radiation exposure monitoring (IHE, 2014b). In this profile the data flow (see Fig. E.1) and the functions of the different actors are described. The interest of national authorities to collect the patient exposure data is clearly identified.

The software used to upload the data from the x-ray equipment or workstation can be made vendor-independent, due to the use of the DICOM standard. In the central database, it is easy to implement analysis functions. Special attention should be paid to data security and integrity of the data especially if data are read remotely. The IHE profiles can be used as a basis for such solutions.

At the present time, several vendors offer commercial solutions for dose management solutions. A typical system consists of a central data storage (database or cloud service) and an access to the collected data using charting features and dashboard like visualisations (often internet browser based).

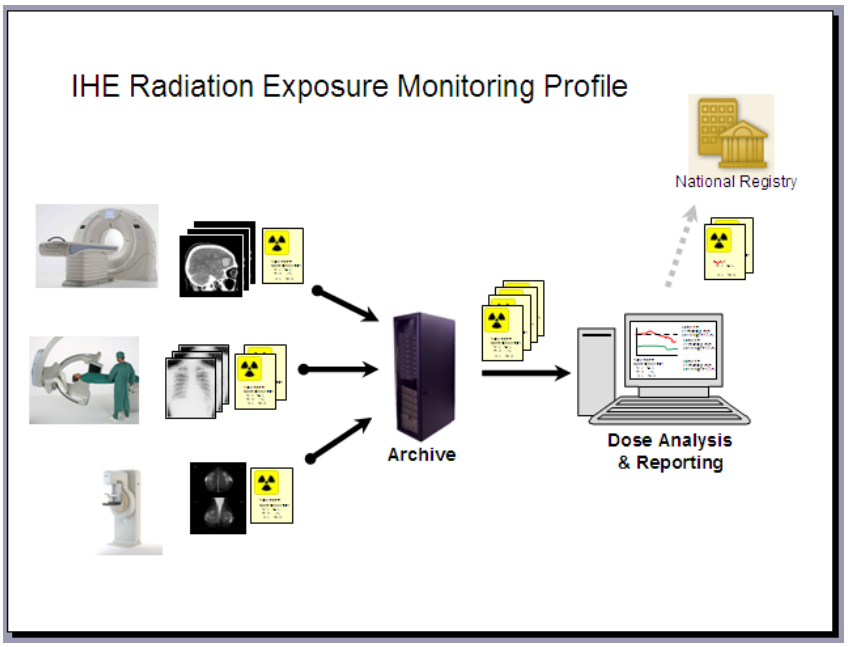

Fig.E.1. Flow of data from the modality to the PACS and the local dose management system. The local dose management systems can then report to national registries. Graphic from the IHE WIKI (http://wiki.ihe.net/index.php?title=Radiation_Exposure_Monitoring).

E.2 Existing dose management systems

The information on existing dose management systems is based on a questionnaire to the software manufacturers, direct contacts to these companies and Internet research. The summary of the products is shown in Table E.1.

Table E.1 Commercial products for automatic patient dose management.

Product	Company	Website/contact
DoseMonitor = NEXO Dose	PHS Technologies Group LLC Bracco	www.dosemonitor.com Enrico.Seccamani@bracco.com,
Dose Track	Sectra	https://www.sectra.com/medical/dose_monitoring/
DoseWatch	GE	http://www3.gehealthcare.com/en/products/dose_management/dosewatch
EasyDoseQM	BMS Informationstechnologie GmBH	http://www.bms-austria.com/
Imalogix	Imalogix	www.imalogix.com,
OpenREM.org		http://openrem.org
Physico	MS Emme Esse	www.emme-esse.com

Product	Company	Website/contact
Radimetrics	Bayer HealthCare	http://www.medrad.com/en-us/info/products/Pages/Radimetrics-Enterprise-Platform.aspx
RDM (Radiation Dose Monitor)	Medsquare	www.medsquare.com
RightDose	Siemens	http://www.healthcare.siemens.com/medical-imaging/low-dose/
S1	RaySafe (Fluke Biomedical)	http://www.raysafe.com/Products/Patient/RaySafe%20S1
TQM /Dose (Total Quality Monitoring)	Qaelum N.V.	http://www.qaelum.com/products/total-quality-monitoring.html

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ANNEX F. DETAILS OF EDRL CALCULATION

In Tables F.1 and F.2, more details of the calculation of the EDRLs (as shown in Tables 10.2 a, b) have been given. The list of countries are the countries, from where the DRL data (official NDRL, proposed NDRL or the 75th percentile determined from a nationwide patient dose distribution) is accepted for the calculation; the actual DRL data can be found in Annexes A or B. Both the mean and median (EDRL) values of the DRL distribution and their difference have been indicated, and also the interquartile value (ratio: 3rd quartile/ 1st quartile).

The interquartile value gives some indication of how feasible the EDRL values are for adoption as a NDRL: high interquartile value means a higher risk that the true NDRL (based on country's own patient dose survey) could deviate significantly from the given EDRL, while for low interquartile value there is higher probability that the true NDRL could be closer to the given EDRL. As can be seen from the interquartile values, for example, the EDRLs for chest CT examinations (interquartile values 1.0-3.5) have a little higher uncertainties than the EDRLs for head CT examinations (interquartile values 1.2-1.4) and for most radiography examinations (interquartile values mostly 1.0 – 2.0).

Table F.1. Calculation of the EDRL for radiography and fluoroscopy.

Radiography and fluoroscopy										
Exam	Age group or weight group	Age group, y	Mean of DRL distribution		**EDRL, median of DRL distribution**		Diff. Median & mean, %	Countries	No of countries	Interquartile value
			$K_{a,e}$, mGy	P_{KA}, mGy cm^2	$K_{a,e}$, mGy	P_{KA}, mGy cm^2				
Head AP/PA	3 months-<1 y	1		220		215	-2	AT, DE, ES	3	1,18
	1-<6 y	5		293		295	1	AT, DE, ES	3	1,14
	≥6 y	10		383		350	-9	AT, DE, ES, LT	4	1,14
Head LAT	3 months-<1 y	1		187		200	7	AT, DE, LT	3	1,11
	1-<6 y	5		253		250	-1	AT, DE, LT	3	1,02
Thorax AP/PA	5-<15 kg	1	0,07		0,06		-10	At, FI, LT	3	1,17
	15-<30 kg	5	0,08		0,08		-5	AT, DK, FI, FR, LT	5	1,43
	30-<50 kg	10	0,12		0,11		-14	AT, FI, FR, LT	4	1,60
	<5 kg	0		17		15	-13	AT, BE, DE, ES, FI, FR, NL	7	1,61
	5-<15 kg	1		29		22	-26	AT, BE, DE, ES, FR, LT, NL	8	1,96
	15-<30 kg	5		42		50	18	AT, BE, DE, ES, FI, FR, LT, NL	8	1,87
	30-<50 kg	10		66		70	5	AT, BE, DE, ES, FI, FR, LT	7	2,20
	50-<80 kg	15		83		87	4	AT, ES, FI, LT	4	1,43
Abdomen AP	15-<30 kg	5	0,60		0,40		-33	AT, FR, LT	3	1,75
	30-<50 kg	10	0,95		0,75		-21	AT, FR, LT	3	1,67
	<5 kg	0		64		45	-29	AT, BE, ES, NL	4	3,14
	5-<15 kg	1		165		150	-9	AT, BE, DE, ES, LT, NL	6	2,00
	15-<30 kg	5		321		250	-22	AT, BE, DE, ES, FR, LT, NL	7	1,22
	30-<50 kg	10		538		475	-12	AT, BE, DE, ES, FR, LT	6	1,73
	50-<80 kg	15		733		700	-5	AT, ES, LT	3	1,90
Pelvis AP	15-<30 kg	5		177		180	2	DE, FR, ES	3	1,15
	30-<50 kg	10		320		310	-3	DE, FR, ES	3	1,27
MCU	<5 kg	0		300		300	0	AT, DE, DK, ES, FI, NL, UK	7	2,00
	5-<15 kg	1		636		700	10	AT, DE, DK, ES, FI, NL, UK	7	1,65
	15-<30 kg	5		736		800	9	AT, DE, DK, ES, FI, NL, UK	7	1,71
	30-<50 kg	10		975		750	-23	AT, DE, ES, UK	4	2,14

Table F.2. Calculation of the EDRL for computed tomography.

Computed tomography										
Exam	Age group or weight group	Age group, y	Mean of DRL distribution		**EDRL, median of DRL distribution**		Diff. Median & mean, %	Countries	No of countries	Interquartile value
			$CTDI_{VOL}$, mGy	DLP, mGy cm	$CTDI_{VOL}$, mGy	DLP, mGy cm				
Head	0-<3 months	0	28		24		-13	BE, DE, FI, NL, PT, UK,	6	1,19
	3 months-<1 y	1	28		28		-2	BE, DE, FI, IT, NL, UK	6	1,22
	1-<6 y	5	38		40		6	BE, DE, FI, IT, NL, PT, UK	7	1,22
	≥6 y	10	52		50		-4	BE, DE, FI, IT, NL, PT, UK	7	1,23
	0-<3 months	0		343		300	-13	AT, DE, ES, FI, NL, PT, UK	7	1,24
	3 months-<1 y	1		404		385	-5	AT, DE, ES, FI, IT, LT, NL, UK	8	1,23
	1-<6 y	5		541		504	-7	AT, DE, ES, FI, IT, LT, NL, PT, UK	9	1,37
	≥6 y	10		719		650	-10	AT, DE, ES, FI, IT, LT, NL, PT, UK	9	1,42
Thorax	<5 kg	0	2,4		1,4		-43	DE, FI, PT, UK	4	2,40
	5-<15 kg	1	1,7		1,8		1	BE, DE, FI, IT, UK	5	1,56
	15-<30 kg	5	3,1		2,7		-15	BE, DE, FI, IT, PT, UK	6	1,56
	30-<50 kg	10	4,5		3,7		-20	BE, DE, FI, IT, PT, UK	6	1,56
	50-<80 kg	15	5,6		5,4		-3	DE, FI, IT, PT	4	1,71
	<5 kg	0		47		34	-27	AT, DE, ES, FI, PT, UK	6	3,47
	5-<15 kg	1		56		49	-12	AT, DE, ES, FI, IT, UK	6	2,73
	15-<30 kg	5		80		70	-12	AT, DE, ES, FI, IT, PT, UK	7	1,73
	30-<50 kg	10		124		115	-7	AT, DE, ES, FI, IT, PT, UK	7	1,52
	50-<80 kg	15		185		198	7	AT, DE, ES, FI, IT, PT	6	1,07
Abdomen	5-<15 kg	1	3,7		3,5		-4	DE, FI, IT	3	1,75
	15-<30 kg	5	4,8		5,35		11	BE, DE, FI, IT	4	1,32
	30-<50 kg	10	6,7		7,3		9	BE, DE, FI, IT	4	1,21
	50-<80 kg	15	12,0		13,0		8	DE, FI, IT	3	1,23
	<5 kg	0		61		45	-26	DE, ES, FI	3	1,60
	5-<15 kg	1		111		118	6	DE, ES, FI, IT	4	1,93
	15-<30 kg	5		139		151	8	DE, ES, FI, IT	4	1,14
	30-<50 kg	10		210		209	-1	DE, ES, FI, IT	4	1,25
	50-<80 kg	15		474		478	1	DE, ES, FI, IT	4	1,23

ANNEX G. PATIENT DOSES AND DRLS IN PAEDIATRIC CARDIAC AND NON CARDIAC PROCEDURES

G.1 Paediatric diagnostic or therapeutic interventional cardiac procedures

G.1.1 Introduction

Interventional cardiology (IC) is a subspeciality of cardiology/radiology, whereby procedures that traditionally used a surgical approach are performed during a heart catheterization. These minimally invasive procedures involve inserting catheters and other devices through superficial arterial and venous access sites. IC can be used to carry out both diagnostic and therapeutic examinations depending on the procedure being carried out.

The number, types and complexity of interventional cardiac (IC) procedures have increased dramatically in recent years due to increased reliability and advancing technology (McFadden et al., 2013, Corredoira et al., 2013, Hijazi and Award, 2008). According to UNSCEAR (UNSCEAR 2013), 4 % of all cardiac angiography is carried out in paediatric patients. Also the use of CBCT in paediatric cardiology has been increasing, because of its potential usefulness by acquiring high resolution 3D images of vascular volumes (Corredoira et al., 2015).

Fluoroscopically guided cardiac catheterizations are an essential technique for the diagnosis and treatment of congenital and acquired heart conditions. Paediatric IC procedures are very different from adult IC procedures not only because of the age of the patients but also because of the diversity of structural anomalies in congenital heart diseases. Pediatric IC procedures are in general longer and more complex than adult procedures (Ubeda et al., 2012; Lock, 2000).

The IC procedures can result in high patient doses, sometimes including also high skin exposure. Patients with complex congenital heart disease are now living longer and may need several IC procedures throughout their lifetime, thus the cumulative dose can become very high. The increased risk of developing a malignancy (Rassow et al., 2000) highlights the importance of establishing DRLs in paediatric IC; the risk for small children is higher because of the higher organ specific risk factor and because the collimation is centred around the heart and more critical radiosensitive organs are being irradiated simultaneously due to their close proximity to one another.

No NDRLs for paediatric IC have been set, but a few papers have been published in recent years, reporting the patient doses in paediatric IC procedures and the development of local DRLs.

G.1.2 Recent publications on patient doses and LDRLs

Onnasch et al. (2007) evaluated P_{KA} values for three different types of angiography systems over a time span of 8 years, for a total of 2859 patients. They observed linear correlation between P_{KA} values and patient weight (body weight) and suggested P_{KA} per patient weight as the appropriate DRL concept. They also observed that this constant of proportionality decreased during the years, mainly due to technological advances rather than the experience of the operators. They observed significant differences of patient dose levels between different types of IC procedures, the mean value of P_{KA} per patient weight being between 0,35 and 1,3 Gy cm^2 kg^{-1}.

Chida et al. (2010) evaluated 239 consecutive paediatric patients who underwent cardiac catheterizations or other IR procedures. They also found good correlation between P_{KA} and patient weight; an example is shown in Fig. G.1. They concluded that patient doses in other IR procedures were higher than in the IC procedures.

Ubeda et al. (2012; 2015) evaluated patient doses in paediatric cardiology at first in a pilot program and more comprehensively for a three years period (2011-2013), in the largest paediatric hospital in Chile, which manages approximately 60 % of all paediatric cardiac procedures in the country. In total, they evaluated 517 consecutive procedures (200 diagnostic and 317 therapeutic). Their results also indicate a reasonable linear correlation between P_{KA} and body weight (R^2 coefficient ranged from 0,247 to 0,698) so that they could suggest P_{KA} per body weight ratios as a basis of the local DRLs. Using this ratio, they calculated the DRLs for different weight groups (10-60 kg), for both diagnostic and therapeutic procedures. They concluded that there was no significant difference between the diagnostic and therapeutic procedures: the 75th percentile value was 0,163 Gy cm^2 kg^{-1} for diagnostic procedures and 0,170 Gy cm^2 kg^{-1} for therapeutic procedures. They noted that DRLs for IR procedures are linked to the complexity of the procedures: if the local values are higher than the DRL, the complexity of the local procedures should be analyzed together with the other factors.

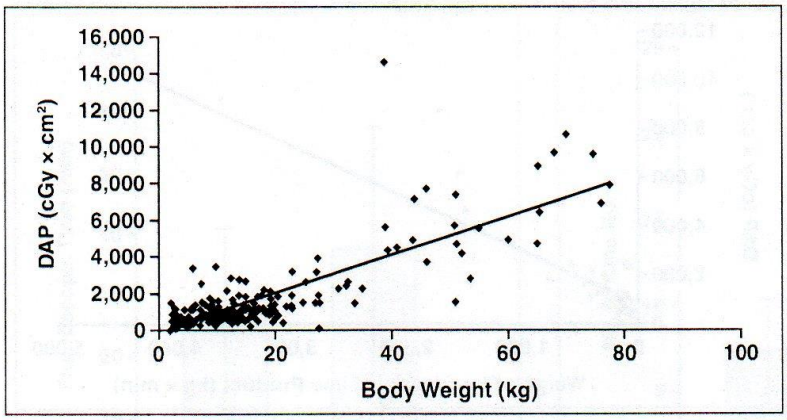

Fig. G.1. P_{KA} as a function of body weight in paediatric patient who underwent cardiac catheterization (r=0.819, p<0.01; regression line y=106.67 x – 130.0) (Chida et al., 2010)

McFadden et al. (2013) gathered data for a total 354 paediatric patients (159 diagnostic and 195 therapeutic procedures) in a dedicated cardiac catheterization laboratory over a 17 month period; the mean patient age was 2.6 years (range newborn – 16 years) and the mean patient weight 14,9 kg (range 2,4 – 112,0 kg). Maximum P_{KA} readings were slightly higher for therapeutic interventions but the difference between diagnostic and therapeutic procedures was not statistically significant (p = 0.59). Patient weight and age had a moderate correlation with P_{KA} (r = 0.557 and r = 0.472, respectively), thus suggesting that either patient weight or age could be used to stratify LDRLs. LDRL values for several age groups were suggested based on the mean of the dose distribution according to the UK practice (IPEM, 2000) (not the 75th percentile as recommended in these EC guidelines). Maximum and minimum P_{KA} readings varied greatly between examinations and there was a high number of extreme outlier points recorded. It was found that the 4 main technical factors that had the most significant impact on the patient dose were: use of antiscatter grid, higher frame rates, complexity of procedure and the duration of fluoroscopy. Three levels of complexity were suggested: standard/uncomplicated, medium and very complex.

Barnaoui et al. (2014) assessed patient exposure levels (P_{KA}, fluoroscopy time and the number of cine frames) in a French reference centre for paediatric IC. In the final analysis, they included all procedures performed more than 20 times for a given weight group, resulting in 801 procedures (288 diagnostic and 513 therapeutic). LDRLs were proposed for all three quantities as the mean values of the distribution; patient weight was used as the DRL parameter, because the technical parameters that influence the dose (tube voltage, mA and filtration) vary with patient weight and

volume. They also calculated the effective doses using the PCXMC program (Tapiovaara and Siiskonen, 2008). The mean P_{KA} for diagnostic procedures was 4.9 Gy cm^2, while for therapeutic procedures the mean P_{KA} values varied from 2.0 Gy cm^2 for atrial septal defect (ASD) to 11.9 Gy cm^2 for angioplasty. For diagnostic procedures, the results were in agreement with some previously reported values, thus suggesting that in diagnostic catheterization, the procedures are roughly standardised. For therapeutic procedures, the agreement with some previous studies was less good. These results also suggest that, compared with DRLs for diagnostic procedures, either lower or higher DRLs should be used for therapeutic procedures, depending on the type of procedure. A wide variation was shown in the results, even though all procedures were performed in the same catheterization room and the vast majority of them by the same radiologist.

Harbron et al. (2015) report from a large multicentre study including 10257 procedures carried out on 7726 patients at 3 UK hospitals from 1994 to 2013. They noticed that P_{KA} was positively correlated with patient mass, and report median P_{KA} (with interquartile range) and median P_{KA} per kilogram for different patient mass ranges, for all 3 hospitals and different eras of data collection. They observed a decrease of dose levels during the years (different eras) and conclude that the impact of technological factor is greater than increased operator experience or gradual refinement of techniques. The usage patterns of antiscatter grids appear to have had the greatest influence on dose. Due to the considerable variation observed in median doses between procedure types, they warn against the classification of procedures as simply diagnostic or therapeutic, in particular when DRLs are being set.

Corredoira et al. (2015) has studied the contribution of 3D rotational angiography, also referred to as cone beam CT (CBCT), to patient doses in a cardiac catheterization laboratory. In four years period (2009-2013), they collected data from 756 procedures (77 % therapeutic) involving 592 patients. CBCT were acquired for 109 patients (18,4 % of the sample). The results were presented separately for five age groups and ten weight groups. The maximum P_{KA} was higher for diagnostic procedures than for therapeutic procedures due to differences in difficulty and complexity and the greater proportion of cine series acquisitions (this observations is contradictory to the experience in the other studies above). The percentage increase of the median P_{KA} due to CBCT was 33 % and 16 % for diagnostic and therapeutic procedures, respectively. The correlation between P_{KA} and weight was poor (r^2 = 0.22…0.28) because in the biplane system the dose from PA-projection may be related to weight but in lateral projection it is related to thorax size and to the complexity of the procedure.

G.1.3 PiDRL survey from two cardiac centres

In the context of the PiDRL project, patient dose data for a few paediatric cardiac procedures were requested from a few centres. Due to practical difficulties, data were received only from two centres, and from this very scarce data (total of 26 and 23 patients), only data for one procedure, patent ductus arteriosus (PDA) occlusion, could be used for comparison with some other published data (Fig. G.2). While the data is too scarce to make any firm conclusions, it seems from Fig. G.2 that there are clear differences of patient dose levels between centres: the data from the most recent studies seem to be lower, which is in agreement with the general trend of decreasing dose levels seen in some of the published studies above (Onnasch et al, 2007; McFadden et al., 2013).

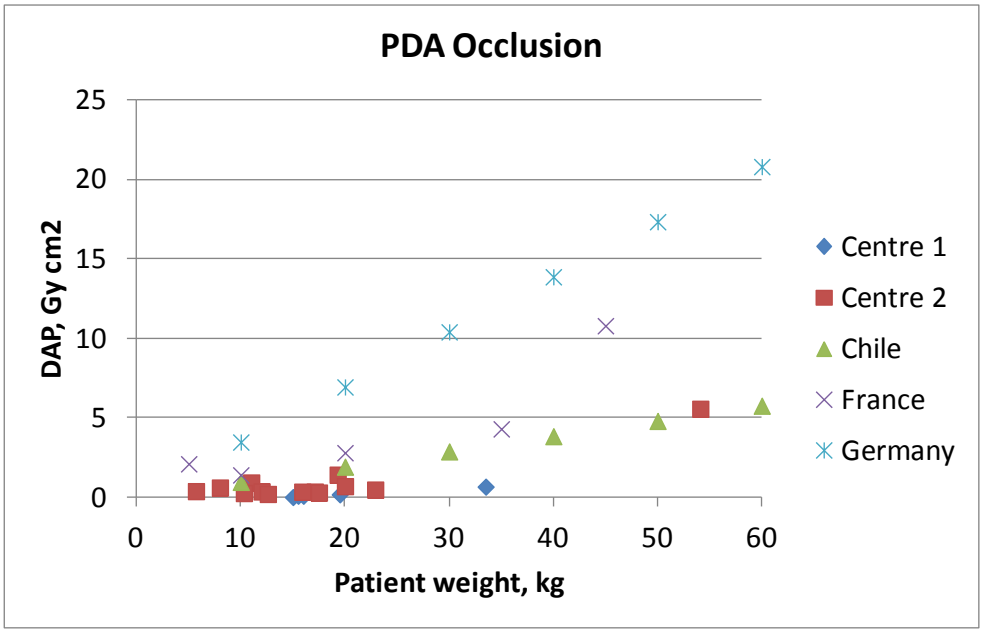

Fig. G.2. Comparison of P_{KA} (DAP) values for paediatric PDA occlusion as a function of patient weight: a few results from two centres in the PiDRL survey (2015), data from Chile (Ubeda et al., 2015; using median value of P_{KA} /weight 0,096 Gy cm^2 kg^{-1}), France (Barnaoui et al., 2014; using median values of P_{KA} per weight group) and Germany (Onnasch et al., 2007; using mean value of P_{KA} /weight 0,347 Gy cm^2 kg^{-1}).

G.1.4 Summary

The observations from the above papers can be summarized as follows:

- The implementation of DRLs for paediatric IC procedures is not as straightforward as for simple radiographic examinations. This is because of the typically broad patient dose distributions. The sources of dose variations in paediatric IC procedures are many-fold: they include the X-ray system specifications and performance, the examination protocol and the quality of preceding echocardiographic examination, patient pathology, in particular the complexity of the cardiac disease, operator skill and the size of the patient and the angle of projection. In particular, the complexity of the local procedures should be analyzed whenever the local values exceed a DRL.
- The size of the patient is the cause of increasing patient dose, not the age. The differentiation of boys and girls is not required. The rationale for relating P_{KA} to patient weight is that the mass of the heart and the volumes of its chambers are growing in proportion to the patient's body weight (not to the body surface area).
- There seems to be a linear increase of P_{KA} with patient weight over two orders of magnitude. Therefore, P_{KA} per patient weight could be used as a DRL, instead of using different P_{KA} values for different age groups; i.e. a single value (constant of proportionality) to cover all patients could be applied.
- There seems to be contradictory results for the difference in patient dose levels between diagnostic and therapeutic procedures; therapeutic procedures have been reported to yield higher dose than diagnostic procedures, on the average, or vice versa, or no significant difference have been reported. On the other hand, therapeutic procedures seem to be less standardised than diagnostic procedures, and also the complexity level of therapeutic

procedures seems to have more variation; therefore, the difference in dose levels between diagnostic and therapeutic procedures can be associated with the type of therapeutic procedures involved. For best accuracy, therefore, DRLs should be defined separately for specified diagnostic or therapeutic procedures.

- There seems to be high variations between the patient dose levels in different centres and also within a centre. In general, the dose levels seem to have decreased over the years due to technological advances.

The comparison of published P_{KA} values or DRLs for IC procedures is difficult mainly due to inconsistent grouping of patients in weight groups. However, data from the most recent publications have been compiled in Tables G.1- G.4. The data has been derived from the published values by taking as the actual comparison parameter the mean value of the weight group in the first column (i.e., 5, 15. 25 kg etc), then using the published P_{KA} per weight ratio, or calculating the mean weight for each published weight band, then fitting a curve through the points (P_{KA} versus mean weight) and finally calculating the P_{KA} from the fitted curve for each weight parameter value.

Table G.1. Summary of published median or mean P_{KA} values (Gy cm^2) for diagnostic IC procedures.

Weight group, kg	Corredoira et al., 2015	Ubeda et al., 2015	McFadden et al., 2013	Harbron et al., 2015	Barnaoui et al.. 2014	Chida et al., 2010
	mean values			median values		
<10	3,27	0,66	1,9	1,4	1,8	4,03
10 - <20	7,7	1,98	4,2	2,2	2,6	14,7
20 - <30	14,3	3,30	5,8	3,3	3,7	25,4
30 - <40	52,3	4,62	12,9	5,1	5,2	36,0
40 - <50	32,4	5,94	12,9	7,7	7,3	46,7
50 - <60	22,7	7,26	17,8	11,6	10,3	57,4
60 - < 70	38,0	8,6	17,8	17,7	14,5	68,0
70 - < 80	17,0	9,9	17,8	26,8	20,5	78,7

Table G.1. Summary of published median or mean P_{KA} values (Gy cm^2) for therapeutic IC procedures.

Weight group, kg	Corredoira et al., 2015	Ubeda et al., 2015	McFadden et al., 2013	Harbron et al., 2015	Barnaoui et al.. 2014
	mean values			median values	
<10	3,25	0,70	1,9	1,4	3,5
10 - <20	6,35	2,10	4,2	2,2	5,6
20 - <30	19,6	3,50	5,8	3,3	9,0
30 - <40	22,3	4,90	12,9	5,1	14,5
40 - <50	34,2	6,30	12,9	7,7	23,4
50 - <60	42,3	7,70	17,8	11,6	37,8
60 - < 70	28,4	9,1	17,8	17,7	61,0
70 - < 80	18,9	10,5	17,8	26,8	98,3

Table G.3. Summary of published 75th percentile P_{KA} values (Gy cm^2) for diagnostic IC procedures.

Weight group, kg	Corredoira et al., 2015	Ubeda et al., 2015	Onnasch et al., 2007
<10	4,72	0,82	2,5
10 - <20	13,0	2,45	7,5
20 - <30	30,1	4,08	12,5
30 - <40	23,0	5,71	17,5
40 - <50	81,9	7,34	22,5
50 - <60	51,9	8,97	27,5
60 - < 70	37,1	10,6	32,5
70 - < 80	68,8	12,2	37,5

Table G.4. Summary of published 75th quartile P_{KA} values (Gy cm^2) for therapeutic IC procedures.

Weight group, kg	Corredoira et al., 2015	Ubeda et al., 2015	Onnasch et al., 2007
<10	3,30	0,85	3,3
10 - <20	9,41	2,55	9,8
20 - <30	11,3	4,25	16,4
30 - <40	24,6	5,95	23,0
40 - <50	27,7	7,65	29,5
50 - <60	44,5	9,35	36,1
60 - < 70	60,0	11,1	42,6
70 - < 80	48,4	12,8	49,2

G.2 Paediatric interventional non-cardiac procedures

As noted in Section 6.3 and C.5.4, there are no published studies related to the establishment of DRLs for paediatric interventional non-cardiac procedures. Therefore, to obtain some understanding of the frequencies and patient doses in these procedures, a limited survey of patient dose data in six dedicated IR centres of the partner countries was carried out in the PiDRL project.

The most common of the 1700 procedures performed in 2011 or later and included in the survey are shown in Table G.5. Inclusion criteria were interventions on patients up to the age of 18 years where P_{KA} and clinical data were available and performed not earlier than in 2011. All centres provided data for age groups whereas weight information was available only from three centres. When the number of procedures was lower than 15 for any age or weight group, the results were excluded from the further analysis.

As an example of the results, Table G.6 presents the 75th percentile data for peripheral insertion of central venous catheters (PICC). This was the most frequent intervention of the survey, with low DRLs compared to other interventions. While the number of patients in many groups of other interventions was not sufficient for evaluation, local DRLs could be derived for most groups of PICC. As for other interventions, the interquartile range was typically high (Q3/Q1 ratio up to 9). Beyond this high variation within one centre, an even more important variation between centres was typical for the majority of the interventions surveyed. PICC is special in that it is often performed

by combined fluoroscopic and ultrasonographic guidance and that the relative contribution of the two imaging methods is highly variable at different places.

In Fig. G.2, the P_{KA} (DAP) values from two centres (centres 3 and 4) are shown as a function of patient weight, for arteriography of abdomen, rotational techniques. A reasonable linear correlation ($R^2 = 0,76$) can be seen despite the scarceness of data; it could be expected that for the interventions in the trunk region, the P_{KA} per patient weight could be roughly constant, analogous to the several observations in paediatric cardiac procedures (Section G.1). In Fig. G.3, another example of the data, P_{KA} values plotted as a function of patient weight, indicates a reasonable linear correlation with weight.

Table G.5. Numbers of paediatric body interventions per centre (total number = 1700), contributed by the six centres.

Type of intervention (*embolization includes chemoembol.)	**Centre 1**	**Centre 2**	**Centre 3**	**Centre 4**	**Centre 5**	**Centre 6**
Embolization* (all justifications) Whole body excl. head + neck + spine	11	28	32	9		
Embolization* (all justifications) Head/brain + neck + spine	1	61	102	33		
Sclerotherapy (venous malformations, lymphangiomas, cysts)	71	60	145	22		
Arteriography	53	47	159	30		
PICC (peripheral insertion of central ven. catheter) + Port/Positioning/"Broviac"	21	35	201	353		43
(GI intervention)	63					
Biliary/hepatic intervention	32			8	80	
Interventions contributed per centre	252	231	639	455	80	43

Table G.6. The 75th percentiles (Q3) of the P_{KA} (DAP)–values (cGy cm^2) for paediatric IR procedures "peripheral insertion of central venous catheters (PICC)" (number of patients in parenthesis). Also shown are the 25th percentile (Q1) and the interquartile range (ratio Q3/Q1), a measure of the spread of values within the age/weight group.

PICC – Port	**C 3**		**C 4**		**C 6**	
	Q3 DRL (n)	Q1, Q3/Q1	**Q3 DRL (n)**	Q1, Q3/Q1	**Q3 DRL (n)**	Q1, Q3/Q1
AGE						
<1y	1.9 (27)	0.34, 6	79.5 (54)	26.3, 3		
1y - <5y	1.9 (68)	0.49, 4	114.3 (116)	37, 3	16.9 (16)	9.6, 2
5y - <10y	3.4 (45)	0.82, 4	112 (85)	26, 4	32.3 (19)	6.3, 5
10y -<15y	9.7 (43)	1.77, 6	161.6 (72)	27.5, 6	46.9 (15)	9.2, 5
15y - 18y	18.1 (18)	5.6, 3	259.8 (26)	30, 9		
WEIGHT						
<5kg	1.8 (15)	0.44, 4				
5 - <15kg	1.8 (58)	0.38, 5	114 (65)	29, 4	16.7 (19)	7.5, 2
15 -<30kg	2.2 (66)	0.64, 3	106 (91)	38, 3	33.2 (17)	6.1, 5
30 -<50kg	12.0 (31)	1.99, 6	129.9 (67)	22, 6	32.8 (16)	12.0, 3
50 -<80kg	10.3 (28)	3.26, 3	126.7 (44)	34, 4		

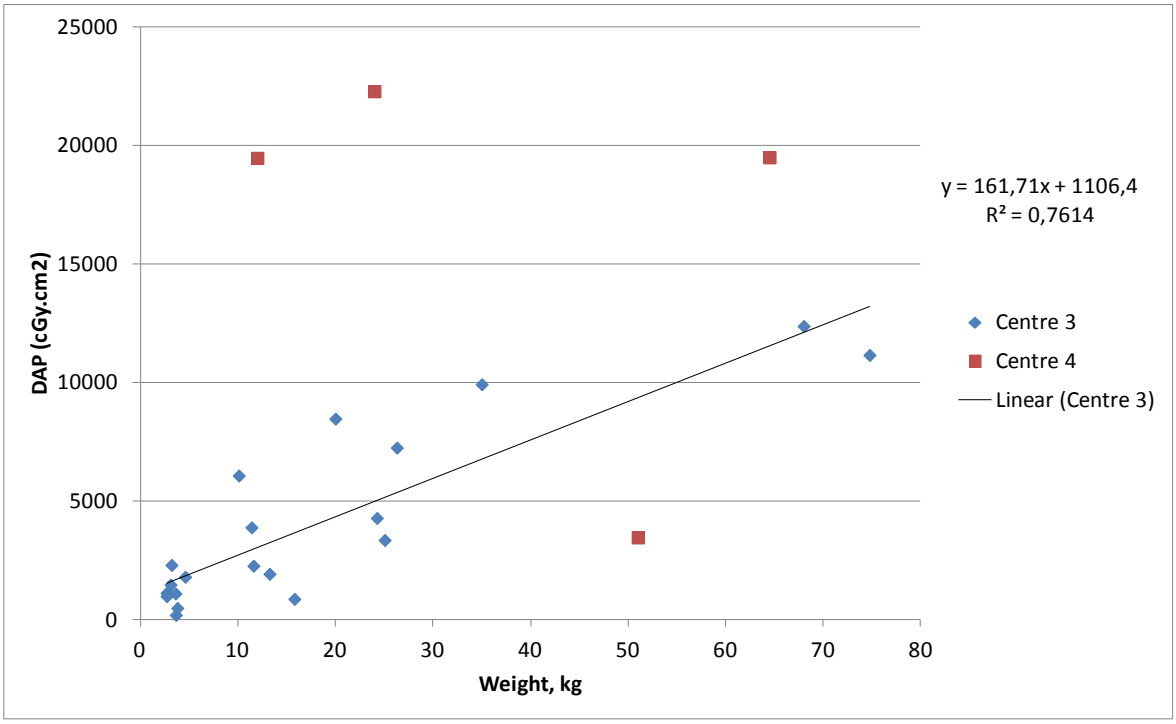

Fig. G.2. P_{KA} (DAP) values as a function of patient weight for "embolization, general" in trunk region, for two centres of the PiDRL survey.

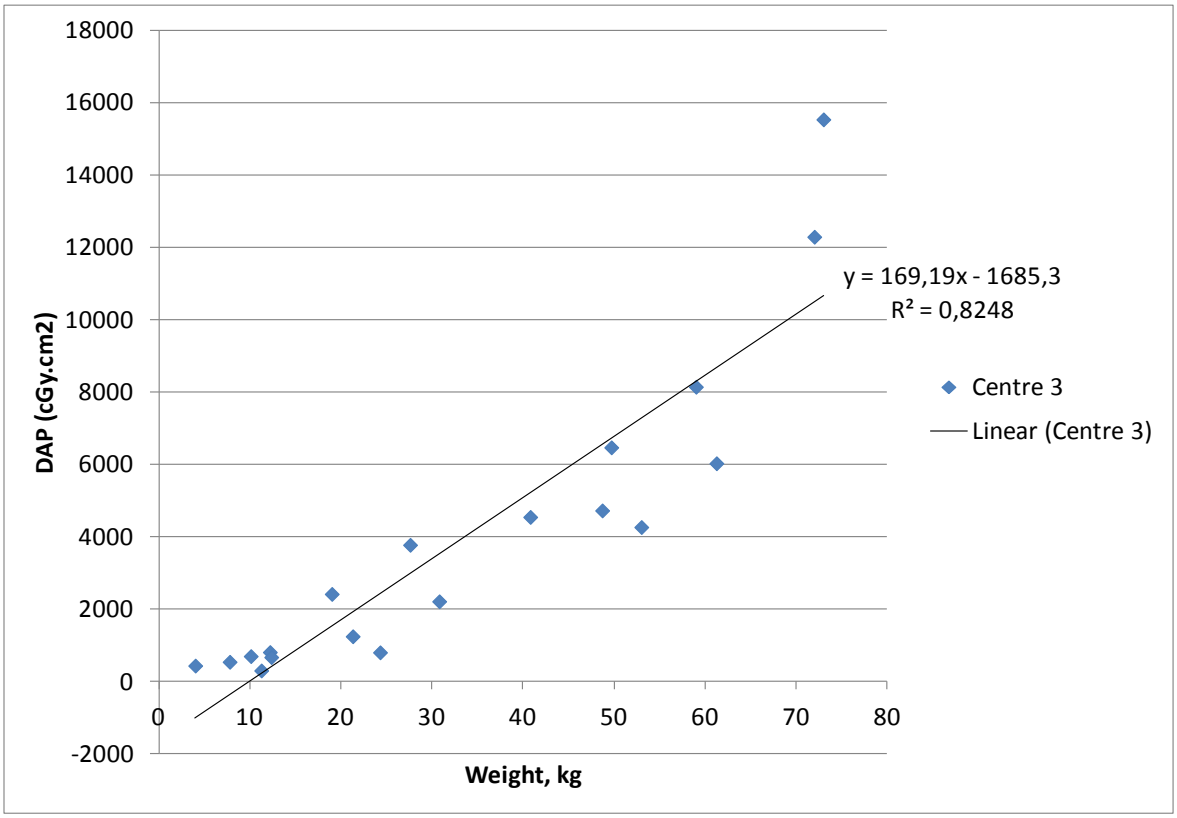

Fig. G.3. P_{KA} (DAP) values as a function of patient weight for "all abdomen, rotational techniques", or one centre in the PiDRL survey.

The comparison of different interventions (Table G.7) clearly identified embolizations (of the head-neck-spine as well as of other body areas) and arteriographies as high DRL interventions. In contrast, PICC, gastrointestinal interventions, biliary interventions and sclerotherapy usually required lower P_{KA} (DAP) values and, thus, showed lower DRLs. Exposure, and consecutively DRLs often – but not consistently - increased parallel to the weight and the age. Table G.7 also demonstrates the high variation of DRLs of the same weight/age group between different centres. Note that the difference between two centres may reach a factor of more than 50.

Table G.7. The 75th percentiles of the P_{KA} (DAP) values (cGy cm^2) compared as local DRLs of different centres for the most important age and weight groups. The different values for one single age/weight group represent the different local DRLs of those centres with at least 15 interventions of this type.

Intervention	**1 - <5y**	**5 - <10y**	**10 - <15y**	**5 - <15kg**	**15- <30kg**	**30 - <50kg**
Embolization Head n-s	9928, 13325		7768, 9195	9105	16470	10889
Embolization body	6550					
Arteriography	2177	4029	4077, 6250, 6797	1690	4223	4541, 27781
Sclerotherapy	26	32, 67, 365	88, 51, 225	39	41	49
PICC (insertion of central ven. cath.)	2, 17, 114	3, 32, 112	18, 260	2, 17, 114	2, 33, 106	12, 33,130
(Gastrointest.)	7		31			
Biliary	55	74	114			

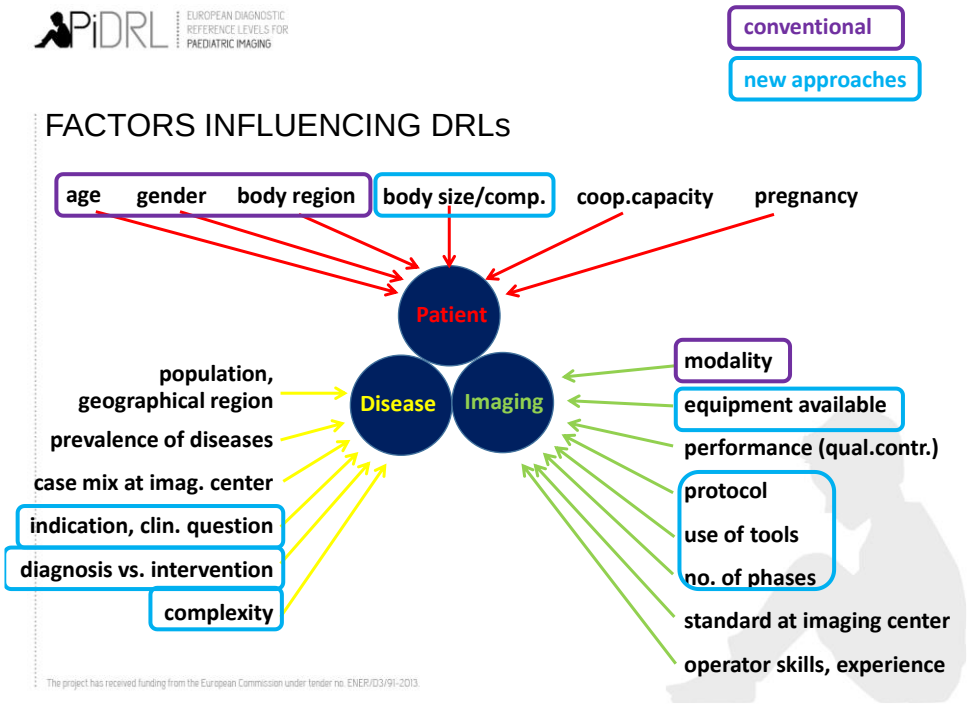

Fig. G.4. Factors affecting patient dose and setting of the DRLs.

There is a large number of factors affecting patient doses (Fig. G.4), and this makes the establishment and use of DRLs very challenging, in particular for paediatric non-cardiac IR procedures. The results of the PiDRL limited study support the conclusion that more studies, collection and comparison of patient dose data from several European centres have to be conducted to obtain sufficient basis to judge the feasibility of the DRLs for paediatric non-cardiac interventions. In view of the wider inter-centre than intra-centre variation, the PiDRL project suggests local and national DRLs are first produced. The evaluation and comparison of a large number of LDRLs may allow the future establishment of European DRLs.

ANNEX H. LIST OF ABBREVIATIONS AND SYMBOLS

AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
ALARA	As low as reasonably achievable
AP	Anterio-posterio
ASD	Atrial septal defect
BSS	Basic safety standards
CBCT	Cone beam computed tomography
CR	Computed radiography
CT	Computed tomography
CTDI	Computed tomography dose index
$CTDI_{vol}$	Volume computed tomography dose index
DAP	Dose-area product
DDM2	Dose Datamed II
DICOM	Digital imaging and communications in medicine
DLP	Dose-length product
DR	Digital radiography
DRL	Diagnostic reference level
EC	European Commission
ESAK	Entrance-surface air kerma (the same as $K_{a,e}$)
ESD	Entrance-surface dose
EU	European Union
EDRL	European diagnostic reference level
GI	Gastro-intestinal
HRCT	High-resolution computed tomography
IAEA	International Atomic Energy Agency
IAK	Incident air kerma (the same as $K_{a,i}$)
IC	Interventional cardiology
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IEC	International Electrotechnical Commission
IHE	Integrating the Healthcare Enterprise
IR	Interventional radiology
$K_{a,i}$	Incident air kerma (the same as IAK)
$K_{a,e}$	Entrance-surface air kerma (the same as ESAK)
$K_{a,r}$	Air kerma at patient entrance reference point (the same as CAK)
KAP	Air kerma-area product (the same as P_{KA})
LAT	Lateral
LDRL	Local diagnostic reference level
MCU	Micturating cysto-urethrography (the same as VCU)
NDRL	National diagnostic reference level
P_{KA}	Air kerma-area product (the same as KAP)
PA	Posterio-anterio
PACS	Picture archiving and communication system
PDA	Patent ductus arteriosus
PET-CT	Positron emission tomography – computed tomography
PICC	Peripheral insertion of central catheters
PiDRL	Paediatric imaging diagnostic reference level
RDSR	Radiation dose structured report

SPECT-CT	Single-photon emission tomography – computed tomography
SSDE	Size-specific dose estimate
TCM	Tube current modulation
UNSCEAR	United Nations Scientific Committee on Effects of Atomic Radiations
VCU	Voiding cysto-urethrography (the same as MCU)

Country codes (EUROSTAT):
(http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes)

AT	Austria
BE	Belgium
BG	Bulgaria
CH	Switzerland
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IS	Iceland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	The Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom