EUCLID | European Study on Clinical DRLs

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European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging

Deliverable 2.1: Report and review on existing clinical DRLs

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Abbreviations

AD	Achievable dose
CA	Coronary angiography
CCTA	Coronary computed tomography angiography
CIRSE	Cardiovascular and Interventional Radiological Society of Europe
CT	Computed tomography
CTDIvol	Computed Tomography Dose Index [mGy]
DAP	Dose Air Product [Gy*cm²], see also KAP
DLP	Dose Length Product [mGy.cm]
DRLs	Diagnostic Reference Levels
EFOMP	European Federation of Organisations for Medical Physics
EFRS	European Federation of Radiographer Societies
EUCLID	European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging (EC Tender Contract N° ENER/2017/NUCL/SI2.759174)
EVAR	Endovascular aneurysm repair
HCC	Hepatocellular carcinoma
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IR	Interventional Radiology
KAP	Kerma Air Product [Gy*cm²] also known as P_{KA}
$K_{a,r}$	Air kerma at the patient entrance reference point
PCI	Percutaneous coronary intervention
PAD	Peripheral Artery Disease
PTA	Percutaneous transluminal angioplasty
PTCA	Percutaneous transluminal coronary angioplasty
TACE	Transarterial chemoembolization
TAVI	Transcatheter aortic valve implantation
TIPS	Transjugular intrahepatic portosystemic shunt

1 Introduction

The concept of Diagnostic Reference Levels (DRLs) is well established and has been widely accepted for many years. Most of the existing DRLs, especially for computed tomography (CT), were built for specific anatomical locations, even in the USA. However, some limitations of this approach were pointed out for CT, as for the same anatomical location one could have several clinical indications with consequently different protocols corresponding to different exposure levels. For example, CT of the chest could correspond to the work-up for pulmonary embolism, lung cancer or even coronary calcium scoring which require corresponding image quality parameters, and hence should have different DRLs. The clinical approach of DRLs was mentioned many years ago by the International Commission on Radiological Protection (ICRP)[1], but the vast majority of European national competent authorities are still considering DRLs for anatomical location and not for clinical indication. However, some countries (Finland, Germany, Denmark, Norway and the UK) recently established DRLs for clinical indications, and some others (France, Switzerland and The Netherlands) are planning to develop DRLs for clinical indications in the near future. In addition, several recently published papers report DRL values for specific clinical indications. ESR's EuroSafe Imaging campaign organised sessions at the European Congress of Radiology (ECR) 2017, and the International Atomic Energy Agency (IAEA) held technical meetings in 2016 and 2017, respectively, in which EuroSafe Imaging promoted this approach.

The goal of this deliverable was to collect information from the European national competent authorities and from the literature in order to further propose a survey for the establishment of DRLs based on clinical indications for CT and interventional radiology (IR).

[1] ICRP, 2017. Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann. ICRP 46(1).

2 Methodology

The goal of this task of the tender was to get comprehensive information on existing clinical DRLs for CT, IR and radiography in order to establish the final list of clinical indications that forms the basis for the data collection in work package 3. However, it was agreed during the kick-off meeting not to include plain X-rays in the survey, but only CT and IR, and to propose DRLs for plain X-rays for selected anatomical locations based on the review of the existing data from competent authorities.

The methodology was based on data collection with three approaches:

1. The national competent authorities of 31 European countries were contacted in September 2017 and asked to provide available national data on CT, interventional radiology and radiography.

   The email letter and contact list are included as Annex 1-2. The replies from the competent authorities are available in Annex 3.

   As agreed during the kick-off meeting, the competent authorities will be re-contacted again before the workshop to ask them for an update on available national data (approx. M23).

2. The External Advisory Panel (EAP) and the Scientific Board (SB) were asked to provide feedback on the initial proposal of clinical indications, which should be surveyed.

3. A comprehensive literature review was undertaken in order to identify which clinical indications were specifically studied. Additional information was: year of publication, CTDi and DLP values for CT and DAP for IR. All publications were collected with the Mendeley reference management software (www.mendeley.com).

3 Status of existing DRLs based on clinical indications

3.1 CT DRLs based on clinical indications

3.1.1 Existing national DRL values published by competent authorities

Table 1 provides an overview of the replies by the competent authorities to the email invitation to provide available national DRL data.

Table 1: Overview of replies by competent authorities

Countries	Reply	No reply	Have DRLs	Calculation process	No DRLs
31	27	4	23	2	2

Twenty-seven of 31 countries replied (the missing four countries are: Croatia, Estonia, Hungary and Iceland). Not all answers were available in English. However, they were translated with the support of the project team members and their networks.

Twenty-three countries have national DRLs in CT: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Slovenia, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Two countries (Cyprus and Portugal) declared they do not have DRLs, and two countries (Italy and Romania) indicated they are in process of calculating DRLs.

Five countries have some clinical indication based DRLs for CT: Denmark, Finland, Germany, Norway and the United Kingdom.

Three countries (France, The Netherlands and Switzerland) are intending to develop clinical indication based DRLs in the near future.

3.1.2 Literature review

Fifty-six papers, articles or reports were considered in the literature review; among them, 17 (see 3.1.3) include clinical DRLs for one or several anatomical areas. It is important to refer to the fact that from the 17 papers, which include clinical DRLs, only ten have a regulatory value and are therefore officially recognised as such by the health authorities.

Considering that the concept of DRLs based on clinical indications is a recent one, the project team found some discrepancy and inconsistency in the classification of the clinical indications. This creates difficulties in comparing the DRL values between the studies as different clinical indications are used.

The anatomical areas for which clinical DRLs were found in the literature are: head (8); cervical (3); chest (6); abdomen (6); abdomino-pelvis (3).

In head CT, trauma/sinusitis is the clinical indication with the highest number of studies (4 of 6). The DLP values range from 90mGy.cm 17 to 350mGy.cm 15.

In cervical CT, it was possible to compare the clinical indication of fracture (2 out of 3 studies). The CTDIvol values range from 20mGy 5 to 26 mGy 11.

Chest CT is the anatomical area with most studies (17). Coronary Computed Tomography Angiography (CCTA) is the clinical indication with the highest number of proposed DRLs (10 out of 17). The DLP values range from 173mGy.cm 1 to 1510mGy.cm 4.

In abdomen CT, liver metastases is the clinical indication with most proposed DRLs (4 out of 7). The DLP values range from 400mGy.cm 15, 17 to 1423mGy.cm 13.

In abdomino-pelvis CT, abscess/lymphadenopathy is the clinical indication with the highest number of proposed DRLs (3 out of 5). The DLP values range from 650mGy.cm 15, 17 to 745mGy.cm 11.

From the literature review, it is obvious that there is a lot of space for improvement in the near future to harmonise the clinical indications for each anatomical area and to define the adequate acquisition protocol to allow for a more objective data analysis and benchmarking, as tools towards optimisation.

The clinical indications considered by the competent authorities and/or in the literature are listed in Table 2 (also see Table 3 to Table 7 for detailed information).

Table 2: CT clinical indications

Head and neck: ▪ Acute stroke ▪ Sinusitis
Spine: ▪ Cervical spine (excluding fracture)
Chest: ▪ Lung cancer ▪ Interstitial lung disease ▪ Coronaries (calcium scoring) ▪ Coronaries (CT angiography) ▪ Pulmonary embolism
Abdomen-Pelvis: ▪ Liver metastases ▪ Abdomen abscess ▪ Acute abdomen ▪ Virtual colonoscopy (polyps/tumour) ▪ Abdominal aorta angiography

3.1.3 Detailed results and comments

3.1.3.1 Competent authorities and literature

Table 3 to Table 7 show detailed data provided by the competent authorities and found in the literature.

A summary of clinical DRLs, based on the 75th percentile of the $CTDI_{vol}$ (mGy) and DLP (mGy.cm) are shown in the following tables, presented by anatomical region (head, cervical spine, chest, abdomen, and abdomen-pelvis) and by clinical indication.

Table 3: Head CT DRLs, based on clinical indications

Reference	Clinical indication	acute stroke/post fossa		acute stroke/cerebrum		acute stroke/brain (whole)		acute stroke/all sequences		Haemorrhage, aneurysms, arteriovenous malformations		metastases, cerebral abscess		Trauma, sinusitis		cholesteatoma	
		CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)
2	**Danish Health Authority (DK) 2015 ***	-	-	-	-	-	-	-	-	58	930	-	-	-	-	-	-
11	**Public Health England (UK) 2016 ***	80	-	60	-	60	-	-	970	-	-	-	-	-	-	-	-
14	**Schegerer et al (DE) 2017 ***	-	-	-	-	-	-	-	-	-	-	-	-	9	120	-	-
15	**Treier et al (CH) 2010 ***	-	-	-	-	-	-	-	-	65	1000	65	1000	25	350	50	250
16	**Van der Molen et al (NL) 2013 ***	-	-	-	-	-	-	-	-	-	936	-	-	-	133	-	-
17	**Wachabauer et al (AT) 2017 ***	-	-	-	-	-	-	-	-	-	-	-	-	-	90	-	-

* Data with regulatory value.

Table 4: Cervical CT DRLs, based on clinical indications

Reference	Clinical indication	Fracture		Disk Pathology		Adenopathy, abscesses	
		CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)
5	**German Federal Office for Radiation Protection (DE) 2016 ***	20	-	25	-	-	-
11	**Public Health England (UK) 2016 ***	26	600	-	-	-	-
15	**Treier et al (CH) 2010 ***	-	-	-	-	30	600

* Data with regulatory value.

Table 5: Chest CT DRLs, based on clinical indications

Reference	Clinical indication	Lung cancer		Interstitial lung disease (axial)		Interstitial lung disease (helical)		Pulmonary embolism		CCTA		Calcium Scoring	
		CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)
1	**Castellano et al (UK) 2017 ***	-	-	-	-	-	-	-	-	-	173	-	-
2	**Danish Health Authority (DK) 2015 ***	16	620	-	-	13	500	-	-	29	230	-	-
3	**Foley et al (IR) 2012**	-	-	7	276	-	-	13	432	-	-	-	-
4	**Fukushima et al (JP) 2012**	-	-	-	-	-	-	-	-	-	1510	-	
5	**German Federal Office for Radiation Protection (DE) 2016 ***	-	-	-	-	-	-	-	-	20	330	-	
6	**Hausleiter et al 2009**	-	-	-	-	-	-	-	-	-	1152	-	
7	**Japan Network for Research and Information on Medical Exposures (JP) 2015**	-	-	-	-	-	-	-	-	90	1400	-	-
8	**Kanal et al (USA) 2017**	-	-	-	-	-	-	19	557	-	-	-	-
9	**Mafalanka et al (FR) 2015 ***	-	-	-	-	-	-	-	-	-	870	-	-
10	**Palorini et al (IT) 2014**	-	-	-	-	-	-	-	-	-	1208	-	131
11	**Public Health England (UK) 2016 ***	12	610	4	140	12	350	13	440	-	-	-	-
12	**Radiation and Nuclear Safety Authority (FI) 2013 ***	11	430	-	-	-	-	-	-	-	-	-	-
13	**Salama et al (EG) 2017**	-	-	-	-	22	421	-	-	-	-	-	-
14	**Schegerer et al (DE) 2017 ***	-	-	-	-	-	-	15	300	-	-	8	119
15	**Treier et al (CH) 2010 ***	-	-	-	-	-	-	-	-	-	1000	-	150
16	**Van der Molen et al (NL) 2013 ***	-	-	-	-	-	276	-	371	-	671	-	51
17	**Wachabauer et al (AT) 2017 ***	-	-	-	-	-	-	-	400	-	-	-	-

* Data with regulatory value.

Table 6: Abdomen CT DRLs, based on clinical indications

Reference	Clinical indication	Liver Metastases		Abcess		Kidney stones/colic		Kidney tumor/colic		Acute Abdomen		Pancreas Adeno Ca	
		CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)
2	**Danish Health Authority (DK) 2015 ***	-	-	-	-	-	-	-	-	17	700	-	-
11	**Public Health England (UK) 2016 ***	14	910	15	745	10	460	13	1150	-	-	-	-
12	**Radiation and Nuclear Safety Authority (FI) 2013 ***	-	-	-	-	7	330	-	-	-	-	-	-
13	**Salama et al (EG) 2017**	31	1423	-	-	-	-	-	-	-	-	-	-
15	**Treier et al (CH) 2010 ***	15	400	-	-	-	-	-	-	-	-	-	-
16	**Van der Molen et al (NL) 2013 ***	-	-	-	-	-	329	-	1371	-	-	-	1000
17	**Wachabauer et al (AT) 2017 ***	-	400	-	-	-	-	-	-	-	-	-	-

* Data with regulatory value.

Table 7: Abdomino-pelvis CT DRLs, based on clinical indications

Reference	Clinical indication	Abscess lymphadenopathy		VC - polyps/tumor		CT angiography (AAA)	
		CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)	CTDIvol (mGy)	DLP (mGy.cm)
11	**Public Health England (UK) 2016 ***	15	745	11	950	-	-
15	**Treier et al (CH) 2010 ***	15	650	-	-	15	650
16	**Van der Molen et al (NL) 2013 ***	-	-	-	-	-	727
17	**Wachabauer et al (AT) 2017 ***	-	650	-	-	-	-

* Data with regulatory value.
Values for the full examination for 11, 15, and 16 and only for single phase in 17.

3.1.3.2 Scientific Board

The SB provided feedback on the preliminary list of clinical indications established in the tender submission (see below Table 8).

Table 8: Preliminary list of clinical indications for CT DRLs in the tender submission

1. Acute head trauma
2. Chronic sinusitis
3. Cervical spine trauma
4. Total body CT in severe trauma
5. Pulmonary embolus
6. Pulmonary metastases
7. Diffuse infiltrative lung disease
8. Coronary calcium scoring
9. Chest-abdomen-pelvis oncologic follow-up (single phase)
10. Abdominopelvic CT for liver and abdominal metastases in colorectal cancer
11. Urinary calculus
12. Appendicitis

Ten out of eleven members replied. Four members agreed with the EUCLID list. However, some suggestions were made:

- To include lumbar spine (3 times), but the indication was not mentioned, and coronary CT angiography (once).
- To remove coronary calcium scoring (2 times: either because rarely performed or because non relevant test), and appendicitis (2 times: because this examination is not recommended)

3.1.3.3 External Advisory Panel

The EAP was also asked to review the preliminary list of clinical indications. Seven members out of twelve provided feedback.

Six members agreed with the EUCLID list.

Concern on the development of DRLs based on clinical indications rather than on anatomical locations was expressed once (Italy).

Consideration of CT in stroke was also suggested once.

3.1.3.4 General comments

The concept of clinical DRLs for CT is already adopted by several countries and furthermore will be developed in several others.

In the literature, only few articles relate to clinical DRLs, and usually for a single indication. Only one article published in the English literature by a Swiss team[15], addresses this topic in a more comprehensive approach (21 indications included).

The preliminary EUCLID list is not far from a consensus considering the suggestions from the competent authorities (see below Table 9).

Table 9: Indications not addressed by the competent authorities (in green) and indications not addressed by EUCLID yet (in red).

Competent authorities (14)	EUCLID (12)
Head and neck: Acute stroke Sinusitis Spine: Cervical spine (exclude fracture) Chest: Lung cancer Interstitial lung disease Coronaries (calcium scoring) Coronaries (CT angiography) Pulmonary embolism Abdomen-pelvis: Liver metastases Abdomen abscess Acute abdomen Virtual colonoscopy (polyps-tumour) Kidney (colic) Abdominal aorta angiography	Head and neck: Acute head trauma Chronic sinusitis Spine: Cervical spine trauma Chest: Pulmonary metastases Diffuse infiltrative lung disease Coronary calcium scoring Pulmonary embolism Abdomen-pelvis: Chest-abdomen-pelvis oncologic follow-up (single phase) Abdominopelvic CT for liver and abdominal metastases in colorectal cancer Appendicitis Urinary calculus Total body CT in severe trauma

In general, the reported DRL values are very inhomogeneous. Large differences are observed for CCTA. Table 5 shows that CCTA DRLs in terms of DLP range from 173 mGy.cm to 1510 mGy.cm. This is expected since recent studies have established DRL values for prospective ECG studies and previous studies for retrospective ECG studies. Mafalanka et al.[9] have established DRLs for CCTA, for prospective and retrospective ECG-gating modes. For prospective studies, the DLP 75th percentile was 370 mGy.cm whereas for retrospective studies the corresponding value was 870 mGy.cm. Several other factors may also contribute to the inhomogeneity of results shown in Tables 3-7. DLP values may refer to individual sequences or to a complete examination (total DLP) and in few cases this information is not included in the DRL report. In addition, different names have been used for likely the same indication (e.g. abscess versus acute abdomen) and the question of whether these differences are related to various interpretations of the name of the clinical indication or to different practices remains open. A semantical refinement with the precise description of the clinical indication should be made in order to minimise any variation related to the meaning of the clinical indication during the survey.

For liver metastases and a few other clinical indications, DRLs in terms of CTDIvol are similar but DRLs in terms of DLP differ considerably (Table 6). The difference in values of total DLP (yet similar levels of CTDIvol) for examinations of the lower trunk between surveys could be a consequence of the present use of increased scan lengths and/or number of sequences (particularly in relation to imaging for different phases in the distribution of contrast medium). A nationwide survey has been conducted in Germany[14] to evaluate the current CT practice and the authors found that the actual scan lengths were significantly larger than the standard scan lengths for most examinations. For the same protocol, there were large differences (up to 120%). The

authors mention that 'instead of examining only 1-2 adjacent cervical and lumbar disks for the diagnosis of disk space disorders with scan lengths of about 4 cm and 6 cm, respectively, the whole portion of the corresponding vertebral column was usually scanned, resulting in mean scan lengths of about 11 cm and 15 cm, respectively'.

Of note is the DRLs established for virtual colonography. Table 7 shows that the DRLs established by the UK are 11 mGy (CTDIvol) and 950 mGy cm (DLP). Virtual colonography is used for screening of asymptomatic individuals and AAPM recommends CTDIvol values from 2 for thin patients to 9 for obese patients (https://www.aapm.org/pubs/CTProtocols/default.asp) for these studies. This means that for this examination there are still opportunities for dose optimisation.

Even if an international comparison is out of the scope of this tender, one should nevertheless mention the American College of Radiology's (ACR) approach, which was well summarised in a recent publication[18] and on its website (http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry). The DRL approach is still based on anatomical locations and not on clinical indications, and DRLs and ADs as a function of patient size were developed for the ten most common adult CT examinations performed in the United States.

Relevant issues of the ICRP report on DRLs[19] published in 2017 are briefly summarised in the following:

- It suggests modifications in the conduct of DRL surveys that take advantage of automated reporting of radiation-dose-related quantities.
- It is mentioned that methods to achieve optimisation that encompass both the DRL process and image quality evaluation should be implemented, explaining why image quality will be included in the EUCLID surveys.
- The clinical task associated with the procedure should be specified, and it may also be important to specify, in detail, both the clinical task associated with the procedure and the body region scanned. The type of data collected will require both anatomical groupings and protocol types. Protocols may also include a variety of imaging tasks. The DRL value should be tied to defined clinical and technical requirements for the selected medical imaging task.
- For CT, the optimal radiation dose varies with patient size. It is therefore necessary to ensure that the survey data reflect values for appropriate patient size ranges.

This publication shows the ICRP acceptance of the concept of DRLs based on clinical tasks (i.e. clinical DRLs).

3.1.4 List of references for CT

(1) Castellano IA, Nicol ED, Bull RK, Roobottom CA, Williams MC, Harden SP. A prospective national survey of coronary CT angiography radiation doses in the United Kingdom. J Cardiovasc Comput Tomogr [Internet]. 2017;11(4):268–73. Available from: http://dx.doi.org/10.1016/j.jcct.2017.05.002
(2) Danish Health Authority. Ct Referencedoser. Copenhagen; 2015.
(3) Foley SJ, McEntee MF, Rainford LA. Establishment of CT diagnostic reference levels in Ireland. Br J Radiol. 2012;85(1018):1390–7.
(4) Fukushima Y, Tsushima Y, Takei H, Taketomi-Takahashi A, Otake H, Endo K. Diagnostic reference level of computed tomography (CT) in Japan. Radiat Prot Dosimetry. 2012;151(1):51–7.

(5) Bundesamt für Strahlenschutz. Diagnostische Referenzwerte für diagnostische und interventionelle Röntgenanwendungen. Bundesanzeiger. AT 15.07.2016: B8.
(6) Hausleiter J. Estimated Radiation Dose Associated With Cardiac CT Angiography. JAMA [Internet]. 2009 Feb 4;301(5):500. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2009.54
(7) Japan Network for Research and Information on Medical Exposures. Diagnostic Reference Levels Based on Latest Surveys in Japan — Japan DRLs 2015. 2015.
(8) Kanal KM, Butler PF, Sengupta D, Bhargavan-Chatfield M, Coombs LP, Morin RL. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology [Internet]. 2017 Jul;284(1):120–33. Available from: http://pubs.rsna.org/doi/10.1148/radiol.2017161911
(9) Mafalanka F, Etard C, Rehel JL, Pesenti-Rossi D, Amrar-Vennier F, Baron N, et al. Establishment of diagnostic reference levels in cardiac CT in France: A need for patient dose optimisation. Radiat Prot Dosimetry. 2015;164(1–2):116–9.
(10) Palorini F, Origgi D, Granata C, Matranga D, Salerno S. Adult exposures from MDCT including multiphase studies: First Italian nationwide survey. Eur Radiol. 2014;24(2):469–83.
(11) Public Health England. National Diagnostic Reference Levels (NDRLs) [Internet]. Vol. 11. 2016. Available from: https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/national-diagnostic-reference-levels-ndrls#fnref:2
(12) Radiation and Nuclear Safety Authority. Reference levels for patient radiation exposure in computed tomography examinations of adults. Helsinki; 2013.
(13) Salama DH, Vassileva J, Mahdaly G, Shawki M, Salama A, Gilley D, et al. Establishing national diagnostic reference levels (DRLs) for computed tomography in Egypt. Phys Medica [Internet]. 2017;39:16–24. Available from: http://linkinghub.elsevier.com/retrieve/pii/S1120179717301679
(14) Schegerer AA, Nagel HD, Stamm G, Adam G, Brix G. Current CT practice in Germany: Results and implications of a nationwide survey. Eur J Radiol [Internet]. 2017 May;90:114–28. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0720048X17300669
(15) Treier R, Aroua A, Verdun FR, Samara E, Stuessi A, Trueb PR. Patient doses in CT examinations in Switzerland: implementation of national diagnostic reference levels. Radiat Prot Dosimetry [Internet]. 2010;142(2–4):244–54. Available from: http://rpd.oxfordjournals.org/content/142/2-4/244.abstract
(16) van der Molen AJ, Schilham A, Stoop P, Prokop M, Geleijns J. A national survey on radiation dose in CT in The Netherlands. Insights Imaging [Internet]. 2013 Jun 15;4(3):383–90. Available from: http://link.springer.com/10.1007/s13244-013-0253-9
(17) Wachabauer D, Röthlin F. Aktualisierung der diagnostischen Referenzwerte für Österreich. Wien; 2017.
(18) Kalpana M. Kanal, PhD, Priscilla F. Butler, MS, Debapriya Sengupta, PhD, Mythreyi Bhargavan-Chatfield, PhD, Laura P. Coombs, PhD, Richard L. Morin, PhD, 2017. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology: Volume 284: Number 1—July 2017.
(19) ICRP, 2017. Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann. ICRP 46(1).

3.2 IR DRLs based on clinical indications

3.2.1 Existing national DRL values published by competent authorities

Table 10 provides a summary of the replies by the competent authorities to the email invitation to provide available national DRL data.

Table 10: Overview of replies by competent authorities

Countries	Reply	No reply	Have DRLs	No DRLs
31	27	4	14	13

Table 11 lists all DRLs for fluoroscopic and interventional radiologic procedures provided by the competent authorities. Some countries are on the way to develop national DRLs for cardiac procedures or IR, but do not have installed them yet. Some countries are just evaluating ongoing studies to define national DRLs. Countries which are going to establish DRLs for IR in near future are indicated with °), countries which are using DRLs from other studies (which are not established national DRLs) are marked with +).

Many countries have DRLs for coronary angiography, usually without giving the number of vessels and projections. Cardiac interventions are summarised as PTCA (angioplasty of coronary arteries), and PCI (percutaneous coronary interventions) without further specifications (number of vessels/lesions; number of stents; stenosis or occlusion).

Only two countries have DRLs for TIPS (France and Switzerland), and only two countries have DRLs for Iliac Stenting (Ireland and Switzerland). For TACE and Cerebral Embolization there are DRLs in Germany, Ireland and Switzerland.

More detailed information regarding existing national DRL values is listed in the following:

- Four countries have a DRLs for PTA: Germany, Luxembourg, Poland, and Switzerland (PTA pelvis/PTA femur/PTA lower leg)
- Eleven countries have DRLs for PTCA: Austria, Cyprus, Czech Republic, Greece, Ireland, Luxembourg, Poland, Slovenia, Spain, Switzerland and UK.
- Seven countries have DRLs for PCI or PCI+CA: Bulgaria, Czech Republic, Finland, France, Germany, Sweden and Switzerland.
- Only one country has an DRL for CA only: Netherlands
- Nineteen countries have DRLs for cardiac interventions or cardiac diagnostics such as CA, PTCA or PCI only: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Finland, France, Germany, Greece, Ireland, Luxembourg, The Netherlands, Norway, Poland, Slovenia, Spain, Sweden, Switzerland and UK.
- Seven countries have DRLs for interventional radiologic procedures stated by the competent authorities: Finland, Germany, Ireland, Luxembourg, Norway (from a study, which is not a national DRL yet), Poland and Switzerland.
- Belgium has a DRL for IR, but these are not stated by the competent authorities
- Denmark, Italy, Latvia, Lithuania, Malta, Portugal, Romania and Slovakia do not have national DRLs for IR. However, some of these countries (Italy, Portugal and Romania) plan to establish DRL's for IR in the near future.

Table 11: Existing national DRLs for cardiac and interventional procedures – part 1
(some fluoroscopy times are indicated in brackets)

Country	Cerebral embolisation	PTCA		PCI		PCI + CA	CA	PTA	TAVI	Embolisation bronchial arteries	TIPS (liver)	Hepatic emoblisation
	DAP [Gy*cm2]	DAP [Gy*cm2]	FT [min]	DAP [Gy*cm2]	FT [min]	DAP [Gy*cm2]						
Austria	---	130	----	----	----	----	60	----	----	----	----	----
Belgium +)	172	188	----	----	----	----	60	----	----	----	----	----
Bulgaria °)	----	----	----	----	----	140 (8.9-18.1 min)	40 (3.8-6.5 min)	----	----	----	----	----
Cyprus (from Greece)	----	130	18	----	----	----	55 (6 min)	----	----	----	----	----
Czech Republic	----	91	----	----	----	91	49	----		----	----	----
Finland *)	----	----	----	75	15	----	30 (4 min)	----	90 (19 min)	----	----	----
France +)°)	----	----	----	80	15	----	38 (6 min)	----	----	135 (38 min)	185 (39 min)	250 (28 min)
Germany	----	----	----	48		55	28	36 (pelvis) 82 (femur) 25 (lower limb)	80	----	----	----
Greece	----	130	18	----	----	----	55 (6 min)	----	----	----	----	----

Country	Cerebral embolisation	PTCA		PCI		PCI + CA	CA	PTA	TAVI	Embolisation bronchial arteries	TIPS (liver)	Hepatic emoblisation
	DAP [Gy*cm2]	DAP [Gy*cm2]	FT [min]	DAP [Gy*cm2]	FT [min]	DAP [Gy*cm2]						
Ireland *)	62	75	----	----	----	----	----	----	----	----	----	----
Luxembourg *)	----	44	----	----	----	----	23	50	----	----	----	----
Malta	----	----	----	----	----	----	----	----	----	----	----	----
Netherlands	----	----	----	----	----	----	80	----	----	----	----	----
Norway +) °)	----	----	----	----	----	----	20.3	----	46.6	----	----	----
Poland *)	----	120	20	----	----	----	60	100 (18 min)	----	----	----	----
Slovenia		100		----	----	----	50	----	----	----	----	----
Spain +) °)	----	67	16	----	----	----	32 (6.7 min)	----	----	----	----	----
Sweden (DRLs from 2008)	----	----	----	----	----	80	---	----	----	----	----	----
Switzerland	350 (50 min)	130	26	----	----	100	50	350 (cerebral or lower limbs)	100	150 (30 min)	350 (40 min)	300 (20 min)
UK	----	40	11.3	----	----	----	31 (4.3 min)	----	----	----	----	----

*) DRLs reported by the competent authorities; +) DRLs from other publications; °) These countries plan to establish national DRLs in near future.

Table 12: Existing national DRLs for cardiac and interventional procedures – part 2
(some fluoroscopy times are indicated in brackets)

Country	Vertebroplasty	Embolisation pelvic arteries	Upper limbs embolisation	All IV lines, Hickman line	All thoracic procedures	All abdominal procedures	All pelvic procedures	All peripheral procedures	Cardiac studies
	DAP [Gy*cm^2]								
Finland	----	----	----	----	----	----	----	----	3,5 (Pacemaker installation)
Germany *)	----	36	----	----	----	----	----	----	----
Greece	----	----	----	----	----	----	----	----	35 (Pacemaker insertion)
Ireland *)	----	----	----	3	8	70	70	30	12 (Pacemaker),55 (Cardiac studies)
Switzerland *)	80 (15 min)	300 (30 min)	150 (30 min)	----	----	----	200	----	30 (Pacemaker insertion)
UK	----	----	----	3 (1.5 min)	----	----	----	----	7 (6 min) Pacemaker

*) DRLs reported by the competent authorities.

3.2.2 Literature review

Approximately 20 papers/studies were considered for the data collection of existing or new proposed DRLs related to clinical indications in interventional radiology. Only European studies were considered and non-European excluded. A comparison between these studies is quite difficult due to their inconsistency in the description of the performed procedure and the missing information of complexity levels during the intervention. Some of the papers provide KAP mean values only instead of mean, median and quartile values or interquartile ranges (i.e. 75% percentile for DRL estimation).

Due to this lack of consistent information regarding the type of procedure and the lack of specification of complexity levels, a wide range of dose and fluoroscopy time values are found in the publications.

Relevant papers are listed in section 3.2.4 and Table 13.

The use of multiple DRL quantities (P_{KA}, $K_{a,i}$, fluoroscopy time and number of acquired images) for interventional fluoroscopy is discussed in the ICRP Publication 135[7]. These quantities may help to identify the cause if the radiation is not optimised and they could simplify the investigation thereafter. Therefore, it is recommended that all available data suitable for DRL quantities should be tracked.

The complexity of the procedure affects the applied dose much more than the patient's weight or fluoroscopy time, and should thus also be part of the data collection and analysis. Ruiz-Cruces[1] classified three levels of complexity for common interventional procedures – these complexity indicators could be used as multiplicators for DRL quantities, or divided each procedure into subgroups of simple medium and complex cases. This information of the complexity level should also be a part of the data acquisition for DRL quantities.

Table 13: Relevant publications.

Caption numbers indicate publication number from chapter 3.2.4.

Procedure	existing National DRL's DAP [Gy*cm²]	existing National DRL's Fluorotime [min]	Relevant studies with 75% Percentile of DAP [Gy*cm²] or proposed DRL	Relevant studies with Mean or 75 percentile Fluoroscopy time [min] or proposed DRL	complexity indices considered
Iliac artery stenting	Germany: 36	Not found	(1)Ruiz-Cruces,R., Vano, E., et al. **84** (CI1)**, 170** (CI2)**, 348** (CI3)	(1)Ruiz-Cruces,R., Vano, E., et al. **21.4** (75%)	Yes, 3 Levels: simple, medium, complex
Abdominal embolization (TACE)	Ireland: "All abdominal procedures" **51.6**	Not found	(2) Cécile Etard, et al. **249,2** (Hepatic chemoembolization)	(2) Cécile Etard, et al. **27.1** (75%, Hepatic chemoembolization)	Yes, 3 Levels.
	Switzerland: "Hepatic embolisation" **300**	Not found	(1)Ruiz-Cruces,R., Vano, E., et al. **170, 303, 881**	(1)Ruiz-Cruces,R., Vano, E., et al. **26.3** (75%, Hepatic chemoembolization)	Yes, 3 Levels: simple, medium, complex
	Germany: 30		(3) Heilmaier et al **210** (CI1), **310** (CI3)	(3) Heilmaier et al. **19.82**(CI1, mean)**, 35.37**(CI3, mean)	Yes, 2 Levels: standard, difficult
Portal hypertension (TIPS)	Switzerland: **350**	Switzerland: **40**	(2) Cécile Etard, et al. **185.8**	(2) Cécile Etard, et al. **38.5** (75%)	No
	Ireland: **144.4**	Not found			
EVAR (endovascular aneurysm repair)	Germany: 24 (aorta thorakal) / 25 (aorta infrarenal) /28 (aorta suprarenal)	Not found	(3) Heilmaier et al. **185** (CI1) **350** (CI3)	(3) Heilmaier et al. **16.83** (CI1, mean) **46.2** (CI3, mean)	Yes, 2 Levels: Standard Abdominal, Difficult and pelvis
			(4) Tuthill, et al. **158.5**	(4) Tuthill, et al. **18.13**	No
			(5) Spink, et al. **173.3 ± 137.2** (Mean±SD with 15% of complex interventions)	(5) Spink, et al. **27.8 ± 18.4** (Mean±SD with 15% of complex interventions	No

CI = Complexity Index; CI1 = standard/simple; CI2 = medium; CI3 = difficult/complex

3.2.3 Detailed results and comments

3.2.3.1 Scientific Board

The SB provided feedback on the preliminary list of clinical indications included in the tender submission (see Table 14).

Table 14: Preliminary list of clinical indications for IR DRLs in the tender submission

1. Percutaneous Treatment of Peripheral Artery Disease (PAD)
2. Endovascular aneurysm repair (EVAR)
3. Transcatheter Arterial Embolization (TAE)
4. Transcatheter Arterial Chemoembolization (TACE)

Ten out of eleven members replied. Thereof, three members of the SB did not give any specific comments on the proposed IR clinical indications. One member specifically agreed with the EUCLID list, while seven members wanted a larger list with cardiac procedures included, or suggested to be more specific in terms of regions or organs.

Some suggestions were made:

- "…Interventional Cardiac Procedures are cruelly missing…"
- "…I suggest that in EVAR and TAE the region or organ should be specified as the dose may vary greatly according to the region…."
- "…some relevant interventional procedures are missing i.e. CA, cerebral aneurysm embolization, carotid angioplasty and stenting, Percutaneous Transluminal Coronary Angiography (PTCA), Pacemaker (PM) and/or implantable cardioverter-defibrillator (ICD) implantation…"

3.2.3.2 External Advisory Panel

Only five of ten members from the EAP provided feedback to IR related procedures. Four did not reply at all and one member did not reply to IR.

Similar to the SB, the EAP also proposed to include more than four indications for IR, especially some cardiac interventions should be included. One respondent suggested splitting a percutaneous treatment of PAD (Peripheral Artery Disease) into Peripheral Angiography (diagnostic procedure) and Peripheral Angioplasty (therapeutic procedure).

One respondent raised the question if DRLs should be separated into radiologic procedures only and procedures performed by vascular or cardiac surgeons, such as CA and EVAR (often performed by vascular surgeons).

The EuroSafe Imaging working group dedicated to paediatric imaging suggested also including paediatric procedures. However, this is out of the scope of this tender project.

3.2.3.3 General comments

One country reported DAP reference values for eleven procedures; all others reported values for between one and three procedures only. This paucity highlights the reluctance of European countries to establish DRLs in IR.

The names of the procedures are not clearly specifying "Clinical indications", but are somehow related to a clinical indication. As an example, all peripheral PTA procedures could be considered in relation with limb ischemia symptoms. However, in some procedures, like cerebral embolisation there would be a need of clarification of the clinical background.

Few multi-center studies have been published on IR DRLs (outside interventional cardiology). Vano et al.[11] collected dose data for 20 procedures for about 1300 patients in 13 European countries. Because of the limited number of patients, preliminary reference levels were proposed only for a few procedures. A retrospective study of nine interventional neuroradiology departments was published in 2011 (Kien et al.[12]). Seven diagnostic (cerebral and spinal angiography) and therapeutic (embolisation and vertebroplasty) procedures were reviewed. For each procedure, three dosimetric parameters were recorded: DAP, fluoroscopy time, and number of images. Results showed interdepartmental variations, up to four-fold for diagnostic procedures and seven-fold for therapeutic procedures. DRLs were proposed for six types of procedures. Bleeser et al.[13] established DRLs for common angiographic and interventional procedures in Belgium. DAP measurements were performed on 21 systems. DRLs were based on about 3200 procedures performed in 17 centres.

A conclusion of all the above studies is that, for the same procedure, reported DAP and fluoroscopy times show a wide range of values which is most likely caused by different complexity levels of the procedure. This is very critical and should be carefully considered in the EUCLID survey.

Ruiz-Cruces et al.[1] developed national diagnostic reference levels for IR, to propose complexity criteria for seven common therapeutic IR procedures, and evaluated their impact on patient doses. For each procedure, the authors established criteria to evaluate the complexity. As expected, the increase in complexity is associated with an increase in the mean DAP values. In a very recent French study (Etard et al.[2]), complexity was assessed for four types of procedures: cerebral angiography (according to the number of cerebral vessels examined), biliary drainage (with or without endoprosthesis insertion), lower limbs arteriography (with or without aortography, without stenting) and vertebroplasty (according to the number of vertebra treated). Dose estimators increase with the complexity of the procedure. These studies show that for IR DRLs, an assessment of the level of complexity is important. Scaling of DRLs by complexity may be useful for some procedures.

Tuthill et al.[4] established reference levels for EVAR for five European centres and proposed an interim European reference level for EVAR procedures based on data from those centres. For the same procedure (abdominal EVAR), fluoroscopy time ranges from 10 minutes to 30 minutes. Similarly, with other studies, the authors found that radiation exposure levels vary greatly between individual patient examinations, hospitals, and countries.

Few research groups have also established local DRLs for angiography and interventional neuroradiology (D'Ercole et al.[8]), abdominal interventional radiology procedures (Hadid et al.[9]l) and EVAR (Foerth et al.[10]).

Cardiac procedures are not included, because the radiology departments recruited for this tender are not doing this kind of procedures. Cardiac procedures are usually performed by cardiologists. This could be compensated by using already established DRLs by competent authorities in most European countries.

Clinical DRLs for interventional procedures should primarily be defined for procedures, which are clinically well established, contribute significantly to patient care and involve a rather high radiation exposure for the patient and operator. The reasons for choosing iliac artery stenting, EVAR, TIPS and TACE are given below:

- **Iliac artery stenting** for arterial occlusive disease (stenosis and occlusion) is one of the most frequently performed endovascular procedures. The complexity can easily be classified using the TASC-classification (see Annex 4). The iliac vessels are located in the pelvis; imaging of stenosis and occlusion frequently requires angled views and magnification. Both factors contribute to high radiation doses for the patient and the operator. Thus, DRLs are relevant for clinical practice. In contrary, endovascular treatment of occlusive lesions in the lower extremities involves a much lower dose for the patient and the operator. Thus, DRLs have a much lower priority.
- Endovascular aneurysm repair (**EVAR**) of abdominal aortic aneurysms is rather frequently performed by interventional radiologists and vascular surgeons. The complexity can be graded by the type of endograft (monoiliac; bifurcated; fenestrated; branched; chimney) and the extension of the aneurysm (aorta normal neck/short neck; aorto + 1 iliac; + both iliacs; involving the iliac bifurcation requiring embolization of the internal iliac/requiring implantation of iliac side branch). Complex anatomy requires detailed imaging (angled views/magnification) and lengthy fluoroscopy of the abdomen and pelvis. Thus, radiation exposure is high for patient and operator.
- The above is also true for **TIPS**. The complexity of the procedure can be graded according to the anatomy (patent vessels/ partial thrombosis of portal vein/diameter of target portal vein branch <10 mm/> 10 mm).
- **TACE** is the most common abdominal embolisation procedure for treatment of hepatic tumours, especially HCC. Complexity can be graded according to the number and size of tumours (for HCC the Barcelona staging system can be applied) and the anatomy of the access vessels (aberrant/accessory hepatic arteries). Patients with left sided tumours and Michels Type 2,4,5 hepatic arterial anatomy are usually more difficult to catheterise. See Annex 5 for hepatic arterial branching patterns.[2]

3.2.4 List of references for IR

(1) Ruiz-Cruces R et al. Diagnostic reference levels and complexity indices in interventional radiology: a national programme, Eur Radiol (2016) 26: 4268
(2) Etard C et al. Patient dose in interventional radiology: a multicentre study of the most frequent procedures in France, Eur Radiol (2017) 27:4281–4290

[2] This paragraph was written before elaboration of deliverable D2.2 in which the project team has selected a different list of IR procedures. However, the paragraph was kept because it highlights the complexity of IR procedures.

(3) Heilmaier C et al. Establishing Local Diagnostic Reference Levels in IR Procedures with Dose Management Software, Journal of Vascular and Interventional Radiology, Volume 28, Issue 3, March 2017, Pages 429-441
(4) Tuthill E et al. Investigation of reference levels and radiation dose associated with abdominal EVAR (endovascular aneurysm repair) procedures across several European Centres. Eur Radiol (2017). https://doi.org/10.1007/s00330-017-4791-2
(5) Spink C et al. Radiation dose reduction during transjugular intrahepatic portosystemic shunt implantation using a new imaging technology, European Journal of Radiology Volume 86, January 2017, Pages 284-288, https://doi.org/10.1016/j.ejrad.2016.11.028
(6) Guidance National Diagnostic Reference Levels (NDRLs) Published 22 January 2016, https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/national-diagnostic-reference-levels-ndrls#national-drls-for-general-radiography-and-fluoroscopy
(7) ICRP, 2017. Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann. ICRP 46(1)
(8) D'Ercole L et al. Proposed local diagnostic reference levels in angiography and interventional neuroradiology and a preliminary analysis according to the complexity of the procedures. Phys Med (2012) 28:61–70
(9) Hadid L et al. Local dose reference levels for abdominal interventional radiology procedures. (2014) Poster C-2053, ECR Congress 2014. doi:10.1594/ecr2014/C-2053
(10) Foerth M et al. Typical exposure parameters, organ doses and effective doses for endovascular aortic aneurysm repair: comparison of Monte Carlo simulations and direct measurements with an anthropomorphic phantom. Eur Radiol (2015) 25:2617–2626
(11) Vano E et al. Patient dose in interventional radiology: a European survey. Radiat Prot Dosim (2008) 129:39–45
(12) Kien N et al. Patient dose during interventional neuroradiology procedures: results from a multicenter study. J Radiol (2011) 92:1101–1112
(13) Bleeser F et al. Diagnostic reference levels in angiography and interventional radiology: a Belgian multi-centre study. Radiat Prot Dosim (2008) 129:50–55

3.3 Radiography DRLs based on clinical indications

3.3.1 Existing national DRL values published by competent authorities

Table 15 provides an overview of the replies by the European competent authorities to the email invitation to provide available national DRLs data.

Table 15: Overview of replies by competent authorities

Countries	Reply	No reply	Have DRLs	Calculation process	No DRLs
31	27	4	24	1	2

Twenty-seven of 31 countries replied (the missing four countries are Croatia, Estonia, Hungary and Iceland). Not all answers were available in English. However, they were translated with the support of the project team members and their networks.

Twenty-three countries have national DRLs in radiography: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Slovenia, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

Two countries (Cyprus and Portugal) declared they do not have DRLs, and two countries (Italy and Romania) indicated they are in process of calculating DRLs.

There is only one country (Norway) that has one clinical indication for the hip examination (fracture).

3.3.2 Literature review

An extensive literature review was done. However, to the best of our knowledge there was no paper found in the recent literature on national DRLs based on clinical indications in radiography.

Regarding radiography DRLs in general, the most comprehensive and complete report in the literature is the final report of the project Dose Datamed 2, which was published in 2014[(2)] and which is considered as still valid. Below, three tables from this report are provided.

Table 16: Basis of DRL values for adult x-ray examinations in European countries

Country	Symbol	Plain radiography	Mammography	Fluoroscopy	Interventional radiology	Computed tomography
Austria	AT	Own survey	EUREF	Own survey	Own survey	Own survey
Belgium	BE	Own survey	No DRLs	No DRLs	No DRLs	Own survey
Bulgaria	BG	Own survey & other	Own survey	Own survey	Own survey	Own survey
Croatia	HR	IAEA BSS 115	IAEA BSS 115	No DRLs	No DRLs	IAEA BSS 115
Cyprus	CY	EU RP 109	EU RP 109	No DRLs	No DRLs	No DRLs
Czech Republic	CZ	Own survey & IAEA BSS 115 & Scandinavian recommendations	EU RP 109	Scandinavian recommendations	No DRLs	EUR 16262
Denmark	DK	Own survey	Own survey	Own survey	No DRLs	Own survey
Estonia	EE	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Finland	FI	Own survey	Own survey	Own survey	Own survey	Own survey
France	FR	Own survey	Own survey	No DRLs	No DRLs	Own survey
Germany	DE	Own survey	Own survey	Own survey	Own survey	Own survey
Greece	EL	No DRLs	Own survey	No DRLs	No DRLs	No DRLs
Hungary	HU	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Iceland	IS	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Ireland	IE	Own survey	EU RP 109	Own survey	UK data	Own survey
Italy	IT	EU RP 109	EU RP 109	EU RP 109	No DRLs	No DRLs
Latvia	LV	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Lithuania	LT	Own survey	Own survey	Own survey	No DRLs	Own survey
Luxembourg	LU	Own survey	EU RP 109	Own survey & EUR 16260 & DE regulation	Own survey & DE regulation	Own survey
Frmr. Yug, Rep. Of Macedonia	MK	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Malta	MT	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Moldova	MD	IAEA BSS 115	IAEA BSS 115	No DRLs	No DRLs	IAEA BSS 115
Montenegro	ME	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Netherlands	NL	Own survey	Own survey	No DRLs	No DRLs	Own survey
Norway	NO	Own survey	Own survey	Own survey	No DRLs	Own survey
Poland	PL	Own survey	No DRLs	No DRLs	No DRLs	EUR 16262
Portugal	PT	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Romania	RO	EU RP 109	IAEA BSS 115	No DRLs	No DRLs	No DRLs
Serbia	RS	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
Slovakia	SK	Unknown	Unknown	Unknown	No DRLs	Unknown
Slovenia	SI	Own survey	No DRLs	No DRLs	No DRLs	Own survey
Spain	ES	Own survey	Own survey	Own survey	Own survey	Own survey
Sweden	SE	Own survey	Own survey	Own survey	No DRLs	Own survey
Switzerland	CH	Own survey	No DRLs	Own survey	Own survey	Own survey
Ukraine	UA	No DRLs	No DRLs	No DRLs	No DRLs	No DRLs
United Kingdom	UK	Own survey	Own survey	Own survey	Own survey	Own survey

Table 17: DRLs given in terms of ESD, mGy

For mammography, the last line with "one projection" is for MGD, mGy (note that compressed breast thicknesses may vary)

Anatomical region	Projections	Most common value	Range	Max/min	Countries with the most common DRL	Countries with higher DRL	Countries with lower DRL
Head, skull, cranium	AP or PA	5	2,5-5	2	CY, CZ, ES, IT, MD, RO, SK	-	BE, BG, CH, UK
	LAT	3	1-3	3	CY, CZ, ES, IT, MD, RO, SK	-	BE, CH, UK
Chest, thorax	PA	0,3	0,15-0,6	4	CY, ES, FR, LT, RO	BG, CZ, HR, IT, MD, SK	BE, CH, FI, UK
	LAT	1,5	0,75-2	2,7	CY, CZ, ES, HR, IT, RO,	LT, MD	BE, CH, FI, FR, UK
Thoracic spine	AP	7	3,5-7	2	CZ, HR, MD, SK	-	FR, LT, UK
	LAT	20	10-20	2	CZ, HR, MD, SK	-	FR, LT, UK
Abdomen	AP or PA	10	4,5-10	2,2	CZ, ES, IT, SK	-	BE, FI, FR, LT, UK
Lumbar spine	AP	10	5-10	2	CY, CZ, ES, FR, HR, IT, LT, MD, RO, SK	-	BE, BG, CH, DK, FI, IE, UK
	LAT	30	10-30	3	CY, CZ, ES, HR, IT, MD, SK	-	BE, BG, CH, FI, FR, LT, UK
	LSJ	40	26-40	1,5	CY, CZ, ES, IT, MD, RO	-	UK
Pelvis	AP	10	3,5-10	2,9	CY, CZ, ES, IT, MD, RO, SK	-	BE, BG, CH, FI, FR, LT, UK
Mammography	CC, MLO or LAT	10	7-12	1,7	CY, DK, ES, FI, IT, LU, RO	BG	EL, FR
	One projection	3	1,3-4; (CZ: 1,3-7,3)	3,1	HR, MD, NO, SK	IE, SE, UK	AT, CZ, DE, FR, LT, NL

Table 18: DRLs given in terms of DAP, mGy cm2

Anatomical region	Projections	Most common value	Range	Max/min	Countries with the most common DRL	Countries with higher DRL	Countries with lower DRL
Head, skull, cranium	AP or PA	650	600-1000	1,7	CH, DE, LU	AT, PL	BE, SI
	LAT	600	500-1000	2	BE, DE, LU, SI	AT, PL	CH
Dental	Panoramic	120	120-200	1,7	FI	FR	-
Chest, thorax	PA	160	120-1000	8,3	DE, IE, LU	AT, BE, BG, CZ, FR, PL	CH, SI, UK
	LAT	600	250-1000	4	CH, LU	AT, CZ, FR, PL	BE, DE, SI
Thoracic spine	AP	1300	970-2200	2,3	DE, LU, SI	FR, PL	IE
	LAT	1700	1200-3200	2,7	DE, LU	FR, IE, NO, PL	SI
Abdomen	AP or PA	3000	2000-8000	4	AT, FI, DE, LU, NL, UK	BE, CZ, FR, NO, PL	IE, SI
Lumbar spine	AP	2300	1500-10000	6,7	DE	BE, BG,CH, CZ, FR, LU, PL	IE, SI, UK
	LAT	4200	2750-8000	2,9	DE, CH	BE, FR, PL	AT, IE, SI, UK
	LSJ	3000	2400-3000	1,3	SI, UK	-	IE
Pelvis	AP	3000	1500-7000	4,7	AT, DE, FI, UK	BE, BG, CZ, FR, LU, PL, SE	CH, DK, IE, NO, SI

More recent papers on national DRLs than this report are limited.

Vodovatov et al.[3] did a survey during the years 2009-2014, to collect adult patient data and parameters of most common radiographic examinations in six Russian regions. 75%-percentiles of typical patient effective dose distributions were proposed as preliminary regional diagnostic reference levels (DRLs) for radiography. They proposed to establish Russian national DRLs in terms of effective dose.

Brink and Miller[1] reported in their editorial in Radiology in 2015 that the United States have no similar requirement and that they have lagged behind Europe in obtaining robust survey data on which to base DRLs. However, recent federal and state recommendations support the use of DRLs and the authors feel more confident that the USA is moving to the right direction.

3.3.3 Detailed results and comments

3.3.3.1 Competent authorities

The only clinical indication considered by the competent authorities (Norway) is fracture.

3.3.3.2 External Advisory Panel

Only six of ten members of the EAP provided feedback on the clinical indications. Four did not reply at all. ICRP did not respond on plain radiography. The feedback provided from other members is provided below:

- EFOMP: Pelvis/hip
- EFRS: Agree that indication based DRLs are not as essential for plain radiography procedures as typically exposure settings do not commonly vary for differing indications - rather mostly based on patient size.
- CIRSE: Abdominal
- IAEA: Pelvis/Hip/PA chest instead of AP chest
- EuroSafe Imaging: PA chest instead of AP chest

3.3.3.3 Scientific Board

Ten out of eleven members of the SB replied. One country (Austria) did not provide a reply for radiography. The other countries provided comments that are summarised below:

- Belgium: One or a few radiographs
- Finland: Include also abdominal, PA chest instead of APM
- France: Concerns regarding the knee
- Germany: Lumbar spine
- Greece: Agreement
- Hungary: Lumbar spine, cervical spine, wrist
- Italy: Abdomen, pelvis, concerns for the knee
- The Netherlands: Agreement
- Switzerland: Concerns regarding the knee

3.3.4 Conclusions

The most comprehensive report on national DRLs is the DDDM2 document. The report provides comprehensive information report from 36 European countries, which were based on national surveys carried out between 2007 and 2010. According to the report of the countries, DRLs were established using the 75th percentile and were set at levels that are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. To our knowledge, there is no other more detailed or recent data published on national DRLs.

The investigation on clinical DRLs in plain radiography revealed that:

1. Only one competent authority has considered clinical indication.
2. One of the two External Advisory Panel members who provided feedback questioned the use of clinical DRLs in plain radiography.
3. There was no clear consensus from the Scientific Board on the proposed list of clinical indications.

For all the above reasons, the project team finally decided not to include plain radiography in the survey and to consider Dose Datamed 2[(2)] as a still valid reference.

3.3.5 List of references for radiography

(1) Brink JA, Miller DL. U.S. National Diagnostic Reference Levels: Closing the Gap. Radiology. 2015 Oct;277(1):3-6. doi: 10.1148/radiol.2015150971. Epub 2015 Jun 24
(2) Dose Datamed 2, 2014. Medical Radiation Exposure of the European Population (Part 1/2), and Diagnostic Reference Levels in Thirty-six European Countries (Part 2/2). Published in the European Commission Radiation Protection series publications, N° 180.
(3) Vodovatov AV, Balonov MI, Golikov VY, Shatsky IG, Chipiga LA, Bernhardsson C. Proposals for the establishment of national diagnostic reference levels for radiography for adult patients based on regional dose surveys in Russian Federation. Radiat Prot Dosimetry. 2017 Apr 1;173(1-3):223-232. doi: 10.1093/rpd/ncw341.

Annexes

Annex 1: Email to competent authorities

[Text removed in public version]

Annex 2: Contact list of competent authorities

[Text removed in public version]

Annex 3: Replies from the competent authorities

[Text removed in public version]

Annex 4: TASC classification

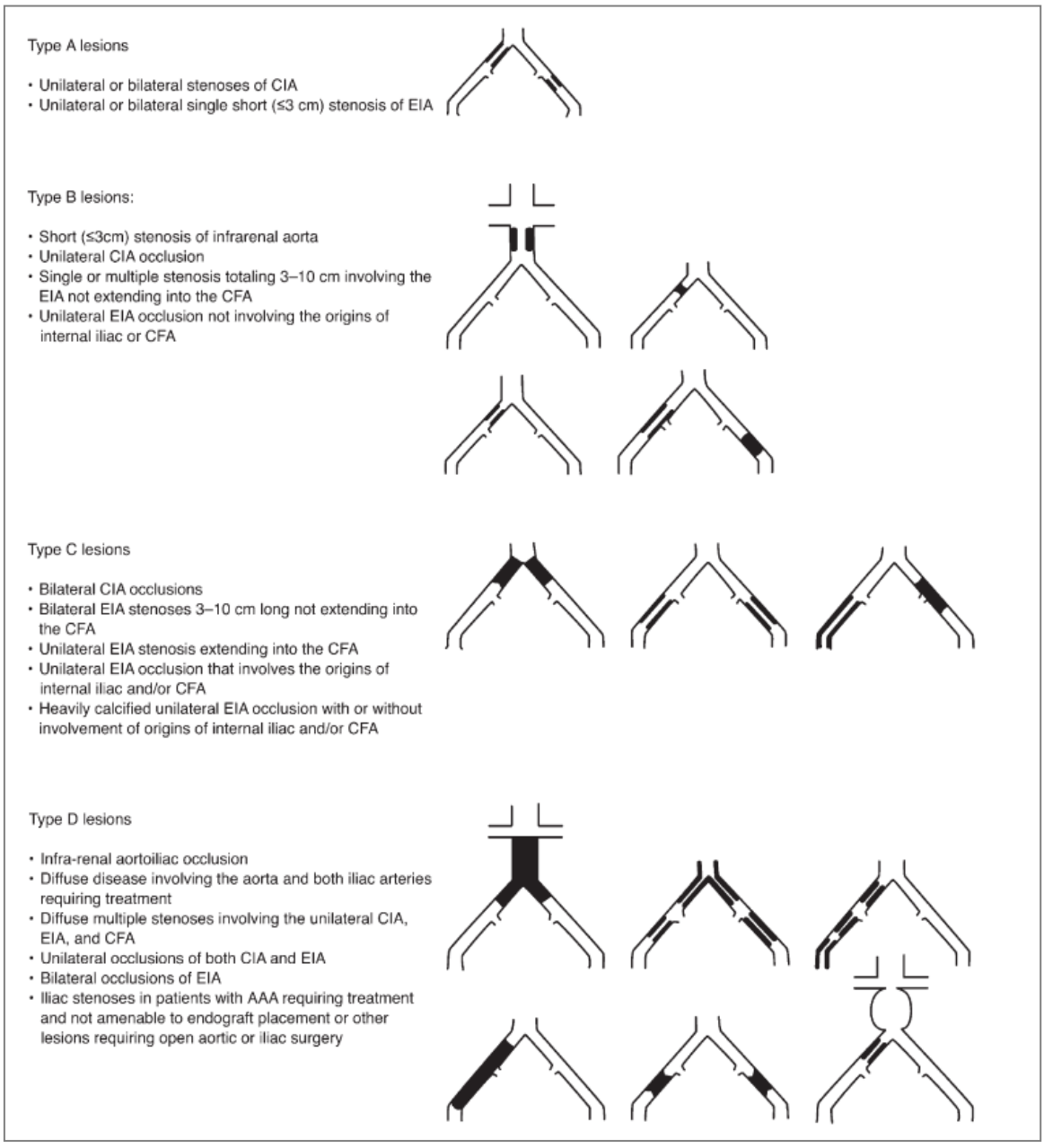
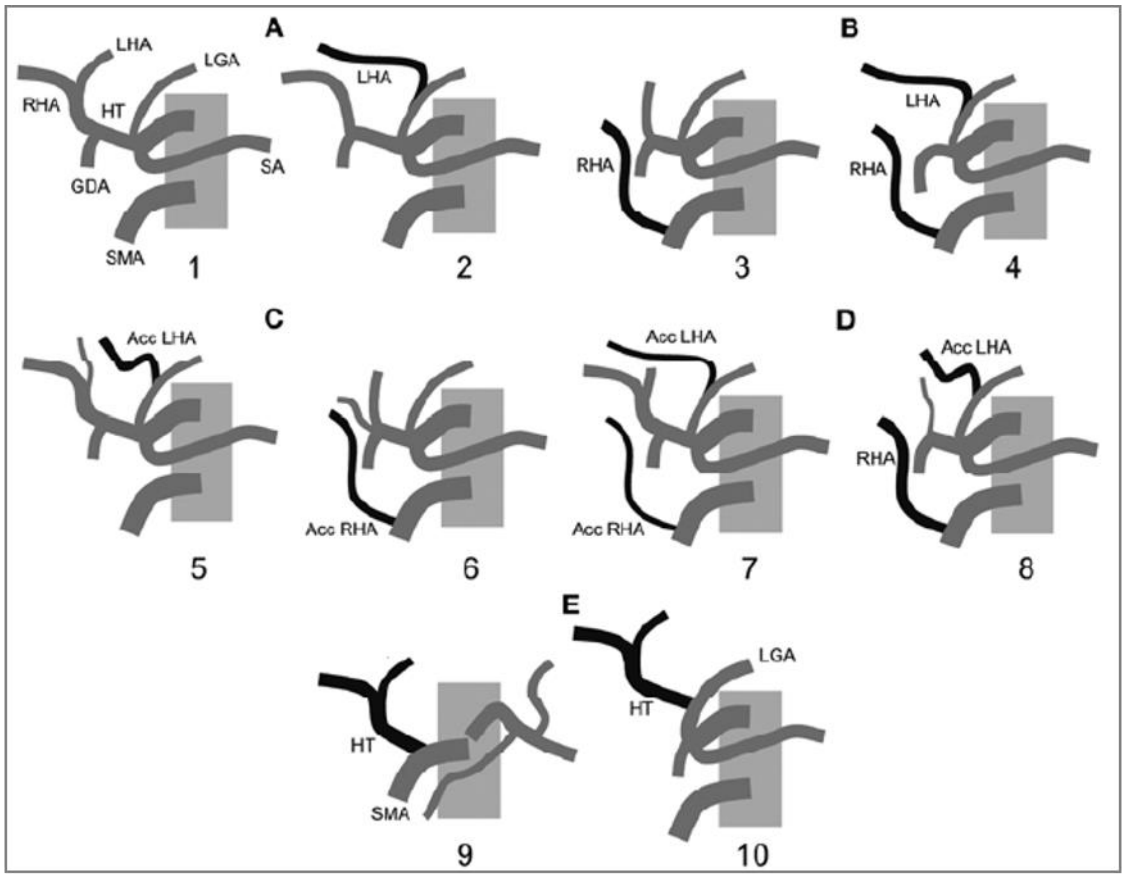


Figure 1: TASC classification[3]

[3] L. Norgren, W.R. Hiatt, J.A. Dormandy, M.R. Nehler, K.A. Harris, and F.G.R. Fowkes on behalf of the TASC II Working Group, 2017. Inter-Society Consensus for the Management of PAD. Volume 45, Issue 1, Supplement, Pages A1–A4, S1–S68 (J Vasc Surgery January 2007).

Annex 5: Hepatic arterial branching patterns



Hepatic arterial branching patterns can be divided into 10 types. Aberrant vessels are indicated in black. LHA = left hepatic artery, RHA = right hepatic artery, LGA = left gastric artery, HT = hepatic trunk, SMA = superior mesenteric artery, Acc = accessory, GDA = gastroduodenal artery, SA = splenic artery. (Adapted with permission from [14]) A, Diagram shows type 1, conventional branching, and type 2, replaced LHA arising from LGA. B, Diagram shows type 3, replaced RHA arising from SMA, and type 4, both replaced LHA and RHA. C, Diagram shows type 5, accessory LHA, and type 6, accessory RHA. D, Diagram shows type 7, accessory RHA and accessory LHA, and type 8, replaced RHA and accessory LHA or replaced LHA and accessory RHA. E, Diagram show type 9, entire HT arising from SMA, and type 10, entire HT arising from LGA.

Figure 2: Hepatic arterial branching patterns[4]

[4] D.B. Macdonald, M.A. Haider, K. Khalili, T.K. Kim, M. O'Malley, P.D. Greig, D.R. Grant, G. Lockwood, M.S. Cattral, 2005. Relationship Between Vascular and Biliary Anatomy in Living Liver Donors. AJR Am J Roentgenol. 2005 Jul;185(1):247-52.