

# **Commission for the Protection From Ionising and Non-Ionising Radiation**

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## **Guidance on the use of Diagnostic Reference Levels for Medical Exposures**

The Commission for the Protection from Ionising and Non-ionising Radiation (Commission) has coordinated the development of these guidelines with other stakeholders.

The Commission in particular acknowledges the support of the Medical Physics Staff at Mater Dei Hospital in supplying data for the National Diagnostic Reference Levels.

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# **1. Introduction**

Monitoring patient dose is a key requirement towards optimisation.

Optimisation of the radiation dose to the patient is a continual process to avoid any unnecessary radiation that does not contribute to the clinical purpose of medical imaging. Referrers, practitioners, persons performing the practical aspects, Medical Physics Experts (MPE)s all have a responsibility in the process of optimisation.

The establishment and periodic review of diagnostic reference levels (DRL) is an essential component of this optimisation process. The analysis of DRL values over time can be useful in identifying dose trends which in turn can be used in the process of optimisation.

DRLs are levels used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the activity of radiopharmaceuticals administered in a specified radiological procedure is unusually high or unusually low for that procedure.

A DRL is a level set for a standard procedure for groups of "standard-sized patients" and not for individual exposures.

All individuals who carry out medical radiological procedures should be familiar with the important role of DRLs in optimisation.

The radiation metric used as a DRL quantity should be easily measured or available and whenever possible, DRLs are to be based on clinical tasks.

DRLs are not individual dose limits for patients or procedures. DRLs should be used as a supplement to professional judgement to aid in the optimisation of medical exposures to ionising radiation.

A focus on DRL quantities alone, without considering image quality could drive the value of the DRL ever downwards to the detriment of image quality. Patient doses must not be reduced such that the images become non-diagnostic.

The contribution of different X-ray examinations to the total collective dose is given in Annex 4.

# 2. National and Facility DRLs

The Basic Safety Standards for Ionising Radiation Regulations<sup>1</sup> (BSS regulations) require the establishment and use of DRLs. The national DRLs are set for common procedures and clinical tasks, allowing undertakings to compare their own Facility DRLs.

Undertakings must ensure that Facility DRLs are established, regularly reviewed and used, taking corrective action where necessary.

<sup>&</sup>lt;sup>1</sup>S.L.585.01. <u>https://legislation.mt/eli/sl/585.1/eng</u>

If Facility DRLs exceed or are substantially lower than National DRL values, an investigation must be conducted by the undertaking to ensure optimal practices and intended outcomes are delivered.

Both National and Facility DRLs are to be reviewed when new technologies are introduced or a medical radiological procedure is changed to ensure that there is adequate optimisation of medical radiological procedures to protect patients.

The National DRLs for Malta are given in Section 6 of this guidance document. Each undertaking should develop their own Facility DRLs and compare the latter with National DRLs. Refer to Section 4 - details on the establishment of Facility DRLs.

National DRLs given in section 6 are set as the median of the dose distributions at the major public hospital in Malta which are considered as Achievable Doses. Facility median values should be compared to the public hospital median. Values higher than the 75% percentile of the public hospital values should trigger an investigation unless there are extenuation circumstances e.g., "patient overly obese"

#### **3. Reviewing of National DRL**

It is recognised that National DRL values will need to be updated frequently to take into account new technologies, procedures and equipment and therefore shall be reviewed at least once every three (3) years.

The Initial DRL values are based on mainly on data provided by the public hospital, the rationale being that the latter has:

- access to raw data;
- access to very large sample sizes; and
- is using various imaging techniques.

The DRL review process will create an opportunity to identify and address any gaps in current DRL data available.

The Commission shall coordinate with the various stakeholders and seek to update the DRL values from data from both the public and private sector as required.

#### 4. Establishing and use of Facility DRLs

#### **4.1. Establishing Facility DRLs**

All undertakings have a requirement under the BSS regulations to establish their own DRLs (Facility DRLs).

It is recommended that undertakings make use of dose monitoring platforms for recording data.

Facility DRLs should be set for representative examinations or procedures performed.

The ultimate responsibility for the establishment and review of Facility DRLs is the responsibility of the undertaking. The undertaking needs to consult with a (MPE) who

depending on the practise shall take the responsibility for DRL as well as contributing to the following:

- Selection of procedures can be made in terms of anatomical region or clinical indication priority to be given to high-dose procedures and the procedures performed most often. Exposure to radiosensitive organs should also be considered.
- Selection of DRL quantity (for example, dose length product (DLP) in Computed Tomography (CT)).
- Identify sample size, including patient weight, in the case of a limited number of examinations these would need to be selected from a specified weight range, this being less important when large sample sizes are collected.
- Advising on paediatric DRLs.
- Establish a median dose for each dose quantity for each procedure or clinical task (A **median value** should be used when setting an individual undertaking's facility DRLs).
- Reviewing the facility DRLs results against national DRLs and take corrective actions as necessary.
- The frequency that Facility DRLs should be reviewed.

In establishing Facility DRLs it is important that practitioners and persons performing the practical aspects are consulted.

#### 4.2. Use of Facility DRLs

The BSS regulations require that undertakings use DRLs. References to DRLs in the BSS regulations are given in Section 7.1 of this document.

As part of the undertaking's radiation protection programme, an undertaking must ensure that practitioners and individuals that conduct medical exposures are informed of the role of DRLs as advised upon by the MPE.

DRLs do not replace professional judgement in connection with individual medical exposures but rather aid in the optimisation of medical exposures.

The first step in using Facility DRLs is for individual room median values to be compared with the National DRL value. If a DRL does not exist for a particular procedure or clinical task, similar internationally established DRL values or peer reviewed literature can be consulted.

When a DRL value is identified as being consistently exceeded, an investigation of equipment and practices must be conducted immediately to ensure optimisation of safety and protection of patients. When the investigation determines the reason that the DRL is consistently exceeded, corrective actions must be taken without undue delay.

# 5. Establishing Specific Facility DRLs

## 5.1. Aspects to be considered when setting up Facility DRLs

Only data for procedures where the image quality was confirmed as adequate for the clinical purpose should be recorded.

For each data set the median, sample size n and the inter quartile range is to be recorded.

## **5.2. Planar Radiography**

#### Priority

Priority should be given to the following body regions and views. For examinations involving more than one view, a separate entry for the total for that examination could also be included.

- Cervical spine: AP, LAT
- Thoracic spine: AP, LAT
- Lumbar spine: AP, LAT
- Skull: AP or PA and LAT
- Chest: PA, LAT
- Chest: AP (useful especially in portable settings)
- Abdomen: AP or PA
- Pelvis: AP
- Hip: AP

#### Patient selection

A sample size *n* of at least 20 patients with weight restriction of 72.5kg +/-10 kg.

For very large studies there is no need to record patient weights as the outlying patient weights will cancel each other out.

#### Data to be recorded

Minimum:

- Procedure type (including clinical indication)
- Equipment
- Date
- Age
- Gender
- Number and type (e.g. PA/AP/Lat) of radiographic projection
- P<sub>KA</sub> per projection
- Weight (Not required for very large surveys)

It is advisable to distinguish between procedures performed within fixed and mobile units.

# DRL Metric

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Air kerma-area product: P_{KA} (Gy.cm<sup>2</sup>)
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# 5.3. Mammography

Applicable to all mammography including screening.

DRL should be evaluated for Cranio-Caudal (CC), Medio-Lateral Oblique (MLO), and Lateral (Lat) views for both left and right breast.

It is recommended that data is also collected from tomosynthesis procedures in order that National DRLs for tomosynthesis can be established.

#### Patient selection

At least 50 patients with possible restriction of the range of compressed breast thickness (50mm  $\pm$  10mm).

#### Data to be recorded

Minimum:

- Procedure type (including clinical indication)
- Equipment
- Date
- Age
- Gender
- Number and type of view (e.g. CC/MLO) of radiographic projection
- Mean Glandular dose per projection
- Compressed breast thickness

DRL Metric

Mean glandular dose  $D_G \mathbf{mGy}$ 

# 5.4. Fluoroscopic Examinations, Interventional and Cardiac

To be given to the more frequent and high dose procedures:

#### Cardiology:

- Coronary angiography (CA)
- Percutaneous coronary intervention (PCI)
- Combined CA and PCI
- Implantable cardioverter defibrillator (ICD), subdivided by channels (typically 1 to 3 channels)
- Pacemakers, subdivided by channels (typically 1 to 3 channels)
- Transcatheter aortic valve implantation (TAVI)

#### Interventional radiology:

- Centre lines
- Embolisation (typically pelvic arteries and bronchial arteries)

- Hepatic embolisation
- Mechanical thrombectomy
- Nephrostomy (single and double)
- Peripherally inserted central catheter (PICC) lines
- Percutaneous transluminal angioplasty (PTA)
- Percutaneous transhepatic cholangiography (PTC)
- Transjugular intrahepatic portosystemic shunt (TIPS)

#### DRL Metric

Air kerma-area product: cKAP (Gy.cm<sup>2</sup>) and total fluoroscopy (screening) time

#### Patient selection

At least 30 patients with weight restriction of 72.5kg +/- 10kg Less restrictive if large number of patients.

#### Data to be recorded

Minimum:

- Procedure type (including clinical indication)
- Equipment
- Date
- Age
- Gender
- Total number of series/images
- Total fluoroscopy time
- Air kerma-area product:  $P_{KA}$  (Gy.cm<sup>2</sup>), screening (for bi-plane systems, this is usually the sum of PKA for frontal and lateral tubes.)
- Weight (for limited number of patients)

# **5.5.** Computed Tomography

#### Priority

More frequent and high dose procedures, however should ensure to include if performed:

- Head
- Cervical
- Chest
- Abdomen
- Abdomen and pelvis
- Chest, abdomen and pelvis

The individual DRL should be provided according to clinical indication and organised under the above body regions.

DRL Metric DLP

#### Patient selection

At least 30 patients with weight restriction of 72.5kg +/- 10kg Less restrictive if large number of patients.

#### Data to be recorded

Minimum:

- Procedure type (including clinical indication)
- Equipment
- Date
- Age
- Gender
- DLP
- Weight (for limited number of patients)

## 5.6. Diagnostic nuclear medicine

As opposed to using the term DRL the term optimal activity can be used.

<u>Priority</u> More frequent and high dose procedures

DRL Metric MBq or MBq Kg<sup>-1</sup>

Patient selection At least 30 patients

#### Data to be recorded

Minimum:

- Procedure type (including clinical indication)
- Equipment
- Date
- Age
- Gender
- Radionuclide/Radiopharmaceutical
- Administered activity
- Patient weight (if procedure uses metric MBq Kg<sup>-1</sup>)

## **5.7. Dental examinations**

Measurements made without patients

Examination parameters

Procedure (intra oral, panoramic, cephalometric, CBCT) Clinical indication targeted for the examination Patient type (adult child) For CBCT the field of view

## **5.8.** Paediatric

The DRL values in Radiation Protection No. 185 European Guidelines on Diagnostic Reference Levels for Paediatric Imaging<sup>2</sup> will be referred to in this guidance.

#### **5.8.1.** Paediatric radiograpy and fluoroscopy

Radiograpy:

Head	AP/PA, Lat
Thorax	AP/PA
Abdomen	AP
Pelvis	AP

Flouroscopy:

Micturating cystourethrography

Paediatric computed tomography

Head Thorax Chest Abdomen

#### 5.8.2. Paediatric interventional procedures

No DRL data available, undertakings to record their values taking into account 7.2.3 of Radiation Protection No. 185 European Guidelines on Diagnostic Reference Levels for Paediatric Imaging.

<sup>&</sup>lt;sup>2</sup> <u>https://op.europa.eu/en/publication-detail/-/publication/6e473ff5-bd4b-11e8-99ee-01aa75ed71a1/language-en</u>

# 6. National DRL values

# 6.1. Planar Radiography

Na	ational DI	RLs	National	National DRL based on the below data from Mater Hospital			ater Dei
for Planar Radiography				KAP (Gy.cm <sup>2</sup> )			
					Quartiles (%)		
	KAP	(Gy.cm <sup>2</sup> )					
Projection	Achievable	Investigation	Samples	25	50	75	IQR
Abdomen AP	0.96	1.8	11 330	0.53	0.96	1.76	1.22
Abdomen PA	1.51	3.0	287	0.81	1.51	2.96	2.15
C Spine AP	0.12	0.18	11 592	0.08	0.12	0.18	0.11
C Spine LAT	0.08	0.13	3 351	0.05	0.08	0.13	0.09
Chest LAT	0.40	0.80	599	0.17	0.40	0.80	0.62
Chest PA	0.10	0.15	151 308	0.07	0.10	0.15	0.07
Hip AP	1.39	2.5	3 527	0.69	1.39	2.52	1.84
L Spine AP	1.92	3.8	24 083	0.93	1.92	3.75	2.82
L Spine LAT	1.66	2.9	9 443	0.93	1.66	2.92	1.99
Pelvis AP	1.20	2.4	8 325	0.60	1.20	2.35	1.75
Skull AP	0.43	0.62	204	0.30	0.43	0.62	0.32
Skull LAT	0.36	0.47	175	0.21	0.36	0.47	0.25
Skull PA	0.56	0.67	193	0.26	0.56	0.67	0.41
T Spine AP	0.53	0.99	2 094	0.30	0.53	0.99	0.69
T Spine LAT	0.82	1.6	1 129	0.40	0.82	1.61	1.21

Planar radiography projections. C- L- T- spine = Cervical- Lumbar- Thoracic-spine.

# 6.2. Mammography

National DRLs for Mammography							
	Glandular Dose (mGy)						
Projection	Achievable	Investigation					
Cranio-caudal	1.09	1.46					
Medio-lateral oblique	1.22	1.80					

National DRL based on the below data from MaterDei Hospital							
Glandular Dose (mGy)							
	Quartiles (%)						
Sample s	75	IQR					
51 844	0.91	1.09	1.46	0.55			
51 820	0.99	1.22	1.80	0.81			

# **6.3. Diagnostic Fluoroscopy**

Diagnostic Fluoroscopy National DRLs			National DR		n the below Hospital uartiles (%		n Mater De
			Samples	25	50	75	IQR
	cKAP	(Gy.cm <sup>2</sup> )					
Procedure	Procedure Achievable Investigation			cKAI	P (Gy.cm	<sup>2</sup> )	
Barium swallow	3.81	6.24	735	2.05	3.81	6.24	4.19
Video fluoroscopy	y 0.64 1.22		54	0.39	0.64	1.22	0.83
	Fluoroscop	y time (min)		Fluore	scopy ti	me	
	Achievable	Investigation		Fluoroscopy time (min)			
Barium swallow	1.0	1.5	735	0.7	1.0	1.5	0.8
Video fluoroscopy	1.2	2.2	54	0.9	1.2	2.2	1.3

# **6.4. General Interventional**

	DRL for ( cerventiona		National DRL based on: Establishing Local And National Diagnostic And Interventional Cardiology And Radiology Reference Levels In A Small European State: The Case Of Malta Radiation Protection Dosimetry (2020), Vol. 191, No. 3, pp. 261–271, Eric Pace et al				
		KAP			(Gy.	cm <sup>2</sup> )	
		y.cm <sup>2</sup> )					
Procedure	Achievable	Investigation		Count	Median	(75 percentile)	
Centre lines	0.3	0.9		269	0.3	0.9	
Embolisation	15.1	58		297	15.1	57.9	
Hepatic embolisation	51.4	96		215	51.4	95.6	
Mechanical thrombectomy	76	120		122	76	120.2	
Nephrostomy single	0.7	2		148	0.7	1.9	
Nephrostomy double				26	1.0	2.0	
PICC lines	0.08	0.03		135	0.08	0.26	
РТА	2.0	5		762	2.0	4.6	
PTC	4.7	8		238	4.7	8.2	
TIPS				9	54.2	111.9	

General interventional procedures: PICC = Peripherally inserted central catheter ;, PTA= Percutaneous transluminal angioplasty; PTC= Percutaneous transhepatic cholangiography; TIPS= Transjugular intrahepatic portosystemic shunt

# **6.5. Interventional cardiology**

National DRL cai	ventional	National DRL based on: Establishing Local And National Diagnostic And Interventional Cardiology And Radiology Referenc Levels In A Small European State: The Case Of Mal Radiation Protection Dosimetry (2020), Vol. 191, No. pp. 261–271, Eric Pace et al			
Procedure	cŀ	KAP		(	Gy.cm <sup>2</sup> )
	(Gy	v.cm <sup>2</sup> )		Median	75 percentile
	Achievable	Investigation	Count		
CA	20.5	31.5	578	20.5	31.5
PCI			53	53.9	105
Combined CA and PCI	68.4	126	165	68.4	126
ICD, 2 channels			20	1.9	2.9
ICD, 3 channels			29	19.3	36.8
Pacemakers, 1 channel			42	2	3.4
Pacemakers, 2 channels	3.5	6.7	134	3.5	6.7
TAVI			25	85.9	101

General interventional procedures:.CA= Coronary angiography; PCI= Percutaneous coronary intervention; ICD= Implantable cardioverter defibrillator; TAVI= Transcatheter aortic valve implantation

# 6.6. Computed Tomography

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National DRL for Computed Tomography							
	DLP (mGy.cm)						
Procedure	Achievable	Investigation					
Abdomen	495	701					
Abdomen and Pelvis	483	672					
Abdominal Aorta CTA	695	1390					
Brain	600	740					
Brain and Facial Bones	864	952					
Coronary Calcium Score CTA	207	285					
HRCT thorax	176	241					
IVU	604	706					
Kidneys	1320	1790					
KUB	185	237					
Liver	1600	2160					
Neck and Trunk	762	1110					
Pancreas	1350	1640					
Pneumonia	189	224					
Pulmonary CTA	197	269					
Sinuses	120	132					
Stroke Investigation	1704	1740					
Thorax	340	519					
Thorax Abdo and pelvis	643	884					
Virtual Colonoscopy	840	1280					

National I	National DRL based on the below data from Mater Dei Hospital							
	DLP (mGy.cm)							
	)							
Samples	25	50	75	IQR				
3 552	314.31	495.03	701.12	386.81				
16 712	306.05	482.72	671.58	365.52				
873	373.78	694.60	1387.93	1014.15				
42 725	508.61	599.59	739.87	231.26				
2 303	751.59	864.40	952.43	200.85				
1 123	149.28	206.93	284.73	135.45				
1 956	117.19	176.30	241.21	124.02				
3 900	418.11	603.94	705.91	287.80				
1 286	925.93	1321.05	1786.24	860.31				
14 048	128.71	184.97	237.42	108.71				
1 292	1169.81	1595.01	2158.84	989.03				
1 822	540.40	761.79	1111.65	571.25				
1 155	940.53	1350.85	1636.92	696.39				
2 975	143.71	188.90	223.85	80.14				
8 226	165.41	196.50	269.12	103.71				
1 316	108.99	120.48	132.55	23.56				
941	1237.24	1703.67	1736.24	499.00				
8 682	164.83	340.03	519.00	354.17				
17 254	466.99	642.66	883.65	416.66				
3 641	550.09	840.15	1284.35	734.26				

CT procedures. CTA = CT Angiography, IVU = Intravenous Urogram, KUB = Kidneys Ureters Bladders, HRCT = High Resolution CT.

# 6.7. Nuclear medicine

National DRLs for Nuclear Medicine						
National DRL based on the	below data from	the Nuclear Medicine De	partment at Mater Dei Hospital in August 2021			
			DRL (Optimal Value) Administered activity or activity per			
Examination	Radionuclide	Radiopharmaceutical	body weight (MBq or MBq.kg <sup>-1</sup> )			
Bone Scan (whole body)	TC-99m	MDP/HMDP	700			
Bone Scan (Three Phase)	TC-99m	MDP/HMDP	200			
Myocardial Perfusion (2-day protocol)	TC-99m	MIBI	400 (stress) 500 (rest)			
Myocardial Perfusion	10-9911		200 (stress)			
(1 day protocol)	TC-99m	MIBI	600 (rest)			
Cardiac Amyloid	TC-99m	РҮР	700			
Renogram (Dynamic)	TC-99m	DTPA	200 (Use PAC for paeds)			
itenogram (Dynamic)	TC-99m	MAG3	70 (Use PAC for paeds)			
Renal Cortex Imaging	TC-99m	DMSA	150 (Use PAC for paeds)			
Lung Ventilation	TC-99m	DTPA	700 (Ventilation Technegas)			
Lung Perfusion	TC-99m	MAA	100			
Lung Clearance	TC-99m	DTPA	1500 (Ventilation Technegas)			
Thyroid Imaging	TC-99m	Pertechnetate	200			
Lymphoscintigraphy	TC-99m	Nanocolloid	37 per injection site ,37 sentinel node imaging, 37 per injection site (sentinel node melanoma)			
Gastric Emptying	TC-99m	Sulphur Colloid	80			
Gastrointestinal Bleed	TC-99m	Sulphur Colloid	600			
Hepatobiliary*	TC-99m	HIDA	150			
Hepatic Haemangioma	TC-99m	Stanous				
Parathyroid	TC-99m	Pertechnetate	50			
Parathyroid	TC-99m	Sestamibi	350			
Thyroid	TC-99m	Na Pertechnetate	200			
Inyloid	I-131	Capsule	185 (post thyroid cancer ablation)			
Meckel's Diverticulum	TC-99m	Na Pertechnetate	370 (Use PAC for paeds)			
MUGA	TC-99m	Stannous	570			
Parathyroid	TC-99m	MIBI	400			
	TC-99m	Na Pertechnetate	50			
Salivary Gland	TC-99m	Na Pertechnetate	150			
MUGA	TC-99m	Stannous	600			
Prostate cancer	Ga-68	PSMA	2/Kg up to Max 200			
PET– Whole body	F-18	FDG	230			
PET– Brain	F-18	FDG	100			
Neuroendocrine Tumours	I-123 Ga-68	MIBG Dotatate	150 (Use PAC for paeds) 2/Kg up to Max 200			
	Ua-00	Dotatale	2/ Kg up to Max 200			

DRLs are determined after an audit on adult patients weighing  $70 \pm 15$  kg

DRL values are the optimised activity to a "standard-sized patient" with tolerance of +/-10%.

For paediatric patients, or adults under 70 kg, use the Paediatric Activity Calculator (PAC)

## 6.8. Dental

National DRL for dentistry	y	
Taken from Current DRL values from UK and Ireland		
Modality	Incident air	DAP
	kema	
	(mGy)	mGycm <sup>2</sup>
Adult Intra oral mandibula	1.2	
Panoramic adult full jaw		81
Cephalometric adult lateral		35
CBCT adult prior to placement of a maxillary molar implant		265

# 6.9. Paediatric

National DRL Paediatric Radiography and fluoroscopy					
taken from :- European Guidelines on Diagnostic reference levels for Paediatric Imaging,					
Radiation Protection 185					
Examination	Age or weight group	Air kerma-area product ( <b>P</b> KA)			
		mGycm <sup>2</sup>			
Head AP/PA	3 months to 1 year	215			
	1 to 6 years	295			
	More than 6 years	350			
Head LAT	3 months to 1 year	200			
	1 to 6 years	250			
Thorax AP/PA **	Less than 5kg	15			
	5kg to 15kg	22			
	15kg to 30kg	50			
	30kg to50kg	70			
	50kg to 80kg	87			
Abdomen AP	Less than 5kg	45			
	5kg to 15kg	150			
	15kg to 30kg	250			
	30kg 50kg	475			
	50kg to 80kg	700			
Pelvis AP	15kg to 30kg	180			
	30kg to 50kg	310			
MCU	Less than 5kg	300			
	5kg to 15kg	700			
	15kg to 30kg	800			
	30kg to 50kg	750 *			

\* Based on 4 national DRLs

\*\* AP/PA DRL applies to both AP and PA projections

National Paediatric DRLs for Computed Tomography						
taken from :- European Guidelines on Diagnostic reference levels for Paediatric Imaging,						
Radiation Protection 185						
Examination	Age or Weight	CTDIvol	DLP			
	Group	mGy	mGy.cm			
Head	Up to 3 months	24	300			
	3months to 1year	28	385			
	1 to 6 years	40	505			
	More than 6years	50	650			
Thorax	Less than 5kg	1.4	35			
	5kg to 15kg	1.8	50			
	15kg to 30kg	2.7	70			
	30kg to50kg	3.7	115			
	50kg to 80kg	5.4	200			
Abdomen	Less than 5kg	-	45			
	5kg to 15kg	3.5	120			
	15kg to 30kg	5.4	150			
	30kg to50kg	7.3	210			
	50kg to 80kg	13	480			

## 7. Annexes

#### 7.1. Annex 1 - References to DRLs in the Regulations

#### 7.1.1. Definition of DRL

The definition of an DRL is given in Regulation 4 as:

""diagnostic reference levels" means dose levels in medical radiodiagnostic or interventional radiology 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;"

#### 7.1.2. The Role of the Commission

Planned amendment to BSS Regulations :Regulation 66(3)(a):

(a) The Commission shall establish and regular review national diagnostic reference levels for radio-diagnostic examinations, having regard to the current European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

#### 7.1.3. The obligations of an undertaking:

Planned amendment to BSS Regulations :Regulation 66(3)(b):

(b) An undertaking shall ensure that their diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels where available.

#### Regulation 70 (e) states:

...

"Undertaking's radiation protection programmes shall include that:

(e) appropriate reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay;"

#### 7.1.4. Role of Medical Physics Experts

Regulation 107(2)(c) states:

"(2) Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:

(c) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;

# 7.2. Annex 2 – Reference material

#### Maltese Legislation

Basic safety standards for ionising radiation regulations <u>https://legislation.mt/eli/sl/585.1/eng</u>

#### **European Guidelines**

Radiation Protection No.154 European Guidance on Estimating Population Doses from Medical X-Ray Procedures <u>https://op.europa.eu/en/publication-detail/-/publication/72d806a2-2fb4-4e4d-a845-3b276feed8eb</u>

Radiation Protection No. 185 European Guidelines on Diagnostic Reference Levels for Paediatric Imaging. https://op.europa.eu/en/publication-detail/-/publication/6e473ff5-bd4b-11e8-99ee-01aa75ed71a1/language-en

Radiation Protection No. 195 European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging https://op.europa.eu/en/publication-detail/-/publication/a78331f7-7199-11eb-9ac9-01aa75ed71a1

#### Published paper on DRLs in Malta

Establishing Local And National Diagnostic and Interventional Cardiology And Radiology Reference Levels In A Small European State: The Case Of Malta Eric Pace, Kelvin Cortis, Joseph Debono, Marvin Grech and Carmel J Caruana

Radiation Protection Dosimetry (2020), Vol. 191, No. 3, pp. 261–271

#### **EU member states dental DRLs referenced**

#### Irish DRLs

Diagnostic Reference Levels Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation Updated July 2021 <a href="https://www.hiqa.ie/sites/default/files/2021-07/Diagnostic-Reference-Levels\_Undertaking-guidance.pdf">https://www.hiqa.ie/sites/default/files/2021-07/Diagnostic-Reference-Levels\_Undertaking-guidance.pdf</a>

#### UK DRLS

Guidance National Diagnostic Reference Levels (NDRLs) from August 2019 <u>https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl</u>

AP	Antero-Posterior	
CA	Coronary Angiography	
CC	craniocaudal	
сКАР	Cumulative KAP	
СТ	Computed Tomography	
CTDIvol	Volume computed tomography dose index	
DLP	Dose Length Product in mGy.cm	
DRL	Diagnostic Reference Level	
IQR	Interquartile Range	
IVU	Intravenous Urogram	
KAP	Or P <sub>KA</sub> Kerma-Area Product in mGy.cm <sup>2</sup>	
LAT	Lateral	
LSJ	lumbo-sacral-joint	
MLO	mediolateral oblique	
MPE	Medical Physics Expert	
PA	Posterior-Anterior	
PICC	Peripherally inserted central catheter	
PAC	Paediatric activity calculator	
PCI	percutaneous coronary intervention	
РТА	percutaneous transluminal angioplasty	
PTC	Percutaneous transhepatic cholangiography	
PTCA	Percutaneous transluminal coronary angioplasty	

# 7.3. Annex 3 - Abbreviations

# 7.4. Annex 4 - X-ray Examinations and their contribution to the total collective dose

Table 6 of RADIATION PROTECTION N° 154 European Guidance on EstimatingPopulation Doses from Medical X-Ray Procedures

Exam type or category		% of total frequency*	% of total collective dose*			
Plai	Plain film radiography					
1	Chest/thorax	12-29	0.7-5.2			
2	Cervical spine	2.0-5.4	0.05-2.3			
3	Thoracic spine	1.0-3.1	0.5-3.7			
4	Lumbar spine (inc. LSJ)	2.8-9.6	2.0-17			
5	Mammography	0.3-15	0.6-4.7			
6	Abdomen	1.1-10	1.1-4.7			
7	Pelvis & hip	6.3-10	2.8-9.4			
Rad	liography/Fluoroscopy					
8	Ba meal	0.3-0.9	0.8-5.9			
9	Ba enema	0.1-2.0	0.5-13			
10	Ba follow	0.05-0.3	0.2-1.6			
11	IVU	0.3-2.0	1.2-8.7			
12	Cardiac angiography	0.2-1.3	1.0-9.9			
	All angiography	1.1-2.4	6.4-16			
CT						
13	CT head	1.8-5.4	3.0-7.9			
14	CT neck	0.06-0.9	0.1-1.1			
15	CT chest	0.5-1.5	6.1-12			
16	CT spine	0.3-2.8	1.5-13			
17	CT abdomen	0.01-3.0	1.9-26			
18	CT pelvis	0.0-1.53	0.3-9.7			
19	CT trunk	0.1-5.6	1.1-27			
	All CT	4.5-15	28-59			
Inte	rventional					
20	PTCA	0.1-0.3	0.5-3.6			

\* Range over 10 DOSE DATAMED countries



