DIAGNOSTIC REFERENCE LEVELS IN DIAGNOSTIC NUCLEAR MEDICINE. PATIENT EXPOSURE MONITORING

10-14 November, Trieste, Italy

Chadia Rizk
Radiation Protection of Patients Unit
International Atomic Energy Agency, Vienna, Austria

Learning objectives

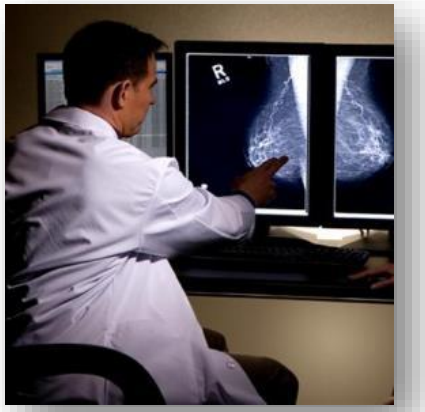
- Explain the necessity of Diagnostic Reference Levels (DRLs).
- Identify the appropriate dose quantities for establishing DRLs.
- Demonstrate methods for collecting data and establishing DRLs.
- Apply DRLs effectively in clinical practice

Principles of Radiation Protection-Medical exposure

- **Justification** of medical exposures:
  Ensuring that a radiation exposure does more good than harm

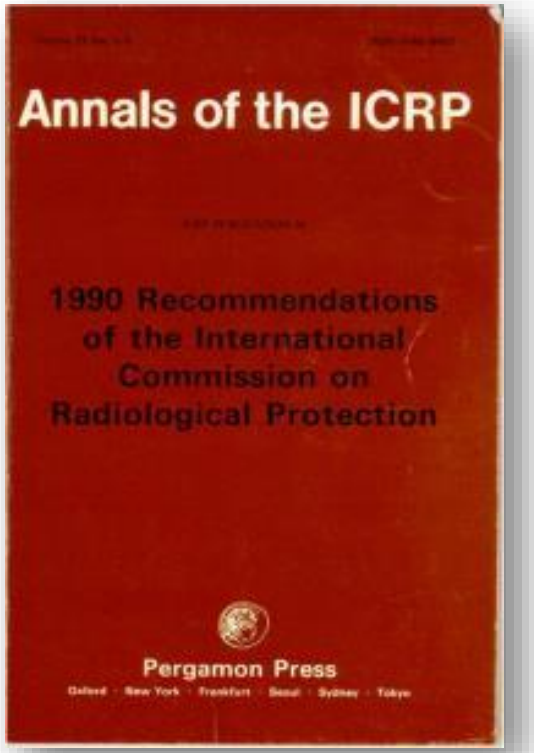
- **Optimization** of protection:
  Keeping the exposure of patients to the minimum necessary to achieve the required diagnostic or interventional objective.

No dose limits apply to medical exposure!

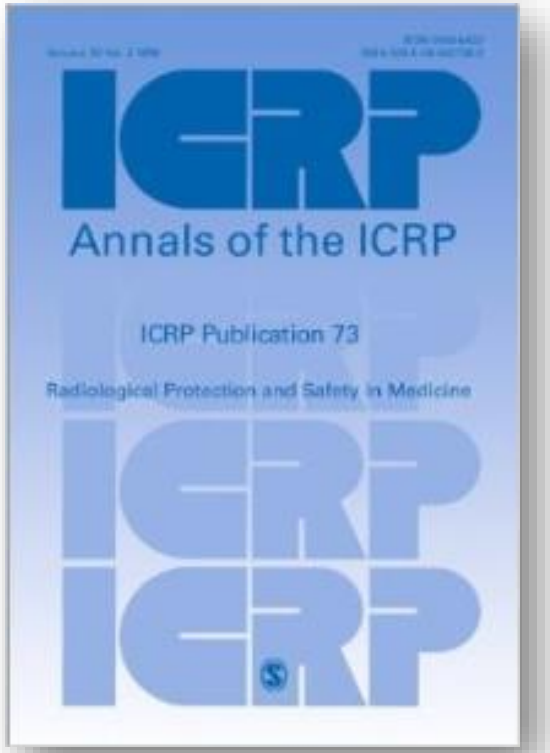


International Recommendations (ICRP)

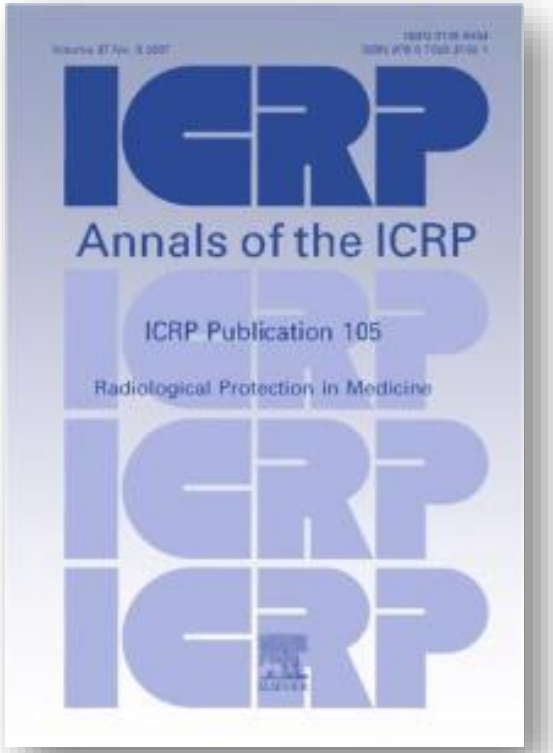
Publication 60, 1990
first mentioned “DRLs”



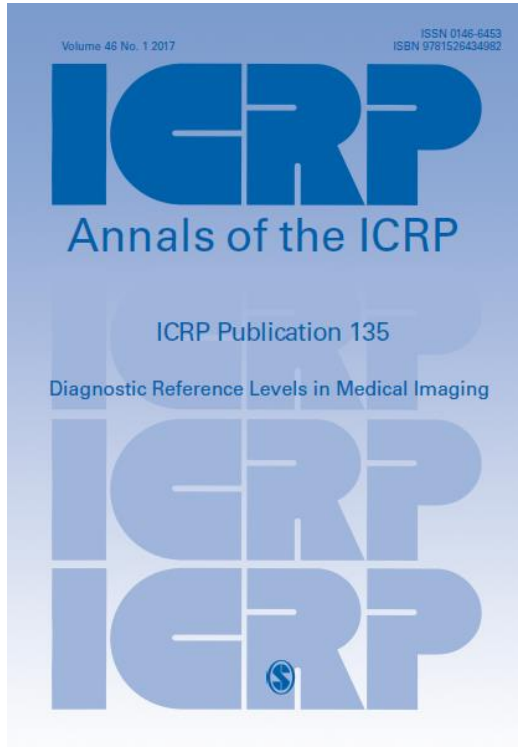
Elaborated in
Publication 73, 1996



Further in
Publication 105, 2007



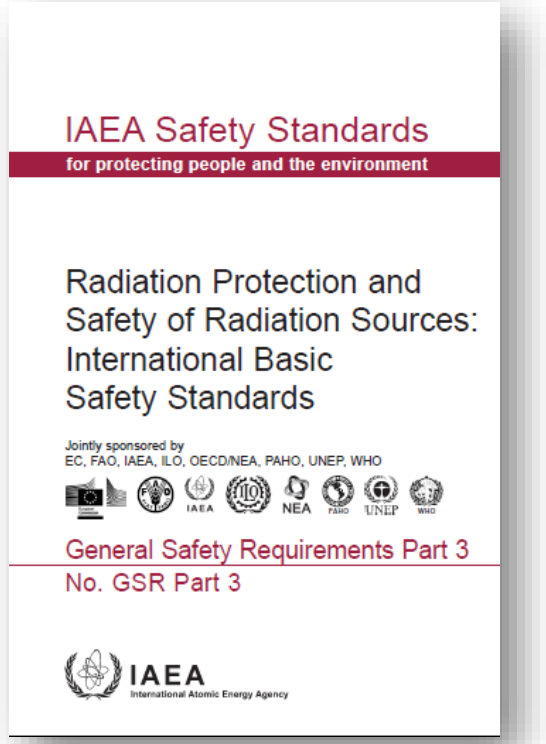
Latest ICRP
Publication 135, 2017



International BSS: DRL definition

Diagnostic Reference Level (DRL)

*"A **level used** in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure"*



International BSS: Optimisation

- Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure

Components to consider:

- Design considerations for equipment
- Calibration
- Quality assurance
- Dosimetry of patients
- Diagnostic Reference Levels (DRLs)
- Operational considerations
- Dose constraints (for carers and comforters)

International BSS: Requirements

Two aspects

- Establishing (national) DRLs
- Using DRLs

What?	Who is responsible?
DRLs should be established and updated periodically	Government: Consultation between the health authority, relevant professional bodies and the regulatory body
Patient dose reviews (audits) performed in each medical facility periodically and local typical doses compared to DRLs	Registrants and licensees: Team of medical physicists, radiographers and radiologists
Investigation if doses above or substantially below DRL	Registrants and licensees: Team of medical physicists, radiographers and radiologists

Who should establish? - BSS

BSS, Requirement 34: Responsibilities of the government specific to medical exposure

The government *shall ensure, that as a result of consultation between the* ***health authority****, relevant* ***professional bodies*** *and the* ***regulatory body****, a set of DRLs is established for medical exposures incurred in medical imaging, including image guided interventional procedures.*

- *Such DRLs shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.*

Who should apply? - BSS

BSS, Requirement 38: Optimization of protection and safety:

3.169. Registrants and licensees shall ensure that:

(a) Local assessments, …., are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established.

Who should apply? - BSS

BSS, Requirement 38: Optimization of protection and safety:

3.169. Registrants and licensees shall ensure that:

(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:

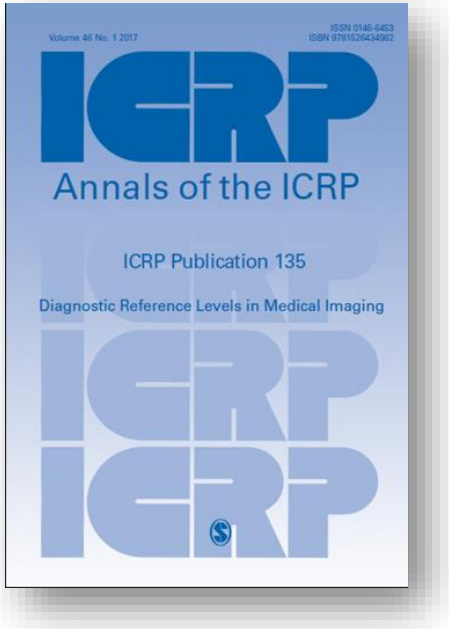
(i) Typical doses or activities exceed the relevant diagnostic reference level; or

(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Establishing DRLs

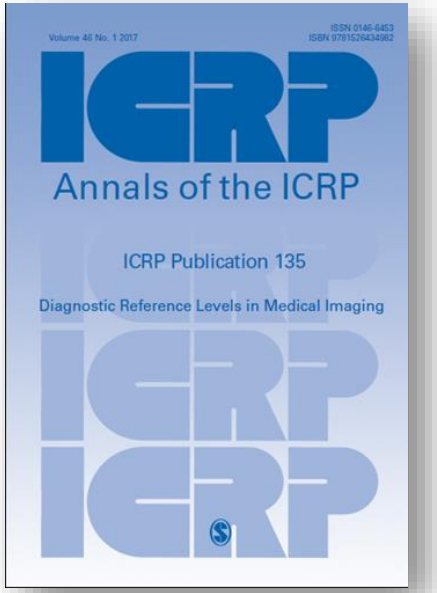
Examinations/Procedures Selection

- Common Examinations:
  - DRLs should be established for procedures that are frequently performed in the region or country.
- Priority-High Dose Examinations:
  - Priority should be given to examinations associated with the highest radiation doses to patients.



Number of facilities

- Large or medium-sized facilities with sufficient workload to ensure that data for a representative selection of patients can be obtained - geographical locations(rural, urban, private, public).
- Sample size (number of rooms) depend on the size of the country and total number of facilities
  - Results from 20–30 facilities are likely to be sufficient in the first instance.
  - In a small country with fewer than 50 facilities, a survey of 30–50% of them may suffice.



Sample size

- Sample size for each room/facility:
  - Depends on the imaging procedure frequency and variability of patient doses
  - Sufficient to assure confidence in the determination of the typical dose.
    - At least 20 patients for radiography
    - At least 30 for diagnostic fluoroscopy and CT
    - More for interventional procedures
    - At least 50 patients for mammography.

- When automated exposure monitoring systems are available:
  - Large samples (e.g. >100 patients), or
  - All patients per procedure per equipment per group

Patient size

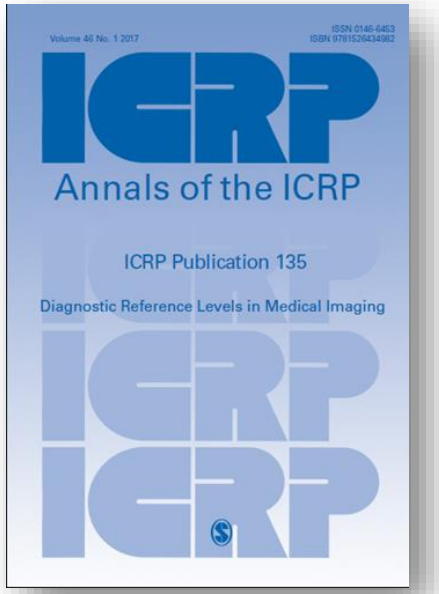
- Adult patients: Standardisation of patient size is usually accomplished through weight restriction.

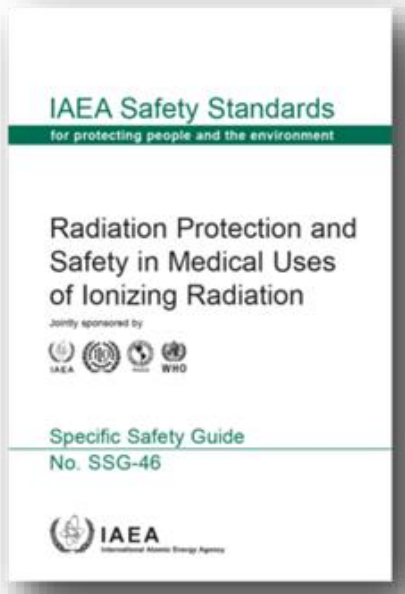
  Ex: based on a sample of patients with agreed range of weight e.g. 50 – 90 kg, aiming for a sample mean 70 kg ± 5 kg (or different for a country/ region)

- Paediatric patients: broad range of sizes and weights
  - Age alone is not a good indicator.
  - Weight categories are preferred :
    - <5 kg
    - 5– <15 kg
    - 15 –<30 kg
    - 30 –<50 kg
    - 50–< 80 kg

DRL quantity

- Should be readily assessed:
  - Preferable, from direct measurement during the examination.
  - Are available from the imaging equipment.
- Must follow the ICRU recommendations





Must indicate the amount of radiation or administered activity applied.

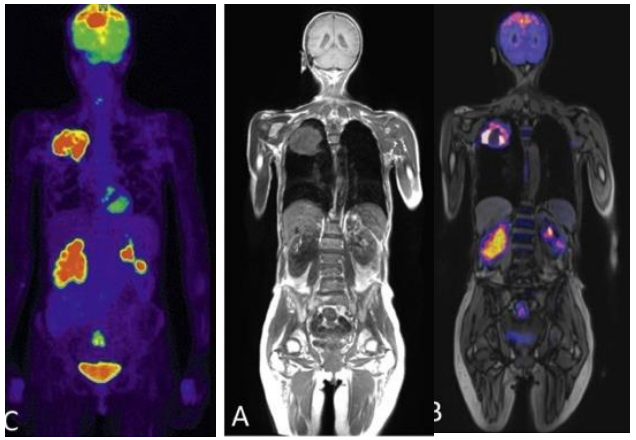
DRL quantities in NM imaging

- Administered activity (MBq)
  - Investigations for which the radiopharmaceutical is concentrated predominantly in a single organ a standard activity could be administered for all adult patients (e.g. thyroid, sentinel node imaging, pulmonary ventilation and perfusion studies)

- Administered activity per body weight (MBq/kg)
  - Children, adolescents, and low-weight patients, others

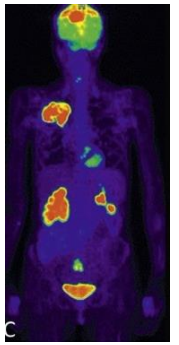
DRL quantities for hybrid imaging

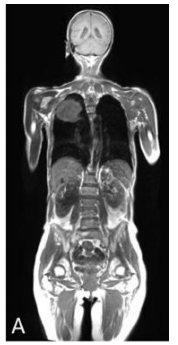
- For SPECT-CT and PET-CT procedures:
  - Radiation from very different modalities
  - Different dose quantities
  - It is appropriate to set and present DRL values for each modality independently



DRL quantities for in hybrid imaging

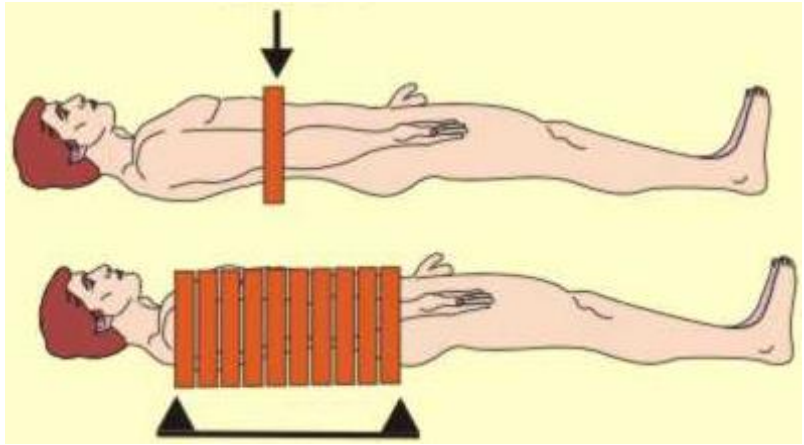
Modality	DRL quantity	Unit
Diagnostic nuclear medicine	Administered activity or activity per body weighty	MBq or MBq kg^{-1}
CT for hybrid imaging	C_{VOL} ($CTDI_{vol}$) $P_{KL,CT}$ (DLP)	mGy mGy cm





DRL quantities for CT

❶ CTDI: Computed tomography dose index
Unit: mGy



❷ DLP: Dose length product
Unit: mGy.cm

Exam Description: QA CT3

Dose Report

Series	Type	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm
1	Axial	S0.000-S0.000	64.38	64.38	Head 16
1	Axial	S35.000-S35.000	64.38	64.38	Head 16
1	Axial	S50.000-S50.000	64.38	64.38	Head 16
			Total Exam DLP:	193.14	

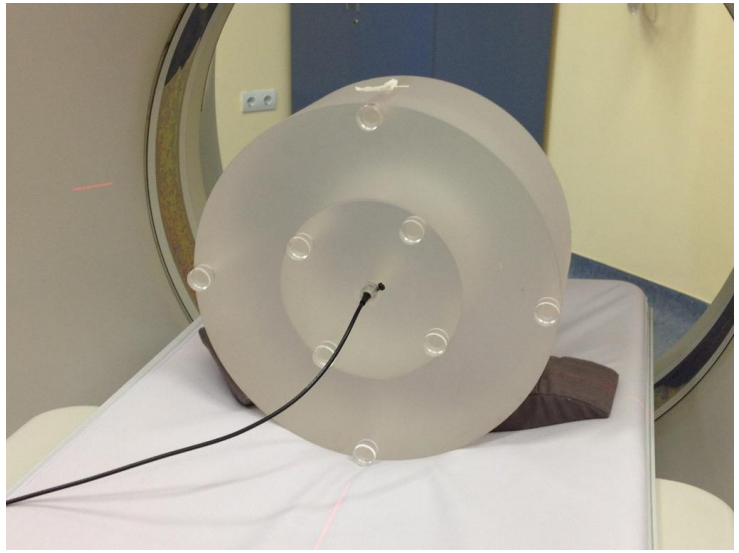
DRL quantities for CT

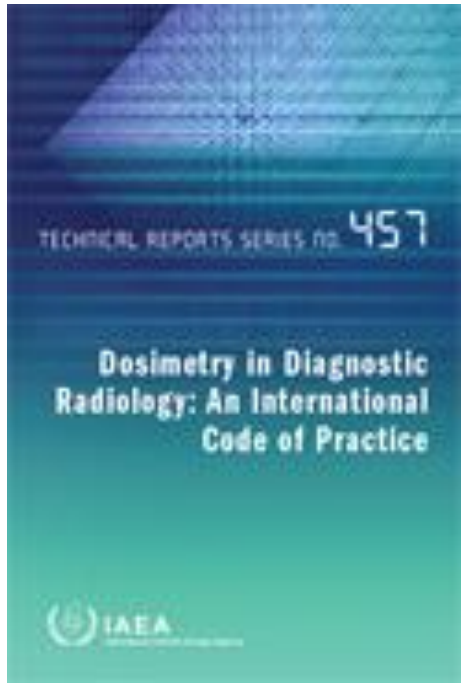
Verification of dose displays: by medical physicists during QC

PMMA phantoms

Φ16 cm

Φ32 cm



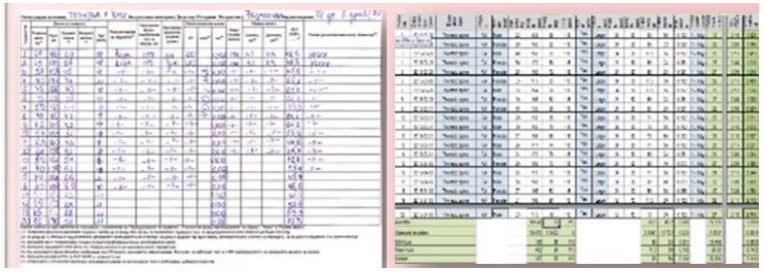


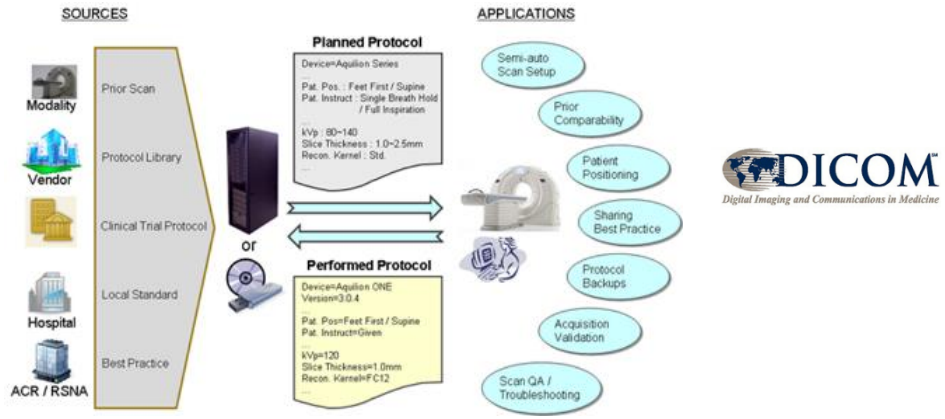
Data collection

- Examination parameters:
  - Modality (e.g. nuclear medicine)
  - Procedure (e.g. renal scintigraphy)
  - Clinical indication targeted for the examination (e.g. suspected urinary tract obstruction)
- Patient parameters
  - Gender, age, weight, body mass index, diameter, etc.
- Acquisition parameters
  - Dose indices/DRL quantity (e.g. administered activity or CTDI, DLP for CT)
  - For CT: exposure parameters (e.g. kV, mA, pitch, ….)

Data recording and Collection Methodology

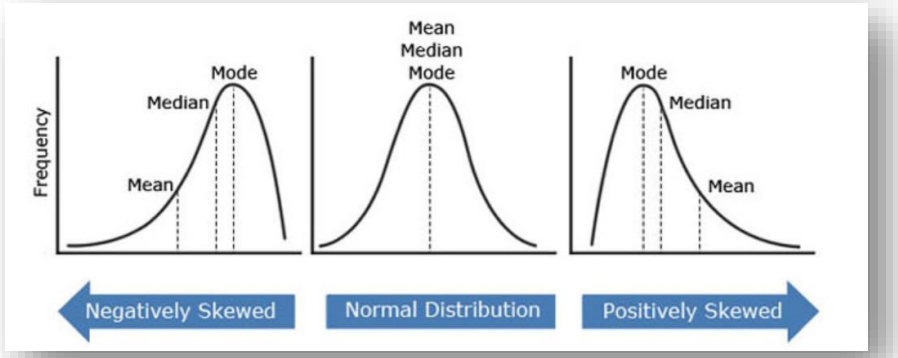
- Manual recording by the local staff (at modality)
- Electronic recording of radiation exposure details in a standard format (at modality)

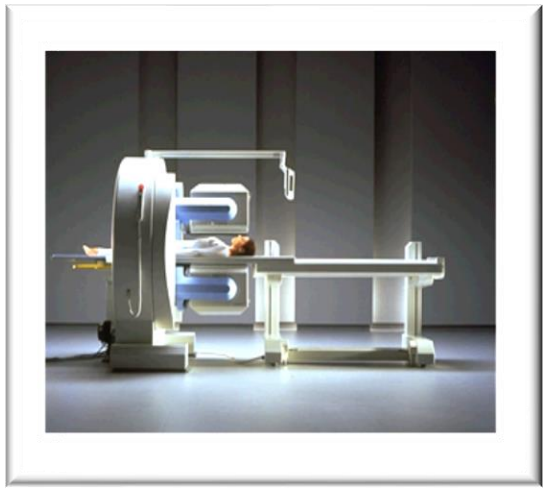




Data analyses for a given facility

- Statistical description: Minimum, Maximum, Average, Standard deviation, Median of patient sample
- Typical dose value = Median

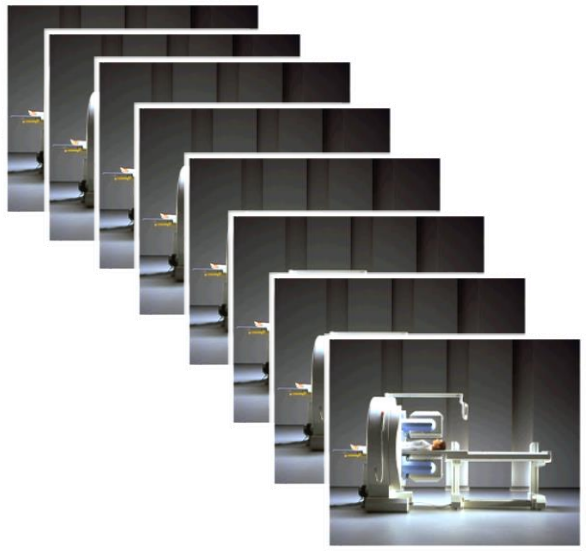


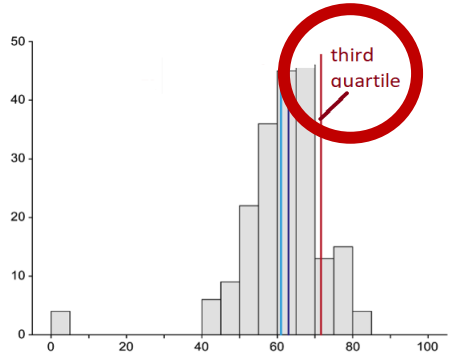


MEDIAN VALUE = TYPICAL DOSE VALUE

Establishing DRL

- Calculate typical value (median) for each facility
- Statistical description: Minimum, Maximum, Average, Standard deviation, Q3 of typical doses (medians) from different facilities
- DRL = rounded third quartile (75th percentile) of median values



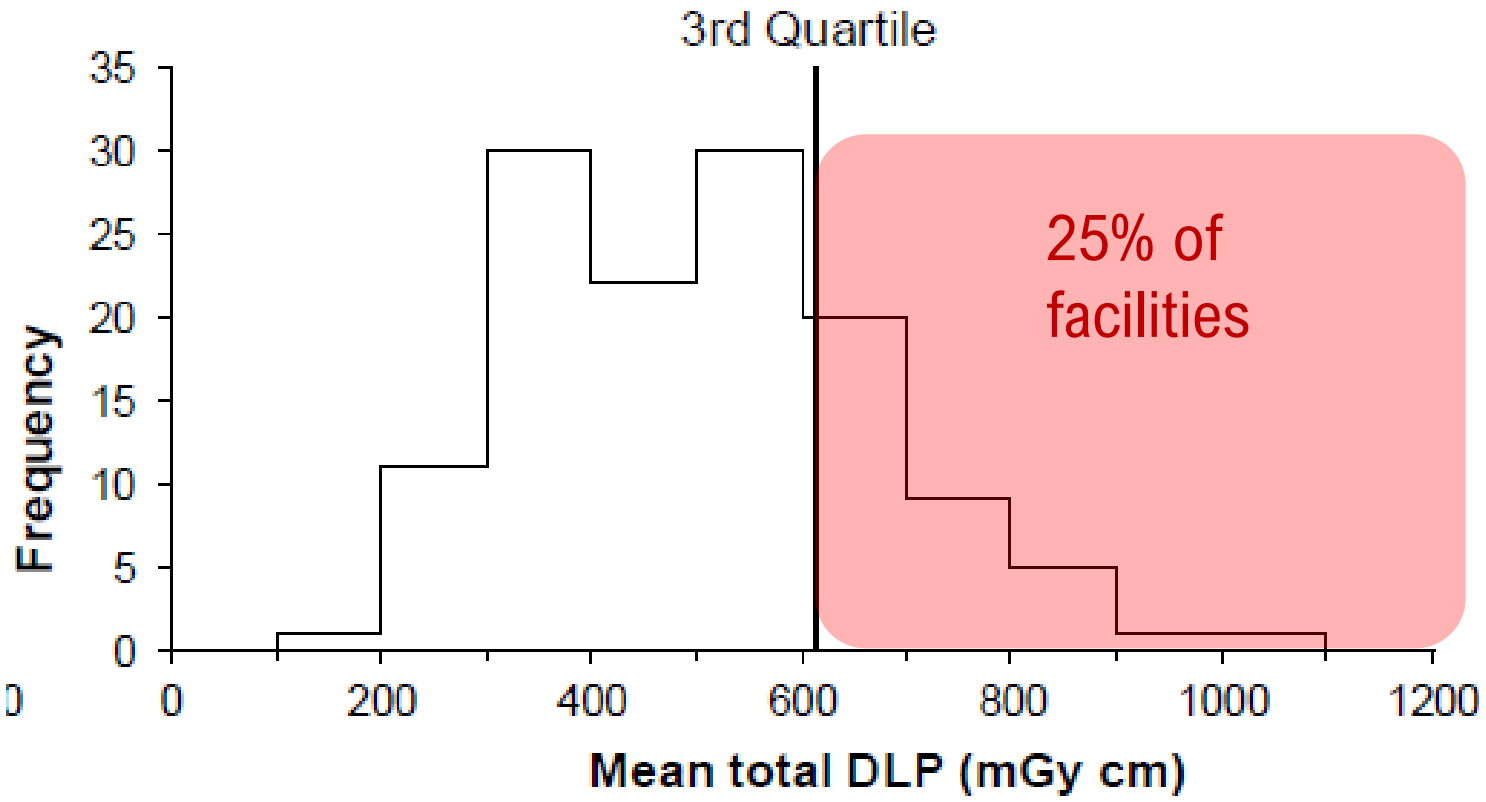


Excludes high dose
'tail' of distribution

THIRD QUARTILE OF MEDIAN VALUES

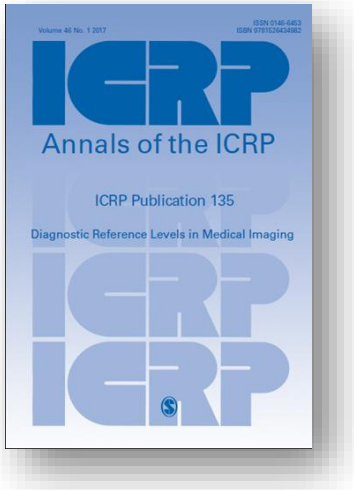
DRL

DRL value


3rd Quartile
25% of facilities
Frequency
35
30
25
20
15
10
5
0
0
200
400
600
800
1000
1200
Mean total DLP (mGy cm)

DRL types

A few healthcare facilities	→	Local DRL value
Multiple facilities throughout a country	→	National DRL value
Representative sample of healthcare facilities or national DRL value from a region	→	Regional DRL value



DRL types and methods of derivation

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

DRL process

- Many players: the imaging facilities, the health authority, the professional bodies, and the regulatory body

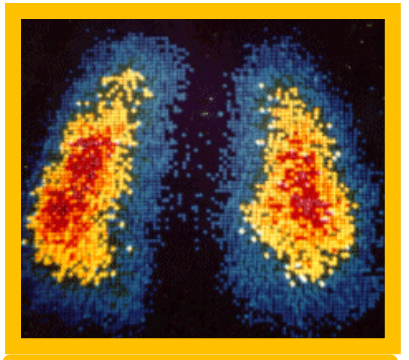
- Collective ownership of the DRLs in:
  - Deciding the methodology
  - Who will manage the data
  - When DRLs should be reviewed and updated.

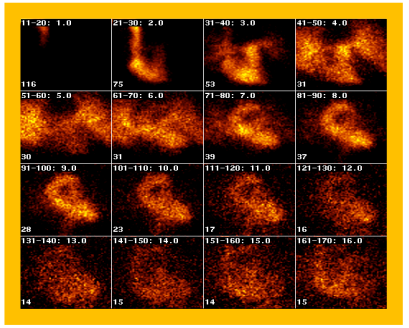
- Administrator of the national database:
  - a national governmental body
  - regulatory body or
  - a professional body.

Human and financial resources needed!

Data set for nuclear medicine

- For most planar nuclear medicine procedures, there are only minor variations in the activity
- For some diagnostic nuclear medicine investigations, administered activities are highly dependent on the intended procedures (cardiac studies, protocols for stress and rest imaging)
- National DRL values in some countries are based on the whole protocol with two injections, while in other countries, DRL values are provided separately for stress and rest imaging





Example: Australia

DRLs for nuclear medicine, including planar nuclear medicine, PET and the CT component of PET/CT procedures.

Category	Procedure Name	Nuclide	Chemical Form	25th percentile	Median	DRL
Cardiac	Gated blood pool scan	Tc-99m	Pertechnetate, RBCs	878	953	1000
Cardiac	MPI 1-day (1st phase)	Tc-99m	Tetrofosmin, MIBI	300	305	350
Cardiac	MPI 1-day (2nd phase)	Tc-99m	Tetrofosmin, MIBI	900	1000	1150
Cardiac	MPI 2-day (1st phase)	Tc-99m	Tetrofosmin, MIBI	350	500	600
Cardiac	MPI 2-day (2nd phase)	Tc-99m	Tetrofosmin, MIBI	350	500	600
Endocrine	Thyroid	Tc-99m	Pertechnetate	200	200	200
Endocrine	Parathyroid (without subtraction)	Tc-99m	MIBI	750	800	800
Endocrine	Parathyroid (protocol includes subtraction)	Tc-99m	MIBI	750	800	900
Endocrine	Parathyroid (thyroid subtraction)	Tc-99m	Pertechnetate	40	60	220
Gastrointestinal	Gastric emptying (solid phase)	Tc-99m	Colloid, DTPA	40	40	40
Gastrointestinal	Colonic transit	Ga-67	Citrate	10	20	20
Genitourinary	MAG3 Renal scan	Tc-99m	MAG3	200	250	300
Genitourinary	DMSA Renal scan	Tc-99m	DMSA	180	200	200
Genitourinary	Renal Imaging DTPA (not GFR)	Tc-99m	DTPA	213	400	500
Hepatobiliary	Hepatobiliary	Tc-99m	HIDA, DISIDA, Mebrofenin	200	200	200
Infection	Infection	Ga-67	Citrate	200	200	220
Lymphatic	Breast SN (same day surgery)	Tc-99m	Colloid	20	40	40
Lymphatic	Breast SN (next day surgery)	Tc-99m	Colloid	42	80	80
Lymphatic	Melanoma SN	Tc-99m	Colloid	20	40	52
Nervous_system	Brain	Tc-99m	ECD, HMPAO	740	750	800
Pulmonary	Lung perfusion	Tc-99m	MAA	200	200	220
Skeletal	Bone scan	Tc-99m	MDP, HDP	800	825	900

https://www.arpansa.gov.au/research-and-expertise/surveys/national-diagnostic-reference-level-service/nm

Example: Australia

DRLs for nuclear medicine, including planar nuclear medicine, PET and the CT component of PET/CT procedures.

PET

Category	Pharmaceutical	MBq/kg			MBq		
		25th percentile	Median	DRL	25th percentile	Median	DRL
Whole body	F-18 FDG	2.8	3	3.5	229	249	270
NETs	Ga-68 DOTA-TATE	2	2	2.2	150	185	200
Prostate cancer	Ga-68 PSMA	2	2	2.2	160	170	200
Prostate cancer	F-18 DCFPyL	3.15	3.55	3.7	240	252	270
Parkinsonian/ Alzheimer's	F-18 FDG	-	-	-	189	200	230

PET CT

Category	Region	CTDIvol (mGy)			DLP (mGy.cm)		
		25th Percentile	Median	DRL	25th Percentile	Median	DRL
PET/CT	**Brain vertex to prox./mid thighs (arms up)**	2.61	3.21	4.2	281	336	430
PET/CT	**Brain vertex to prox./mid thighs (arms down)**	3	3.77	5.3	339	412	555
PET/CT	**Brain vertex to toes (arms up)**	2.27	2.74	3.9	428	488	675
PET/CT	**Brain vertex to toes (arms down)**	2.62	3.01	4.6	479	570	825
PET/CT	**Brain**	-	-	-	-	-	325

https://www.arpansa.gov.au/research-and-expertise/surveys/national-diagnostic-reference-level-service/nm

Example: France

Summary of results of analysis of nuclear medicine data by adult examination type, for 2019-2021 data, in terms of administered activity

Examination type	Radiopharmaceutical / protocol		N 2019-2021	Median weight (kg)	Administered activity (MBq)		P75/P25 ratio
					DRL	P50	
Bone	^{99m}Tc HDP/DPD		219	72.0	670	662	1.13
Lung perfusion scan	^{99m}Tc MAA		153	72.5	225	194	1.49
Thyroid scan	^{123} I (sodium iodide)		47	70.0	8	7.5	1.25
	^{99m}Tc (sodium pertechnetate)		112	69.8	110	108	1.44
Myocardial perfusion SPECT with stress test and/or pharmacological stimulation	^{99m}Tc MIBI/tetrofosmin	1 day/1st inj.	136	77.5	285	267	1.22
		1 day/2nd inj.	136	77.5	785	760	1.23
		2 days/1st inj.	26	79.3	615	550	1.45
		2 days/2nd inj.	26	79.3	615	535	1.50
	^{201} Tl (thallium chloride)	1st injection	20	75.5	110	101	1.44
		Reinjection	18	75.5	37	35	1.66
Equilibrium radionuclide ventriculography	^{99m}Tc human serum albumin/red blood cells		76	70.5	740	733	1.08
Dynamic renal scan	^{99m}Tc MAG3		87	69.0	180	177	1.63
	^{99m}Tc DTPA		9	68.0	255	168	1.41
Brain perfusion SPECT	^{99m}Tc ECD		2	71.0	800	727	1.03
	^{99m}Tc HMPAO		12	70.0	695	656	1.24
Tumour FDG PET	^{18}F FDG		193	70.0	245	191	1.35

https://nrd.asnr.fr/sites/nrd/files/2023-12/2019-2021%20Report%20on%20DRLs.pdf

Example: France

Summary of results of analysis of nuclear medicine data by adult examination type, for 2019-2021 data, in terms of administered activity per body weight.

Examination type	Radiopharmaceutical / protocol		N 20192021	Median weight (kg)	Activity per BW (MBq/kg)		P75/P25 ratio
					DRL	P50	
Bone	^{99m}Tc HDP/DPD		219	72.0	9.5	9.2	1.12
Myocardial perfusion SPECT with stress test and/or pharmacological stimulation	^{99m}Tc MIBI/tetrofosmin	1 day/1st inj.	136	77.5	3.7	3.5	1.23
		1 day/2nd inj.	136	77.5	10.3	9.7	1.21
		2 days/1st inj.	26	79.3	7.7	7.0	1.52
		2 days/2nd inj.	26	79.3	7.7	7.0	1.48
	^{201}Tl (thallium chloride)	1st injection	20	75.5	1.4	1.38	1.45
		Reinjection	18	75.5	0.5	0.48	1.58
Tumour FDG PET	^{18}F FDG		193	70.0	3.5	2.6	1.24

https://nrd.asnr.fr/sites/nrd/files/2023-12/2019-2021%20Report%20on%20DRLs.pdf

Example: France

Summary of analyses performed on the CT part of a full body PET-CT scan with FDG for scans to mid-thigh and foot in adults, for 2019–2021 data, in terms of volume computed tomography dose index (CTDIvol)

Examination type	N 2019-2021	$CTDI_{vol}$ (mGy)				P75/P25 ratio
		DRL	AD	P75	P50	
PET-CT with FDG head to mid-thigh	100	7	5	5.5	4.7	1.36
PET-CT with FDG head to foot	32	7	5	4.7	4.1	1.41

Summary of analyses performed on the CT part of a full body PET-CT scan with FDG for scans to mid-thigh and foot in adults, for 2019–2021 data, in terms of dose length product (DLP)

Examination type	N 2019-2021	DLP (mGy.cm)				P75/P25 ratio
		DRL	AD	P75	P50	
PET-CT with FDG head to mid-thigh	100	650	500	566.4	493.1	1.39
PET-CT with FDG head to foot	32	1200	900	817.4	726.5	1.49

https://nrd.asnr.fr/sites/nrd/files/2023-12/2019-2021%20Report%20on%20DRLs.pdf

Example: France

Summary of results of analysis of paediatric nuclear medicine data, by examination type

Examination type	Weight category (kg)	N	Median weight (kg)	Administered activity (MBq)		P75/P25 ratio
				DRL	P50	
Dynamic renal scan	[5-15]	13	9.0	25	20.7	1.29
	[15-25]	4	18.0	35	33.1	1.11
	[25-35]	1	29.0	45	40.9	-
	[35-45]	0	-	50	-	-
Renal cortical scan	[5-15]	13	10.0	20	23.9	1.57
	[15-25]	8	19.8	35	39.3	1.64
	[25-35]	4	27.8	50	41.7	1.20
	[35-45]	1	40.0	60	67.7	-
Bone	[5-15]	10	11.3	95	103.6	1.09
	[15-25]	8	18.3	170	153.1	1.08
	[25-35]	10	30.0	240	237.6	1.05
	[35-45]	6	39.3	310	298.9	1.05
	[45-55]	4	50.5	375	404.8	1.27
Tumour FDG PET	[5-15]	1	12.9	40	68.7	-
	[15-25]	3	20.0	70	70.2	1.07
	[25-35]	3	29.5	100	100.8	1.17
	[35-45]	3	40.5	125	124.5	1.20
	[45-55]	4	50.0	150	140.4	1.26

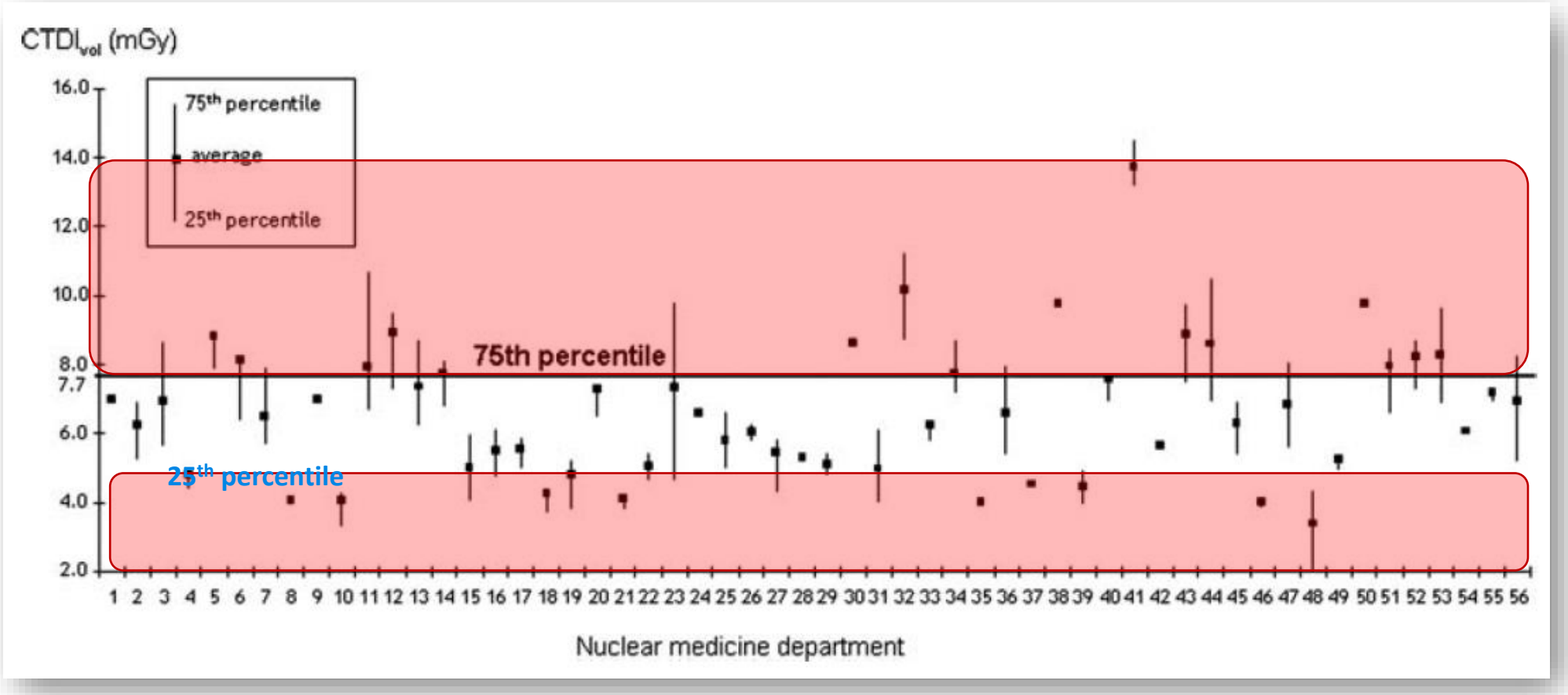
https://nrd.asnr.fr/sites/nrd/files/2023-12/2019-2021%20Report%20on%20DRLs.pdf

Using DRLs for optimization

Using national DRL as a trigger for review

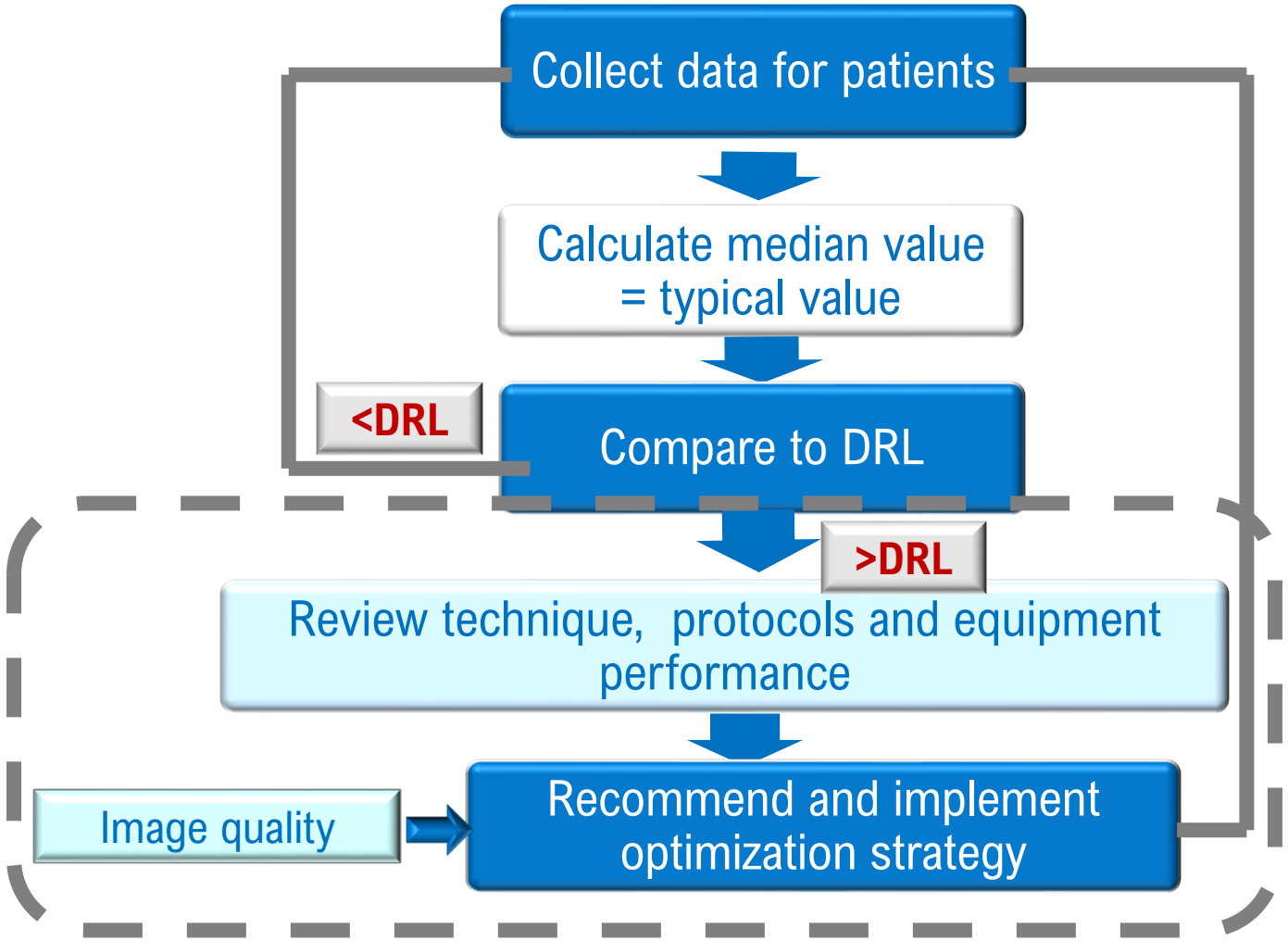
- **At each medical radiation facility**
  - Assessments of typical dose values for common procedures
  - Typical dose value: median value of the distribution of data collected from a representative sample
  - Results compared with relevant DRLs, and if:
    - Exceed the relevant DRLs; or
    - Substantially below the relevant DRL and images not of diagnostic quality
  - Review of adequacy of optimization of patient protection
  - Corrective action, if indicated

Using national DRL as a trigger for review

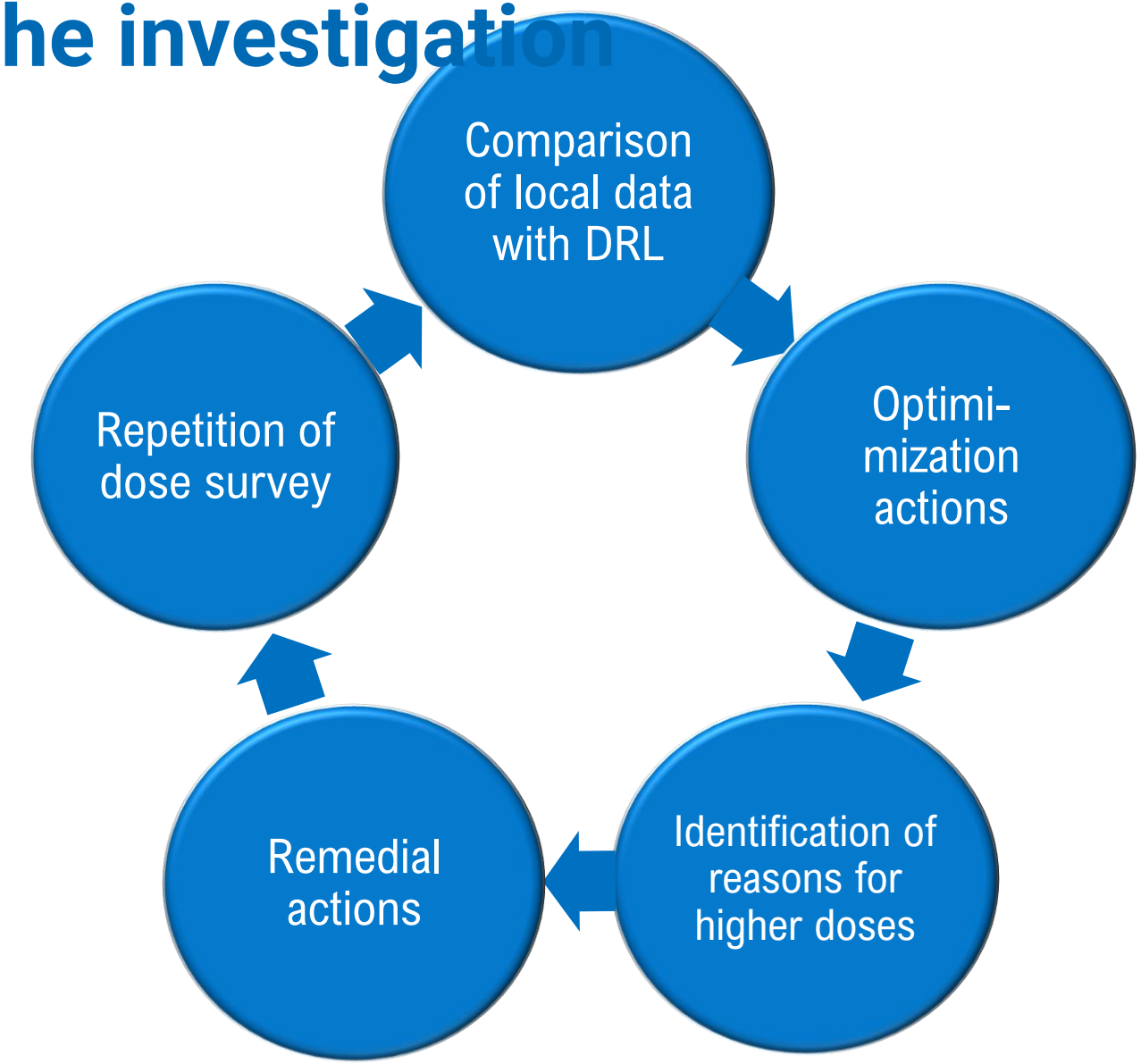


Etard C, et al. National survey of patient doses from whole-body FDG PET-CT examinations in France in 2011. Radiat Prot Dosimetry. 2012 Dec;152(4):334-8.

Application of DRLs in NM and hybrid imaging



Outcome of the investigation



Update of DRL values

- Local surveys of DRL quantities:
  - In the 3- 5 year intervals
  - Whenever substantial changes in technology or software have been introduced, new imaging protocols, or postprocessing of images become available.
- If continuous collection of data is possible, the dose management process may take the form of a regular review

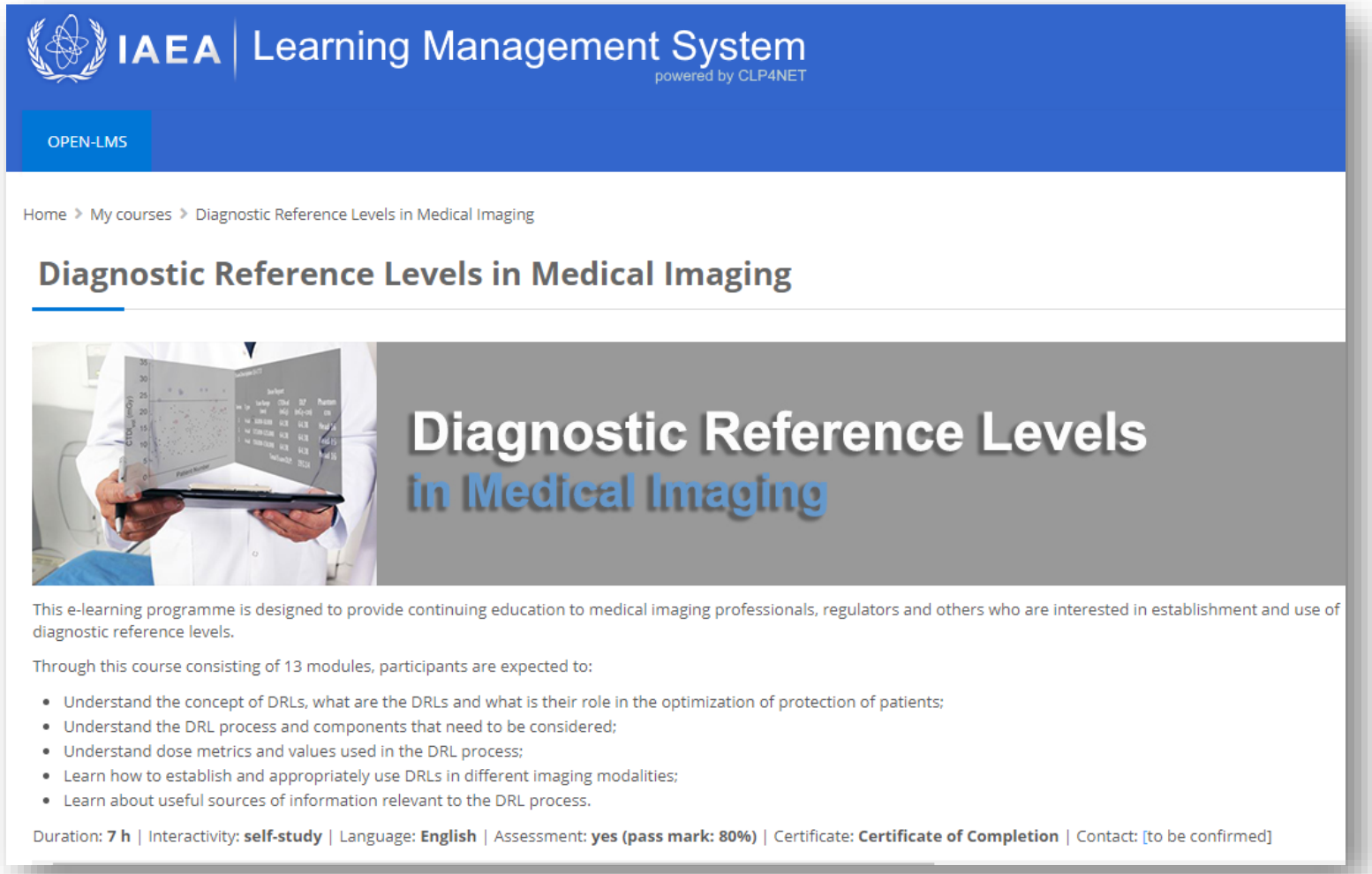
Summary

- Patient dose audit and DRLs are important (useful and valuable) tools for optimization of protection of patients in medical exposure
  - DRLs should be established and updated periodically
  - Dose audits should be performed in each medical facility and local typical values compared to DRLs
  - Local investigation if doses above or substantially below DRL
  - Intervention / optimization of clinical protocols

Summary

- DRLs are NOT:
  - dose limit;
  - borderline between good and poor medical practice;
  - applied to individual patient exposure
  - to be set in term of effective dose
  - to be set for therapy (radiotherapy and radionuclide therapy)

IAEA eLearning course on DRLs



c.rizk@iaea.org