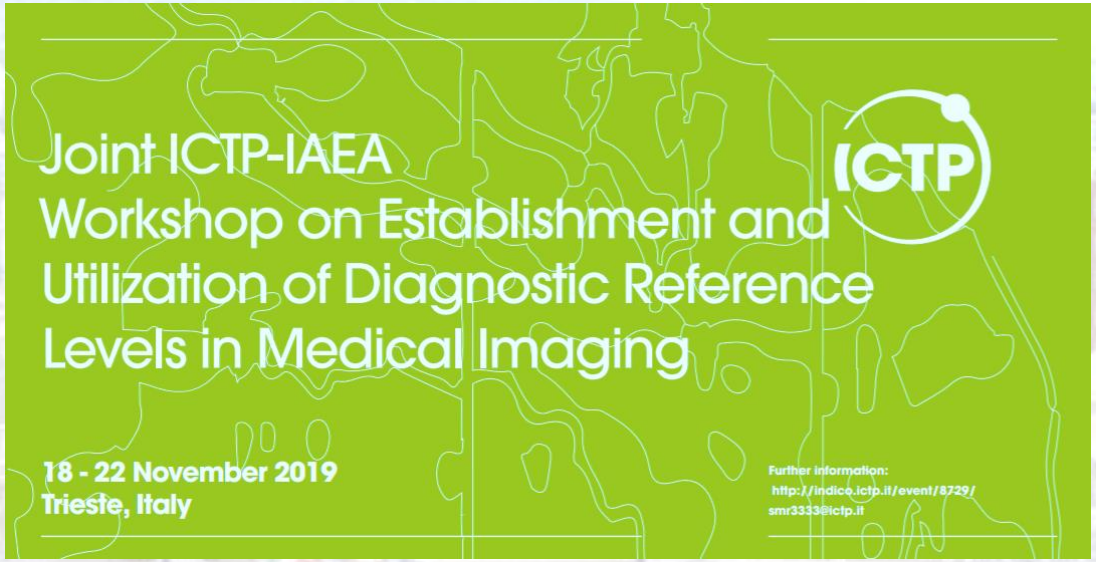


EXPOSURE MONITORING AND DRLS IN FLUOROSCOPY AND FGI PROCEDURES – QUANTITIES, PROCEDURES, METHODS

Dott.a Annalisa Trianni
Medical Physics Department
ASUIUD/Italy

Outline

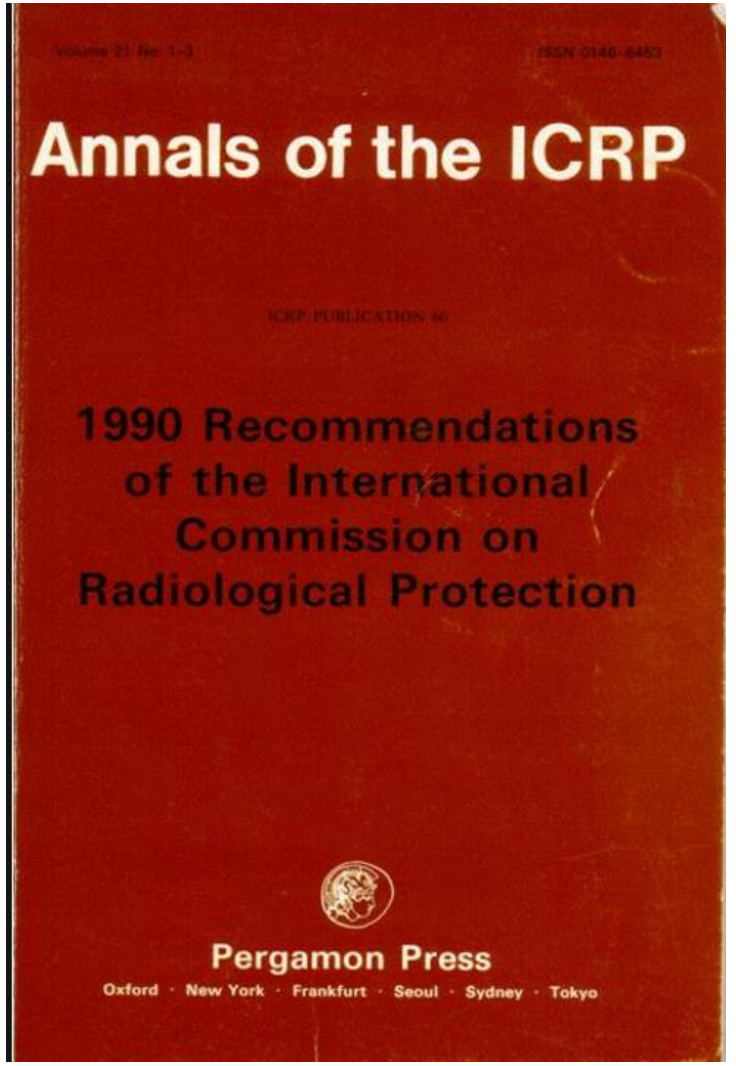
- DRLs in interventional – introduction
- Quantities
- Procedures and Methods
- Reccomendations

INTRODUCTION

DRL – ICRP 60 (1990)

Introduced as Dose Constraints:

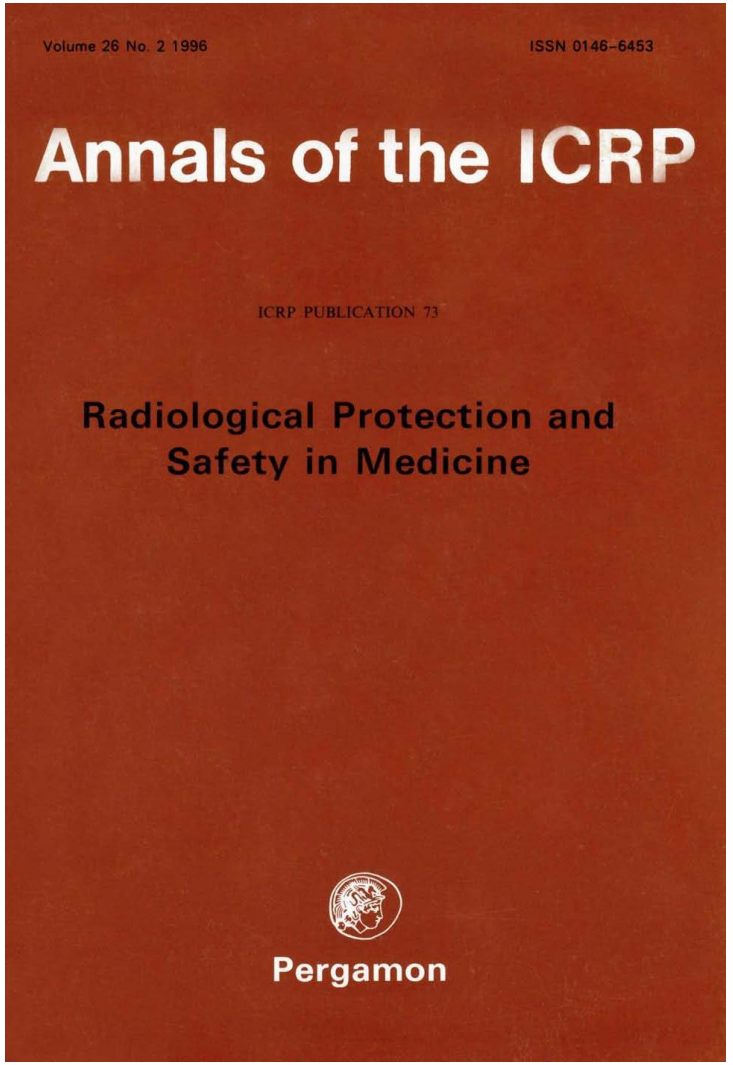
*"..Considerations should be given to the use of **dose constraints**, or investigation levels, selected by appropriate or regulatory agency, for application in some common diagnostic procedures…"*



DRL – ICRP 73 (1996)

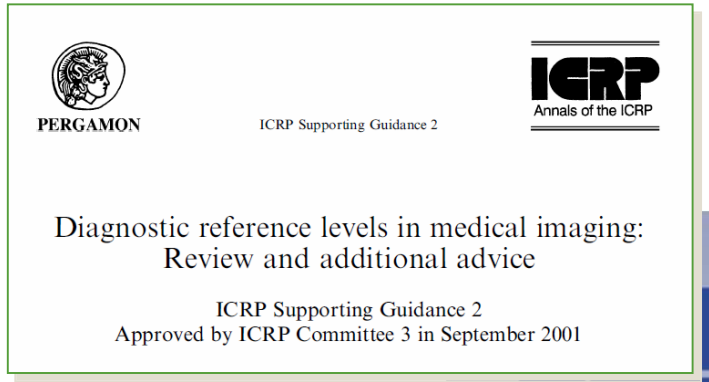
Introduced the term “diagnostic reference level”

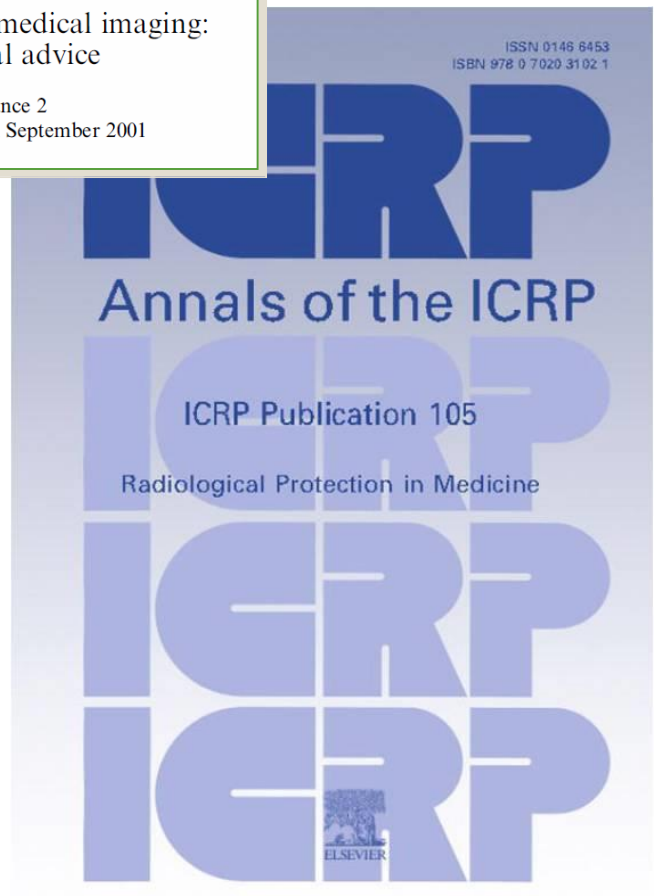
“.. Dose limits/constraints are not applicable. ***To use diagnostic reference levels****. A DRL is not a limit and dose not apply to a single patient… It is a form of investigation level to identify unusually high levels, which calls for local review if consistently exceeded”*



DRL – ICRP Guidance (2001) – ICRP 105 (2007)

- For fluoroscopically guided interventional procedures → to promote the management of patient doses with regard to avoiding unnecessary **stochastic radiation risks**.
- A potential approach → taking into consideration also the relative '**complexity**' of the procedure.
- More than one quantity (i.e., **multiple** diagnostic reference levels).
- **Not for deterministic risks** (i.e., radiation induced skin injuries)





Example – Complexity in IC – 2000

- In therapeutic procedure the severity of the treated pathology influences the complexity of the procedure and the patient dose

Catheterization and Cardiovascular Interventions 51:1–9 (2000)

Clinical and Technical Determinants of the Complexity of Percutaneous Transluminal Coronary Angioplasty Procedures: Analysis in Relation to Radiation Exposure Parameters

Guglielmo Bernardi,[1*] MD, Renato Padovani,[2] PhD, Giorgio Morocutti,[1] MD, Eliseo Vaño,[3] PhD, Maria Rosa Malisan,[2] PhD, Massimo Rinuncini,[1] MD, Leonardo Spedicato,[1] MD, and Paolo M. Fioretti,[1] MD

Example – Preliminary DRL in IC – 2003

Eur Radiol (2003) 13:2259–2263
DOI 10.1007/s00330-003-1831-x

VASCULAR–INTERVENTIONAL

V. Neofotistou
E. Vano
R. Padovani
J. Kotre
A. Dowling
M. Toivonen
S. Kottou
V. Tsapaki
S. Willis
G. Bernardi
K. Faulkner

Preliminary reference levels in interventional cardiology

Table 3 Preliminary reference levels proposed

	PTCA	CA
DAP (Gy×cm^2)	94	57
FT (min)	16	6
No. of frames	1355	1270

Example – Preliminary DRL in IR – 2003

Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study

Part I: Overall Measures of Dose

Donald L. Miller, MD, Stephen Balter, PhD, Patricia E. Cole, PhD, MD, Hollington T. Lu, MS, MA, Beth A. Schueler, PhD, Michael Geisinger, MD, Alejandro Berenstein, MD, Robin Albert, MD, Jeffrey D. Georgia, MD, Patrick T. Noonan, MD, John F. Cardella, MD, James St. George, MD,[1] Eric J. Russell, MD, Tim W. Malisch, MD,[2] Robert L. Vogelzang, MD, George L. Miller III, MD,[3] and Jon Anderson, PhD

SOCIETY OF INTERVENTIONAL RADIOLOGY

J Vasc Interv Radiol 2003; 14:711–727

2003

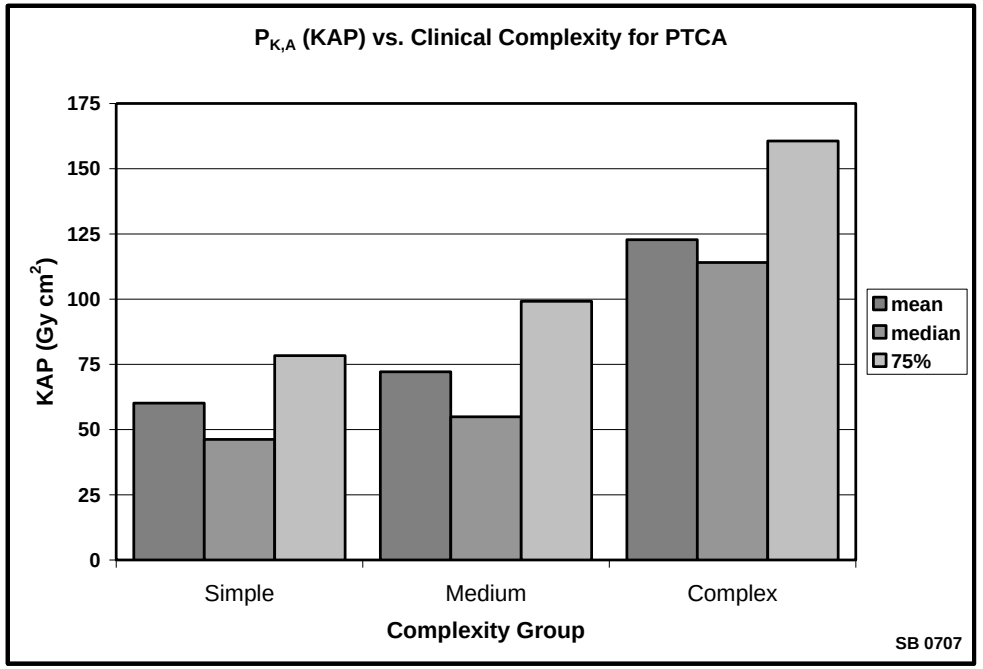
Procedure	Cases	Mean fluoroscopy time (min)	Mean number of images	Mean DAP Gy.cm2	Mean cumulative dose Gy
TIPS	135	38,7	231	335.4	2.00
Biliary drainage	123	23.6	15	70.6	0.91
Renal stent	103	21.6	159	190.0	1.61
Iliac stent	93	18.4	241	212.8	1.34
Hepatic chemoembol.	126	16.8	216	282.3	1.41
Pelvic fibroid embol.	90	29.5	305	298.2	2.46
Vertebroplasty	98	16.2	77	78.1	1.25

Seven academic medical centers; 2142 procedures

In Europe, a similar survey (SENTINEL) has been finished

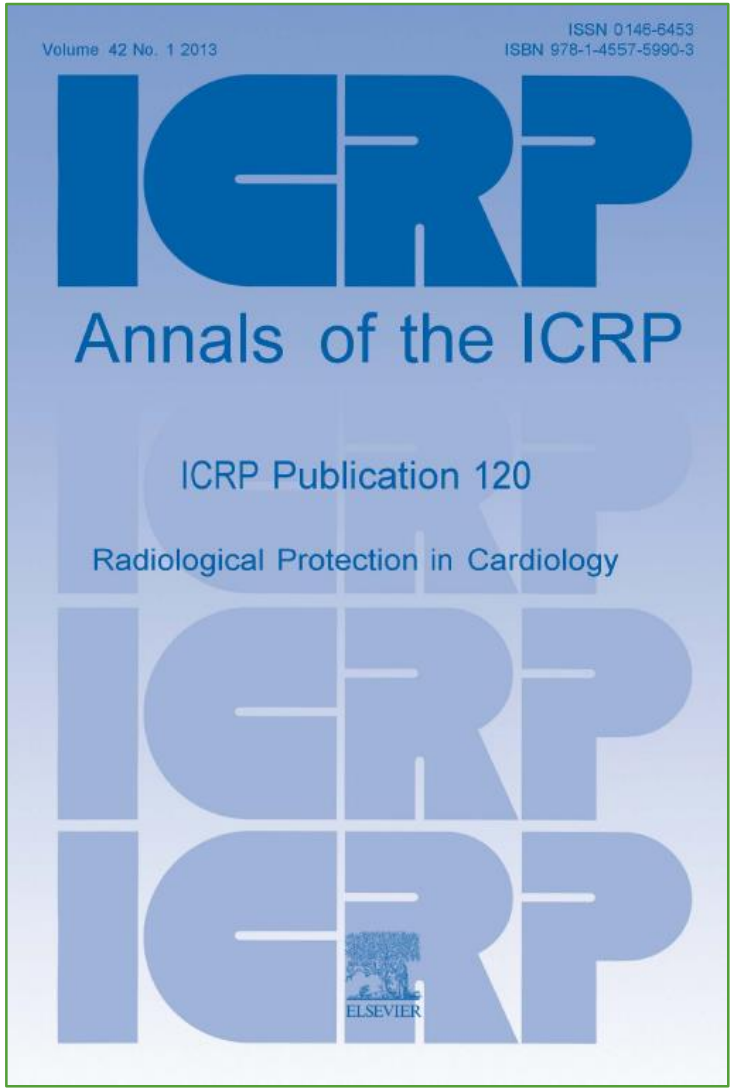
Example – IAEA CRP Study – 2006

- More 1000 PTCA procedures analyzed
- Determinants for complexity of procedures identified
- Procedures grouped according to the level of complexity (Complexity Index)
- Reference levels assessed as a function of CI



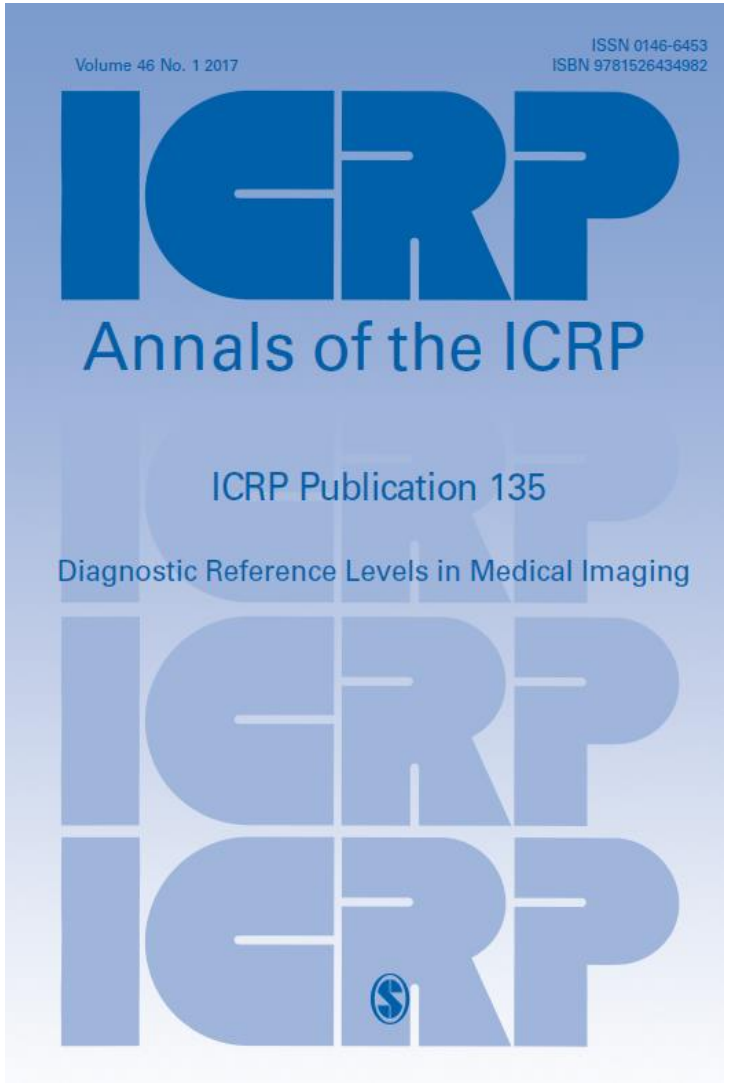
ICRP 120 (2013)

- **Training in radiological protection** should be included in the quality assurance programme for all staff
- **The QA programme should include patient dose audits (including comparison with diagnostic reference levels)** for fluoroscopy, computed tomography, and scintigraphy.
- Periodical evaluation of image quality and procedure protocols should be included in the QA programme.
- The QA programme should establish a trigger level for individual clinical follow-up
- **Patient dose reports should be produced, archived, and recorded in the patient's medical record**.



ICRP 135 (2017)

1. Introduction
2. Considerations in conducting surveys to establish DRLs
3. Radiography and diagnostic fluoroscopy
4. **Interventional procedures**
5. Digital radiography, computed tomography, nuclear medicine, and multi-modality procedures
6. Paediatrics
7. Application of DRLs in clinical practice
8. Summary of main point



Definition

- **Diagnostic reference level (DRL)**. A tool used to aid in optimisation of protection in the medical exposure of patients for diagnostic and interventional procedures. It is used in medical imaging with ionising radiation to indicate whether, in routine conditions, the patient dose or administered activity (amount of radioactive material) from a specified procedure is unusually high or low for that procedure.

Introduction

- DRLs are most useful for diagnostic imaging examinations, such as chest radiography, with relatively few procedural variables (NCRP, 2010). They are more **challenging** to implement for interventional procedures, where the assumption of a ‘standard’ examination is not valid.

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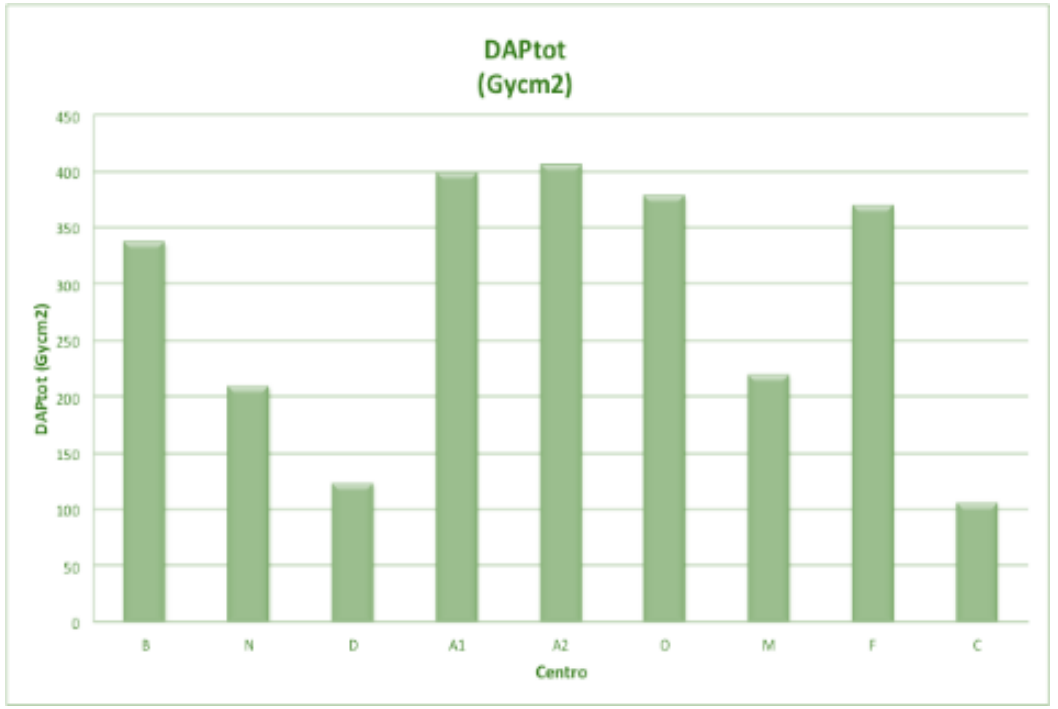
- DRLs are most useful for diagnostic imaging examinations, such as chest radiography, with relatively few procedural variables (NCRP, 2010). They are more **challenging** to implement for interventional procedures, where the assumption of a 'standard' examination is not valid.

- For fluoroscopically guided interventional (FGI) procedures the Commission has stated that, in principle, DRLs could be used for dose management, but they are difficult to implement because of the **very wide distribution of patient doses**, even for instances of the same procedure performed at the same facility.

Liver embolization, Italy, 2011



QUANTITIES

Definition

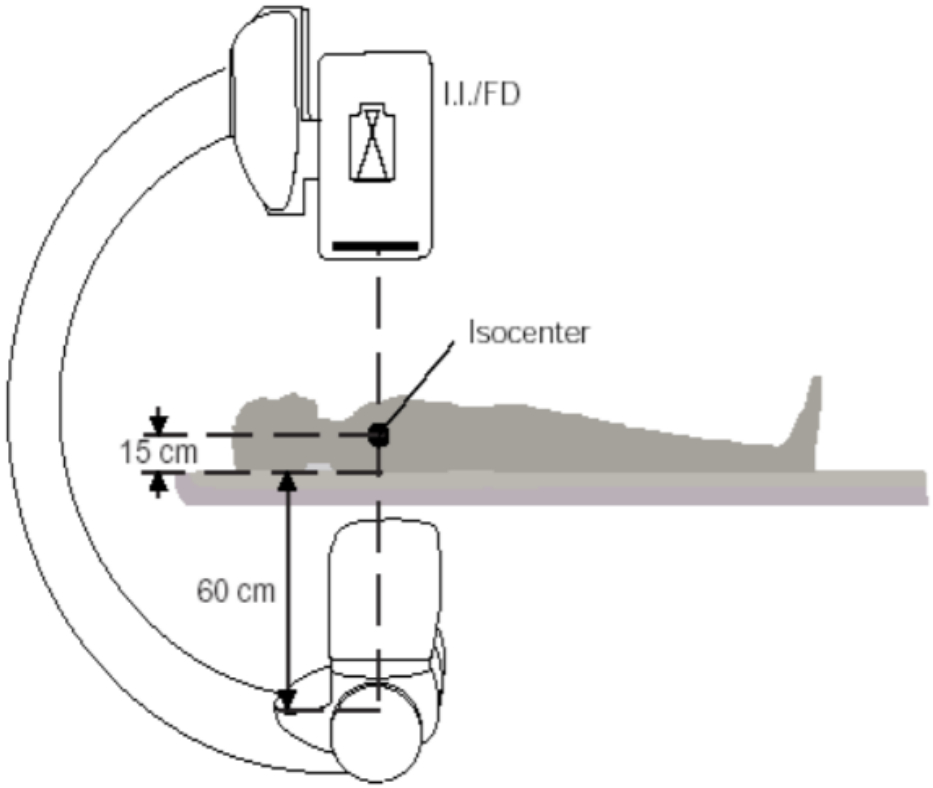
- **DRL quantity**. A commonly and easily measured or determined radiation dose quantity or metric (e.g. PKA, Ka,r) that assesses the amount of ionising radiation used to perform a medical imaging task. The quantity or quantities selected are those that are readily available for each type of medical imaging modality and medical imaging task.

Appropriate quantities

- **DRL quantity**. A commonly and easily measured or determined radiation dose quantity or metric (e.g. PKA, Ka,r) that assesses the amount of ionising radiation used to perform a medical imaging task. The quantity or quantities selected are those that are readily available for each type of medical imaging modality and medical imaging task.

1. **air kerma-area product (PKA),**
2. **cumulative air kerma at the patient entrance reference point (Ka,r),**
3. **fluoroscopy time,**
4. **and the number of radiographic images** (e.g. cine images in cardiology and digital subtraction angiography images in vascular procedures).

Reference Air Kerma



- 1 cm above the patient support for interventional x-ray equipment with the x-ray source assembly below the patient support;
- 30 cm above the patient support for interventional x-ray equipment with the x-ray source assembly above the patient support;
- **15 cm from the isocenter in the direction of the focal spot for c-arm interventional x-ray equipment**

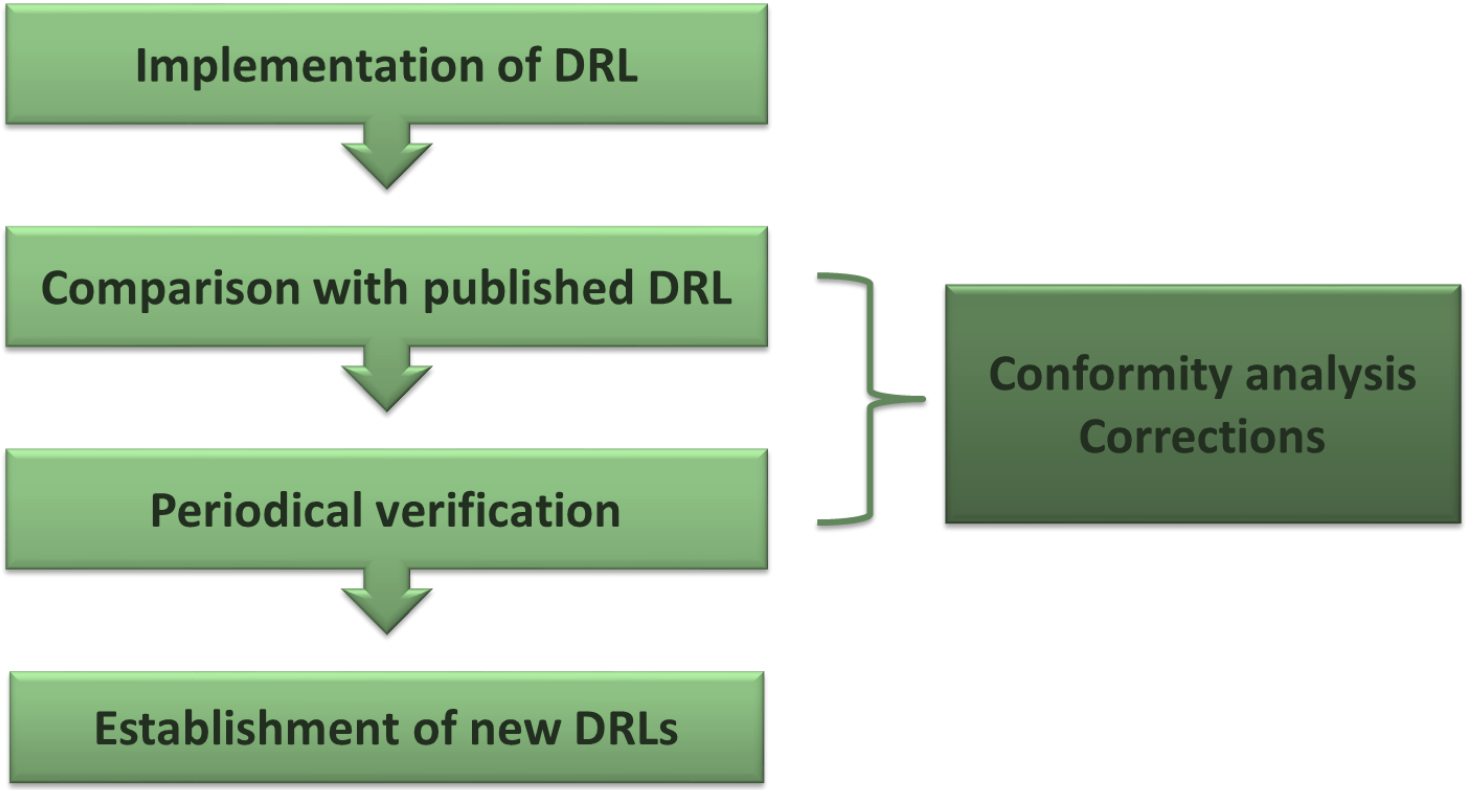
Radiation metrics and effective dose

- Effective dose is not appropriate as a DRL quantity
- Effective dose is not a measurable quantity and does not assess the amount of ionising radiation used to perform a medical imaging task
- Its use could introduce extraneous factors (stochastic risk in the average population) that are not needed and not pertinent for the purpose of DRLs

PROCEDURES AND METHODS

Definition

- **DRL process**. The cyclical process of establishing DRL values, using them as a tool for optimisation, and then determining updated DRL values as tools for further optimisation).



Implementation of DRLs for IR

- For the most accurate comparisons of dosimetric data among populations undergoing FGI procedures, it would be desirable to normalise PKA and Ka,r data by compensating for differences in **patient body habitus and weight**

Implementation of DRLs for IR

- For the most accurate comparisons of dosimetric data among populations undergoing FGI procedures, it would be desirable to normalise PKA and Ka,r data by compensating for differences in **patient body habitus and weight**
- For interventional procedures, **complexity** is a determinant of patient dose, and should ideally be evaluated individually for each case. A **multiplying factor** for the DRL may be appropriate for more complex cases of a procedure

Data Sample

- The Commission recommends setting local and national DRL values based on surveys of the DRL quantities for procedures performed on **appropriate samples of patients**. The use of phantoms is not sufficient in most cases

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AUTOMATED COLLECTION

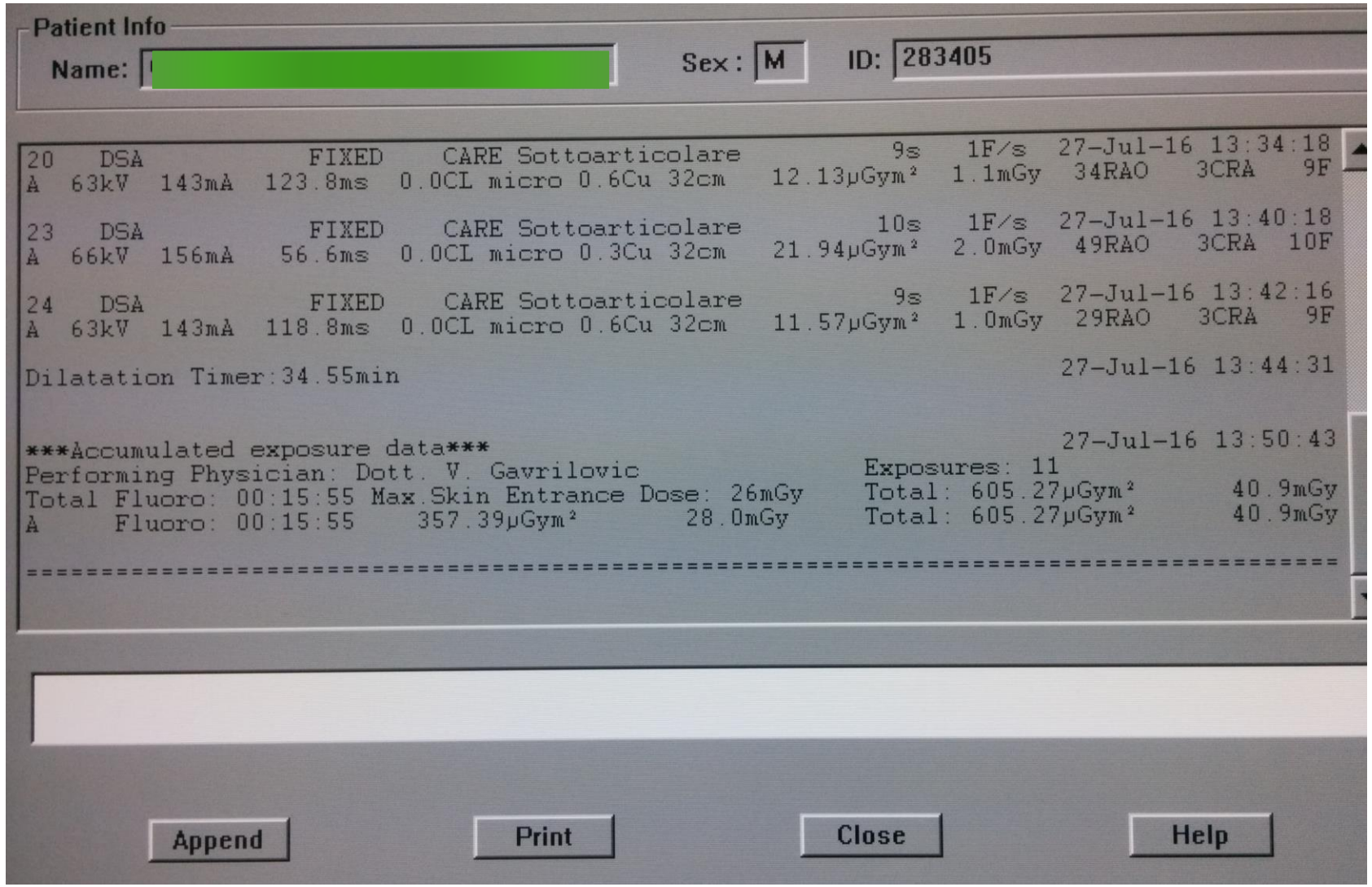
Dose Objects

- *Dose Display and Proprietary Report*
- DICOM Header
- Modality Performed Procedure Step
- Radiation Dose Structured Report (RDSR)

Dose Objects

- ***Dose Display and Proprietary Report***
- DICOM Header
- Modality Performed Procedure Step
- Radiation Dose Structured Report (RDSR)

Dose Display



Dose Display e Proprietary Report

- Data useful but poor
- Extraction software → Optical Character Recognition → create a RDSR
  - Open Source
    - Dose Utility" - dclunie.com
      by David Clunie (PixelMed)
    - "Radiance" - radiancedose.com
      by Tessa Cook (Hospital of U of Pennsylvania)
    - "GROK" – dose-grok.sourceforge.net
      by Graham Warden (Brigham and Women's Hospital)
  - Others
    - "Valkyrie" (considering open source)
      by George Shih (Weill-Cornell)
    - ACR Triad Site Server (included in ACR participation)
      by Mythreyi Chatfield (ACR)

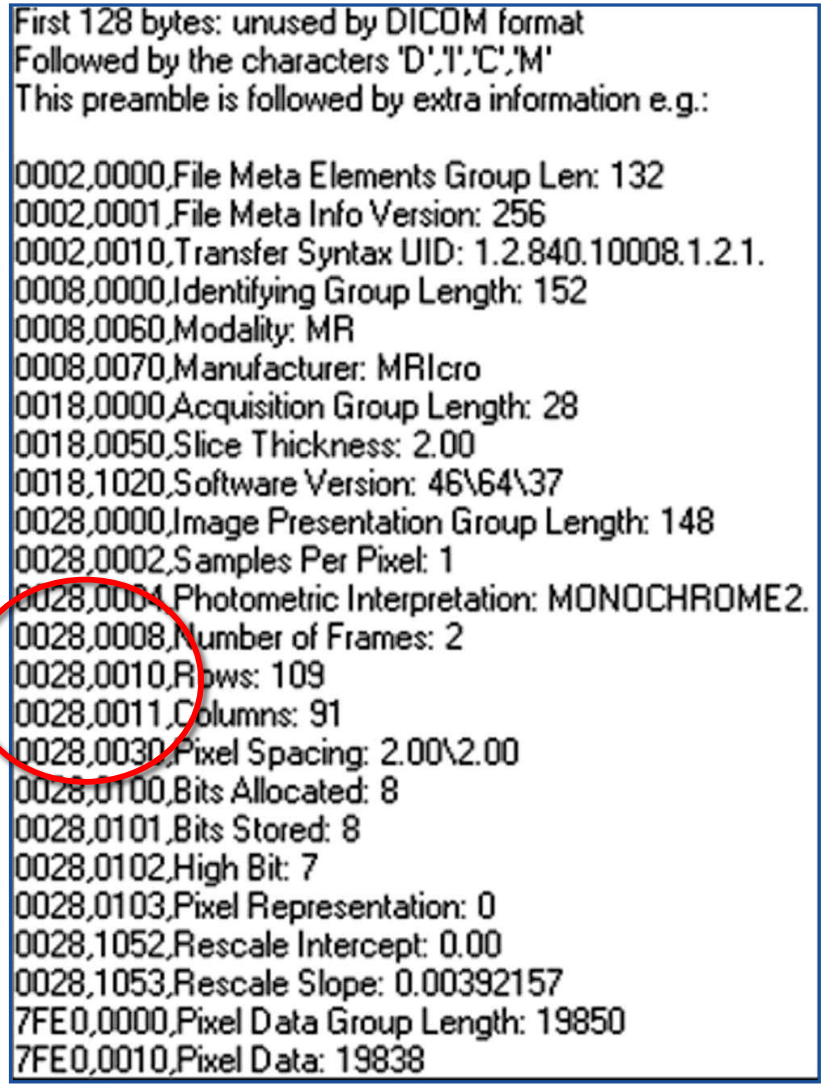
Dose Objects

- *Dose Display and Proprietary Report*
- **DICOM Header**
- Modality Performed Procedure Step
- Radiation Dose Structured Report (RDSR)

DICOM Header

- Text file → a lot of information (depending on the modality and the manufacturer):
  - Patient data
  - Procedure data
  - Geometry
  - Image characteristic
  - Estimated dose quantities

- Information encoded in TAGs



DICOM Header

- PRO
  - Information stored in the archive

DICOM Header

- PRO
  - Information stored in the archive

- CONS
  - Information stored together with the image:
    - no image – no data;
    - often several reconstructions from a single exposure, so need to take care not to add header information from these non-original exposures
  - Information not complete
  - Huge amount of data stored

Dose Objects

- *Dose Display and Proprietary Report*
- DICOM Header
- **Modality Performed Procedure Step**
- Radiation Dose Structured Report (RDSR)

DICOM MPPS

- MPPS (Modality Performed Procedure Step) is a notification message from the modality to the RIS/ PACS.

- Again a lot of information included (depending on the modality and the manufacturer):
  - Patient data
  - Procedure data
  - Geometry
  - Image characteristic
  - Estimated dose quantities

DICOM MPPS

- PRO
  - Information stored independently from the images

DICOM MPPS

- PRO
  - Information stored independently from the images

- CONS
  - Intended to manage scheduling system
  - Limited ability to encode complex data
  - Transient message, nor a persistent object
  - Not intended to be “stored” or queried → no rules

New Supplement

Radiation dose module retired from the MPPS SOP class (2017)

Rationale:

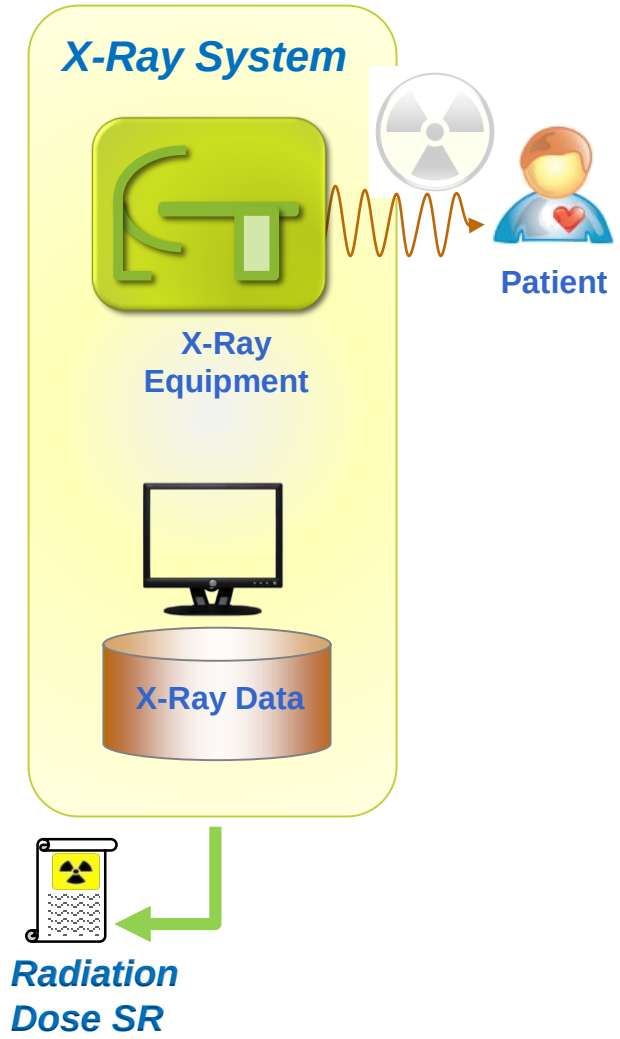
- Module published in 1998 but not widely adopted
- It dose not provide a means of persistently storing nor managing the highly structured radiation information needed
- REM profile based on RDSR not MPPS

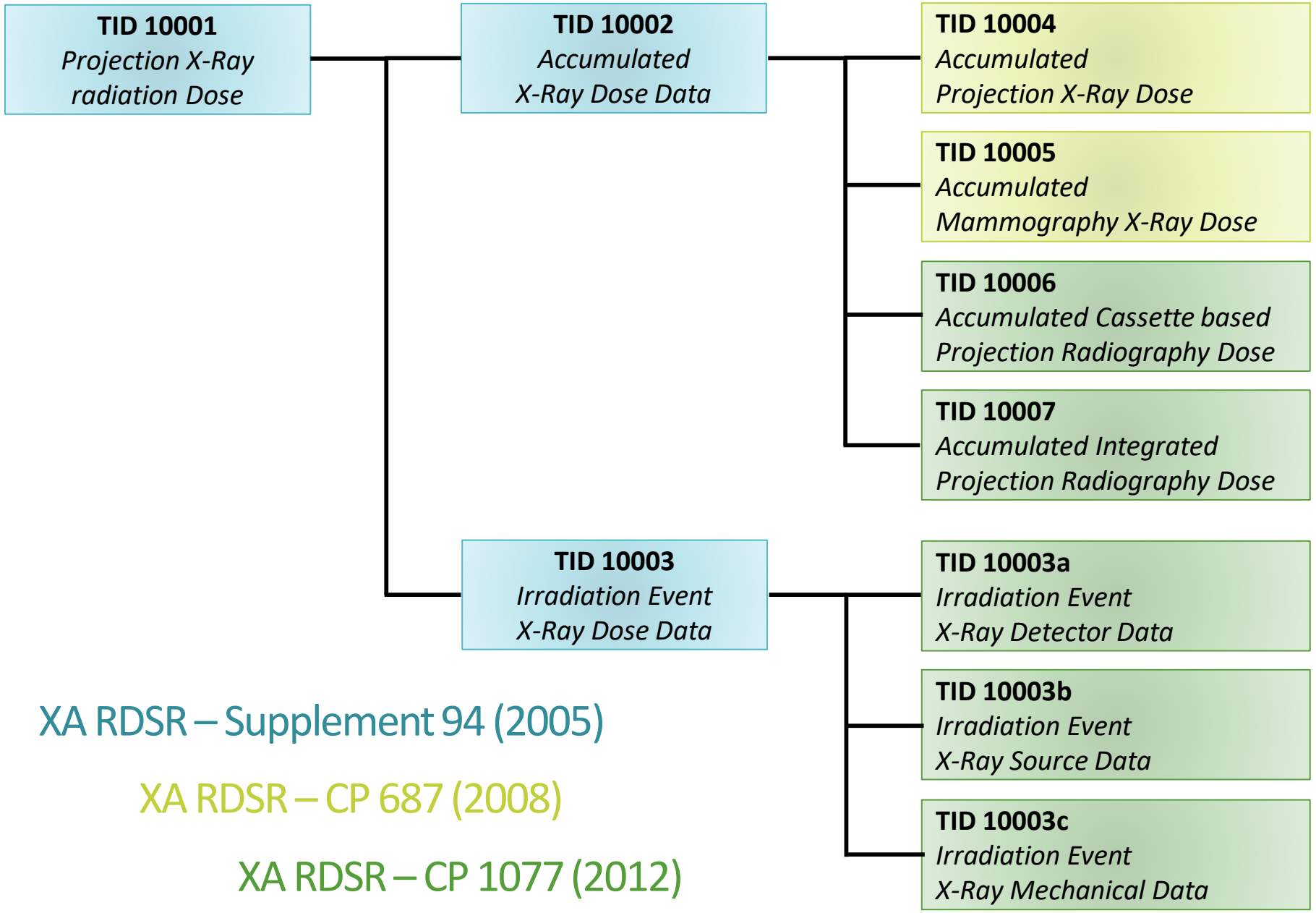
Dose Objects

- *Dose Display and Proprietary Report*
- DICOM Header
- Modality Performed Procedure Step
- **Radiation Dose Structured Report (RDSR)**

Radiation dose structured report

- Developed in 2005 for projection X-ray (Supplement 94)
- Used to convey exposure characteristics and dose generated by imaging devices (output, geometry, exposure data,…)





XA RDSR – Supplement 94 (2005)

XA RDSR – CP 687 (2008)

XA RDSR – CP 1077 (2012)

Which information *can be* there?

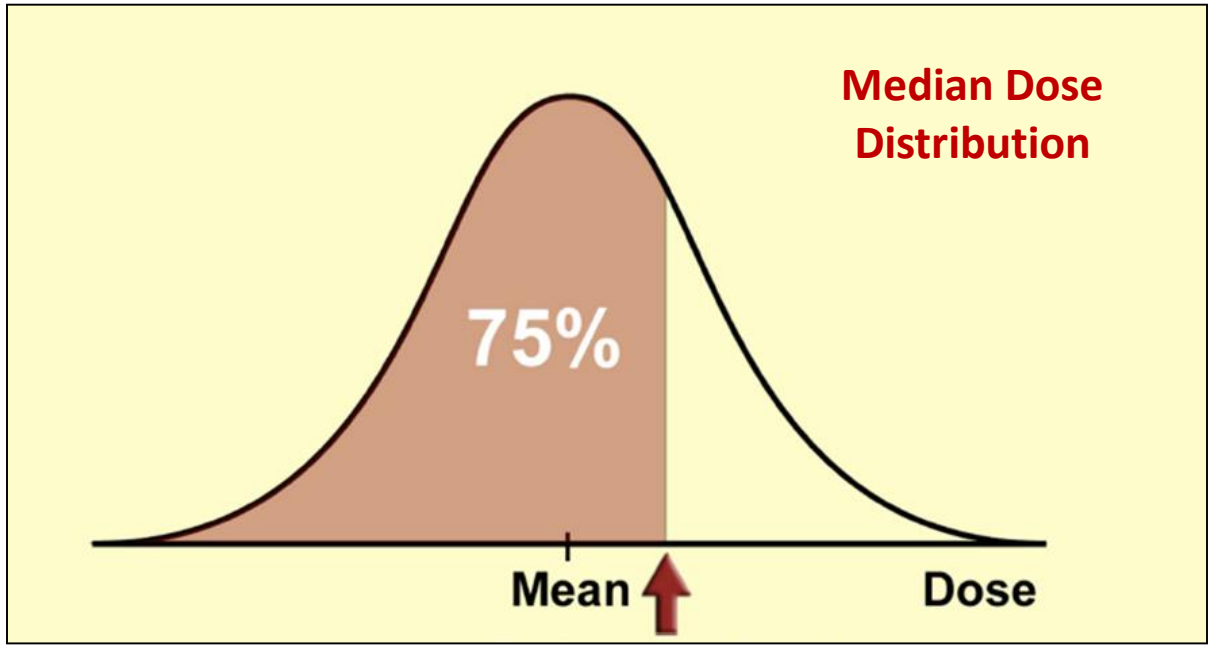
- Patient info (Name, birth date, height, weight, ….)
- Procedure info (Date and time, type, target region….)
- Source info (kV, mA/mAs, additional filtration, ….)
- Exposure info (KAP, CK, CTDI, DLP, …)

Pros

- Persistent document-like object
- Store to PACS, RIS, XDS, CD media
- Extensible, coded, structured content
- Contains accumulated & per event exposure
- Contains detailed technique description

DRL definition

DRL value. A selected numerical value of a DRL quantity, set at the **75th percentile of the medians** of DRL quantity distributions observed at multiple facilities or in some specific cases, the 75th percentile of the DRL quantity distributions observed at one or more local healthcare facilities. Regional DRL values can also be based on the median values of the available national DRLs.



Alternative method

- A different method can be applied to characterise and analyse the amount of radiation used for FGI procedures, without the need for the clinical data (pathology information, image analysis, and technical and clinical complexity factors) that are usually difficult to collect (NCRP, 2010)

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- A different method can be applied to characterise and analyse the amount of radiation used for FGI procedures, without the need for the clinical data (pathology information, image analysis, and technical and clinical complexity factors) that are usually difficult to collect (NCRP, 2010)
- **Information from the full distribution** → data from all cases (Advisory data set)

Verification

- **Median values** (not mean values) of the distributions of data collected from a representative sample of standard-sized patients should be used for comparison to DRLs.

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- A DRL value is considered to be exceeded when the **local median value of a DRL quantity for a representative sample of standard-sized patients is greater than the local, national, or regional DRL value**.

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  - High radiation doses may reflect poorly functioning equipment or incorrect equipment settings, suboptimal procedure performance, operator inexperience, or high clinical complexity

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  - **High radiation doses** may reflect poorly functioning equipment or incorrect equipment settings, suboptimal procedure performance, operator inexperience, or high clinical complexity
  - When the facility's median value of a DRL quantity is **lower than the median value** of the national or regional DRL survey distribution, image quality (or diagnostic information, when multiple images are used) may be adversely affected and should be considered as a priority in the review.

Verification

- Comparison with the relevant DRL values should, when possible, take into account the level of complexity of the procedures in the sample. When this information is not available, **median, 25th, and 75th percentile values** of the facility data should be compared with the corresponding percentile values of the national ADS

Multiple DRL quantities

- The Commission recommends that data **for all suitable DRL quantities** that are available should be tracked for interventional procedures at facilities where these procedures are performed

DRLs (UK)

Interventional procedures on adult patients

Interventional procedure	DAP per exam (Gy cm^2)	Fluoroscopy time per exam [3] (minutes)
Biliary intervention	43	14
Facet joint injection	6	1.4
Hickman line insertion	3	1.5
Nephrostomy	13	6.7
Oesophageal stent	13	5
Pacemaker (permanent)	7	6
Percutaneous transluminal coronary angioplasty (PTCA) (single stent) [4]	40	11.3

Values from HPA-CRCE-034: Doses to patients from radiographic and fluoroscopic x-ray imaging procedures in the UK (2010 review).

DRLs in IR (Image Wisely)

Steven Y. Huang et al., Procedure- and Patient-Specific Factors Affecting Radiation Exposure , 2015

Procedure	Reference Dose (Gy)	KAP (Gy cm^2)	Fluoroscopy Time (min)	No. of Images
Transjugular intrahepatic portosystemic shunt creation	3.00	525	60	300
Biliary drainage	1.40	100	30	20
Nephrostomy				
For obstruction	0.40	40	15	12
For stone access	0.70	60	25	14
Pulmonary angiography	0.50	110	10	215
Inferior vena cava filter placement	0.25	60	4	40
Renal or visceral angioplasty				
Without stent	2.00	200	20	210
With stent	2.30	250	30	200
Iliac angioplasty				
Without stent	1.25	250	20	300
With stent	1.90	300	25	350
Bronchial artery embolization	2.00	240	50	450
Hepatic chemoembolization	1.90	400	25	300
Uterine fibroid embolization	3.60	450	36	450
Other tumor embolization	2.60	390	35	325
Gastrointestinal hemorrhage localization and treatment	3.80	520	35	425
Embolization in the head				
For AVM	6.00	550	135	1500
For aneurysm	4.75	360	90	1350
For tumor	6.20	550	200	1700
Vertebroplasty	2.00	120	21	120
Pelvic artery embolization for trauma or tumor	2.50	550	35	550
Embolization in the spine for AVM or tumor	8.00	950	130	1500

DRLs (Italy)

Tabella 4.5. Valori LDR per radiologia interventistica (corpo, neurologica, cardiologica, gastroenterologica) nell'adulto nella pratica radiologica italiana

Procedura	Valori LDR	
	KAP *Gycm²*	Tempo fluoroscopia *min*
Angiografia cerebrale	115	10
Embolizzazione aneurismi cerebrali	180	45
PTA e/o stenting carotideo	100	20
Embolizzazione o chemoembolizzazione epatica	400	20
CPRE	45	
Interventistica biliare percutanea	45	
TIPS	500	40
Vertebroplastica	80	15
Endoprotesi aorta addominale	158	18
Coronarografia	70	7
Angioplastica e/o stenting coronarico (CA+PCI)	160	19
Impianto di pacemaker	20	8
Ablazione cardiaca con radiofrequenza *	110	40

Livelli diagnostici di riferimento per la radiologia diagnostica ed interventistica, Rapporti ISS 17/33, 2017

European (2018)

The median total P_{KA} values (in Gy cm^2) for each procedure and each country. The last two columns are the 3rd quartiles (without and with weight restriction) of the data on each row. The median P_{KA} values that are based on less than five data points are given in parentheses. DRL was calculated from medians with at least five data points. *Includes ablation. The 3rd quartiles in parenthesis are calculated without this values.

Procedure	BE	HR	CZ	FI	FR	GR	IR	LB	PL	RS	ES	SE	CH	3rd quartile	3rd quartile (restr)
CA	35.6		35.5	21.2	22.0	–	35.3	12.8	14.1	42.2	34.2	17.5	65.7	35.5	36.8
PCI	87.3	35.9	89.8	45.7	57.6	44.5	73.0	37.7	28.5	98.1	63.4	31.7	135	87.3	68
CTO	–	–	–	–	120	–	(271)	–	–	–	–	143	–	137	–
TAVI	(305.4)	(55.4)	130	89.4	134	193	87.1	99.2	–	–	25.9	87.2	96.8	130	140
PI SCH	–	–	2.18	1.86	–	5.60	2.63	2.40	–	2.97	–	1.43	–	2.80	3.8
PI DCH	–	–	2.28	3.20	–	(25)	2.53	3.84	–	5.16	–	0.86	–	3.65	4.23
PI CRT	–	–	18.4	31.4	14	6.63	15.8	4.96	–	19.2	5.82	4.13	–	18.4	20.8
EF AVNRT	–	–	0.97	3.67	–	–	(2.26)	–	–	–	–	2.73	–	3.2	4.75
EF FL	–	–	0.96	14.5	–	–	–	–	–	–	–	6.58	–	10.5	–
EF AF	–	–	2.51	29.2	–	–	4.84	–	–	–	–	8.41	–	13.6	16.0
EF ALL	–	–	1.09	14.5	3.5	5.28	3.5	109.1*	–	–	13.7	6.53	–	14.1 (11.9)	(13.5)

The median cumulative air kerma C_K values (in mGy) for each procedure and each country. The last column is the 3rd quartile of the data on each row. The median C_K values that are based on less than five data points are given in parentheses. DRL was calculated from medians with at least five data points. *Includes ablation. The 3rd quartile in parenthesis is calculated without this value.

Procedure	BE	HR	CZ	FI	FR	GR	IR	LB	PL	RS	ES	SE	CH	3rd quartile
CA	478	178	359	299	274	–	416	186	271	486	578	–	–	463
PCI	1170	747	965	736	803	661	1631	602	626	1481	1320	–	–	1245
CTO	–	–	–	–	1467	–	(4352)	–	–	–	–	2204	–	2020
TAVI	(2123)	(537)	826	1292	894	1550	866	932	–	–	269	1196	810	1196
PI SCH	–	–	–	19	–	53	35	20	–	28	–	10	–	33
PI DCH	–	–	–	28	–	(238)	26	30	–	48	–	6	–	30
PI CRT	–	–	–	295	99	63	150	43	–	176	–	34	–	163
EF AVNRT	–	–	–	36	–	–	(23)	–	–	–	–	–	–	36
EF FL	–	–	–	150	–	–	–	–	–	–	–	–	–	150
EF AF	–	–	–	374	–	–	70	–	–	–	–	–	–	298
EF ALL	–	–	–	150	–	47	42	894*	–	–	–	–	–	150 (73)

Establishing the European diagnostic reference levels for interventional cardiology, T. Siiskonen et al, Physica Medica 54 (2018)

Multiple DRL quantities

- The Commission recommends that data **for all suitable DRL quantities** that are available should be tracked for interventional procedures at facilities where these procedures are performed
- It simplifies the evaluation

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  - if P_{KA} exceeds the DRL value but Ka,r is within an acceptable range, there may be insufficient attention to collimation
  - If the median P_{KA} and/or Ka,r in a particular institution exceeds the corresponding DRL value, evaluation of fluoroscopy time and the number of acquired images may help to determine whether these are contributing factors

Actions

- If the median values of the DRL quantities are higher than expected, investigation of the fluoroscopic equipment is appropriate.
  - PMMA slab phantom that simulate patients provide an excellent method for evaluating equipment performance in terms of Ka,e and air kerma rate. They can provide assessments of radiation levels from the different imaging programmes available on the fluoroscope

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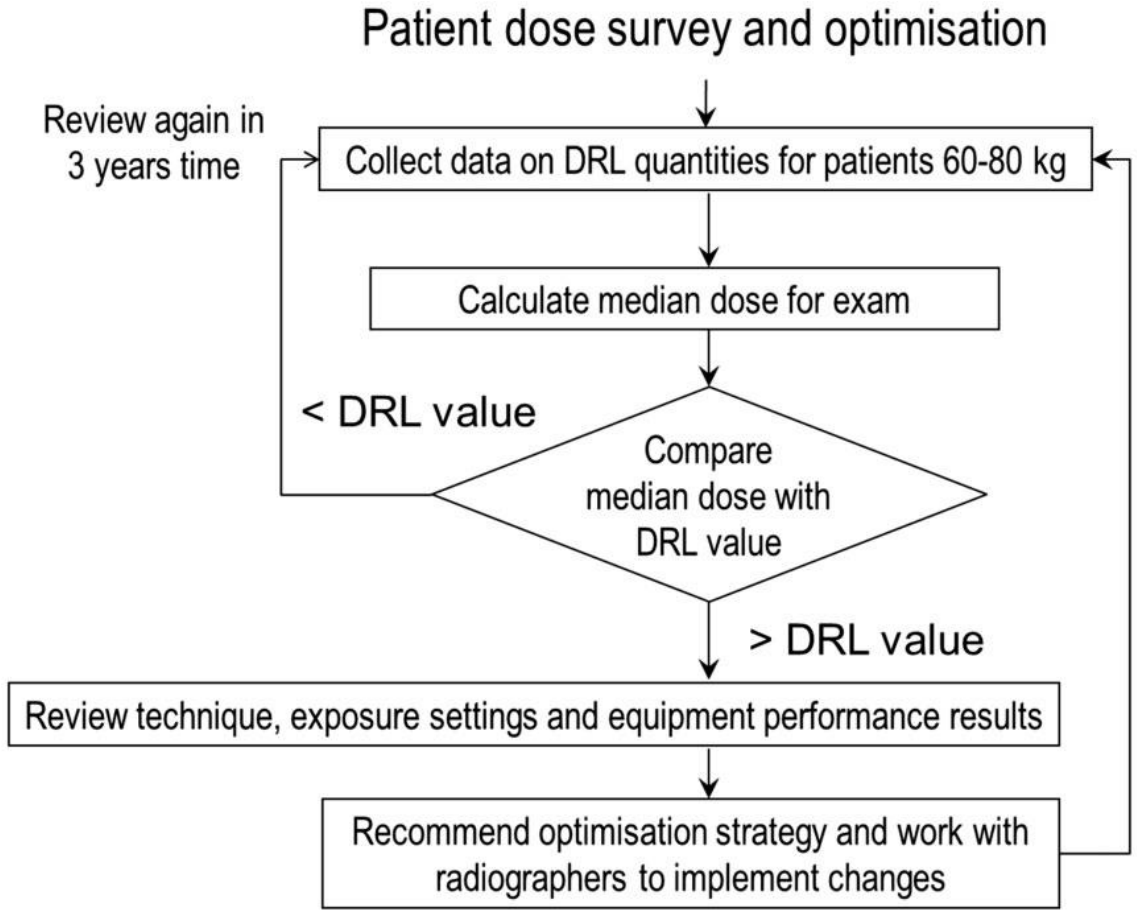
  - If the fluoroscopic equipment is functioning properly and within specification, procedure protocols and operator technique should be examined (2^{nd} step)

Local Audits

- The DRL **audit process does not stop after a single assessment**
  - Repeat after any optimisation, and after an appropriate time interval.
- **Local surveys** of DRL quantities, as part of the clinical audit, should be performed **annually for CT and interventional procedures.**
  - If continuous collection through automated collation of data from electronic databases even more frequently to identify trends



DRL Revision

- National and regional DRL values should be revised at **regular intervals (3-5 years)** or more frequently when substantial changes in technology, new imaging protocols or post-processing of images become available.

RECCOMENDATIONS

ICRP recommendations for IR (summary)

- DRL values shall **not be used for individual patients or as trigger** (alert or alarm) levels for individual patients or individual examinations.
- All individuals who have a role in subjecting a patient to a medical imaging procedure should be familiar with DRLs as a tool for optimisation of protection
  - The concept and proper use of DRLs should be included in the **education and training** programmes of the health professionals involved in medical imaging with ionising radiation.
  - Periodic training sessions to involve interventionists in the radiation safety culture.
- **Calibrations of all dosimeters**, kerma-area product meters, etc., used for patient dosimetry should be performed regularly and should be traceable to a primary or secondary standard laboratory.

ICRP recommendations for IR (summary)

- Comparison of local practices to DRL values is **not sufficient, by itself**, for optimisation of protection
  - **Image quality or, more generally, the diagnostic information** provided by the examination (including the effects of post-processing), must be evaluated as well, and methods to achieve optimisation should be implemented.

ICRP recommendations for IR (summary)

- Hospital Information Systems and Radiology Information Systems can provide data for large numbers of patients. As with all DRL surveys, the results rely on the **accuracy of data entry.**
  - The accuracy of DRL quantity data produced by and transferred from x-ray systems should be periodically verified by a medical physicist.

ICRP recommendations for IR (summary)

- The process to set and update DRLs should be both flexible and dynamic.
  - **Flexibility** is necessary for procedures where few data are available (e.g. interventional procedures in paediatric patients), or from only one or a few centres.
  - A **dynamic** process is necessary to allow initial DRLs to be derived from these data while waiting for a wider survey to be conducted.
- When a procedure is not performed on a regular basis in most hospitals, local DRL values may be determined using the data from a single large hospital with a relevant workload of procedures (e.g. a specialised paediatric hospital).
- **Local DRLs** set by a group of radiology departments or even a single facility can play a role, where effort has already been invested in optimisation. Local DRL values can also be set for newer technologies that enable lower dose levels to be used in achieving a similar level of image quality.

ICRP recommendations for IR (summary)

- Priorities when dosimetric values (for groups of patients) are **substantially higher** from DRLs (usually, the first action should be a re-evaluation of the X-ray system and the proper use of validated protocols).
  - Corrective actions should be implemented **without undue delay**.