Joint ICTP-IAEA Workshop on Establishment and Utilization of Diagnostic Reference Levels in Medical Imaging

Dose audits in lack of automatic exposure monitoring systems

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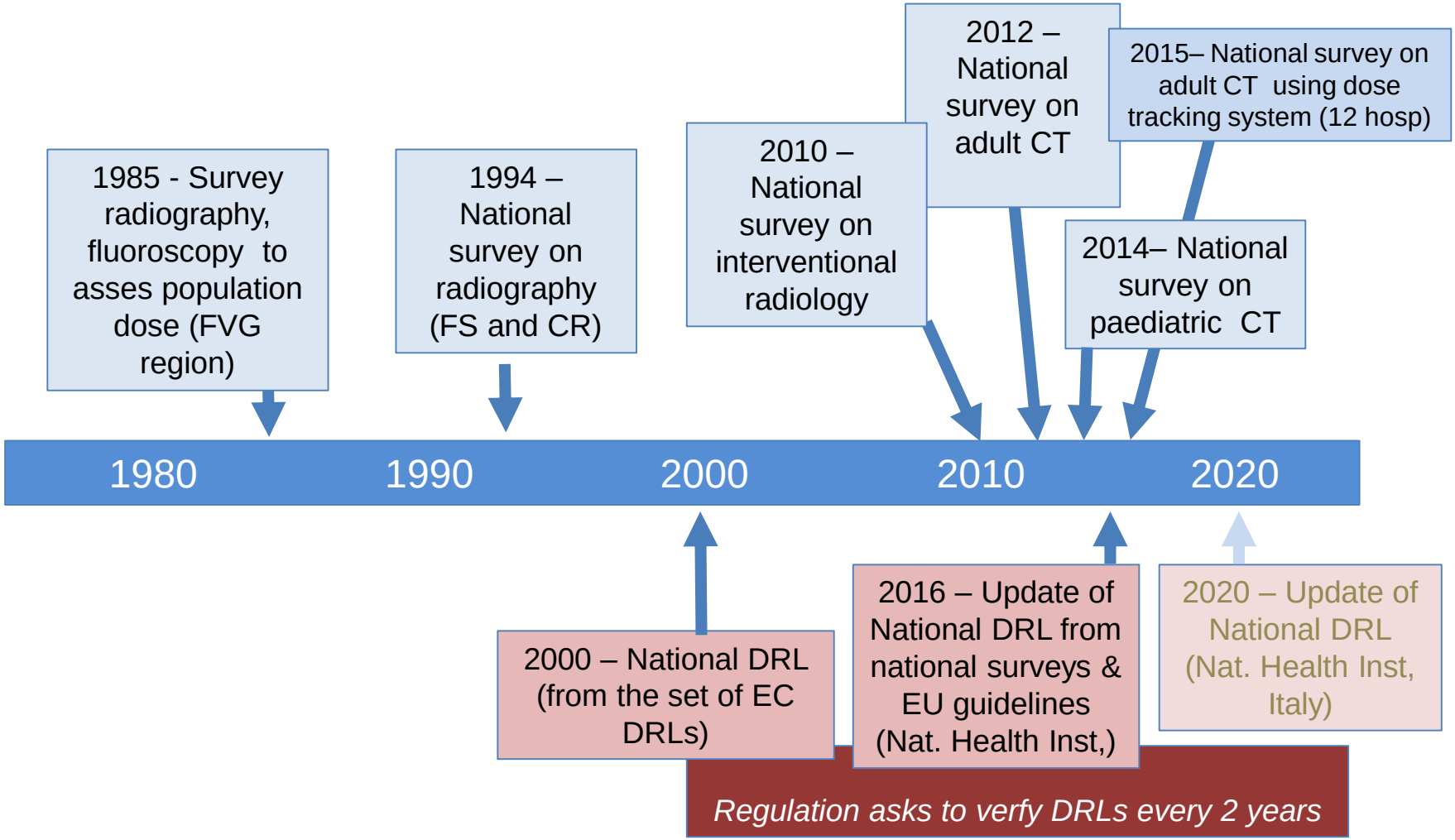
Italian actions in monitoring patient exposure and DRL assessment and use



Dose audits in lack of automatic exposure monitoring systems

- Survey for the DRL assessment
  - Sampling
  - Simple vs complex forms
- Use of the DRLs

Aim of the survey: DRL assessment

Term	Area and facilities surveyed	Value in distribution used to set DRL	Application
Typical values	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 optimisation
Local	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 optimisation
National	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 optimisation is needed
Regional	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

From ICRP 135, 2017

How to start

- Who? National body, medical physics/radiology associations, group of medical physicists, etc. can take the initiative to develop a national project

- To remember in developing the project:
  - Most of survey experience are seeing a voluntary participation of facilities/staff
  - Because of this, we have to balance properly the amount of work we can request,
  - e.g. too many data to collect can bring to poor data quality, missed data

1st step: Procedure types for the survey

- Number of procedure types as a function of the workload we can request to facilities
- 2-4 most frequent procedures per installation type (radiography, CT, IR) if:
  - it is the first survey in the country
  - there is a low awareness of patient exposure
- Procedure list should include the clinical task associated with the procedure (limited clinical tasks to include)

- Clinical indication example (Canadian CT survey, 2016)

Table 1: *Standard CT examinations (anatomical region) surveyed and corresponding clinical indications that are most likely used (not a completely exhaustive list).*

Anatomical Region	Clinical Indication
Routine Head [Adult]	Headache, Cerebrovascular Accident (CVA), or Transient Ischemic Attack (TIA)
Chest [Adult]	Primary cancer, known/suspected metastasis or lung nodule follow-up
Abdomen, Pelvis [Adult]	Primary/metastatic work-up or abscess
Chest, Abdomen, Pelvis [Adult]	Lymphoma staging, follow-up or Trauma
Pediatric Head	Trauma, including non-accidental injury
Pediatric Chest	Detection of malignancy, Trauma
Pediatric Abdomen	Detection of malignancy, Trauma

Procedure types: how to select

- National data on procedure frequencies can help in selecting the most frequent procedure types

Contribution to collective doses of different radiography, fluoroscopy and IR examinations in Europe (EC, 2008)

Examination	Percentage of total frequency of all radiology examinations (%)	Percentage contribution to collective dose (%)
Radiography		
Chest/thorax	12–29	0.7–5.2
Mammography	0.3–15	0.6–4.7
Abdomen, pelvis, and hip	7.4–14.3	2.9–14.1
Spine (thoracic and lumbar)	3.8–12.7	30.1
Intravenous urography	0.3–2.0	1.2–8.7
Radiography/fluoroscopy		
Barium meal	0.3–0.9	0.8–5.9
Barium enema (N.B. now often replaced by CT colonoscopy)	0.1–2.0	0.5–13
Cardiac angiography	0.2–1.3	2.8–9.4

Sample of facilities for a national survey

- The sample should cover:
  - a representative selection of healthcare providers (large/small hospitals, clinics)
  - and, represent all geographical areas

Example: European Guidelines on Diagnostic Reference Levels for Paediatric Imaging (RP no. 185)

- DRLs should be based on national patient dose surveys with a representative sample of all radiological institutions in the country when available.

- DRLs based on very limited surveys or on measurements only in phantoms, as well as DRLs adopted from international recommendations or from other countries, should only be used as preliminary values until data from the relevant national patient dose surveys are available.

Example: Sampling experience in UK

- In stratified sampling (university or general hospital, clinics strata) also geographical distribution has to be assured
  - To compare no. rooms/area with no. examinations/year in each area
    - We need national/area workload statistics (no. of exams per type of examination)
  - Problem to consider: not all invited hospitals supply data (e.g. those knowing to have high doses, without QA programme or without medical physicists)

NRPB-W14, Doses to Patients from Medical X-ray Examinations in the UK, 2000 Review

Example: Sampling experience in UK

- After the collection of data we can realise that some regions are under/over-represented (higher % of rooms in the sample)

TABLE 1 Comparison of NHS radiology workload with database sample size on a regional basis

Region	% of UK radiology workload	% of NHS hospitals in database	% of room mean doses per exam in database
England – North	27	22	46
England – Midlands & East	22	21	22
England – South	20	15	6
England – London	15	10	12
Scotland	8	21	10
Wales	5	5	2
Northern Ireland	3	6	2
	100	100	100

NRPB-W14, Doses to Patients from Medical X-ray Examinations in the UK, 2000 Review

Example: Sampling experience in UK

- … or, hospital size clusters can be over/under-represented

TABLE 2 Percentage of hospitals in the UK and the National Patient Dose Database as a function of the number of beds

	Percentage of hospitals	
Number of beds per hospital	UK	NPDD 2005
0-49	34	25
50-249	33	33
250-499	16	20
500-999	16	21
1000+	1	1

Source: Informa Healthcare 2003

- In these cases, some data can be removed from the database or it should be verified the influence on the DRL value

NRPB-W14, Doses to Patients from Medical X-ray Examinations in the UK, 2000 Review

Example: Sampling experience in UK

- " following experience of previous surveys, a sufficient sample is taken to be at least 10 hospitals, 20 rooms and 100 patients. ….." (NRPB UK 2005)

To remember: sampling methods

- **5 types of sampling: Random, Systematic, Convenience, Cluster, and Stratified.**
  - **Random** sampling. Each element in the population has an equal chance of occurring
  - **Systematic** sampling. The list of elements is "counted off". That is, every *k*th element is taken.
  - **Convenience** sampling. In convenience sampling, readily available data is used. It is very easy to do, but it's probably the worst technique to use.
  - **Cluster** sampling is accomplished by dividing the population into groups -- clusters. The clusters are randomly selected, and each element in the selected clusters are used.
  - **Stratified** sampling divides the population into groups called strata. E.g. university hospitals, regional, clinics. A sample is taken from each of these strata using either random, systematic, or convenience sampling.

Sample of facilities for a national survey (ICRP 135)

The sample should cover a representative selection of healthcare providers and represent all geographical areas

Large country:

- Results from 20–30 facilities are likely to be sufficient in the first instance, if a sufficient number of patients from each facility are included

Small country (<50 facilities):

- A survey of 30–50% of the facilities may be sufficient

- Limitation: convenience sampling can affect representativeness of the sample

Sample of facilities for a national survey (ICRP 135)

- The initial establishment of national or regional DRL values is the first step in a continuing process.
- Thereafter, surveys will need to be repeated periodically to evaluate changes and update DRL values
- Subsequent surveys may take the form of:
  - collation of measurements made by local medical physicists or radiology staff,
  - automated data collection
  - continuing participation in a national registry.

Patient samples

- Standardisation: usually through weight restriction
- Adults: typically 50–90 kg to achieve a 70-kg mean, or different range fitting the country typical adult patient size
- Paediatric: weight bands are recommended:
  - <5 kg, 5–<15 kg, 15 –<30 kg, 30 –<50 kg, and 50–< 80 kg.
  - If not available, age bands around 0, 1, 5, 10, and 15 years

Patient samples

- Patients/room/examination type:
  - At least 20 for radiography
  - At least 30 for CT, fluoroscopy
  - At least 50 for mammography (or restriction on breast thickness)
  - 30 or more for IR, depending on the dose variability

Example: European Guidelines on Diagnostic Reference Levels for Paediatric Imaging (RP no. 185): sample of patients

Another recommendation

Sample size:

- Radiography: at least 10 patients per procedure type and per patient group
- CT & fluoroscopy & IR : at least 20 patients per procedure type and per patient group

DRL quantities for radiography, fluoroscopy and IR

- DRL quantities:
  - Radiography and fluoroscopy : Entrance surface air kerma $K_{a,e}$, Air kerma area product P_{KA}
  - Mammography: $K_{a,e}$, Mean glandular dose D_G
  - IR: P_{KA}, Incident air kerma at the IRP $K_{a,r}$, no. images, fluoroscopy time
  - CT: $CTDI_{vol}$, DLP (single scan and total)

- Set the DRL with multiple quantities provide a guide to good practice, and can simplify the investigation of practices at a facility

- Example: Multiple DRL quantities for DRL in IR cardiac procedures

Procedure	TF (min)	KAP (Gycm^2)	CK all'IRP (mGy)
Coronarography			
Studio INAIL (6 centri italiani, 2012) (57)*	8,1	58,7	-
Studio GISE (27 centri italiani, 2013) (58)	7,1	67,8	988
Studio ISS (12 centri italiani, 2013) (48)	7	53	826
Studio EU (Neofotistou e al.2003) (31)	6	57	-
Studio IAEA (Balter e al.2008) (29)	9	50	-
PCI			
Studio INAIL (6 centri italiani, 2012) (57)*	16,9	128,6	-
Studio GISE (27 centri italiani, 2013) (58)	18,8	160	2934
Studio ISS (12 centri italiani, 2013) (48)	17,5	125	2155
Studio EU (Neofotistou e al, 2003) (31)	16	94	-
Studio IAEA (Balter e al.2008) (29)	22	125	-

DRL quantities: accuracy

- Accuracy of measured or computed DRL quantities
  - To collect information on:
    - Calibration checks of dose indicators (when used)
    - Calibration of dosimeters used in the facility to measure radiation output, CTDI, etc.

- e.g. for a radiography projection, *Ka,e* is usually assessed from output measurement and patient exposure data are collected with a form for each projection

$$K_{a,e} = Y(kV_p, d).mAs.(\frac{d}{FSD})^2.BS(kV, filtration, beam\ area)$$

FSD: focus-skin distance, BS: backscatter factor

DRL quantities: accuracy

- FROM TRS 457. Typical uncertainties for output measurements.
  Relative expanded (k=2) uncertainties are from 5.4 to 12.6%.

TABLE 8.2. EXAMPLES OF TYPICAL UNCERTAINTY BUDGETS FOR QUANTITIES DIRECTLY MEASURED BY DIAGNOSTIC DOSIMETERS

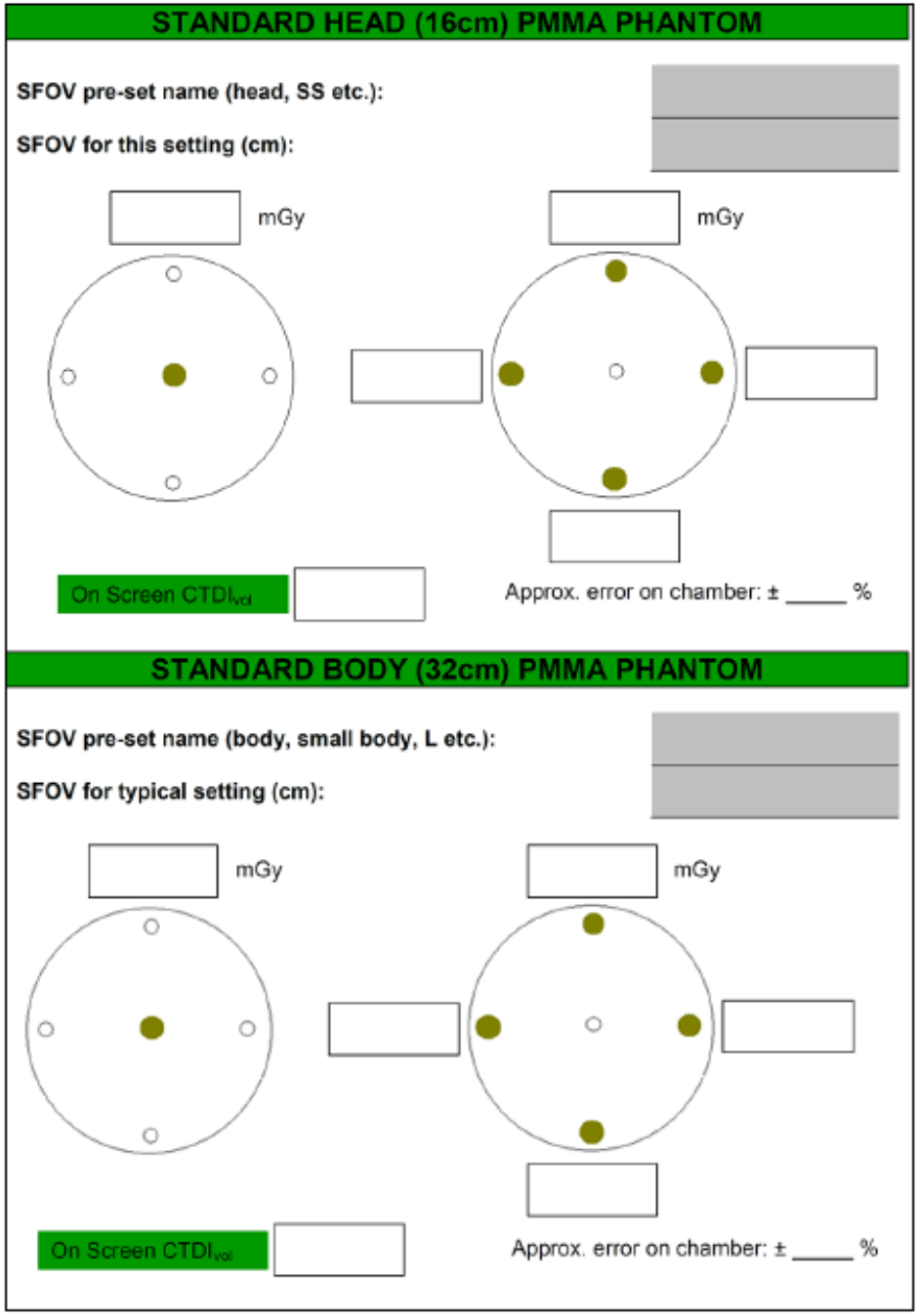
Influence quantity	IEC 61674 L (±%)	Uncertainty (k = 1)/%		
		Scenario 1	Scenario 2	Scenario 3
Intrinsic error, $N_{K,Q}$ or $N_{K,Q_0}k_Q$	5	2.89	1.6	1.6
Radiation quality, i.e. differences between SSDL and user	5	2.89	1.5	0.5
Kerma rate	2	1.15	0.5	0.5
Direction of radiation incidence	3	1.73	1.0	0.5
Air pressure	2	1.15	0.5	0.5
Temperature and humidity	3	1.73	0.5	0.5
Electromagnetic compatibility	5	2.89	1.5	1.0
Field size/field homogeneity	3	1.73	1.0	1.0
Operating voltage	2	1.15	1.2	1.0
Long term stability of user's instrument	2	1.15	1.0	0.5
Relative combined standard uncertainty (k = 1)		6.3	3.5	2.7
Relative expanded uncertainty (k = 2)		**12.6**	**7.0**	**5.4**

$$K_{a,e} = Y(kV_p, d).mAs.(\frac{d}{FSD})^2.BS(kV, filtration, beam\ area)$$

Propagating the uncertainties: the provided (unaccurate) FSD can increase substantially the uncertainty of $K_{a,e}$.
The other quantities can have a little impact on the combined uncertainty.

From the IAEA Code of practice for dosimetry in diagnostic radiology (TRS457)

- Example of form to collect CTDI dose measurements results and their accuracy



Canadian Computed Tomography Survey, National Diagnostic Reference Levels, 2016

Uncertainty of the mean and of the median values

- DRL value is based on the distribution of the median values.

- The uncertainty of the mean

$$u\overline{x_{mean}} = {\bar{x}}/{\sqrt{N}}$$

- With N the total number of data points and N=(2n+1), the uncertainty of the median

$$u\overline{x_{median}} = u\overline{x_{mean}}\sqrt{\pi(2n+1)/4n}$$

Valid if outliers are symmetric.

If not (this is the case with patient doses), repeated samples can provide an assessment of the uncertainty of the median

from mathworld.wolfram.com/StatisticalMedian.html

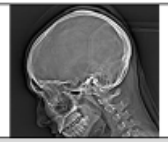
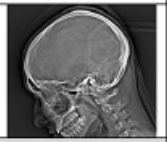
Forms for patient examination data collection

- Data of a DRL surveys are usually provided on a voluntary bases (convenience sampling).
- Forms should be carefully designed taking into account staff skills and time requested to fill the form
- Too complex forms can reduce accuracy and completeness of data collected
- Play attention: do not require data you will not use or analyse

Forms for data collections

- Example of simple form for CT exams

Examination: Routine head [Adult]
Indication: (circle) Headache, Cerebrovascular Acc. (CVA), Transient Ischemic Attack (TIA)

Individual Patient Survey		Provide data for each axial or helical scan sequence in exam		
		Sequence 1	Sequence 2	COMMENTS
Indicate actual start and end positions with lines on each image.				Shielding Type (if any) ❑ Bismuth ❑ Lead
Describe anatomical range scanned Scanned range (cm)				Mark with lightly shaded bar
Age (yrs.) / Weight (kg, lbs) / Sex (M, F)		/ /	/ /	
Axial Dimensions (cm) AP. / LAT.		/	/	
IV contrast? Indicate phase name		❑Y ❑N	❑Y ❑N	
Detector Configuration (e.g. 24x1.2mm)				
SFOV (mm) / pre-set name (e.g. Head, S)		/	/	
Tube voltage (kV)				
Tube rotation time (s)				
Tube current (mA)				
Displayed mA·s (mAs ❑ mAs/slice ❑ effective mAs ❑)				
Auto-dose reduction used? Name / mA		❑Y ❑N /	❑Y ❑N /	
Axial Scanning	**Helical Scanning**	❑ Axial ❑ Helical	❑ Axial ❑ Helical	
No. Axial Slices	Scan Length (cm)			
Table incr. (mm)	Pitch			
Over scan or partial scan angle (+° or -°)	Table speed/travel (mm per rotation)			
Console $CTDI_w$	Console $CTDI_{vol}$			
Rx / Reconstructed slice thk / Spacing (mm)		/ /	/ /	
Console DLP – SEQUENCE (mGy · cm)				
Console DLP – EXAM (mGy · cm)				

Canadian Computed Tomography Survey, National Diagnostic Reference Levels, 2016

Forms for data collections

- Example of simple form for CT exams for this workshop

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
Data collection form for adult patients																			
		Patient data							Exposure parameters								Dose data displayed		
Patient No	Data of examination (Year-Month-Day)	Gender (male/ female)	Age (years)	Height (cm)	Weight (kg)	Scout image/images: AP; PA; Lat	Sequence number	Contrast material used (No/ Oral/ Intravenous/ Rectal)	kV	mA (2)	mAs (2)	t_{rot} (s) (3)	Pitch, p	Beam width (NxT), mm (4)	Scanning range (cm)	Scanning mode (axial / helical)	CTDI (mGy) (5)	Reference phantom (16 cm o 32 cm)	Total DLP (mGy.cm) (6)
1	2019/04/23						1												
							2												
							3												
2																			

A more complete and complex form

Acquisition 1 details		See notes on scanner specific hel	
CTDI phantom size (cm) (i.e. 16 cm head or 32 cm body)*:			[a]
Is Automatic Exposure Control (AEC) used?*			[b]
AEC name (e.g. AutomA, ZDOM, CARE Dose 4D, SureExpose):			[c]
AEC setting type (e.g. ref noise index, reference mAs, etc):			[d]
AEC setting value (e.g. SD 7.5, ref mAs 200):			[e]
minimum mA for AEC (where applicable):			[f1]
maximum mA for AEC (where applicable):			[f1]
mA where AEC is not used:			[f2]
Is iterative reconstruction used?			
Iterative recon type (e.g. ASIR, SAFIRE, iDose, AIDR):			[g]
Iterative recon value (e.g. ASIR 40%, SAFIRE 3, iDose level 4):			[h]
Radiation beam collimation	- Collimated Beam width (mm):		[i]
	- Number of slices:		[j]
	- Detector size (mm) (e.g. 0.625,0.6):		[k]
Is Automatic tube voltage selection used? (eg. CarekV)			
If no, Fixed Tube voltage (kV):			[l]
Tube rotation time (s):			[m]
Primary image slice thickness (mm):			[n]
Scan field of view (SFOV) (mm):			[o]
Reconstruction field of view (DFOV) (mm):			[p]
Axial or helical?			[q]
Pitch (where applicable):			[r]
Reconstruction algorithm or kernel (e.g. B30; FC17; Std)			[s]
Is contrast used?			
Anatomical landmarks for start and	Start point (e.g. base of skull)		
end points	End point (e.g. vertex)		

Forms for the 4th UK CT Dose Survey, Medical Dosimetry Group, Public Health England, 2019

Use of DRLs

- Local surveys of DRL quantities should normally be periodically performed.
- In the absence of continuous collection of data:
  - about every 3 years, more frequently (annual) for CT and interventional procedure (ICRP 135); or according to national regulations

- Survey should be part of the regular review and optimisation process, part of the QA programme

Use of DRLs

- Median values of DRL quantities for a specific x-ray room should be compared with DRL values to identify whether the local median values are **substantially higher or lower**
- In these case, an investigation should be undertaken on
  - Image quality
  - Equipment performance
  - Procedure protocol
  - Operator skill
  - In IR, complexity of procedures

Survey for optimisation

- In the optimisation process, account must always be taken of the diagnostic information required for the medical imaging task.
- The median (the 50th percentile) of the national DRL distribution (the **Achievable value**) represents a first target in the optimisation process
  - Multiple DRLs and Achievable values are helping in identifying reasons of lack of optimisation

Conclusions

- The DRL process has been implemented in many countries and applied with good results.
- Common limitations in DRL assessment:
  - Voluntary participation to the survey can bring to biased DRLs
  - Image quality is frequently not assessed; it is frequently assumed images are of requested quality
  - Uncertainty of dose indicators, output measurements, focus-patient distance (provided for Ka,e assessment), breast thickness, etc. should be considered
  - Use of median value gives equal weight to each room, irrespective of the actual workload

Conclusions

- Common errors in the local survey for the comparison with national DRLs and Achievable values:
  - Sample of patients of different age/weight class [from national one]
  - Sample of procedures with different clinical tasks
  - Inaccuracy of dose indicators, radiation measurements
  - In IR, sample of procedures of different level of complexity