

National DRLs in radiology Evolution of the methodology and future challenges

22/04/2017

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Health & Environment – Health protection

2013/59/EURATOM

ISSN 1977-0677

Official Journal

L 13

of the European Union

Article 106

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 February 2018.

★ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom 1

2013/59/EURATOM

- Definition

(20) "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;

2013/59/EURATOM

- Establishment

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

- Use

(f) appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay.

2013/59/EURATOM

- Use

2. Member States shall ensure that depending on the medical radiological practice, the medical physics expert takes 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:

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

Establishment

- For which procedures do we have to establish DRLs?
 - In function of frequency and dose contribution
 - Well established
- For which dosimetric quantities do we have to establish DRLs?
 - K_a , DAP, DLP, $CTDI_{vol}$, AGD, etc.
 - Relatively well established but under discussion (e.g. SSDE)

Table 6: Top 20 Exams

Exam type or category
<i>Plain film radiography</i>
1. Chest/thorax
2. Cervical spine
3. Thoracic spine
4. Lumbar spine (inc. LSJ)
5. Mammography
6. Abdomen
7. Pelvis & hip
<i>Radiography/Fluoroscopy</i>
8. Ba meal
9. Ba enema
10. Ba follow
11. IVU
12. Cardiac angiography
<i>All angiography</i>
<i>CT</i>
13. CT head
14. CT neck
15. CT chest
16. CT spine
17. CT abdomen
18. CT pelvis
19. CT trunk
<i>All CT</i>
<i>Interventional</i>
20. PTCA
<i>All interventional</i>
TOTAL 1-20

European Commission, Radiation Protection 154, European Guidance on Estimating Population Doses from Medical X-Ray Procedures, 2008

Establishment

- How do we establish DRLs?
 - from practitioners' experience?
 - from existing values? (european, other countries?)
 - from dose distributions?
 - from local surveys?
 - from national surveys?
 - from international surveys?

Establishment

- How do we establish DRLs?

3. PROCEDURES FOR ESTABLISHING DIAGNOSTIC REFERENCE LEVELS

3.1. *Diagnostic Radiology*

- (24) In accordance with the MED, DRLs should be established both for diagnostic radiology and for nuclear medicine, and if they are consistently exceeded investigation and appropriate corrective action should be taken. Therefore, in diagnostic radiology this level should be higher than the median or mean value of the measured patient doses or doses in a phantom. Given that the curve giving the number of examinations and their doses is usually skewed with a long tail, the level of the 75th percentile seems appropriate. The use of this percentile is a pragmatic first approach to identifying those situations in most urgent need of investigation.

European Commission, Radiation Protection 109,
Guidance on Diagnostic Reference Levels (DRLs)
for Medical Exposures, 1999

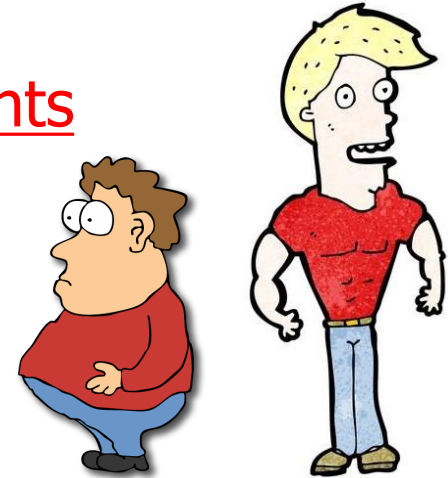


Establishment

- How do we establish DRLs?
 - The question of standard-sized patients
 - The question of the distribution
 - The question of pooling

Standard-sized patients

- How do we establish DRLs?
 - The question of standard-sized patients
 - 70 kg
 - + 20 cm AP trunk thickness
 - 70 ± 3 kg ; 70 ± 10 kg
 - not considered:



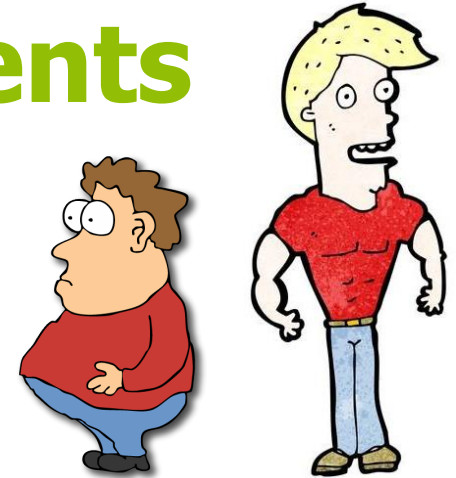
(18) Because of a shortage of standard-sized patients some countries take all patients available in the measurement period and take the average of the dose results as the outcome for a standard-sized patient. This will give a reasonable idea of the dose, provided that the number of patients is not too small: say, a minimum of 10 patients.

European Commission, European Guidelines on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN, June 1996

European Commission, Radiation Protection 109, Guidance on Diagnostic Reference Levels (DRLs) for Medical Exposures, 1999

Standard-sized patients

- How do we establish DRLs?
 - The question of standard-sized patients
 - First Belgian survey (2006-2010)



Examination	Number of rooms	All patients		Standard patients						proposed DRL (cGy.cm ²)	
		P25	P75	70 ± 3 kg		70 ± 5 kg		70 ± 10 kg		P25	P75
				P25	P75	P25	P75	P25	P75		
Abdomen	71	99	337	133	330	129	322	118	315	120	330
Pelvis face (AP)	111	120	396	176	441	174	447	169	458	170	450
Thorax PA	97	11	34	13	36	13	36	13	36	13	35
Thorax lateral	87	31	98	42	109	42	113	40	112	40	110
Thorax bed	30	11	23	12	22	12	21	11	21	12	25
Lumbar spine total	90	640	2090	780	2210	790	2220	760	2150	750	2100
face	79	89	290	99	270	100	276	97	275	95	280
profile	77	189	525	211	506	209	508	207	508	200	500
Skull total	27	59	168	-	-	-	-	-	-	60	150
face	17	4	58	-	-	-	-	-	-	25	(60)
profile	18	21	54	-	-	-	-	-	-	20	(50)

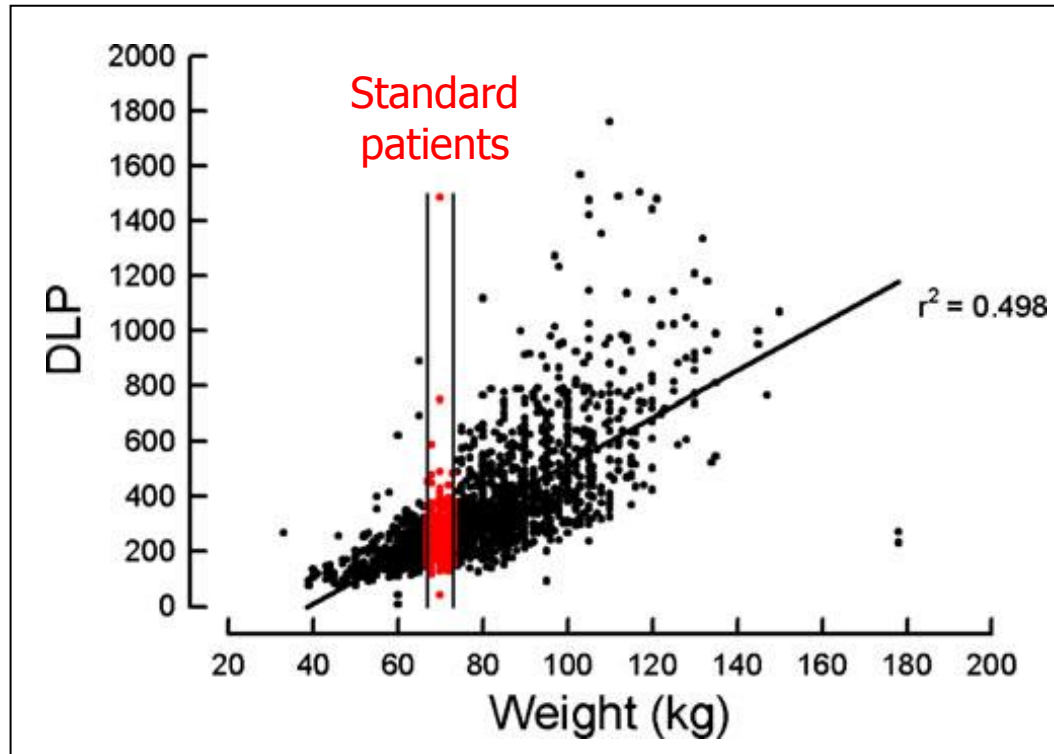
#patients : from 1000 to 5000

Standard-sized patients

- How do we establish DRLs?
 - The question of standard-sized patients
 - First Belgian survey (2006-2010)
 - FANC-decree patient dosimetry (2011)
 - no more weight
 - 20 data (sufficient ?)

Standard-sized patients

- How do we establish DRLs?
 - The question of standard-sized patients



Lumbar spine CT

S. Taylor et al., 2016,
Eur. Radiol. 27(1): 365-373

Standard-sized patients

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 - The question of standard-sized patients
 - First Belgian survey (2006-2010)
 - FANC-decree patient dosimetry (2011)
 - no more weight
 - 20 data (sufficient ?)
 - ICRP 2016 (draft) :

ICRP, Diagnostic Reference Levels in Medical Imaging, Draft for consultation, 2016

(86) Where automated methods of recording values of DRL quantities are available, it may be possible to collect data for large numbers of patients (>100) at each facility (Goenka et al., 2015; MacGregor et al., 2015). Where this is possible, restrictions on weight can be removed. Results rely on the accuracy of data entry, and may not include patient weight. Exclusion of the highest and lowest 5% of the data will eliminate outliers and data with gross errors from the analysis. Specific considerations for development of DRLs for paediatric patients are discussed in Chapter 6.

Standard-sized patients

- Belgian DRLs
 - 2012 : CT
 - 2013 : CT

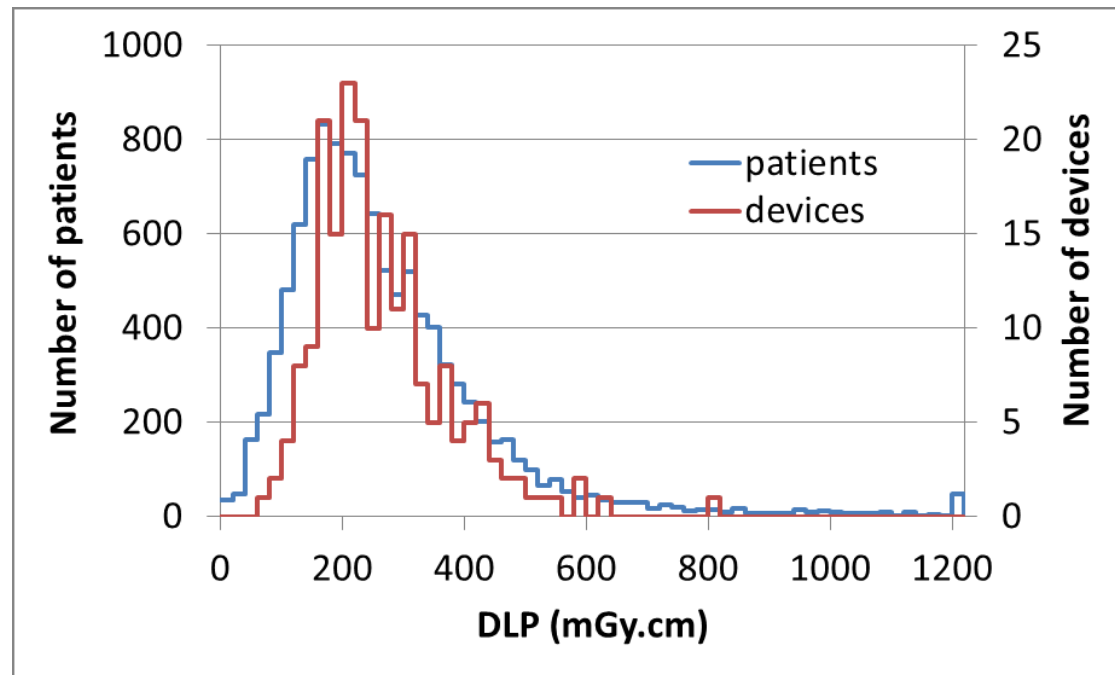
Examination	CTDI _{vol} (mGy)		DLP (mGy.cm)			
	Single examination		Single examination		Full examination	
	Q1	Q3	Q1	Q3	Q1	Q3
Abdomen	7	13	280	600	330	780
Angio CT of the thorax	6,5	20	160	420	190	460
Cardiac (CCTA)	9	47	125	620	190	800
Colon	4	9	180	410	300	600
Cervical spine	15	32	230	530	240	540
Lumbar spine	17,5	32	340	680	340	680
Skull (brain)	38	58	570	980	650	1020
Sinuses	3	8	40	110	40	110
Thorax	5	10	160	340	160	340
Thorax-abdomen	6,5	13	280	640	525	1050

Distribution

- How do we establish DRLs?
 - The question of the distribution
 - Belgian DRLs : based on P75 calculated from **all patients**
 - sensitive to outliers, erroneous data
 - bias in the representation of departments/devices
(More and more departments send more than 20 data (up to 2000!))
 - **Remember** : DRL is a tool for standard practices
 - should be representative for the practices and devices
 - use of the distribution on **average per device**

Distribution

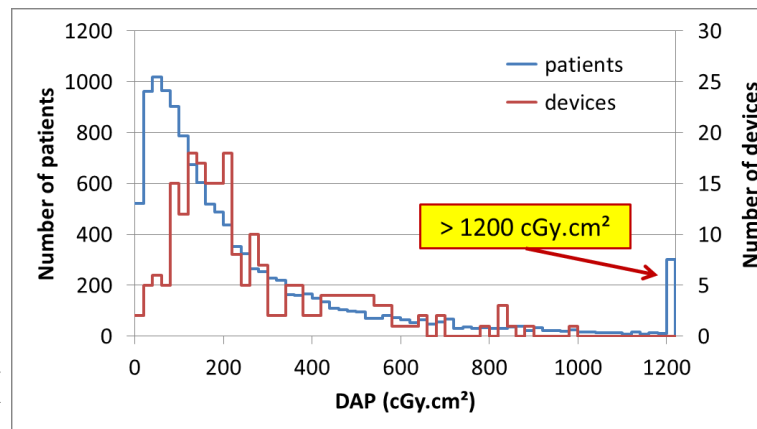
- How do we establish DRLs?
 - The question of the distribution
 - 2014 : CT and RX, MAM, IR



Distribution

- How do we establish DRLs?
 - The question of the distribution
 - 2014 : CT and RX, MAM, IR
 - use of the distribution on average per device
 - outliers?
 - exclusion of highest and lowest 5% ?
 - low and/or high cut-off values ? (done for Belgian RX DRLs 2014)

Abdomen RX



Distribution

- How do we establish DRLs?
 - The question of the distribution
 - 2015 : CT
 - use of the distribution on **median per device**
 - ➔ lower sensitivity to outliers/erroneous data 😊
 - ➔ better estimate of the “mean” practice

Distribution

- How do we establish DRLs?
 - The question of the distribution
 - 2015 : CT
 - use of the distribution on median per device
 - lower sensitivity to outliers/erroneous data 😊
 - better estimate of the “mean” practice
 - ICRP 2016 (draft) :
- **The Commission now recommends that the median value (not the mean value) for the DRL quantity from each of the facilities in the survey should be used. National DRLs should be set as the 75th percentile of median values obtained in a sample of representative centres.**

Distribution

- How do we establish DRLs?
 - The question of the distribution
 - ICRP 2016 (draft) :

(86) Where automated methods of recording values of DRL quantities are available, it may be possible to collect data for large numbers of patients (>100) at each facility (Goenka et al., 2015; MacGregor et al., 2015). Where this is possible, restrictions on weight can be removed. Results rely on the accuracy of data entry, and may not include patient weight. Exclusion of the highest and lowest 5% of the data will eliminate outliers and data with gross errors from the analysis. Specific considerations for development of DRLs for paediatric patients are discussed in Chapter 6.



Pooling

- How do we establish DRLs?
 - The question of pooling
 - More and more departments send more than 20 data (up to 2000!) – but not all!
 - Sometimes, very few data are sent for some procedures
→ median values for dataset with less than 5 data not included in the distribution (CT 2015)
 - Sometimes, big centers send 20 data for each procedure
→ is the median value representative for their practices?

Pooling

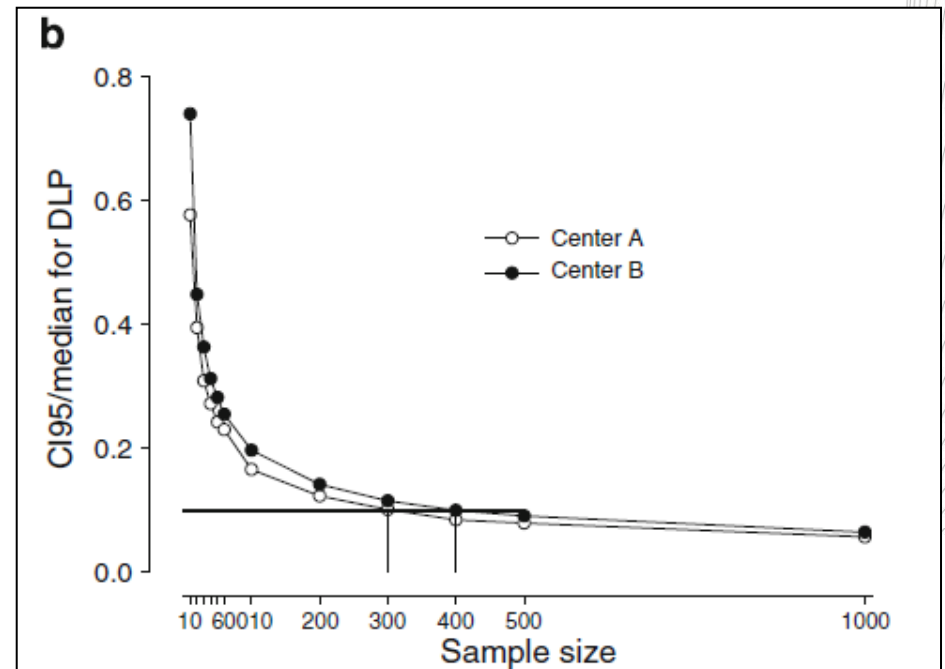
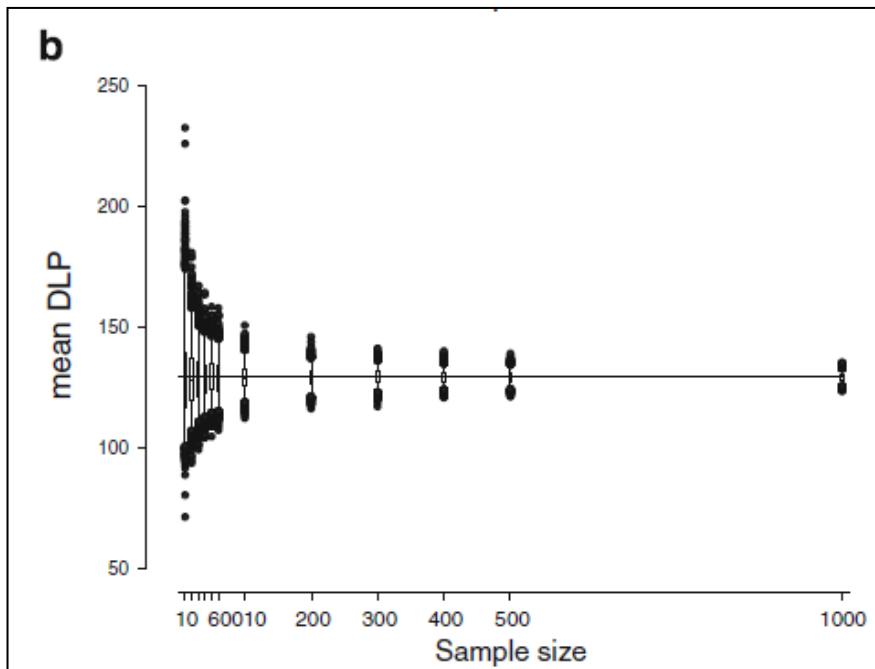
- How do we establish DRLs?
 - The question of pooling
 - Sometimes, big centers send 20 data for each procedure
→ is the median value representative for their practices?
 - ICRP 2016 (in draft) :

(88) A survey of the DRL quantity for a particular examination in a hospital would normally involve the collection of data for at least 20 patients for radiographic examinations (IPSM, 1992). However, data for more patients will be required when there are a greater variation and wide range of results. This is especially true for fluoroscopy, where differences in patients' disease states and operator technique contribute to the variation. A group of at least 30 patients within the agreed weight range is preferable for diagnostic fluoroscopy procedures (IPSM, 1992). Even larger numbers of patients may be needed for interventional procedures (Chapter 4). For mammography, 50 patient measurements are recommended because of variation in breast size.

Pooling

- How do we establish DRLs?
 - The question of pooling

S. Taylor et al., 2016, Eur. Radiol. 27(1): 365-373



Thorax CT

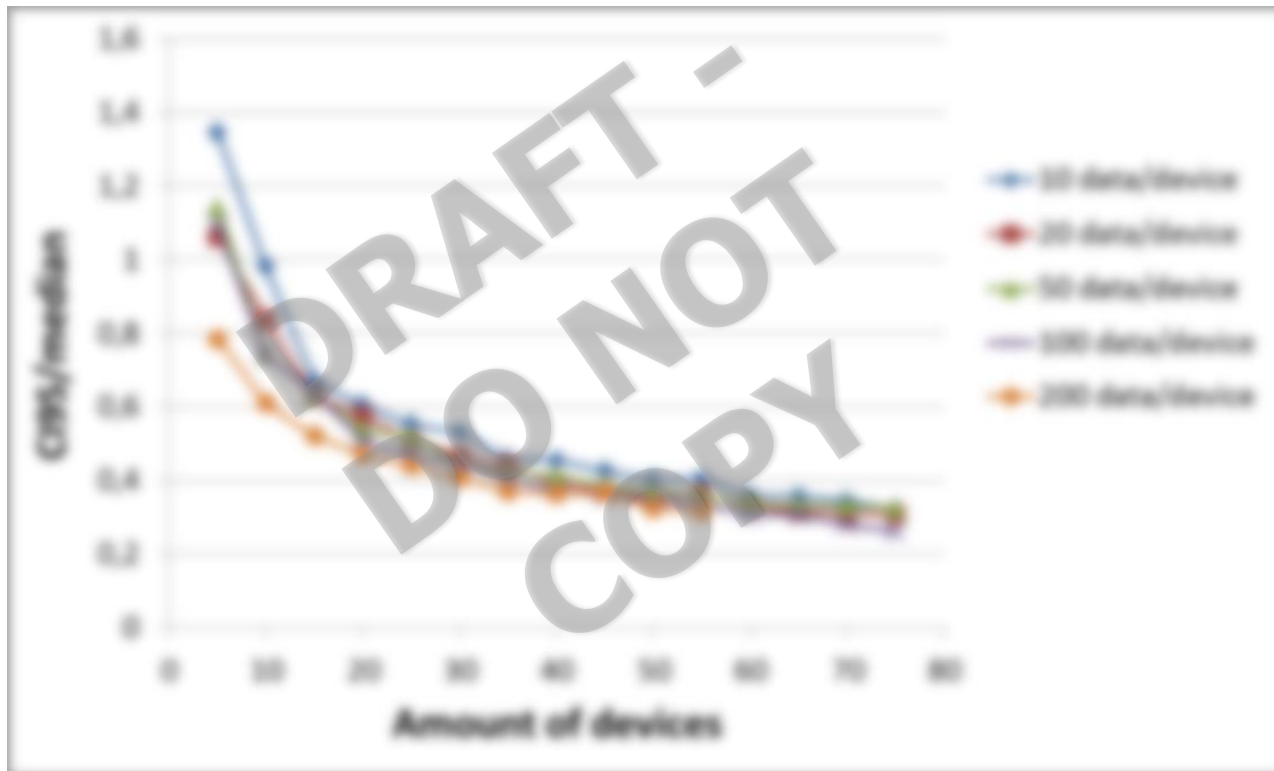
Pooling

- How do we establish DRLs?
 - The question of pooling
 - To assess a good estimate of the median for one device
 - > 100 patients
 - To assess a good estimate of the median or P75 from the distribution of the median values per device
 - function of the **number of devices!!**

Pooling

- How do we establish DRLs?
 - The question of pooling

T. Vanaudenhove et al., 2017, *To be published*



Abdomen CT

Pooling

- How do we establish DRLs?
 - The question of pooling
 - To assess a good estimate of the median for one device
 - > 100 patients
 - To assess a good estimate of the median or P75 from the distribution of the median values per device
 - function of the **number of devices!!**
 - less dependency with the number of data per device when the number of devices is larger than 20-30

Pooling

- How do we establish DRLs?
 - The question of pooling
 - ICRP 2016 (in draft) :

2.3.2. Facilities

(75) The first step in setting DRLs is to carry out surveys of patient examinations across the geographical area to which the DRL will apply. In a developed country with hundreds of healthcare facilities, a survey of them all would be a mammoth task. A random selection of a small proportion of all the healthcare facilities as a sample can provide a good starting point. Thus, 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 (Section 2.3.3). In a small country with fewer than 50 facilities, an initial survey of 30% to 50% of the facilities may suffice. In subsequent surveys, as the data collection infrastructure improves, the number of facilities included can be extended to give more representative coverage.

Why all this

- All this seems to be only statistics...

BUT :

- DRL is a **quantitative tool/indicator**
→ must be well-defined, well-established

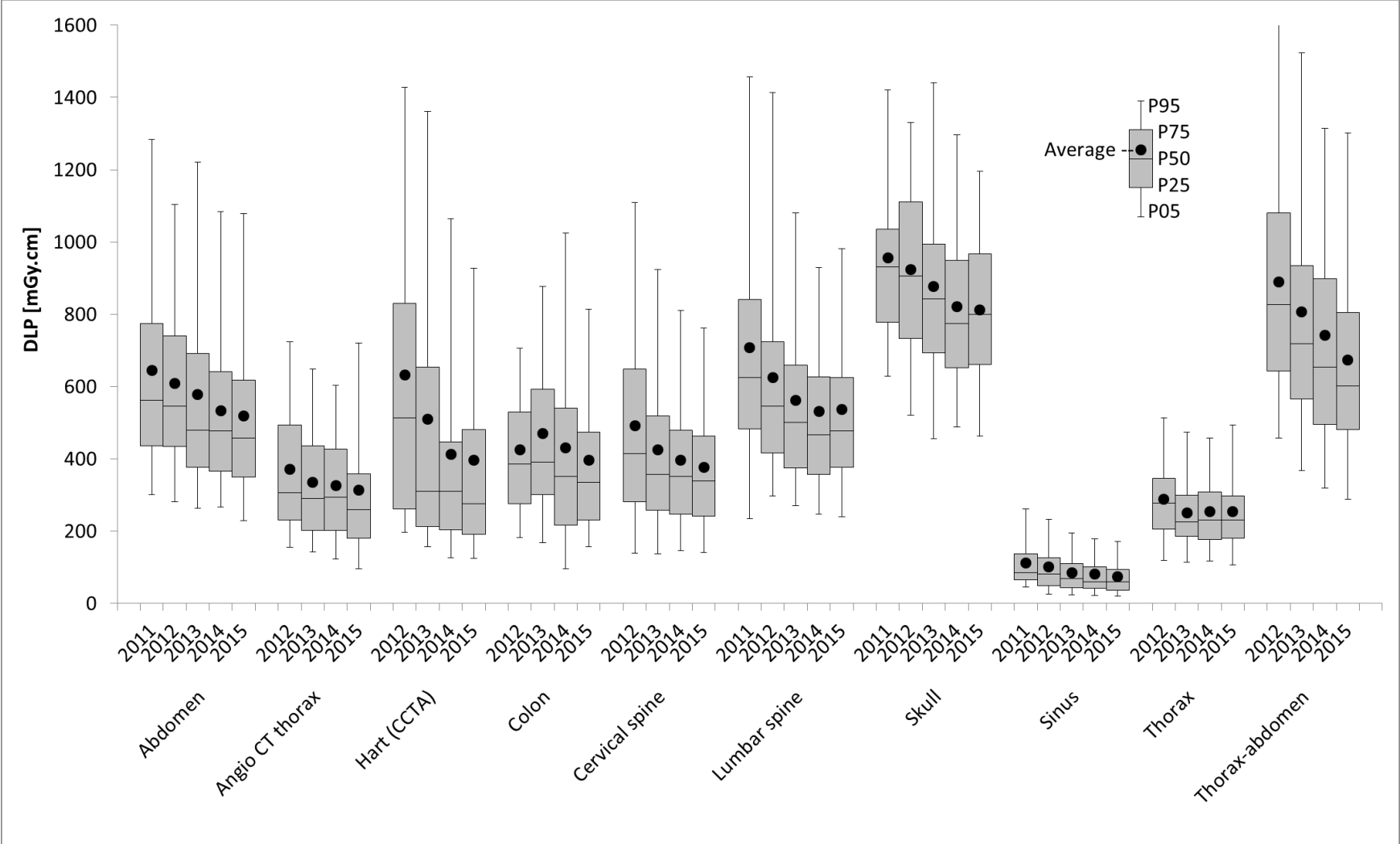
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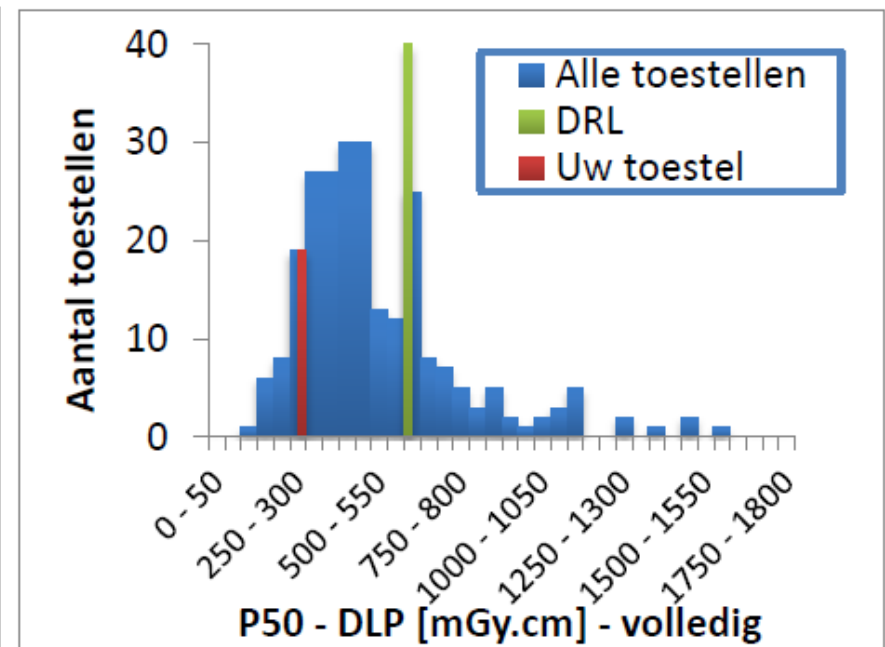
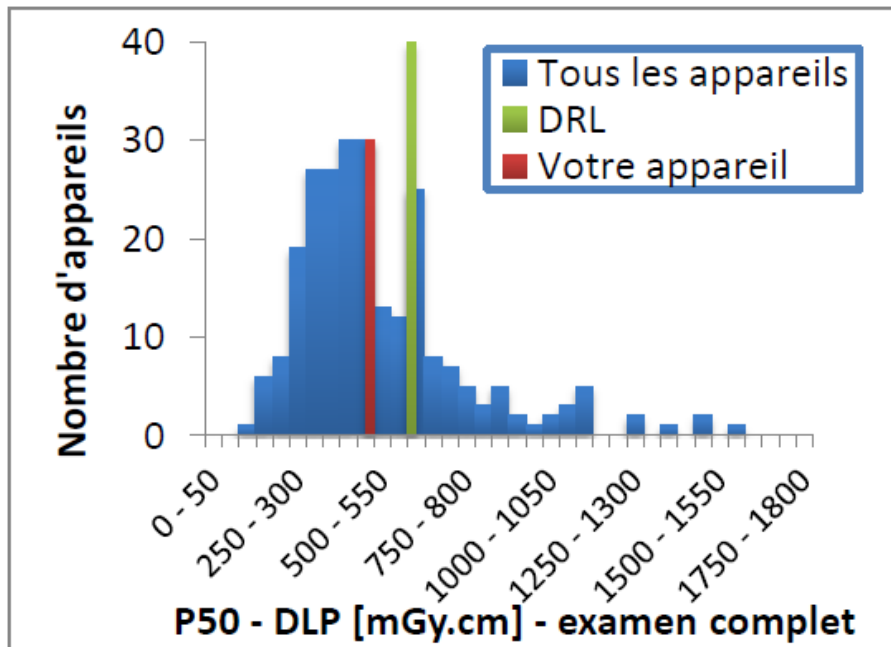
- DRL is a **quantitative tool/indicator**
 - ➔ must be well-defined, well-established
 - ➔ should allow follow-up

Why all this



Follow-up

- January 2017 :
Personalized feed-back to departments (CT 2015)



Why all this

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Why all this

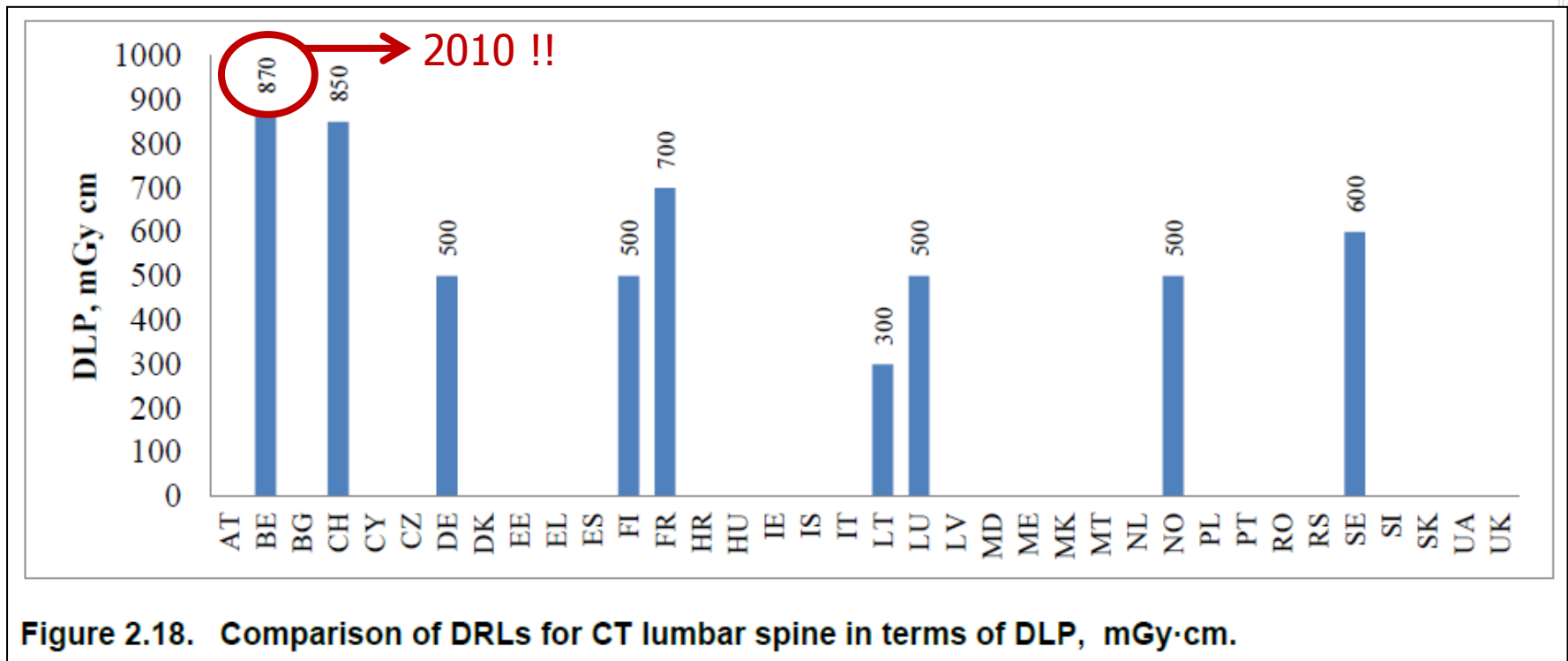
- All this seems to be only statistics...

BUT :

- DRL is a **quantitative tool/indicator** that
 - ➔ must be well-defined, well-established
 - ➔ should allow follow-up
 - ➔ should allow international comparison,
the methodology must be similar!!

International benchmarking

Lumbar spine CT



European Commission, Radiation Protection N°180, *Diagnostic Reference Levels in Thirty-six European Countries*, 2014

International benchmarking

Lumbar spine CT

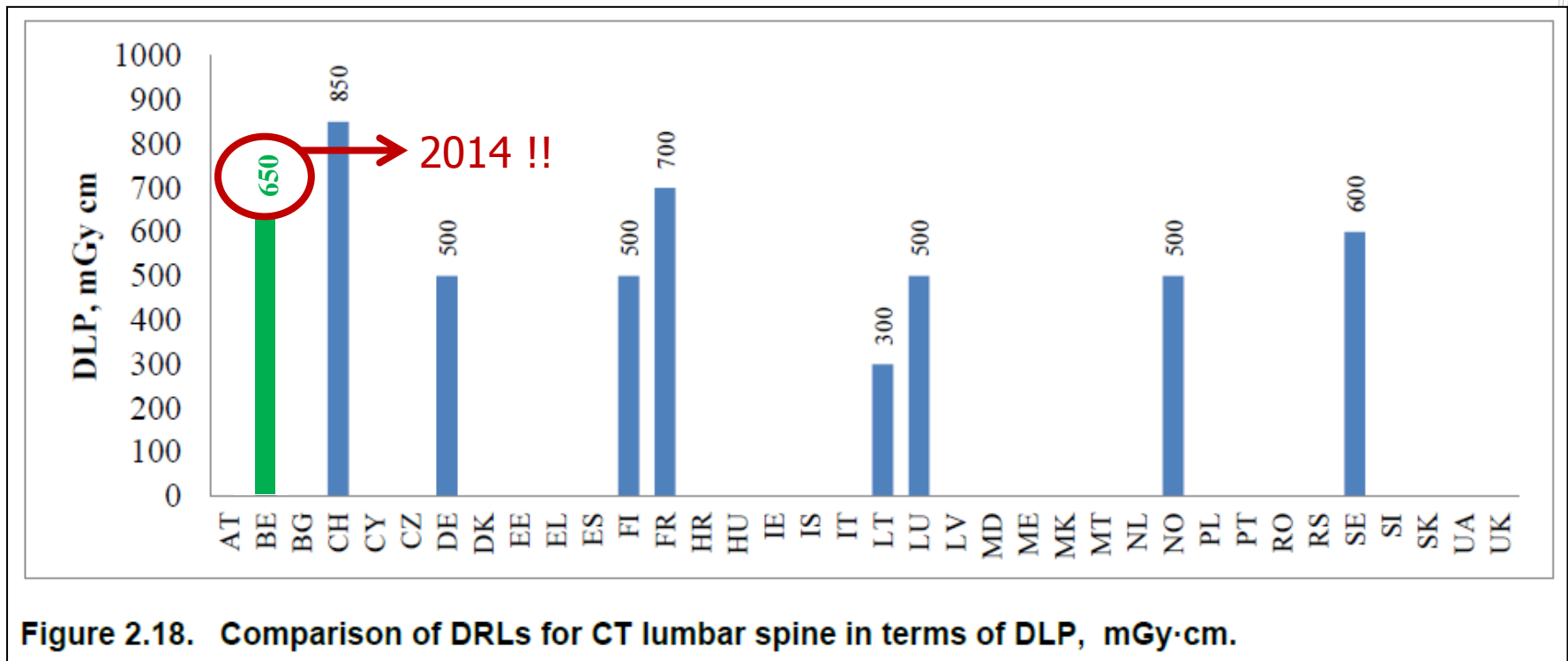


Figure 2.18. Comparison of DRLs for CT lumbar spine in terms of DLP, mGy·cm.

European Commission, Radiation Protection N°180, *Diagnostic Reference Levels in Thirty-six European Countries*, 2014

International benchmarking

- e.g. France : DRL <> P75

Type d'examen	N	PDL en mGy.cm			CV	% NRD	> NRD	Variation
		NRD	75 ^e	25 ^e				
Encéphale	492	1050	921	729	18 %	- 12 %	5,9 %	- 7 %
Thorax	389	475	413	269	31 %	- 18 %	12 %	- 10 %
Thorax-abdomen-pelvis	191	1000	950	668	24 %	- 5 %	18 %	- 9 %
Abdomen-pelvis	385	800	709	499	25 %	- 11 %	9,1 %	- 7 %
Rachis lombaire	266	700	824	605	27 %	+ 18 %	52 %	s.o.*

International benchmarking

Lumbar spine CT

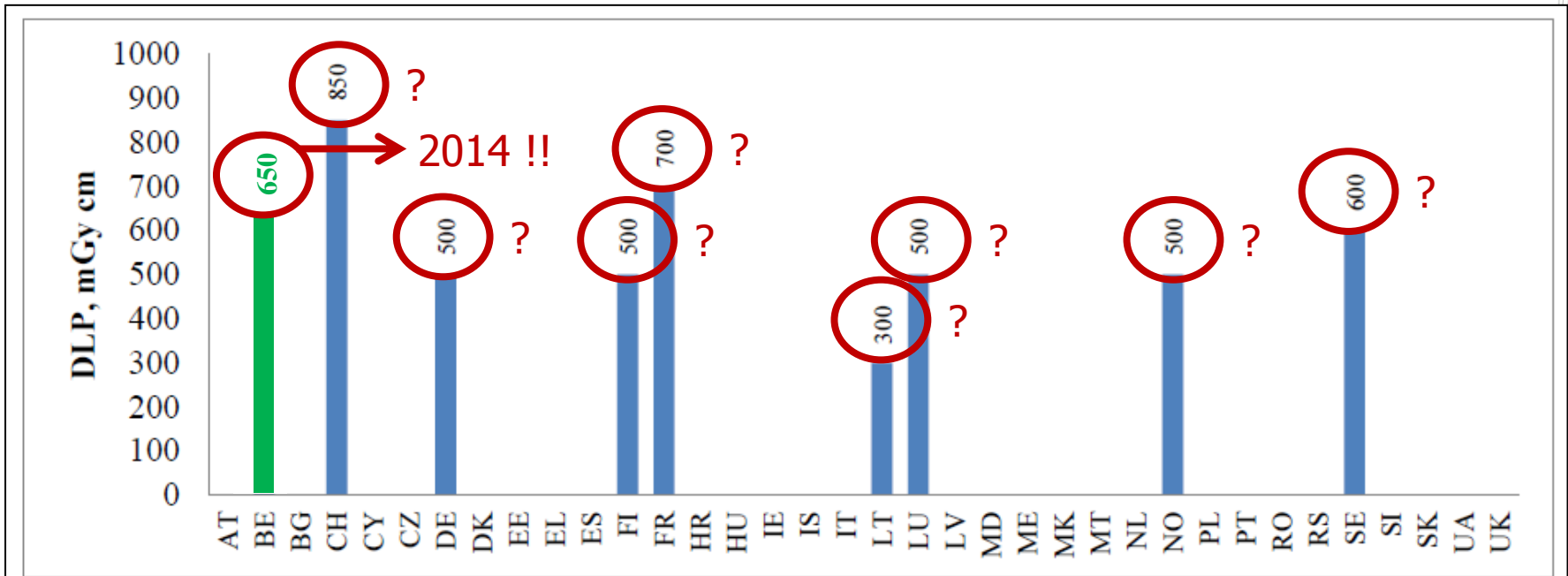


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