

## Refresher Course 7 Medical

### Application of diagnostic reference levels in medical practice

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Diagnostic reference levels (DRLs) are defined in the Council Directive 97/43 Euratom [1] as “Dose levels in medical radio diagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied”. Thus DRLs apply only to diagnostic procedures in radiology or nuclear medicine and does not apply to radiation therapy.

#### Rationale for radiation protection in medicine

The need to optimize the protection of patients results from the fact that medical exposures are by far the largest source of exposition of artificial origin. The average effective dose per caput ranges between 0.5 and 2 mSv in the developed countries, at a level corresponding to a significant fraction of the dose received from exposure to natural radiations. Diagnostic medical exposures are in the domain of low doses delivered at high dose rate, but in interventional radiology, higher doses may be delivered locally. Medical exposures are also peculiar because the total population is potentially concerned, although most of the examinations are performed in rather old patients.

Radiation protection of patients is based on the application of the 2 major radiation protection principles, i.e., justification and optimisation. The third principle of dose limitation does not apply because images must meet quality criteria in order not to compromise the clinical value associated with the exposure, i.e., the diagnosis or the therapeutic strategy. The application of a dose limit to medical exposure would have been a non sense with potential detrimental consequences.

**Justification.** The practice exposing patients to ionising radiations is clearly justified because the clinical benefit of the medical examination outweighs the risk associated with the exposure to ionising radiations. The ultimate objective is to perform only useful procedures which result being positive or negative is expected to comfort the diagnosis or to change patient management; otherwise, the practice is not justified. One must keep in mind that the benefit is immediate for the patient while the stochastic risk of low doses of ionising radiations, if it exists, is very small and at a long term. However, the large collective dose due to medical exposures justifies the application of the radiation protection principles. In order to fulfill the justification principle, guidelines have been developed for both prescriber and practitioners. Such guidelines have been published by the European community with the title “Referral guidelines for imaging “[2].

**Optimisation.** Once a medical test exposing to ionizing radiations has been decided, the corresponding exposure must be optimised: the dose of radiations which is delivered must be kept as low as reasonably achievable but high enough for obtaining the required diagnostic

information, taking into account economic and social factors. In order to fulfill the optimisation, it is requested that written protocols for every type of standard practice are established for each equipment. Indeed, these protocols must describe each step of the procedures. In order to meet this goal, ASN has requested from the French professionals to establish optimised protocols; the method of expert's consent has been used to achieve standardisation of these. Protocols have been made available as guidelines for the professionals.

### **Diagnostic reference levels**

In order to evaluate that the procedures are effectively optimised and remained optimised as the time passes, it is necessary to establish quantitative indicators regarding the doses delivered. Furthermore, these indicators should provide an evaluation of the performance of the medical examination and thus could be used to continuously improve the procedures. This can be accomplished by a longitudinal monitoring of the indicators in a given institution for a given medical device, and by making comparison of the indicators between different institutions of the same or of different countries.

In order to be useful, these indicators must fulfill the following criteria:

- they must be clearly defined and be easy to measure or to calculate;
- they must give directly to the operators an indication of the importance of the dose delivered to the patient;
- they must allow easy correlations with the technical parameters of the medical examination;
- they must be adapted to all types of radiological equipments.

Such perfect indicators applicable to diagnostic medical imaging meet the definition of the "diagnostic reference levels" (DRL). The concept of DRL was introduced in 1996 by ICRP in its recommendation 73 [3]: a DRL is not a dose limit, and it does not apply to a single individual on a case by case. On the contrary, a DRL must be established for typical examinations for groups of standard-sized patients ( $70 \pm 3$  kg and 20 cm antero-posterior trunk thickness) or standard phantoms for broadly defined types of equipment. Indeed, DRLs must be obtained for specific groups of children distinguished by age, size and weight.

Thus DRLs are essentially guides to the rather indistinct borderline between "good and normal practice" and "bad and abnormal practice". DRLs should not be bypassed if good and normal practices are used. It must also be clear that the goal is not to deliver doses constantly lower than DRLs because images of poor quality would not provide the diagnostic information. Indeed the doses delivered to patients whose weight exceeds largely the standard size patient used to measure DRLs will be greater than DRLs. Furthermore, doses may be even higher if the clinical status of the patient justifies the corresponding exposures to ionising radiations.

The goal is clearly to use DRLs to control the level of optimisation of the procedures. In practice, dose indicators must be measured in each institution, essentially for the most frequent procedures and for the most irradiating ones; local reviews of the values of these indicators must be regularly undertaken and compared with national DRLs; then corrective actions must be taken whenever DRLs are consistently exceeded.

### **The choice of parameters as DRLs**

Which parameters to select as DRLs ? Guidance on diagnostic reference levels for medical exposure has been made available by the European Commission in the booklet Radiation protection 109 [4].

In conventional radiology, two parameters have been used to express DRLs: the entrance surface dose (ESD) and the dose area product (DAP).

- ESD is the absorbed dose (mGy) measured in air at the intersection of the axis of the X ray beam and the patient's skin surface; ESD includes retro scattered rays. ESD can be easily calculated or even better measured with a thermo-luminescent dosimeter (TLD) or with ionisation detectors placed on the patient's body;
- DAP is the product of the mean absorbed doses in air in the section of the X ray beam in the absence of scattering medium by the section of the beam. Thus DAP unit is  $\text{Gy}\cdot\text{cm}^2$ . DAP is a more practical parameter and can be easily measured with an ionisation chamber placed at the window of the X ray tube.

ESD and DAP are also used in interventional radiology but the complexity of the procedures makes them more difficult to be used as DRLs.

In computed tomography, two parameters have also been used to express DRLs: the weighted computed tomography dose index ( $\text{CTDI}_w$ ) and the dose length product (DLP).

- CTDI is equal to the integral of the dose profile along a line perpendicular to the tomographic plane for a single slice, divided by the nominal slice thickness. A convenient assessment of CTDI can be made using a pencil ionisation chamber with an active length of 100 mm and the value is normalized to unit radiographic exposure (mAs). In practice, a  $\text{CTDI}_w$  is calculated as a linear combination of the  $\text{CTDI}_c$  measured at the center of rotation and the  $\text{CTDI}_p$  measured at the periphery of the phantom, 10mm below the surface  $\text{CTDI}_w = (\text{CTDI}_c + \text{CTDI}_p)/3$ . CTDI is rather a robust value which is provided by the manufacturer of the CT equipment.
- DLP is equal to the product of  $\text{CTDI}_w$  by the length of the volume exposed to the X ray beam.

In nuclear medicine, DRLs are expressed in administered activities (MBq) rather than as absorbed doses since the activity is the most simple parameter to measure.

### **How to collect your own local dose indicators ?**

In order to collect your own dose indicators, you apply the methodologies described in the previous paragraph. In order to obtain meaningful values, measurements must be carried out in a significant number of patients (20 is a minimum) or experiments with phantoms. Thus for each given procedure, the average of these measurements can be considered as the local dose indicator of your department. They are measured in priority for the most common procedures and for those which deliver the highest doses.

### **How to establish international/national DRLS**

Once you have obtained your own dose indicators, you need to compare them with reference values. If we suppose that each department has carried out its own measurements, a very large number of values can be collected for the same procedure.

For a given DRL in diagnostic radiology (for example DAP for antero-posterior chest X ray), the curve plotting the number of observations for each observed value of that dose indicator is usually a skewed curve with a long tail in the upper values. Since the median and the mean value represent the most commonly observed and the average value of the dose indicator, it

has been proposed by the NRPB to pick up as reference level, i.e., the DRL, the value of the third quartile. Twenty years ago, the NRPB gathered in the UK a large number of measurements carried out in a large number of centres representative of the radiology practice in the United Kingdom. In 1991-1992, the European Commission carried out a large survey in different Member States and established ESD as DRLs in radiology [5 - 6].

In nuclear medicine, the third quartile approach does not apply and the national DRL is the administered activity necessary to obtain a good image during a standard procedure.

Directive 97/43 Euratom has requested that each Member States of the European Union either determines its own DRLs or adopts those established by the European Commission.

In France, DRL levels have been determined as a combination of European DRLs and of values resulting from French surveys. A ministerial order of 12 February 2004 has made compulsory the annual measurement of local dose indicators by the practitioners; the local values are collected by the Institute of radiation protection and nuclear safety (IRSN) who has the responsibility to update national DRLs when new significant data are available.

### **How to use international/national DRLS for optimising your practice**

DRLs determined with the third quartile provide a clever way to implement a continuous process of optimisation. Indeed 75% of the local dose indicators are below the national DRL; one can estimate that local dose indicators fitting in this category demonstrate a good quality practice. For the 25 % of local dose indicators which are above the national DRL, one can have a pragmatic approach and consider that the corresponding procedure is not fully optimised. Thus the radiologist is encouraged to search why her/his own local dose indicator is above the national DRL, to identify the possible causes and to act on them. Consequently, new local dose indicators can be determined and the new values should fall in the third quarter of the DRL distribution.

At the level of a country, national DRLs should be re-evaluated periodically. Then dosimetric surveys should demonstrate, at least at the beginning of the process, an evolution of the distribution of dose indicator levels and a decrease of the DRL values.

### **Conclusion**

DRLs are certainly a clever tool for continuously optimising the medical procedures and the radiation protection of the patients. However, one must not forget the 2 following statements:

- the justification principle must be respected first, because the best way to protect the patient is not to carry a useless test ;
- radiation protection of the patient is a continuous process and local dose indicator values in the good range should not prevent the radiologist/nuclear medicine physician to continue to optimise their practice.

### **References**

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[5] European guidelines on quality criteria for diagnostic radiographic images. European Commission, EUR 16260 EN, June 1996

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