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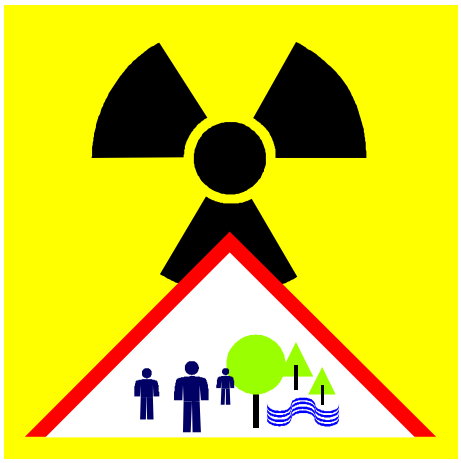

GUIDANCE ON DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR MEDICAL EXPOSURES

European Commission

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Radiation Protection 109

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1999

Directorate-General
Environment, Nuclear Safety
and Civil Protection

CONTENT

FOREWORD

The work of the European Commission in the field of radiation protection is governed by the Euratom Treaty and its implementing Council Directives.

The most significant of these is the Basic Safety Standards Directive (BSS) on the protection of exposed workers and the public (80/836/Euratom), revised in 1996 (96/29/Euratom).

In 1984, the Council of Ministers issued a Directive, supplementing the BSS, on the protection of persons undergoing medical exposures (84/466/Euratom). Revised in 1997, this is now called the Medical Exposure Directive (MED) (97/43/Euratom). The MED must be transposed into national law by 13 May 2000.

According to Article 4(2) of the MED, Member States shall promote the establishment and the use of diagnostic reference levels (DRLs) for diagnostic examinations in radiology and nuclear medicine and the availability of guidance for this purpose.

This booklet is designed to give guidance on the establishment of DRLs on both a legislative and a practical level.

It was developed with the assistance of the group of health experts established under Article 31 of the Euratom Treaty.

This guidance is not binding on Member States and has, by definition, a limited scope. It in no way claims to be an exhaustive scientific report. It forms part of a number of technical guides drawn up to facilitate implementation of the MED.

The document is structured as follows:

A general introduction providing background information and definitions. This is followed by a chapter on implementation in the legislation and application in daily practice. The thirdchapter discusses procedures for establishing DRL's in diagnostic radiology and nuclear medicine in separate sections because of the difference in the philosophy for setting the DRL's in each case. Chapter 4 gives a number of relevant definitions and is followed by an annex presenting the differences between Member States as regards the amount of activity administered.

It is my hope that this guide can be of help to the competent authorities in the Member States as well as to medical practitioners, medical physicists and all those directly or indirectly involved in radiodiagnostic and nuclear medicine procedures.

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1. INTRODUCTION

(1) The Medical Exposure Directive applies to the following medical exposures:

> *Art 1(1)*
> *This Directive supplements Directive 96/29/EURATOM on the Basic Safety Standards and lays down the general principles of the radiation protection of individuals in relation to the exposure mentioned in § 2 and 3.*
>
> *Art 1(2)*
> *This Directive shall apply to the following medical exposure:*
> *(a) the exposure of patients as part of their own medical diagnosis or treatment;*
> *(b) the exposure of individuals as part of occupational health surveillance;*
> *(c) the exposure of individuals as part of health screening programmes;*
> *(d) the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic, or therapeutic, research programmes;*
> *(e) the exposure of individuals as part of medico-legal procedures.*

(2) Dose limits do not apply to medical exposures (Art 6(4)(a) of the Basic Safety Standards Directive – 96/29/EURATOM). Nevertheless, apart from natural background, medical exposures are at present by far the largest source of exposure to ionising radiation of the population, and radiation protection measures to prevent unnecessarily high doses from medical exposures should be taken. However, as ionising radiation has enabled great progress to be made in the diagnostic, therapeutic and preventive aspects of medicine, the use of ionising radiation in medicine is justifiable.

(3) In general**,** efficient radiation protection includes the elimination of unnecessary or unproductive radiation exposure. In general terms, the main tools to achieve this aim are justification of practices, optimisation of protection and the use of dose limits**.** As dose limits do not apply to medical exposures, individual justification (good clinical indication) and optimisation are even more important than in other practices using ionising radiation.

Optimisation means keeping the dose "as low as reasonably achievable, economic and social factors being taken into account" (ICRP 60). For diagnostic medical exposures this is interpreted as being as low a dose as possible which is consistent with the required image quality and necessary for obtaining the desired diagnostic information.

(4) In the context of optimisation, one of the changes compared with the earlier Directive (84/466/EURATOM) is the introduction of Diagnostic Reference Levels (DRLs) following the recommendation of the ICRP in its Publication 73 (ICRP 73). Art. 4(2)(a) of the MED requires the Member States to promote the establishment and the use of these levels and to ensure that implementation guidance is available, while Art. 4(3) requires quality assurance programmes to be established.

> *Art 4(2) Member States shall*
> *(a) promote the establishment and the use of diagnostic reference levels for radiodiagnostic examinations, as referred to in Article 1(2) (a), (b), (c) and*

(e) and the availability of guidance for this purpose having regard to European diagnostic reference levels where available.

(5) DRLs assist in the optimisation of protection by helping to avoid unnecessarily high doses to the patient. The system for using DRLs includes the estimation of patient doses as part of the regular quality assurance programme.

It should be stressed that DRLs are not to be applied to individual exposures of individual patients.

A diagnostic reference level is a level set for standard procedures for groups of standard-sized patients or a standard phantom. It is strongly recommended that the procedure and equipment are reviewed when this level is consistently exceeded in standard procedures (ICRP 73, § 100). Corrective action should be taken as appropriate.

DRLs are defined in the MED as follows:

> ***Diagnostic Reference Levels:*** *dose levels in medical radiodiagnostic 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.*

If DRLs are consistently exceeded, local reviews are required (Article 6(5):

> *Article 6(5)*
> *Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective actions are taken where appropriate*

(6) DRLs are supplements to professional judgement and do not provide a dividing line between good and bad medicine (ICRP 73, § 101)

(7) As the definition shows and Art 4(2) (MED) states, DRLs are only applicable to diagnostic radiological procedures, both in diagnostic radiology and in nuclear medicine.

However, as will be explained in Chapter 3, DRLs are applied in these areas in a different way.

In radiotherapy, including therapeutic nuclear medicine, all exposures of target tissues should be specially planned for each patient, with the doses as low as possible in non-target tissues. A system of reference levels is therefore not applicable in radiotherapy. Other measures, such as dose inter-comparison programmes between radiotherapy centres, should be applied for optimisation purposes**.**

(8) The aim of this document is to give guidance on principles, and explanations on the establishment and application of DRLs, not only to competent authorities but also to professional groups involved in the practical implementation of medical radiological procedures.

(9) This document is structured as follows:

Chapter 2 provides explanations and guidelines about the legal implementation and the practical application of diagnostic reference levels in general. Chapter 3 deals with the establishment of these levels and gives some examples of the levels already used in Europe. As both the assessment and the application of DRLs are different for radiological and nuclear medicine examinations, this chapter is divided into two sections. In Chapter 4 some definitions are given and, finally, tables showing examples of the activities administered in different Member States are presented in an annex.

2. LEGAL IMPLEMENTATION AND PRACTICAL APPLICATION IN PRACTICE OF DRLS

(10) As stated previously, a DRL is a level set for a standard procedure, for groups of standard-sized patients or a standard phantom and not for individual exposures and individual patients. Taking this into account, if this level is consistently exceeded a review of procedures and/or equipment should be made and corrective action should be taken as appropriate.

However, exceeding this level does not automatically mean that an examination is inadequately performed and meeting this level does not automatically mean good practice, as there may be poor image quality.

As procedures for examinations are not identical, each procedure needs its own DRL.

(11) DRLs should be set by Member States taking into account individual national or regional circumstances such as the availability of equipment and training. However, as such circumstances do not differ dramatically between the Member States of the European Union, harmonised levels might be feasible and are certainly preferable.

If Member States wish, in the first instance the proposed DRLs published by the EU in 'European Guidelines on Quality Criteria for Diagnostic Radiographic Images' [EUR96] can be used for radiodiagnostic purposes (Table 3.1).

(12) The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in observed dose distributions. They should be adequately adapted to new techniques or methods.

(13) In nuclear medicine, it does not seem feasible at present to set harmonised levels as administered activities differ widely between different countries. However, if the radiopharmaceutical used is the same, it is worth considering why in some Member States for some examinations higher administered activities are used than in other Member States, while for other examinations it is the other way around. Annex I gives an illustration of these differences, without expressing any opinion as to which values are the most appropriate ones.

(14) In principle, DRLs are applicable for standard procedures in all areas of diagnostic radiology, both in radiodiagnostics and nuclear medicine. They are, however, particularly useful in those areas where a considerable reduction in individual or collective doses may be achieved or where a reduction in absorbed dose means a relatively high reduction in risk:

(i) frequent examinations, including health screening;

(ii) high-dose examinations such as CT and procedures which require long fluoroscopy times, such as for interventional radiology; and

(iii) examinations with more radiosensitive patients, such as children.

However, it should be recognised that it is rather more difficult to establish DRLs for CT, interventional radiology and groups of children than it is for more frequent, less complex exposures.

Therefore priority could be given to the more simple and frequent examinations (see § 29).

(15) After the DRLs have been established, the patient dose either in standard phantoms or groups of standard-sized patients should be assessed on equipment in every room of every radiological facility periodically, with the long-term aim of annual assessments, and after every major change or service. These measured doses should be compared with the pre-established DRLs.

(16) There are two different methods for applying DRLs : using a phantom or using patients.

The use of a phantom has some advantages. Normally one or two exposures for each view, for each examination type and for each item of radiological equipment are sufficient. However, using a phantom is only possible if :

- the DRLs are set for a phantom and that specific (type of) phantom is available for all radiological facilities, or
- conversion factors from the phantom to patients are available.

(17) For some examinations the number of patients available in a relatively short period is insufficient. Moreover, patients can differ widely in size and shape, so in fact there are only a few ‘standard-sized patients’. The report quotes as an example DRLs developed for standard-sized patients with 20 cm AP trunk thickness and 70 kg weight [EUR96]. [EUR96] recommends that measurements be performed on standard-sized patients or patients close to standard size, preferably with an average weight, that is 70 ± 3 kg. For mammography, a standard phantom should be used**.**

(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.

As people’s size and shape also differ between populations, a typical range of patient per country can be assessed. For the use of harmonised DRLs, correction factors should be assessed and applied.

(19) If the measured doses on a sample of standard-sized patients or on a standard phantom for a standard procedure consistently exceed the relevant DRL, a local review of the procedures and the equipment should be performed.

(20) These DRL-related reviews related to DRLs will cause, in most cases, a reduction of the doses in the upper end of the tail of the curve giving the number of examinations and their doses. So, if for example, national authorities or professional bodies set the DRL at the 75th percentile or some other percentile of the dose curve in diagnostic radiology for a particular examination, this value should decrease over time.

Moreover, both in diagnostic radiology and nuclear medicine new techniques and improved procedures could influence dose distribution or administered activity in either direction.

(21) As mentioned before, meeting the DRL does not always mean that good practice is performed. Quality assurance including quality control should be maintained even if the DRL is not exceeded and particularly so if the doses are far below the DRL.

(22) Moreover, dose is not the only aspect: constantly checking image quality and a periodical clinical audit process (see Article 6 MED) will optimise the system. See also Chapter 3 of [EUR96].

(23) DRLs are also an important tool for clinical audit, which can provide a basis for a retrospective evaluation and for recommendations to improve procedures.

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.

(25) DRLs for diagnostic radiology should be based on doses measured in various types of hospitals, clinics and practices and not only in well-equipped hospitals. Examples of DRLs which have already been used for several years in various Member States are given in Table 3.1. These values represent the 75th percentile entrance surface doses measured in surveys and trials carried out in 1991/2 in different Member States [EUR96]. Table 3.2 gives DRLs expressed in dose area products (DAPs).

If Member States wish to establish their own national DRLs, measurements have to be performed. Entrance surface doses, dose area products or other dose related parameters can be used.

Appendix I of [EUR96], [Nor96] and [NRP92] give methods of dose measurement to check compliance with the criteria and provide guidance on sampling of hospitals.

(26) As mentioned before, because patients and the information required differ widely, DRLs are only applicable to standard procedures, standard phantoms or groups of standard-sized patients, and for specific groups of children distinguished by age, size and weight.

(27) DRLs can be assessed using entrance surface doses, measured with a TLD fixed on the patient's body, or the DAP [$Gycm^2$].

The DAP is more practical because

(i) the whole examination is recorded;
(ii) the position of the patient in the beam is less important than it would be with a TLD, so the measurement does not interfere with the examination of the patient and
(iii) there is no need to disturb the patient with the measurements.

The reports mentioned in § 21 give DRLs for both methods (see Tables 3.1 and 3.2).

For CT, the weighted CT Dose Index ($CTDI_W$) and the Dose Length Product (DLP) are suitable quantities to be used as DRLs.

(28) There are also some disadvantages in using the DAP. As the absorbed organ dose needs to be measured, there should be a fixed relationship between the DAP and the absorbed dose. However, this is sometimes not the case, especially in paediatrics, and when fluoroscopy is used as in cardiology and interventional radiology. In paediatrics, where small areas are

exposed, the DAP can be low while the absorbed dose is high. On the other hand, when a large area is exposed, the DAP can be high but the absorbed dose low. Furthermore, in fluoroscopy the field size is often changed during the procedure.

However, suitable devices to overcome these problems are not widely available, but DAP-meters are, and use of DAP concerning DRLs is recommended. Nonetheless the disadvantages should be recognised and other, additional measurements, e.g. skin dose measurements, should be performed in the case of non-standard paediatric or fluoroscopic procedures.

(29) DRLs are particularly useful for more common examinations, or examinations which may involve high doses or are frequently performed, such as:

- chest posterior anterior (PA) and lateral (LAT), dental radiography, lumbar spine anterior posterior (AP), lateral (LAT) and the lumbo-sacral joint (LSJ), which give relatively high doses and which are frequently performed;
- mammography: the breast is, relatively speaking, a highly radiosensitive organ and in screening programmes mammography is used on healthy persons;
- barium enema, which is a complex examination requiring several views and fluoroscopy;
- coronary angiography and some interventional radiological procedures such as Percutaneus Transluminal Coronary Angioplasty (PTCA), which require long fluoroscopy times and (therefore) give high doses;
- types of CT-examinations giving high doses, such as Brain General, Face and Sinuses, Chest General, Abdomen General, Lumbar Spine and Pelvis General.

(30) When setting DRLs for procedures performed with digital systems it is important to remember that the level of image quality can be selected by the user, or automatically set by the X-ray system. In either case,

(i) the selected level of image quality must be justified by clinical requirements, otherwise the patient dose will be increased without clinical justification;
(ii) the X-ray system and the image processing software must be optimised. If not, the patient dose will be increased without a better outcome;
(iii) as digital images are very easy to obtain, the practitioner should be aware of the patient dose per image and should limit the number of images to what is strictly necessary for the diagnosis of a particular patient.

(31) When performing fluoroscopy, one has to be aware that the automatic brightness control may have been adjusted to an increased level due to deterioration of the image chain, meaning that patient doses from fluoroscopy may be abnormally high.

If examinations are performed for which DRLs are not available, it is recommended to use the mean number of images and the mean total fluoroscopic time as temporary DRLs.

(32) Last but not least, human factors are involved. Doses can be unnecessarily high due to inattention, indifference or too much work pressure, although they may sometimes also be due to individual reluctance to accept generally-accepted standard procedures. DRLs can encourage changes in working procedures by showing what is possible in other departments.

See also Table 5 of the National Protocol for Patient Dosimetry (NRP92)

3.2. Nuclear Medicine

(33) In diagnostic nuclear medicine, DRLs are expressed in administered activities (MBq) rather than as absorbed doses.

(34) This reference administered activity is not based on the 75th percentile but on the administered activity necessary for a good image during a standard procedure. In standard diagnostic nuclear medicine procedures, a poorly-functioning gamma camera or other equipment are factors that can necessitate a higher activity. Another important factor influencing the administered activity is the quality of the dose calibration.

(35) As in diagnostic radiology human factors also play a role, such as mistakes made owing to inattention, indifference or individual reluctance to accept generally-accepted standard procedures.

(36) Apart from the quantity used, DRLs in nuclear medicine differ in two ways from those in diagnostic radiology:

- The DRL in nuclear medicine is a guidance level for administered activities. It is recommended that this level of activity be administered for a certain type of examination in standard situations. (In diagnostic radiology, if the DRL is consistently exceeded there should be a review or investigation.)
- In nuclear medicine, for a the recommended amount of administered activity the outcome may be poor. This indicates that the efficacy of gamma cameras, the dose calibration or the procedures used by the staff need to be checked. (In diagnostic radiology, the criterion is normally a satisfactory image. However, the dose needed for this image quality can be too high and, in this case, the radiological equipment should be checked.)

(37) This results in a major difference between the system of diagnostic reference levels for diagnostic radiology and diagnostic nuclear medicine: for diagnostic radiology the DRL is a level that is not expected to be exceeded and the dose in standard procedures should be below that level, while in nuclear medicine, where the DRL is also expected not to be exceeded in standard procedures, the DRL should be approached as closely as possible.

(38) Therefore, in nuclear medicine, an ‘optimum’ value for a DRL should be used instead of a percentile: a reference level for administrations of activities of radionuclides sufficient to obtain information for standard groups of patients (adults and children) can be set nationally, based on the experience of the professional groups (‘expert judgement’). The administered activities vary widely between Member States. Annex I gives some examples (the given values may not be representative for the whole country in some cases).

(39) However, the recommended methods mentioned in (38) are starting points. Even when meeting the DRLs, the practitioners should be encouraged to reach the same good outcome using lower administered activities, e.g. by changing procedures or equipment.

(40) For children the administered activity should be a proportion of that for adults. In practice this can be determined by weighing the child or by age. Basing the factor simply on weight

gives an activity uptake comparable to that for adults but for children aged under 10 tends to result in a low count density**,** e.g. due to relatively larger organ mass or a shorter retention time. The European Association of Nuclear Medicine's Task Group on Paediatrics (EANM90), using nomograms for surface area, has produced a list of fractions of adult activity (Table 3.3) which give the same count density as that for an adult patient, although the effective dose is higher. These fractions are suitable for most nuclear medicine examinations.

Both the first two methods require a minimum activity of 1/10th of the adult value, otherwise imaging times may be very long in children and it might be difficult to keep them still (see Table 3.4).

(41) Finally, administered activity may be based on age (Webster, Clarke or Young's methods - mentioned in EANM90) and this gives approximately the same values as those in Table 3.3.

Where there is increased uptake in growing bone (67Ga, or phosphate / phosphonates) lower activities may be administered. However, as a child's brain is proportionately large, an increase above the proportion stated is required for brain imaging agents.

3.3. European reference levels

(42) The MED states in Art 4(2) (see (4)) that, where available, European diagnostic reference levels should be used. The currently available European DRLs for diagnostic radiology are given in Table 3.1. In Table 3.2, however, other acceptable levels used in different Member States, expressed in $Gycm^2$, are given.

(43) The levels referred to in (29) all relate to frequent, relatively low-dose exposures. The exposures requiring the most attention, however, are those in paediatrics and high-dose examinations such as CT-scans and interventional radiography. At present there are some European DRLs for exposures to children [EUR96a], which are given in Table 3.1a. No European values are as yet available for other groups. Nevertheless, in some Member States dose levels are used for interventional radiography.

(44) For nuclear medicine there are no recommended DRLs at a European level. However, some countries such as the UK and the Netherlands have guidance on optimal values for almost all types of examinations produced by the professional groups and approved by the competent authorities.

Table 3.1 Examples of Diagnostic Reference Doses, expressed in entrance surface dose per image, for **single views**, 1996 Quality Criteria Reference Doses [EUR96]

Radiograph		1996 Quality Criteria Reference Dose Entrance Surface Dose per **SINGLE VIEW** [mGy]*)
Chest Posterior Anterior (PA)		0.3
Chest Lateral (LAT)		1.5
Lumbar spine Anterior Posterior or v.v. (AP)		10
Lumbar spine Lateral (LAT)		30
Lumbar spine Lumbo-Sacral Joint (LSJ)		40
Breast Cranio-Caudal (CC)	with grid	10
Breast Medio-Lateral Oblique (MLO)	with grid	10
Breast Lateral (LAT)	with grid **)	10
Pelvis Anterior Posterior (AP)		10
Skull Posterior Anterior (PA)		5
Skull Lateral (LAT)		3
Urinary Tract either as plain film or before administration of contrast medium		10
Urinary Tract after administration of contrast medium		10

*) Criteria for radiation dose to the patient: The entrance surface dose for standard-sized patients is expressed as the absorbed dose in air (mGy) at the point of intersection of the beam axis with the surface of a standard-sized patient (70 kg body weight or 5 cm compressed breast thickness), backscatter radiation included.

**) This view is not mentioned in the report, but is added here for completeness.

Table 3.1a Examples of Diagnostic Reference Doses in Paediatrics, for standard five-year-old patients, expressed in entrance surface dose per image, for single views, 1996 Quality Criteria Reference Doses [EUR96a]

Radiograph	1996 - 5-year-old patient Quality Criteria Reference Dose Entrance Surface Dose per SINGLE VIEW [µGy] *)
Chest Posterior Anterior (PA)	100
Chest Anterior Posterior (AP, for non-co-operative patients)	100
Chest Lateral (LAT)	200
Chest Anterior Posterior (AP NEWBORN)	80
Skull Posterior Anterior/ Anterior Posterior (PA/AP)	1500
Skull Lateral (LAT)	1000
Pelvis Anterior Posterior (AP)	900
Pelvis Anterior Posterior (AP - INFANTS)	200
Abdomen (AP/PA with vertical/horizontal beam)	1000
Full Spine Posterior Anterior / Anterior Posterior (PA/AP) ONLY FOR STRICTLY CLINICAL INDICATIONS	no values as yet available
Segmental Spine (PA/AP)	no values as yet available
Segmental Spine (LAT)	no values as yet available
Urinary Tract (AP/PA) either as plain film or before administration of contrast medium	no values as yet available
Urinary Tract (AP/PA) after administration of contrast medium	no values as yet available
Micturating Cystourethrography (MCU)	no values as yet available

*) Criteria for radiation dose to the patient: The entrance surface dose for standard-sized patients is expressed as the absorbed dose in air (µGy) at the point of intersection of the beam axis with the surface of a paediatric patient, backscatter radiation included.

Table 3.2 Dose area products for total examinations [NRP96] and [Nor96]

Examination	Reference Dose Dose Area Product TOTAL EXAMINATION [Gy cm^2]	
	NRPB, 1996	Nordic 96
Chest		1
Pelvis		4
Lumbar spine		10
Urography	40	20
Barium meal *	25	25
Barium enema	60	50

*) This examination is rarely performed nowadays

Table 3.3 Fraction of adult administered activity for different age groups of children (see however, minimum amounts given in Table 3.4).
Recommended by the Paediatric Taskgroup of the EANM (European Association of Nuclear Medicine) [Pie90]

kg	Fraction of adult adm. act.	kg	Fraction of adult adm. act.	kg	Fraction of adult adm. act.
3	0.1	22	0.50	42	0.78
4	0.14	24	0.53	44	0.80
6	0.19	26	0.56	46	0.82
8	0.23	28	0.58	48	0.85
10	0.27	30	0.62	50	0.88
12	0.32	32	0.65	52-54	0.90
14	0.36	34	0.68	56-58	0.95
16	0.40	36	0.71	60-62	1.00
18	0.44	38	0.73	64-66	
20	0.46	40	0.76	68	

Table 3.4 Minimum amounts of administered activities FOR CHILDREN in MBq

Radiopharmaceutical	Minimum administered activity for children [MBq]
Gallium-67-citrate	10
I-123-Amphetamine (brain)	18
I-123-Hippuran	10
I-123-Iodide (thyroid)	3
I-123-MIBG	35
I-131-MIBG	35
Tc-99m-albumin (cardiac)	80
Tc-99m-colloid (liver and spleen)	15
Tc-99m-colloid (marrow)	20
Tc-99m-colloid (gastric reflux)	10
Tc-99m-DTPA (kidneys)	20
Tc-99m-DMSA	15
Tc-99m-MDP (phosphonate)	40
Tc-99m-Spleen (denatured RBC)	20
Tc-99m-HIDA (biliary)	20
Tc-99m-HMPAO (brain)	100
Tc-99m-HMPAO (WBC)	40
Tc-99m-MAA or microspheres	10
Tc-99m-MAG3	15
Tc-99m-pertechnetate (micturating-cystography)	20
Tc-99m-pertechnetate (First Pass)	80
Tc-99m-pertechnetate (Meckel’s diverticulum/ectopic gastric mucosa)	20
Tc-99m-pertechnetate (thyroid)	10
Tc-99m-RBC (blood pool)	80

4. DEFINITIONS

Clinical audit:

A systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary.

Diagnostic Reference Levels:

Dose levels in medical radiodiagnostic practices and, 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 when good and normal practice regarding diagnostic and technical performance is applied.

Health screening:

A procedure using radiological installations for early diagnosis in population groups at risk,

Quality Assurance:

All those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

Quality control:

Is a part of quality assurance. The set of operations (programming, co-ordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured and controlled.

Radiodiagnostic:

Pertaining to *in vivo* diagnostic nuclear medicine, medical diagnostic radiology, and dental radiology.

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EUR96 European Guidelines on Quality Criteria for Diagnostic Radiographic Images, European Commission, EUR 16260 EN, June 1996

EUR96a European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics, European Commission, EUR 16261 EN, June 1996

ICR73 ICRP Publication 73 (Annals of the ICRP Vol. 26 No. 2 1996) *Radiological Protection and Safety in Medicine*; Pergamon Press, Oxford. 1996

MED84 Council Directive 84/466/EURATOM of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment, Official Journal of the European Communities, No L 265

MED97 Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, Official Journal of the European Commission, No L 180

NOR 1996 Nordic guidance levels for patient doses in diagnostic radiology. The radiation protection and nuclear safety authorities in Denmark, Finland, Iceland, Norway and Sweden. Report on Nordic radiation protection co-operation No. 5, 1996.

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ANNEX I DIFFERENCES IN ADMINISTERED ACTIVITIES IN MEMBER STATES

General remarks: 1) if for a specific examination no value is given for a country it does not mean that this examination is not being performed in the country
2) values are presented for adults in a normal biological situation except regarding residual thyroid and cancers/metas

Organ / Diagnosis	Radio-pharmaceutical	mSv (E) /100 MBq	Netherl. [1]	United Kingdom [2]	Spain	Finland [3]	Italy [4]	Ger. [5]	Port. [6]	Sweden [7]	France	Denmark [8]
Brain												
Cerebral blood flow	Tc-99m-HMPAO	1	500	740	740	660 (444-900)	740	500	600	830 / 1110	750	776 (125-945)
	I-123-iofetamine(IMP)	32	200	185								
	Tc-99m-ECD	1		500			740				750	740
Benzodiazepine receptors	I-123-IBZM						740	185				
Dopamine receptors	I-123-iomazenil					120 (111-185)		185				
Thyroid												
Uptake and scan	Tc-99m-pertechn.	1.3	80-180	80		130 (74-185)	74	50		120 / 140		
	I-123-NaI	15	20	20		12 (7.4-18.5)	18			115 / 150		
Kinetics and scan before I-131 therapy	I-131-NaI	1500		0.2	1.1	3 (0.7-3.7)	0.37	3		2 / 100		
	I-123	15		2		6 (0.7-15)	1.9					
Residual thyroid cancer and metas (5% uptake presumed).	I-131-NaI	230	400		170	185					185	
	I-123-NaI	3.8	400		(74-370)						(0.3-3700)	

Organ / Diagnosis	Radio-pharmaceutical	mSv (E) /100 MBq	Netherl. [1]	United Kingdom [2]	Spain	Finland [3]	Italy [4]	Ger. [5]	Port. [6]	Sweden [7]	France	Denmark [8]
Heart and blood vessels												
Perfusion (myocardial scan or SPECT)	Tc-99m-sestamibi	1.25	150 - 350 9	300	740	1020 (820-1050)	rest: 370 stress: 925			700 / 1650	1000	
	Tc-99m-tetrofosmin	± 1		400 (SPECT)						750 / 1250	1000	615 (450-860)
	Tc-99m-colloid (HSA)	± 1		800		730 (550-740)	idem		740	560 / 750		
Myocardial infarct.	Tc-99m-pyrophos.	0.5		600			925					
Function/CAD	Tc-99m-pentetate	1.15	750	800			555			650 / 650		
Ventricular function / equil.	Tc-99m-RBC	1	500			570 (370-740)	rest 925 stress 1110	600				710 (73-1110)
Viability scan	Tl-201-chloride	22.5	100 reinj. 50			199 (74-111)	stress 111 reinj. 55.5	75		150 / 80	200	94 (72-100)
Phleboscint.	Tc-99m-MAA		80	80								
Deep vein thromb.	I-125-fibrinogen (uptake test)	10		4	3.7		3.7					

Organ / Diagnosis	Radio-pharmaceutical	mSv (E) /100 MBq	Netherl. [1]	United Kingdom [2]	Spain	Finland [3]	Italy [4]	Ger. [5]	Port. [6]	Sweden [7]	France	Denmark [8]
Blood and immune system												
Bone marrow	Tc-99m-colloid	1		400			555	550		270 / 600		
Spleen	Tc-99m-denat RBC	2	80	100					73	90 / 195		
Blood pool	Tc-99m-normal RBC	± 1		800			1.85-3.7		555	530 / 800		233
Eryth.-volume	Cr-51-labelled erythrocytes	37.5	6 kBq/kg	0.8			3.7					2.2
Plasmavolume	I-125/131 HSA	30		0.2			0.37			360 / 450		0.22 (0.07-1)
Iron distribution	Fe-59-chloride	1000	1.3 kBq/kg	0.4			0.37-0.56					
Skeleton												
Bone scan	Tc-99m-MDP/HDP	0.5	< 40y: 400 > 40y: max 800	600 SPECT:800	740	610 (370-740) SPECT:700	925 SPECT: 740					
Detection of abscesses, tumours etc.												
Leucocyte scan	In-111-labelled WBC	45	30	20			18.5			20/20 ??		16 (9-30)
	Tc-99m-labelled WBC	± 1	500	200		290 (110-666)	555		222	190/1000		471 (195-800)
Gallium scint.	Ga-67-citrate WB	11.3	150	150			222		148	270 / 370	400	106
	lungs		40						111			
Neuroendocrine tumour detection	I-131-MIBG	20	30	20			18.5		37	20 / 40	100	34
	I-123-MIBG	1.8	300	400	370		185				250	217

Organ / Diagnosis	Radio-pharmaceutical	mSv (E) /100 MBq	Netherl. [1]	United Kingdom [2]	Spain	Finland [3]	Italy [4]	Ger. [5]	Port. [6]	Sweden [7]	France	Denmark [8]
Lungs												
Perfusion	Tc-99m-MAA or SPECT	1.25	100	100 200		110 (50-185)	110 220	200	111	105/ 1000	300	112 (50-185)
Ventilation	Kr-81m gas usually < 5 min	0.003	450-750 MBq/min	6000							1000 MBq/l	
	Tc-99m-aerosols	± 1	1000		370		1110	1000	444	280 / 2000		13 (7-40)
	Xe-133-gas	0.1		400			740	3700		280 / 2000	1100 MBq/l	396
Gastrointestinal tract												
Gastric reflux	Tc-99m-Sn-colloid	2.25	10	40			37		37	20 / 30		
Schilling test	Co-57-cyanocob.	250	0.02	0.1		0.0185 +	0.037		0.0185	0.032 / 0.3		0.14
	Co-58-cyanocob.	500				0.0296						0.29
Meckel's div.	Tc-99m-pertechn.	1.25	200	400			150		185	170 / 400	200	238 (74-500)
Liver / spleen scan (Kupffer cells)	Tc-99m-Sn/S/alb-colloid or phytate	1	80	80 SPECT 200	185		222		185	200 / 800		83 (45-217)
Bile duct scan	Tc-99m-HIDA / DISIDA / IODIDA	1.3	40	150			222	370	185	145 / 195		173 (30-370)

Organ / Diagnosis	Radio-pharmaceutical	mSv (E) /100 MBq	Netherl. [1]	United Kingdom [2]	Spain	Finland [3]	Italy [4]	Ger. [5]	Port. [6]	Sweden [7]	France	Denmark [8]
Kidneys												
Renal function / GFR	I-125-IOT / IOH	1	(+ IOH) 2	2								
	I-125-DTPA					70 (37-370)	185 (100-200)	150				
	Cr-5-EDTA	0.2		3		4.4 (2-7)				3 / 62		3.8 (1.8-36)
Static imaging	Tc-succimer (DMSA)	0.88	80	80			185	70	111	50 / 200	200	68
Renography / ERPF (eff. renal plasma flow)	Tc-DTPA	0.67	80	300		130 (111-148)		150	111	125 / 1000	200 (74-740)	165 (20-350)
	Tc-MAG3	0.7	40	100		110 (60-370)	100	200	111	90 / 1000	280	92 (3-210)
	I-123-hippurate (IOH)	1	20	20		9 (0.35-37)	75	110	111		74-740	
	I-131-IOH		2				1.85-3.7		0.074			3.4 (0.9-11.1)
	I-125-IOH	1		2			1.85-3.7					
Micturating cystogram	Tc-Na-pertechn.	1.2	30	25					37			

1 The Netherlands: values recommended by the Dutch Society Nuclear Medicine, only to be exceeded in special cases. Adopted by national authorities.
2 UK: ICRP-53
3 Finland: the mean value and the range of lowest and highest values used (1994)
4 Italy: maximum values for adults and complex examinations; usually less, size and age dependant.
5 Germany: data supplied by the German authorities and some other data from a large institute.
6 Portugal: data from one large department and some additional data.
7 Sweden: average for Sweden / maximum individual activity used.
8 Denmark: average for Denmark and (lower-highest value) 1994

ABSTRACT

The Medical Exposure Directive (97/43/Euratom) requires the Member States to promote the establishment and use of diagnostic reference levels (DRL) for diagnostic examinations and to ensure availability of relevant guidance. This guide provides explanations about the establishment and the implementation of DRLs at the legislative level and in practice. It makes a distinction between DRLs for radiological and nuclear medicine examinations as far as the philosophy is concerned and gives a number of examples. Finally, a list of administered activities used in nuclear medicine practice in some Member States is presented.