# CRITERIA FOR ACCEPTABILITY OF RADIOLOGICAL (INCLUDING RADIOTHERAPY) AND NUCLEAR MEDICINE INSTALLATIONS

**Radiation Protection No 91** 

### **Foreword**

The work of the European Commission in the field of radiation protection is governed by the Euratom Treaty and the Council Directives made under it.

The most prominent 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 Council issued a complementary Directive to the BSS on the protection of persons undergoing medical exposures (84/466/Euratom) revised in 1997 (97/43/Euratom).

Both Directives require the establishment by the Member States of criteria of acceptability of radiological (including radiotherapy) installations and nuclear medicine installations.

Experience showed that drawing up such criteria, especially as regards the technical parameters of the equipment, sometimes created difficulties.

Therefore in 1990, the Commission took the initiative to develop examples of criteria of acceptability (Bland, N.R.P.B.).

Following two constructive meetings with competent authorities of the Member States (18/9/1992 and 30/3/1994) a need for extension to specific radiological and nuclear medicine installations was forwarded. In 1995 an inquiry among competent authorities was made (Kal & Zoetelief) to make an evaluation of the existing situation resulting in a new report suggesting additional criteria for these installations.

This report, amended with data from other sources, was discussed with competent authorities in Luxembourg on 4 and 5 September 1996.

The result is a flavour of criteria of acceptability applicable to facilities in use for radiology, radiotherapy and nuclear medicine. These criteria are not binding to the Member States but were prepared to assist competent authorities in their task to establish or to review criteria of acceptability, also called minimum criteria. They should not be confused with the requirements for design and construction of radiological and nuclear medicine equipment as mentioned in annex I, part 2, § 11,5 of the Council Directive on medical devices (93/42/EEC).

This report will be reviewed on a regular basis in order to take into account new scientific and technical data as appropriate.

It forms part of a series of technical guides on different subjects developed to facilitate the implementation of the Directive on medical exposures. It is my hope that the document will help to ensure continuing improvement in radiation protection in the medical field.

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## INTRODUCTION

The purpose of this document is to specify minimum standards of performance. The criteria presented here are to be considered as "remedial levels", that is levels of performance at which remedial action needs to be initiated. The execution of remedial actions will be based on a formal assessment of the equipment's performance. Following this assessment, agreement should be reached on a reasonable timescale for corrective action (withdrawal or replacement of equipment, renovation) to be undertaken and any specific circumstances under which the equipment may continue to be used. Additional more thorough and accurate measurements may be needed to determine the cause of the change in performance. It should be stressed that the proposed criteria are not to be used as recommended values for quality control purposes.

The present document considers diagnostic installations in general, specific installations such as conventional and computed tomography, dental radiography, mammography equipment, radiotherapy installations and nuclear medicine installations.

With respect to digital radiography the knowledge on criteria based on experience and expertise of manufacturers, competent authorities and users is still insufficient; therefore criteria cannot be given at the moment. Future developments have to be awaited.

The equipment used in pediatric radiology may be different from that used for adults. However, the criteria for radiological equipment used in pediatric radiology are not different from those used in general. Additional requirements concern the small size of the paediatric patients as well as specific conditions for examination related to the smaller patient dimensions. Adequate layout of equipment and suitable radiation shielding for personnel that must stay close to the patient must be present. Some old equipment may not work properly when the exposure times are very short; the equipment must not restrict the use of high speed screens and films. The collimators of paediatric equipment need to be adjustable to smaller dimensions than some simple equipment used for general applications may allow. In practice care is needed to ensure that any exposure of children is always clinically justified and the level of exposure is optimized in each individual case (CEC, 1996a).

In Chapter 1 physical parameters of diagnostic installations in general are described. For special applications as covered in Chapters 3 to 6 additional criteria are formulated. In the case that for special applications (Chapters 3 to 6) no criteria are included, those formulated in Chapter 1 are valid. The Chapters 2 and 3 deal with criteria regarding film processing and conventional fluoroscopy. For conventional and computed tomography criteria are provided in chapter 4. Criteria for dental radiography are presented in Chapter 5. In Chapter 6 a summary has been given of the report on European guidelines for quality assurance in mammography screening with respect to criteria for mammography equipment (CEC, 1993; 1996b). The final chapters deal with criteria for radiotherapy and nuclear medicine installations. The report contains as appendices a list of abbreviations, definition of terms and references.

#### 1. DIAGNOSTIC RADIOGRAPHIC INSTALLATIONS IN GENERAL

The parameters and criteria mentioned in this chapter are applicable to general radiographic X-ray equipment. They are not intended for specialised X-ray equipment such as that covered in chapters 3 to 6. For instance, for mammography more stringent criteria may be applicable. For special applications as covered in Chapters 3 to 6 additional criteria are formulated. In the case that for special applications no criteria are included, those formulated in Chapter 1 are valid. A criterion for a specific equipment part does not necessarily imply that this part, e.g. light beam diaphragm or AEC, is present.

#### Kilovoltage accuracy

- Variation with changes in tube current
   The maximum variation should be less than 10%.
- Precision of tube voltage
   For all generators: for repeated meaurements the deviation in the tube voltage should be less than ± 5% from the mean value.

### Total filtration

- The total filtration in the useful beam should be equivalent to not less than 2.5 mm Al.

#### Exposure time

- For indicated exposure times greater than 100 ms, the actual exposure time should be within  $\pm$  10% of the indicated exposure time.

### Radiation output

- Magnitude
  - With a total filtration of 2.5 mm Al, the output should be greater than  $25 \mu$  Gy/mAs at 1 m for true 80 kV operation.
- Consistency of output The output should be constant within  $\pm$  20% of the mean for repeated exposures, for a given tube voltage and filtration within the range used in practice, e.g. a tube voltage of 80 kV and a filtration of 2.5 mm Al.
- Variation with change in indicated current
   The variation should be less than 15%.
- Variation with change in indicated tube current exposure time product The variation should be less than 20%.

### Alignment

- X-ray/light beam alignment The sum of the misalignment of the visually defined field with the respective edge of the X-ray field in each of the principal directions should not exceed 3% of the distance from the focus to the centre of the visually defined field, and the sum of the deviations in both perpendicular directions should not exceed 4%.
- Field alignment
   When the axis of the X-ray beam is perpendicular to the plane of the image receptor, the centre of the X-ray field and the centre of the image receptor should be aligned to within 2% of the focus-image receptor distance.
- X-ray/light beam centreing The alignment of the light beam diaphragm cross-wire with the X-ray beam centre should not differ by more than  $\pm$  1% of the focus to film distance.
- Light beam/Bucky centreing The alignment of the beam diaphragm cross-wire with the centre of the film in the Bucky should not differ by more than  $\pm$  1% of the focus to film distance.
- Orthogonality of X-ray beam and image receptor
   The angle between the central axis of the X-ray beam and the plane of the image receptor should not differ by more than 1.5 degrees from 90 degrees.

#### Collimation

- The X-ray beam should be collimated in such a way that the total exposed area for fixed focus image receptor distance remains within the borders of the selected image receptor.
- Automatic collimation
   The X-ray beam shall not differ by more than 2% of the focus to image receptor distance at any side of the image receptor. One should be able to use smaller fields than the whole image receptor area.

### Focal spot size

 While no absolute standard is specified, focal spot size determinations should be carried out throughout the working life of a tube as part of the quality control procedure to indicate the extent of any deterioration and enable the continued suitability of the tube to be assessed.

### Grid

- Artefacts
  - An X-ray image of the grid should be made at 50 kV. No disturbing artefacts should be visible.
- Moving grid
   The lamellae of a moving grid should not be visible on the image at the shortest exposure time used in practice.

### Automatic exposure control

- Limitation of overexposure
   The maximal focal spot charge should be less than 600 mAs (not in the case of fluoroscopy and tomography).
- Limitation of exposure time (single exposure)
   The exposure time for a single exposure should be limited to a maximum of 6 s.
- The difference in optical density between two exposures at the same AEC settings, one with a short and the other with a long exposure time, should be less than 0.3 OD.
- For a fixed attenuator thickness the maximum difference in test image optical density as a function of the tube voltage range used in practice should not exceed ± 0.3 OD.
- For a fixed tube voltage the maximum difference in test image optical density as a function of attenuator thickness should not exceed  $\pm$  0.3 OD of the average value of test image optical density taken over attenuator thicknesses covering the patient thickness range met in practice at this tube voltage. Appropriate phantom thicknesses for different tube voltages have been proposed (DIN, 1990).

### Leakage radiation

 Leakage radiation from the housing measured at a distance of 1 m from the focus should not exceed 1 mGy in one hour at the maximum rating specified by the manufacturer for the tube in that housing.

## 2. FILM PROCESSING, PROPERTIES OF IMAGE RECEPTORS AND VIEWING CONDITIONS

In this chapter critria are described in order to ensure that the conditions for producing consistent radiographs of adequate quality on radiographic and photographic materials are maintained. For mammography additional or more stringent criteria may be applicable, see chapter 6.

Intensifying screens and cassettes

- Condition and cleanliness of screen(s) and cassette
   No serious artefacts should be visible on exposed films.
- Light-proofness
   Of cassette

   No black edges should be visible on an unexposed film in the cassette after exposure during two times 10 minutes (i.e. both sides) on a viewing box with a brightness of at least 1000 cd/m<sup>2</sup>.
- Film

   screen
   contact

   The cassette should not cause areas of visible differences of density or unsharp areas on the radiograph. This can be checked e.g., with a metal mesh placed on the cassette.

### Film processing

- Base and fog should be less than 0.30 OD.
- Speed index
   Deviation from the baseline value of the speed index should be less than 0.20 OD.
- Contrast index
   Deviation from the baseline value of the contrast index should be less than 0.20 OD.

### Darkroom

Light leakage
 No appreciable light leaks should be visible after adaptation of the eyes for at least five minutes to the darkroom with safelights and other lights off.

<sup>\*</sup> A diagnostic unit is defined in this context as those X-ray facilities which share the film-screen combinations

Safe
 A pre-exposed film of unit optical density exposed at normal working distance for 4 min to darkroom conditions with safelights on and lights on in surrounding rooms should not show an increase of the density by more than 0.10 OD from a part of the same film not exposed to the darkroom conditions.

### Viewing conditions

Viewing
 Brightness should be at least 1700 cd/m<sup>2</sup>
 Inhomogeneity should be less than 30 %.

### Environment

Background roomlight at 1 m distance from viewing box should be less than 50 lux.

#### 3. FLUOROSCOPY

In this chapter additional requirements are formulated. In the case criteria are not given those given in chapters 1 and 2 are applicable.

#### Dose rate

At least one of the two following criteria should be met:

- a) The maximum dose rate at the entrance screen without grid (diameter 25 cm) of a conventional image intensifier should not exceed  $0.8~\mu$  Gy/s for exposure of an appropriate phantom (e.g. 20 cm PMMA) with automatic dose rate control and automatic brightness control.
  - For special high dose rate applications e.g. interventional radiology, the maximum dose rate should not exceed 1.0  $\mu$  Gy/s.
  - For other sizes of entrance screens the dose rate may be adapted in inverse proportion to the square of the diameter.
- b) The maximum dose rate including backscatter at the skin of the patient or at the surface of some form of patient substitute (e.g. 25 cm PMMA phantom) on the side facing the X-ray tube should not exceed 100 mGy/min.

#### Resolution

The resolution of the image intensifier TV chain combination should be at least 0.8 line pair per mm at a field size of 30 - 35 cm determined from the use of a specified test object (e.g. Hüttner type 18 resolution grating or Leeds test object). For field sizes of 23 - 25 cm and 15 - 18 cm these values are 1.0 and 1.4 lp/mm respectively. In a spot image, the resolution should be at least 2.0 lp/mm.

#### Threshold contrast

The contrast threshold under automatic operation estimated from the TV monitor image should be 4% or less.

#### Timer

A means of termination should operate automatically when a predertimined integrated fluoroscopy time not exceeding 10 min has elapsed. An acoustic signal should warn of the impending termination at least 30 s in advance to enable the device to be reset if exposure needs to be prolonged.

#### Cinematography

- For adequate cine studies using a 23-cm diameter image intensifier the entrance dose rate should be less than 0.20  $\mu$  Gy/frame. Typical patient entrance dose rates are 0.10-0.30 Gy/min for 25 frames/s with a 20 cm PMMA phantom.

### Radiation/image field size

 The ratio of the areas of the radiation field and the image intensifier entrance surface should not exceed 1.15. It is considered good practice to see the edges of the collimators on the TV image.

#### 4. CONVENTIONAL AND COMPUTED TOMOGRAPHY

In this chapter additional requirements for conventional and computed tomography are formulated. In the case criteria are not given those given in chapters 1 and 2 are applicable.

### 4.1 Conventional tomography

### Cut height level

Agreement to between indicated and measured cut height level should be within ± 5 mm.

### Cut plane incrementation

– In incrementing from one tomographic cut plane to the next, the cut height should be reproducible to within  $\pm 2$  mm.

### Exposure angle

– Indicated and measured exposure angles should agree to within  $\pm$  5° for units operating at angles greater than 30°; for smaller angles, the agreement should be better.

### Cut height uniformity

The density of the image of the hole in a lead sheet should be nearly uniform or should vary in uniformity according to the pattern expected for the particular tomographic unit. The image should reveal no unexpected overlaps, inconsistencies of exposures, or asymmetries in motion.

#### Spatial resolution

- The tomographic unit should resolve a #40 mesh screen pattern (1.6 lp/mm).

### 4.2 Computed tomography

### Image noise

The standard deviation of the CT numbers in the central 500 mm<sup>2</sup> region of interest for a water or tissue equivalent phantom should not deviate more than 20% from the baseline value.

#### CT number values

- The deviation in the CT number values for water or tissue equivalent material and materials of different densities in a consistent position in the field should be less than  $\pm$  20 HU or 5%.

### CT number uniformity

The standard deviation of the CT number averaged over a 500 mm<sup>2</sup> region of interest for water or tissue equivalent material at the centre and around the periphery of phantoms should be less than or equal to 1.5% of the base line value.

### Computed tomography dose index (CTDI)

 The measurements of CTDI for a single slice for each available beam shaping filter and for each available slice thickness should not deviate more than ± 20% from the baseline value.

#### Irradiated slice thickness

- The full width at half maximum of the dose profile should not differ more than  $\pm$  20% from baseline values.

### High contrast resolution (spatial resolution)

- The measurements of full width at half maximum of the point spread function of a pin, or the edge response function of an edge should not differ more than  $\pm 20\%$  from baseline value.

### Low contrast resolution

 Polystyrene pins of 0.35 cm diameter inserted in a uniform body water phantom should be visible in the image.

#### 5. DENTAL RADIOGRAPHY

In this chapter additional requirements for dental radiography equipment are formulated. In the case criteria are not given those given in chapters 1 and 2 are applicable.

The criteria in this chapter are for dental radiographic equipment using an intra-oral film (or with the same equipment an extra-oral film), but excluding panoramic dental radiographic equipment. Users may choose to apply the criteria to panoramic dental equipment as well, but in this case they should take care to ensure that the chosen criteria are suitable for that application. For cephalometric radiography the criteria in chapter 1 may be applied to this type of equipment.

### Radiation quality

The operating tube voltage should be at least 50 kV.

#### **Filtration**

- The filtration in the useful beam should be equivalent to at least 1.5 mm Al at tube voltages of up to 70 kV and 2.5 mm in excess of 70 kV.

#### **FSD**

The focus skin distance should be at least 20 cm for equipment with maximum selectable tube voltages in excess of 60 kV, and at least 10 cm for equipment with maximum selectable tube voltages of 60 kV and lower.

#### Beam size

 The field size diameter should be at maximum 60 mm at the outer end of the beam applicator.

#### Timer

- The accuracy should be at maximum 20%.
- The precision should be at maximum 10%.

### Output

- For tube voltages in the range of 50-70 kV the output should be 30-80  $\mu$  Gy/mAs at 1 m from the focus.

#### 6. MAMMOGRAPHY

The values described in this chapter are based on the recommendations in the European guidelines for quality assurance in mammography screening (CEC, 1996b).

### 6.1 X-ray generation and control

### X-ray source

Dose rate

- The dose rate at a distance equal to the FFD should be at least 7.5 mGy/s.

Source-to-image distance

 The source-to-image distance should be according to the manufacturers' specification and typically is ≥600 mm.

Alignment of X-ray field/image receptor

 Thorax side: X-rays should cover the film by no more than 5 mm outside the film. Lateral sides: X rays should cover the film to the edges.

### **Tube voltage**

Accuracy and precision

- Accuracy for tube voltages in the range 25 to 31 kV should be less than  $\pm$  1 kV; the precision should be less than  $\pm$  0.5 kV.

#### **AEC-system**

Optical density control setting

- The optical density (including base and fog) at the reference point of the developed film should remain wihin  $\pm$  0.15 OD to the target value. Target value is typical in the range of 1.3 to 1.8 OD, base and fog included.
- The optical density control step-size should be in the range 0.10-0.20 OD per step.

Short term precision

- The deviation of the mean value of exposures should be less than 5%.

Long term precision

– The long term precision should be better than  $\pm$  0.20 OD from the baseline optical density value.

Object thickness compensation

– All object density variations should be within the range  $\pm$  0.15 OD, in respect to the routine optical density.

Tube voltage compensation

 $-\;$  All optical density variations should be within the range  $\pm~0.15$  OD.

### Compression

Compression force

– The compression of the breast tissue should be firm but tolerable. There is no optimal value known for the force, but attention should be given to the applied compression and the accuracy of the indication. The maximum automatically applied force should be in the range of 130 to 200 N (≈ 13 to 20 kg).

Compression plate alignment

 Minimal misalignment is allowed, less than 15 mm is acceptable for asymmetrical load and in the direction towards the nipple, less than 5 mm for symmetrical load.

### 6.2 Bucky and image receptor

Anti scatter grid

- The grid system exposure factor should be  $\leq 3$ .

Inter cassette sensitivity and variation in optical density range when exposed with the same settings of the X-ray equipment with AEC

- The exposure range, in terms of mGy (or mAs), should be within  $\pm$  5% for all cassettes.
- The maximum difference in optical density between all cassettes should be less than 0.20 OD.

### 6.3 Film processing

Film processing

- Base and fog (Dmin)
   The Dmin should be 0.2 OD.
- Speed index Reference to baseline value should be  $\pm$  10%.
- Contrast
   The mean gradient (MGrad) should be > 2.8.
- Daily performance
   The daily performance of the processor can be assessed by sensitometry.
   After the processor has been used for about one hour each morning and at approximately the same time daily, perform the sensitometry. The variability of the parameters can be calculated over a period of time eg. one

The variability for all parameters should be less than  $\pm$  10%.

#### **Darkroom**

See chapter 1 and the following additional criteria:

Film hopper and cassettes

No extra fogging.

### 6.4 Viewing conditions

Viewing box

The brightness should be in the range of 2000-6000 cd/m<sup>2</sup>. The ambient light level should be below 50 lux.

### 6.5 System properties

Reference dose

The entrance surface air kerma should be ≤ 10 mGy for a 40 mm PMMA phantom, ≤ 12 mGy for 45 mm PMMA, and ≤ 20 mGy for 50 mm PMMA.

Image quality

- Spatial resolution
   In both directions the resolution should be over 12 lp/mm for measurement with test object placed 4 cm above table (on top of PMMA), and on midline, 6 cm in from chest-wall side of film.
- Threshold contrast visibility
   For measurements of contrast of large details with a test object inside a
   45 mm thich PMMA phantom, a limiting value < 1.3% contrast for a</li>
   6-mm detail is suggested.

### Exposure time

 The exposure time should be less than 2 s when imaging a 45 mm PMMA phantom.

#### 7. RADIOTHERAPY

These criteria are valid for the normal clinical use of radiation therapy equipment and not (necessarily) for brachytherapy, intraoperative, dynamic, palliative and whole body radiation therapy equipment. In addition, radiation therapy treatment simulators are excluded from consideration. As indicated in the Introduction, the criteria presented may be used as remedial levels at which corrective action needs to be initiated. In a very few occasions, it might be justified to use the equipment clinically, even if the remedial level has been exceeded. Such a decision can only be taken after careful consideration of the responsible clinical physicist, with the knowledge of the clinicians and radiographers. For example, curative treatments demand a high stability of the treatment table height, especially during lateral irradiation. If due to mechanical tolerances the table height cannot be adjusted within the tolerance level, it still may be justified to perform palliative posterior-anterior or anterior-posterior treatments if no alternatives are present at all.

The values given in Table 7.1 are based on recommendations in WHO (1988) and NCS (1995), with some modifications.

Table 7.1: Tests on mechanical, geometrical and beam performance and on light field accuracy with remedial action levels

Test	remedial action level				
<ul><li>Gantry rotation</li></ul>	± 1°				
<ul><li>Yoke rotation</li></ul>	± 0,2°				
- Isocentre	$\pm 2 \text{ mm}$				
<ul> <li>Source distance indicators</li> </ul>	± 2 mm				
<ul> <li>Beam axis indicators</li> </ul>	$\pm 2 \text{ mm}$				
<ul> <li>Numerical field indicators</li> </ul>	$\pm 2 \text{ mm}$				
<ul> <li>Light field indication:</li> </ul>	$\pm 2 \text{ mm}$				
<ul> <li>Collimation system rotation:</li> </ul>	± 1°				
<ul> <li>Treatment couches</li> </ul>					
• lateral and longitudinal scales:	2 mm				
• vertical scales:	2 mm				
• vertical deflection (with patient load):	5 mm				
- Treatment verification systems: manufacturer's	<ul> <li>Treatment verification systems: manufacturer's specification</li> </ul>				
(gantry angle, field size, collimator rotation, treatment time or monitor units,					
beam energy, etc.)					
<ul><li>Immobilization devices:</li></ul>	$\pm 2 \text{ mm}$				
(moulds, casts, breast bridges, head supports, arm or leg supports, bite-blocks,					
etc.)					
<ul><li>Patient alignment devices:</li></ul>	± 2 mm				
Beam performance and light-field accuracy					
<ul> <li>Light field indication (density measurements)</li> </ul>	± 1 mm per edge				
<ul> <li>Central axis dose calibration at reference position</li> </ul>					
in phantom:	$\pm$ 3% (photons)				
•	± 4% (electrons)				
<ul><li>Constancy checks:</li></ul>	, ,				
cobalt-60 and cesium -137 units:	± 2%				

	orthovoltage X-ray units:	$\pm 2\%$
	accelerators:	$\pm 2\%$
_	Linearity of monitor:	± 1%
_	Timer of cobalt-60 unit:	$\pm 0.01 \text{ min}$
_	Check electrons/photons radiation type should be con-	rrect
_	X-ray beam:	
	beam flatness:	$\pm 3\%$
	beam symmetry:	± 3%
_	Cobalt-60 and cesium-137 units:	
	beam symmetry:	± 3%
_	Orthovoltage X-ray units:	
	beam symmetry:	± 6%
_	Electron beams	
	flatness and symmetry:	± 3%
_	Transmission factor of wedges and compensators: $\pm 2\%$	
_	Dose monitoring system	

precision:	$\pm$		0.5%
linearity:	$\pm$		1%
dose rate eff	fect:	$\pm$	2%
stability:	$\pm$		2%
gantry angle	: +3%		

gantry angle:  $\pm 3\%$ 

### Treatment planning system (ICRU, 1986)

- A computerized dose distribution can be considered as sufficiently accurate if calculated and measured doses differ by less than 2% at points of relevance for the treatment.
- In regions involving very steep dose gradients, the observed position of a given isodose curve should differ from its calculated position by less than 0.3 cm.

#### 8. NUCLEAR MEDICINE

The criteria given here have been chosen as ones to tests that can fairly easily be done on a regular basis in departments of nuclear medicine. If the criteria are not achieved this should be taken as an indication of the need to undertake further investigations to establish the causes and to help decide on remedial action. The criteria for gamma camera for planar and SPECT use and isotope calibrator are derived from IPSM Report 65 (IPSM, 1992).

### **Gamma camera** (high resolution collimator - <sup>99m</sup>Tc)

### Uniformity

— The variation should be less than  $\pm$  10% within used field. The test should be performed with and without collimator and at a specified energy windows (E  $\Omega$  10%).

### Sensitivity

- The sensitivity (ability to detect the gamma rays emitted from a radioactive source in cps/MBq) should differ less than 20% from baseline value.

### *Centre of rotation (SPECT)*

- The deviation of the centre of rotation should be stable within half a pixel.

#### Multi-headed camera

### Sensitivity

– Differences in sensitivity between any of the heads should be less than 10%.

### Geometry

- Pixel by pixel correspondence of opposed views should be within a half a pixel.

### Isotope calibrator

### Linearity

- Linearity should be less than  $\pm$  5% over the range of activities used.

### Reproducibility

- The reproducibility should be less than  $\pm 5\%$ .

#### Accuracy

 The instrument accuracy should be less than 5% for gamma emitters of energy greater than 100 keV, and less than 10% for beta emitters and low energy gamma emitters.

## **Appendix A1: LIST OF ABBREVIATIONS**

AEC: automatic exposure control

CEC: Commission of the European Communities

CT: computed tomography

CTDI: computed tomography dose index

DG: Directorate General

EC: European Community

FSD: focus-skin distance

HU: Hounsfield unit (HU =  $1000/(\mu/\mu_0-1)$ ), where  $\mu$  is the linear attenuation

coefficient for the tissue in question and  $\mu_0$  is the linear attenuation coefficient for water. The CT number for air is about -1000 and the CT

number for water is assigned a value of 0, with one HU being

equivalent to about 0.1% of the linear attenuation coefficient for water.

HVL: half value layer

ICRU: International Commission on Radiological Units and Measurements

IEC: International Electrotechnical Commission

IPSM: Institute of Physical Sciences in Medicine

NCS: Nederlandse Commissie voor Stralingsdosimetrie.

NEMA: National Electrical Manufacturers' Association

OD: optical density

PMMA: polymethylmethacrylate

SPECT: single photon emission computed tomography

TNO: Netherlands Organization for Applied Scientific Research

WHO: World Health Organization

## **Appendix A2: DEFINITION OF TERMS**

The definitions given here may not be universally applicable but do express the meaning of the terms as used in this document.

#### Absorbed dose:

 The quotient of the mean energy imparted by ionising radiation to the matter in an infinitesimally small volume element by the mass of matter in this volume element (adapted from ICRU 1980).

#### Accuracy:

The closeness of an observed value of a quantity to the true value. The percentage of difference between measured value (m) and true value (t) according: 100 x (m-t)/t.

### Automatic exposure control (AEC) system:

 A mode of operation of an X-ray machine by which the tube loading is automatically controlled and terminated when a pre-set radiation exposure to the image receptor is reached. The tube potential may or may not be automatically controlled.

### Base and fog (Dmin):

- The optical density of a non exposed film after developing.

*Baseline value (a reference value of a functional parameter):* 

- either the value obtained for this parameter in the initial constancy test immediately following a status test; or
- where described in a corresponding Particular Standard, the mean value of values obtained in a series of initial constancy tests, immediately following a status test.

#### Breast compression:

 The application of pressure to the breast during mammography so as to immobilize the breast and to present a more uniform breast thickness to the X-ray beam.

### Consistency:

see precision, the measurements are usually performed over a period of time.

### Constancy test:

Each of a series of tests, carried out

- to ensure that the functional performance of equipment meets established criteria; or
- to enable the early recognition of changes in the properties of components of the equipment.

#### Contrast index:

 The difference in density steps found between the step nearest to the speedpoint and the step nearest to a density at 2.0 above base and fog.

### Conversion factor:

- The ratio of two quantities, usually expressed as a multiplying factor (unless otherwise stated) for converting the value of one quantity into the other.

### Computed tomography dose index (CTDI):

- The integral of a dose profile D(z), divided by the nominal slice thickness T:  $CTDI = (1/T) \int D(z) dz$ , where D(z) is the dose profile as a function of position z along a line perpendicular to the tomographic plane.

#### Deviation:

Percentage of difference between measured value (m) and prescribed value (p) according: (m/p-1) x 100%.

#### Dmin:

see Base and fog

### Entrance surface dose (ESD):

 The absorbed dose in air, including the contribution from backscatter, measured at a point on the entrance surface of a specified object e.g., a patient s breast or a standard phantom.

#### Established criteria:

 In a quality assurance programme, acceptable variations in results of a constancy test which signal satisfactory functional performance of the equipment tested.

#### Grid:

 A device which is positioned close to the entrance surface of an image receptor to reduce the quantity of scattered radiation reaching the receptor.

### *Grid system exposure factor:*

The ratio of the incident air kerma in air with the grid system in place to the incident air kerma in air without the grid system. The grid system exposure factor is dependent on the type of grid, radiation quality, field size and object thickness. It is recommended to measure at 28 kV and to use a 4 cm thick PMMA phantom.

#### Half-value layer (HVL):

 The thickness of aluminium absorber which attenuates the air kerma of a collimated X-ray beam by half under conditions of limited scatter.

### Mammography:

 The X-ray examination of the female breast. This may be undertaken for health screening of a population (mammography screening) or to investigate symptoms of breast disease (symptomatic diagnosis).

#### MGrad:

- The property which expresses the filmcontrast in the diagnostic range. It is calculated as the slope of the line through the points D1 = Dmin + 0.25 OD and D2 = Dmin + 2.00 OD.

### Net optical density:

Optical density excluding base and fog.

### *Optical density (OD):*

 The logarithm of the ratio of the intensity of perpendicularly incident light on a film to the light intensity transmitted by the film.

### Output:

see Radiation output

#### PMMA:

- Polymethylmethacrylate. Trade names include Lucite, Perspex and Plexiglass.

#### Precision:

 The variation (usually relative standard deviation) in observed values usually for a set of measurements made at about the same time.

### *Quality assurance (as defined by the WHO):*

 All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service (ISO 6215-1980). Satisfactory performance in service implies the optimum quality of the entire diagnostic process, i.e. the consistent production of adequate diagnostic information with minimum exposure of both patients and personel.

### *Quality control (as defined by the WHO):*

The set of operations (programming, coordinating, carrying out) intended to maintain or to improve [...] (ISO 3534-1977). As applied to a diagnostic procedure, it covers monitoring, evaluation, and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled.

#### Radiation dose:

 A generic term for a variety of quantities related to and including absorbed dose, such as air kerma, entrance dose, exit dose etc.

### Radiation output:

 The air kerma measured free-in-air (without backscatter) per unit of tube loading at a specified distance from the X-ray tube focus and at stated radiographic exposure factors.

#### *Radiation quality:*

 A measure of the penetrating power of an X-ray beam, usually characterised by a statement of the tube potential and the half-value layer.

### Reference dose value:

The value of a quantity obtained for patients which may be used as a guide to the acceptability of a result. In the 1996 version of the European Guidelines on Quality Criteria for Diagnostic Radiographic Images it is stated that the reference value can be taken as a ceiling from which progress should be pursued to lower dose values in line with the ALARA principle. This objective is also in line with the recommendations of ICRP Publication 60 that consideration be given to the use of dose constraints and reference or investigation levels for application in some common diagnostic procedures. The European Commission has prepared specific guidance on the aim and development of diagnostic reference levels.

Repeatability:

see Precision

Reproducibility:

see Precision, the measurements are often made over a period of time.

#### Speed:

Sensitivity; the property of the film emulsion directly related to the dose. The speed is calculated as the x-axis cut-off at optical density 1.00 + Dmin, also called "speedpoint". The higher the figure speed, the more dose is needed to obtain the right optical density. Since the film curve is constructed from a limited number of points, the speed must be interpolated. Linear interpolation will result in sufficient accuracy.

Speedpoint:

see Speed

Status tests:

- Tests carried out to establish the functional status of equipment at a given time.

Treshold contrast:

- The contrast that produces a just visible difference between two optical densities.

### *Tube potential:*

- The potential difference (kilovolt, kV) applied across the anode and cathode of the X-ray tube during a radiographic exposure.

#### Variation:

The absolute difference of two individual measurements (a and b) divided by the mean of those figures according: ((a-b)/(1/2a+1/2b)) x 100%.

## **Appendix A3: REFERENCES**

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