

## RADIATION SAFETY DIRECTORATE

Pursuant to Article 26-e, paragraph 1, item 13 of the Law on Ionising Radiation Protection and Radiation Safety (Official Gazette of the Republic of Macedonia No. 48/02 and 135/07), the Director of the Radiation Safety Directorate hereby adopts a

### **RULEBOOK ON THE CRITERIA FOR THE APPLICATION OF IONISING RADIATION SOURCES IN MEDICINE, VETERINARY MEDICINE, PHARMACY AND STOMATOLOGY (\*)**

#### Article 1

This Rulebook shall prescribe the criteria for the application of ionising radiation sources in medicine, veterinary medicine, pharmacy and stomatology.

#### Article 2

Certain terms used in this Rulebook shall have the following meaning:

1) “Automatic exposure control system” shall be a device for automatic control and stopping of the exposure when the image receptor dose reaches the previously set value;

2) “Reference (baseline) value” shall be the value of a given parameter established when putting into use a certain device intended for comparison of the results obtained in subsequent examinations with the objective of determining each change in the performances of the equipment over time. This term shall also refer to the results obtained when the equipment for which there are no results of the examination before it has been put into use is examined for the first time;

3) “CT dose index” shall be the absorbed dose along the line which runs parallel to the rotation axis of the computed tomograph. It shall be determined as an integral of the dose profile  $D(z)$  as a function of position  $z$  along a line perpendicular to the tomographic plane divided by the slice thickness  $T$ :

$$\text{CT dose index} = \frac{1}{T} \int D(z) dz ;$$

4) “CT number” shall be the number used for representation of the middle attenuation of X-ray radiation related to any elementary field of the image obtained with computed tomography and it shall be calculated as follows:

$$\text{CT number} = \left( \frac{\mu_{\text{мат}}}{\mu_{\text{вода}}} - 1 \right) \times 1000 ;$$

where  $\mu_{\text{мат}} = \mu_{\text{mat}}$  and  $\mu_{\text{вода}} = \mu_{\text{water}}$  are the linear attenuation coefficient of the X-ray beam in a given material and in water respectively. It shall be expressed in Hounsfield units (HU), the

\* This Rulebook shall comply with 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 and repealing Directive 84/466/EURATOM (CELEX 31997L0043)

value for water is - 0 HU, while the value for air is -1 000 HU;

5) “Entrance surface dose” shall be the absorbed dose in the air, including scattered radiation, measured at a point of the entrance surface of a patient or a phantom;

6) “Grid” shall be a device positioned in the immediate surroundings of the entrance surface of an image receptor in order to decrease the scattered radiation reaching the image receptor;

7) “Optical density (OD)” shall be the measure of film darkening defined as a logarithm of the ratio of the intensity of the light falling perpendicularly on the film to the intensity of the light passing through the film;

8) “Radiation output” shall be the air kerma measured in the air of the central axis of the X-ray beam without return scattering of the concrete distance from the focus per unit of X-ray tube loading (mAs). It shall be used as a measure of the performance of the X-ray tube and it shall be expressed in mGy/mAs;

9) “Threshold contrast” shall be the contrast causing the least visible difference between two optical densities;

10) “Variation (change)” shall be the absolute difference of the values of two individual measurements (a and b) divided by the mean of those two measurements expressed in percentages:

$$\left( \frac{a-b}{\frac{1}{2}a+\frac{1}{2}b} \right) \times 100\%$$

11) “Accuracy” shall be the deviation of the measured value of a given quantity from its real

$$\frac{m-t}{t} \times 100\%$$

value expressed in percentages and calculated as:  $\frac{m-t}{t} \times 100\%$ , where m is the measured value of the quantity, and t is the true value of that quantity;

12) “Deviation” shall be the difference between the measured value m and the prescribed

$$\frac{m-p}{p} \times 100\%$$

value p of a given quantity expressed in percentages:

13) “Precision” shall be the variation (usually relative standard deviation) of measured values usually for a set of measurements made at about the same time;

14) “PMMA” shall be the abbreviation for polymethylmethacrylate. The terms Lucite, Perspex and Plexiglass are also used;

15) “Half-value layer” shall be the thickness of aluminium attenuator which decreases the air kerma of the primary X-ray beam by half, and

16) “Kerma” shall be the kinetic energy released in a material per mass unit and it shall be the quotient of the sum of starting kinetic energies  $dE_k$  of all electrified particles released by indirect ionisation in an element per volume  $dV$  of the material and mass  $dm$  of that volume element:

$$K = \frac{dE_k}{dm}$$

and it shall be expressed in Gray (Gy).

#### Article 3

Ionising radiation sources applied in medicine, veterinary medicine, pharmacy and stomatology shall be X-ray machines, accelerators, sealed radioactive sources, devices with sealed radioactive sources and unsealed radioactive sources.

#### Article 4

The ionising radiation sources used in medicine shall be subject to quality control examinations in accordance with the regulations on ionising radiation protection and radiation safety.

#### Article 5

The voltage of the tube of the X-ray machine for diagnostic procedures in medicine shall not exceed 150 kV.

#### Article 6

The housing holding the tube of the X-ray machine should have an opening that would admit only the useful radiation beam.

The dose rate of the admitted radiation through the housing of the X-ray device intended for diagnostics (including the blend) in any direction at a distance of 1 m from the focus should not exceed 1 mGy/h under a maximum charge with a sealed opening for admitting the useful beam.

#### Article 7

The X-ray radiation applied in medicine shall be filtrated. The filters shall be built-in as permanent filters which cannot be removed without using tools and additional filters, which can be set or removed as the need should arise.

The element symbol and thickness of the filter materials shall be impressed at a visible place on the housing of the X-ray tube. The specified filter thickness shall refer to the total filtration.

The total filtration of the useful radiation beam shall not be smaller than 2,5 mm equivalent aluminium thickness (2,5 mm Al), unless otherwise provided by the provisions of this Rulebook.

#### Article 8

Under conditions of total filtration of 2,5 mm Al in diagnostics, the radiation output should be greater than 25  $\mu$ Gy/mAs at a distance of 1m, when operating at a voltage of 80 kV.

#### Article 9

The X-ray beam in diagnostics should be collimated in a manner that the total exposed surface under fixed focus – image receptor distance remains within the dimensions of the image receptor.

#### Article 10

The maximal charge of the focus in diagnostics should be smaller than 600 mAs (excluding fluoroscopy and tomography).

The time of each separate exposure in graphics should be delimited to a maximum of 6 s.

#### Article 11

The timer for turning off the X-ray machine in diagnostics shall be such that it will stop the tube from functioning after the expiration of the selected image-taking time, being at the same

time backed-up with an alternative tube turning-off option which will be activated if the usual turning-off method fails.

The timer referred to in paragraph 1 of this Article shall preclude the possibility for re-activation of the X-ray tube before the completion of the previous radiation.

#### Article 12

The focus-film distance when scanning with X-ray machines, excluding stomatological X-ray machines, shall not be smaller than 100 cm.

#### Article 13

The X-ray machine used for scanning shall be a built-in device for delimiting the radiation field size, as well as a light indicator of the radiation field size.

#### Article 14

The additional criteria for application of X-ray machines in diagnostics, the image receptor processing system, the image receptor, the conditions for viewing the images, computerised radiography readers, the direct digital radiography system, diagnostic monitors, film printers and scanners shall be given in Appendix 1, which is a constituent part of this Rulebook.

#### Article 15

The X-ray machine may be used for screening only if it is equipped with an electronic image intensifier or flat panel detectors and a TV set.

The housing of the X-ray tube, the collimator for delimiting the useful beam and the electronic image intensifier intended for screening should be set in a manner that the useful beam will not exceed the entrance surface of the electronic intensifier or the flat panel detector.

#### Article 16

The housing and carrier of the electronic intensifier or the flat panel detector of the X-ray machine intended for screening should provide protection which is at least equivalent to the protection of lead with a thickness of 2 mm at an X-ray tube voltage of 100 kV. For voltages in the range from 100 kV to 150 kV, the protection should be increased to an equivalent protection of lead with a thickness of 0,01 mm for each kV.

#### Article 17

The focus-patient skin distance for stationary X-ray machines intended for screening shall not be smaller than 30 cm.

#### Article 18

The X-ray radiation used for screening with mobile X-ray machines in operating theatres should be filtered with an aluminium filter with a minimal thickness of 3 mm.

#### Article 19

The dose rate during screening should meet one of the following criteria:

- the maximum dose rate at the entrance of the conventional image intensifier without grid (25 cm diameter) shall not exceed 0,8  $\mu\text{Gy/s}$  for exposure of an appropriate phantom with automatic dose rate control and automatic TV set brightness control. In cases of extraordinary application of high dose rate modes as in interventional radiology, the maximum dose rate shall

not exceed 1  $\mu\text{Gy/s}$ . For different diameters of the image intensifier, the dose rate shall be determined in accordance with the inverse proportion to the square of the diameter;

- the maximum dose rate, including scattered radiation on the patient's skin or on the surface of an appropriate patient substitute (25 cm phantom) on the side facing the X-ray tube shall not exceed 100 mGy/min.

#### Article 20

The high-contrast resolution of the TV set image intensifier during screening should be at least 0,8 lp/mm at a field size of 30-35 cm, determined from the use of a specified test object. For field sizes of 23-25 cm and 15-18 cm, the resolution values should be 1,0 lp/mm and 1,4 lp/mm respectively. For a technique of scanning small areas, i.e. for a technique of enlarging, the resolution should be at least 2,0 lp/mm.

#### Article 21

The system of termination of the screening procedure should operate automatically before the expiration of the predetermined time not exceeding 10 min. An acoustic signal should warn of the impending termination at least 30 s before the expiration of the time, to enable the device to be reset if exposure needs to be prolonged.

The switch turning on the X-ray tube for screening should be uninterruptedly pressed (with a foot or hand depending on the type and intended purpose of the device) during the scanning.

#### Article 22

For adequate cine studies using a 23-cm diameter image intensifier the entrance dose rate should be less than 0,20  $\mu\text{Gy/frame}$ .

#### Article 23

The ratio of the areas of the radiation field and the image intensifier entrance surface should not exceed 1.15.

#### Article 24

The additional criteria for the application of X-ray machines intended for screening shall be given in Appendix 2, which is a constituent part of this Rulebook.

#### Article 25

The X-ray machine intended for breast scanning (mammography) should have a device for breast compression and a moveable grid for absorbing scattered radiation.

#### Article 26

The measured size of the focus of the X-ray mammography machine should be smaller than 0,5 mm, while the focus-cassette distance should not be smaller than 60 cm.

#### Article 27

The X-ray mammography machine should have permanent built-in filters whose equivalent thickness should not be smaller than 0,5 mm Al or 0,03 mm Mo.

The thickness of the half-value layer of the X-ray beam of the X-ray mammography machine at a voltage of 28 kV should be from 0,30 mm Al to 0,40 mm Al for Mo/Mo anode/filter material combination and from 0,30 mm Al to 0,50 mm Al for Mo/Rh and Rh/Rh anode/filter material combinations.

#### Article 28

The voltage of the X-ray tube of the X-ray mammography machine should not be above 50 kV and it should be set progressively by 1 kV.

#### Article 29

The dose rate at a distance equal to the focus-film distance should be at least 7,5 mGy/s.

#### Article 30

The additional criteria for the application of X-ray mammography machines shall be given in Appendix 3, which is a constituent part of this Rulebook.

#### Article 31

The output radiation beam being emitted from the X-ray tube of the computed tomography device should be limited in a manner that its slice does not exceed the entrance surface of the active part of the receiving radiation detector.

#### Article 32

The additional criteria for the application of X-ray machines intended for computed tomography shall be given in Appendix 4, which is a constituent part of this Rulebook.

#### Article 33

The voltage of the tube of the X-ray machine used for teeth screening should not be smaller than 50 kV.

#### Article 34

The filtration of the useful radiation beam of the dental X-ray machine should be equivalent to at least 1,5 mm Al for a voltage of 70 kV and at least 2,5 mm Al for a voltage above 70 kV.

The type and thickness of the filter of the X-ray machine should be indicated on the housing of the X-ray tube.

#### Article 35

The tube of the dental X-ray machine should provide that the focus-patient's skin distance is at least 20 cm at an X-ray tube voltage above 60 kV and at least 10 cm at an X-ray tube voltage of 60 kV or less. The focus-patient's skin distance of the X-ray machine for panoramic dental screening should not be less than 15 cm.

#### Article 36

The radiation field at the outer end of the tube of the dental X-ray machine should not have a diameter larger than 60 mm.

The size of the field of the cassette holder of the panoramic dental radiographic device should not be larger than 10 cm x 15 cm. The total radiation field should not exceed the size of the opening of the useful radiation beam of the X-ray tube housing for more than 20%.

#### Article 37

For voltages of the dental X-ray machine tube between 50 kV and 70 kV, the radiation output should be within the interval 30-80  $\mu$ Gy/mAs at a distance of 1m from the focus.

#### Article 38

The dental X-ray machine should have a built-in light signal device indicating whether the device is plugged in the electric network, as well as a light signal device that is turned on at the time of screening and off after the expiration of the predetermined screening time.

#### Article 39

The control device of the X-ray machine intended for therapy should indicate clearly the operating status of the equipment at any given time.

#### Article 40

The dose rate of the radiation admitted through the housing of the X-ray machine intended for radiotherapy at a distance of 1m from the focus at a maximal voltage and the corresponding maximal current should not exceed:

- 1 mSv/h, when the maximal tube voltage is smaller than 150 kV, and
- 10 mSv/h, when the maximal tube voltage is above 150 kV.

The dose rate of the radiation admitted through the housing of the X-ray machine intended for radiotherapy at a distance of 5 cm from the housing surface should not exceed 300 mSv/h when the maximal tube voltage is above 150 kV.

#### Article 41

The rate of the dose absorbed in the air of radiation admitted through the X-ray tube housing at a voltage of 5 kV to 50 kV of the radiotherapy device at a distance of 5 cm of any available point on its surface should not exceed 1 mGy/h.

#### Article 42

The collimator for delimiting the useful radiation beam and the tube positioned on the housing for directing the primary beam of therapeutic X-ray machines with a tube voltage of 150 kV to 500 kV should fulfil the criterion referred to in Article 40 of this Rulebook in proportion to the radiation they admit and they should not admit more than 2% of the primary radiation beam.

#### Article 43

Therapeutic X-ray machines with a tube voltage of 150 kV to 500 kV should be provided with additional timer that would terminate the radiation if the primary timer fails to do so.

The additional timer referred to in paragraph 1 of this Article should be set for at least 10% longer radiation time than the time set on the primary timer.

#### Article 44

The additional criteria for the application of therapeutic kilovoltage X-ray machines shall be given in Table 1 of Appendix 5, which is a constituent part of this Rulebook.

#### Article 45

Accelerators used for radiotherapy in medicine should be provided with a double system for radiation termination in a manner that if the primary one fails to terminate the radiation, the secondary one will do as soon as the dose increases for more than 10% of the dose determined in the therapeutic procedure.

Accelerators should have an additional switch for radiation termination if the two systems referred to in paragraph 1 of this Article fail to do so.

#### Article 46

The radiation that is admitted through the accelerator when the collimator is completely sealed at a distance of 1m from the electronic direction should not exceed 0,5% from the largest rate of the dose absorbed in water measured on the axis of the radiation beam at a distance at which the therapy is being performed.

#### Article 47

The additional criteria for the application of accelerators for radiotherapy shall be given in Table 1 of Appendix 6, which is a constituent part of this Rulebook.

#### Article 48

The criteria for the application of X-ray machines for simulation and computed tomograph for simulation in radiotherapy shall be given in Tables 1 and 2 of Appendix 7, which is a constituent part of this Rulebook.

#### Article 49

The generator of short-lived radionuclides applied in medicine should be layered with the appropriate protection and projected in a manner that the dose rate of the outer surface of the layer should not be above 0,5 mGy/h.

#### Article 50

The criteria for the application of callibrators and gamma cameras in nuclear medicine shall be given in Table 1 of Appendix 8, which is a constituent part of this Rulebook.

#### Article 51

The dose rate of the non-useful radiation of the outer surfaces of stationary devices with sealed radioactive sources should not be above 1 mGy/h, while at a distance of 1m it should not be above 0,03 mGy/h. When the device with a sealed radioactive source also serves for transmission, the dose rate of the device surface should not exceed 0,5 mGy/h, while at a distance of 1m it should not exceed 0,02 mGy/h.

#### Article 52

The additional criteria for the application of a cobalt-60 device for teletherapy shall be given in Table 1 of Appendix 9, which is a constituent part of this Rulebook.

#### Article 53

For a period of three years from the date of entry into force of this Rulebook, filters with a thickness above 2,3 mm equivalent to the thickness of aluminium may be used in X-ray machines that are in use.

#### Article 54

With the entry into force of this Rulebook, Articles 16, 52, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86 and 109 of the Rulebook on placing on the market and using radioactive materials above the defined limit of activity, X-ray machines and other apparatuses that produce ionising radiation, as well as on the protective measures against radiation of those sources (Official

Gazette of the SFRY, No. 40/86 and 45/89) shall cease to apply.

## Article 55

This Rulebook shall enter into force on the eighth day from the date of its publication in the Official Gazette of the Republic of Macedonia.

No. 01-1083/4

Director,

16 September 2010

PhD Nuzi Shahin

Skopje

## APPENDIX 1

### **Additional criteria for the application of X-ray machines in diagnostics, as well as of the image receptor processing system, the image receptor, the conditions for image viewing, computerised radiography readers, direct digital radiography system, diagnostic monitors, printers and film scanners**

**I. Additional criteria for the application of X-ray machines in diagnostics** The mechanical functionality and electrical installation of the device should not endanger patients or individuals exposed during work.

#### **1. X-ray tube voltage**

##### **1.1 Precision and repeatability:**

The maximal deviation of the predetermined value from the measured one should be less than  $\pm 10\%$ .

##### **1.2 Variations with change in tube current:**

The maximal variations (changes) should be less than 10%.

##### **1.3 Voltage precision:**

For all generators: the deviation of the measured values of the tube voltage should be within  $\pm 5\%$  from the mean value.

#### **2. Exposure time**

For the predetermined exposure time longer than 100 ms, the measured exposure time should be within  $\pm 10\%$  from the predetermined exposure time, while for the predetermined exposure time shorter than 100 ms, the measured exposure time should be within  $\pm 25\%$  from the predetermined exposure time.

#### **3. Radiation output**

##### **3.1 Consistency:**

The radiation output should be constant within  $\pm 20\%$  of the mean for repeated exposures for a given tube voltage and the appropriate filtration characteristic of the activity.

##### **3.2 Variation with change in indicated current:**

Variations should be less than 15%.

### **3.3 Variations with change in indicated mAs:**

Variations should be less than 20%.

## **4. System geometry**

### **4.1 X-ray and light beam alignment:**

The sum of the deviation of the visually defined field with the respective edge of the X-ray field in any direction 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%.

### **4.2 X-ray field and image receptor alignment:**

When the central ray 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.

### **4.3 X-ray and light beam centring:**

The alignment of the centre of the light field and the centre of the X-ray beam should not differ for more than  $\pm 1\%$  of the focus-film distance.

### **4.4 Centring of the light beam and the system containing the image receptor and/or anti-scatter grid (Bucky):**

The alignment of the centre of the light field and the centre of the image receptor should not differ for more than  $\pm 1\%$  of the focus to image receptor distance.

### **4.5 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.

## **5. Automatic collimation:**

The margins of the X-ray beam shall not differ by 2% of the focus to image receptor distance at any side of the image.

## **6. Grid**

### **6.1 Artefacts:**

No artefacts should be visible on an X-ray image of the grid made at 50 kV.

### **6.2 Grid mobility:**

The lamellae of a moving grid should not be visible on the image at the shortest time used in practice during screening.

## **7. Automatic exposure control system:**

### **7.1 Difference in optical density at different exposure times:**

The difference in optical density between two exposures at the same automatic set parameters, one with a short and the other with a long exposure time, should be less than 0.3 OD.

### **7.2 Difference in optical density at different voltages:**

At a fixed thickness of the attenuation object (phantom), the maximal difference in the optical

density of the image as a function of the tube voltage used in practice should not exceed  $\pm 0,2$  OD.

### **7.3 Difference in optical density at different object thickness:**

At a fixed tube voltage the maximal difference in the optical density of the image as a function of the attenuation object (phantom) thickness should not exceed  $\pm 0,3$  OD of the mean optical density of the images obtained for the attenuation object (phantom) thickness simulating a mean patient thickness at the same tube voltage.

### **7.4 Repeatability of the response of the automatic exposure control system:**

A kerma in the air should not differ by more than 10% of the mean under the same exposure conditions.

### **7.5 Check of the settings of the automatic exposure control system:**

The optical density (including the optical density of an unexposed film after it has been developed) at a reference point of the developed film should remain within  $\pm 0,30$  OD of the target value. The target value typically falls within 1,0 OD to 1,5 OD, including the optical density of an unexposed film after it has been developed.

### **7.6 Chamber variation:**

The optical density at a reference point of the developed film for each chamber should not differ by more than 0,2 OD of the mean value.

### **7.7 Image receptor dose in computerised radiography (CR) and direct digital radiography (DDR):**

The image receptor dose in computerised radiography (CR) and direct digital radiography (DDR) should be smaller than 10  $\mu$ Gy per image.

## **8. Focus size:**

There is no absolute standard for focus size, but it should be measured before putting the tube into use, as well as periodically during its lifetime with the objective of determining the eventual focus degradation.

### **9. Focus-mass distance (only for a conventional tomograph):**

The alignment of the indicated and the measured focus-mass distance should be within  $\pm 5$  mm.

### **10. Step for changing the slice plane (only for a conventional tomograph):**

In the transition from one tomograph slice to another, the focus-mass distance repeatability should be within  $\pm 2$  mm.

### **11. Exposure angle (only for a conventional tomograph):**

The indicated and measured exposure angles should be aligned within  $\pm 50$  for units that operate at angles larger than 300 and smaller for smaller angles.

### **12. Darkening uniformity (only for a conventional tomograph):**

The density of image darkening at an opening on a lead plate should be almost uniform or deviate minimally from the uniform, in accordance with the pattern expected for the particular

tomographic unit. The image should reveal no unexpected overlaps, inconsistencies of exposures, or asymmetry in motion.

### **13. Spatial (high-contrast) resolution**

High-contrast resolution should amount to more than 2,8 lp/mm for a dose smaller than or equal to 10  $\mu$ Gy and more than 2,4 lp/mm for a dose smaller than or equal to 5  $\mu$ Gy.

The tomographic unit of a conventional tomograph should have a resolution of at least 1.6 lp/mm.

### **14. Contrast**

All fields should be visible on the gray scale.

## **II. Additional criteria for the application of the image receptor processing system, the image receptor, the conditions for image viewing, computerised radiography readers, direct digital radiography system, diagnostic monitors, printers and film scanners**

### **1. Intensifying screens (foils) and cassettes:**

#### **1.1 Condition and cleanliness of the screen (foil) and cassette:**

No serious artefacts should be visible on exposed films.

#### **1.2 Light-proofness of the cassette:**

No black edges should be visible on an unexposed film in the cassette after two exposures of 10 minutes each on a viewing box with a brightness of 1000 cd/m<sup>2</sup>.

#### **1.3 Film-screen (foil) contact:**

The cassette should not cause areas of visible differences of density or unsharp areas on the image.

#### **1.4 Relative sensitivity of the screen (foil)-film combination:**

Film densities obtained at identical exposure conditions (same dose, voltage, filtration, etc.) should not differ by more than 0.3 OD for film-screen combinations of the same type.

### **2. Film processing**

#### **2.1 Optical density of an unexposed film after its processing:**

The optical density of an unexposed film after its processing should be smaller than 0.3 OD.

#### **2.2 Sensitivity index:**

The deviation from the reference value of the sensitivity index should be smaller than 0.20 OD.

#### **2.3 Contrast index:**

The deviation from the reference value of the contrast index should be smaller than 0.20 OD.

### **3. Darkroom:**

#### **3.1 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.

### 3.2 Safelights:

The optical density of the part of an unexposed film kept for 4 min under darkroom conditions with the safelights and other lights in the surrounding premises should not show an increase of the density by more than 0.10 OD from the covered part of the same film not exposed to the darkroom conditions.

## 4. Image viewing conditions

### 4.1 Viewing box:

Brightness per unit area should be at least 1700 cd/m<sup>2</sup>†. Inhomogeneity should be less than 30 %.

### 4.2 Ambience illumination:

The illumination of the room at a distance of 1m from the viewing box should be less than 50 lux when the viewing box is off.

## 5. Readers in computerised radiography (CR readers) should fulfil the following criteria:

5.1	Dark sound	Agfa: SAL ≤ 130; Fuji pixel value ≤ 280; Kodak EI <sub>GP</sub> ≤ 80; Kodak EI <sub>HR</sub> ≤ 380 u Konica pixel value ≤ 3975;
5.2	Linearity and characteristics of a signal transmission system	According to the manufacturer's specification
5.3	Signal annulment efficiency	The attenuator should not be visible in the second image
5.4	Exposure index consistency	Indicated exposure should be aligned with the measured one within the range of 20%
5.5	Detector dose indicator consistency	Variations in calculated indicated exposures should not differ by more than 20% between the image receptors in CR for the same exposure
5.6	Reader pace errors	≤ 2%
5.7	Fogging	There should be no fogging
5.8	Image quality High-contrast resolution (Limit spatial resolution) Contrast	≥ 2,8 lp/mm for doses < 10 μGy ≥ 2,4 lp/mm for doses < 5 μGy
5.9		All fields on the gray scale should be visible
5.10	Low-contrast resolution	According to the manufacturer's specification
5.11	Laser beam function	A continuous edge should be visible along the length of the image
5.12	Muare figures	Muare figures should not be visible

---

† For a transitional period of 3 years from the date of entry into force of this Rulebook, the brightness per unit area of the viewing box may be at least 1500 cd/m<sup>2</sup>.

## **6. The direct digital radiography system (DDR system) should fulfil the following criteria:**

6.1 Dark sound	There should be no excessive sound in the system
6.2 Linearity	According to the manufacturer's recommendations
6.3 Keeping the previous image	There should be no visible artefacts from a previous exposure
6.4 Exposure index	Indicated sensitivity should not show a difference larger than 20% from indicated equivalent exposures
6.5 Uniformity	Mean value $\pm 5\%$
6.6 Reader pace errors	$\leq 2\%$
6.7 Resolution uniformity	There should be no fogging
6.8 Image quality	$\geq 2,8$ lp/mm for doses $\leq 10$ $\mu$ Gy
High-contrast resolution (Limit spatial resolution)	$\geq 2,4$ lp/mm for doses $\leq 5$ $\mu$ Gy
6.9 Contrast	All fields on the gray scale should be visible

## **7. Diagnostic monitors should fulfil the following criteria:**

7.1 Relation between the lightest and the darkest part of the monitor	$> 200$
7.2 Luminiscence of the black and white monitor field	Black: reference (baseline) value $\pm 35\%$ White: reference (baseline) value $\pm 30\%$
7.3 Distortion (for a CRT monitor)	10%
7.4 Resolution	During a visual check, the high and low contrast resolutions should not differ from the reference (baseline) value
7.5 DICOM gray scale  (GSDF = DICOM Standard function of light intensity in the fields on the gray scale)	GSDF $\pm 15\%$
7.6 Uniformity	$\leq 40\%$
7.7 Luminiscence variations between adjacent monitors	$\leq 40\%$
7.8 Room brightness	$\leq 25$ lux

## **8. Printers should fulfil the following criteria:**

8.1 Optical density consistency	Reference (baseline) value $\pm 0.30$
8.2 Image uniformity	$\leq 10\%$

**9. Film scanners should fulfil the following criteria:**

- 9.1** Difference in the gray scales of film and scanned image  $\leq 10\%$
- 9.2** Difference in the uniformity of film and scanned image  $\leq 10\%$
- 9.3** Difference in the distortion of film and scanned image  $\leq 10\%$
- 9.4** Difference in the spatial resolution of film and scanned image During a visual check, the high and low contrast resolutions should not differ from the reference (baseline) value

**APPENDIX 2**

**Additional criteria for the application of X-ray machines intended for screening**

In addition to the criteria applicable to X-ray machines in diagnostics and the image receptor processing system, the image receptor, the image viewing conditions, computerised radiography readers, the direct digital radiography system, diagnostic monitors, printers and film scanners prescribed by the provisions of this Rulebook, which also apply to X-ray machines intended for screening, the latter should fulfil the following criteria:

**1. Threshold of contrast:**

The threshold of contrast in cases where the TV monitor has automatically set parameters should be 4% or less.

**2. Cinematography:**

The typical entrance dose rate of the patient should be 0.10-0.30 Gy/min at an operational modus of 25 images/s with a phantom of 20cm.

**3. It is considered good practice if the collimator edges are visible on the TV image.**

**APPENDIX 3**

**Additional criteria for the application of X-ray machines intended for breast screening (mammography)**

**1. Generator of X-ray radiation and control**

**1.1 X-ray source**

### **1.1.1 Source-image distance:**

The source-image receptor distance should be in accordance with the manufacturer's specification and typically more than or equal to 600 mm.

### **1.1.2 X-ray field and image receptor alignment:**

Thorax side: X-rays should cover the film by no more than 5 mm out of the edges of the film.

Lateral side (left-right): X-rays should cover the film to the edges.

### **1.2 Tube voltage:**

The accuracy of tube voltage from 25 kV to 31 kV should be smaller than  $\pm 1$  kV, while precision should be smaller than  $\pm 0,5$  kV.

### **1.3 Automatic exposure control system:**

#### **1.3.1 Optical density control:**

The optical density (including the optical density of an unexposed film after it has been developed) at a reference point of the developed film should remain within  $\pm 0,15$  OD of the target value. The target value typically falls within 1,3 OD to 1,8 OD, including the optical density of an unexposed film after it has been developed.

Optical density may be set within the range of 0,10-0,20 OD, while the difference in the optical density at a reference point of the developed film between the greatest and the smallest sensitivity of the automatic exposure control system should be equal to, or greater than 1.0 OD.

#### **1.3.2 Short-term precision:**

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

#### **1.3.3 Long-term precision:**

Long-term precision should be greater than  $\pm 0,20$  OD of the optical density reference (baseline) value.

#### **1.3.4 Object thickness compensation:**

Variations in optical density, depending on the object thickness, should be within the range of  $\pm 0.15$  OD<sup>‡</sup>, in respect of the optical density obtained for a PMMA phantom of 4cm.

In digital mammography, the value of the contrast-sound ratio for other thickness values of a PMMA phantom should be at least:

- 15% more than the value of the contrast-sound ratio for PMMA phantom thickness of 5cm, for a 2 cm thick phantom;
  - 10% more than the value of the contrast-sound ratio for PMMA phantom thickness of 5cm, for a 3cm thick phantom;
  - 5% more than the value of the contrast-sound ratio for PMMA phantom thickness of 5cm, for a 4cm thick phantom;
  - 3% more than the value of the contrast-sound ratio for PMMA phantom thickness of 5cm, for a 4,5 cm thick phantom;
- and to:
- 5% less than the value of the contrast-sound ratio for PMMA phantom thickness of 5cm,

---

<sup>‡</sup> For a transitional period of 3 years from the date of entry into force of this Rulebook, the variations in optical density in respect of the object thickness should be within the range of  $\pm 0,20$  OD of the optical density for a 4cm thick PMMA phantom.

for a 6 cm thick phantom;

- 10% less than the value of the contrast-sound ratio for PMMA phantom thickness of 5cm, for a 7 cm thick phantom.

### **1.3.5 Tube voltage compensation:**

Variations in optical density, depending on the tube voltage, should be within the range of  $\pm 0,15$  OD, in respect of the optical density obtained for a PMMA phantom of 4, 5 cm.

### **1.3.6 Compression**

#### **1.3.6.1 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 - 20 kg).

#### **1.3.6.2 Compression plate alignment:**

Minimal misalignment of the positioning of the compression plates is allowed, less than 15 mm being acceptable for asymmetrical positioning (when the compression plate presses the breast at a plane positioned sidelong in respect of the supporting plate plane) in the direction towards the nipple and less than 5 mm for symmetrical positioning (when the compression plate presses the breast at a plane parallel to the supporting plate plane).

### **1.4 Bucky and image receptor**

#### **1.4.1 Anti-scatter grid:**

The exposure increase factor due to the application of an anti-scatter grid should be  $\leq 3$ .

#### **1.4.2 Inter cassette sensitivity and variation in optical density when exposed with the same settings of the X-ray equipment with automatic exposure control:**

The exposure range, expressed in mGy (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.

### **1.5 Film processing**

The optical density of an unexposed film after its processing:  $D_{min} = 0.2$  OD.

- Sensitivity index:

The sensitivity index should be  $\pm 10\%$  in respect of the reference (baseline) value<sup>§</sup>.

- Contrast:

The mean gradient ( $MGrad_{0.25-2.0}$ ) should be greater than 2.8.

- Daily performance<sup>\*\*</sup>: 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 month. The variability for all

---

<sup>§</sup> Compliance with this criterion shall be required 5 years after the date of entry into force of this Rulebook.

<sup>\*\*</sup> Compliance with this criterion shall be required 5 years after the date of entry into force of this Rulebook.

parameters should be less than  $\pm 10\%$ .

### **1.6 Darkroom:**

In addition to the criteria to be fulfilled by the darkroom laid down in Appendix 1 of this Rulebook, the following criteria should also be met:

#### **1.6.1 Film hopper and cassettes**

No extra fogging.

#### **1.7 Image viewing conditions**

Viewing box: The brightness per unit area should be in the range of 2000-6000  $\text{cd/m}^{2\dagger\dagger}$ . Illumination in the room should be under 50 lux.

### **1.8 System properties**

#### **1.8.1 Reference dose:**

The entrance surface air kerma for a 45 mm PMMA phantom depending on the darkening should be smaller than or equal to 13 mGy for darkening of 1.2 OD, smaller than or equal to 15 mGy for darkening of 1.4 OD, smaller than or equal to 17 mGy for darkening of 1.6 OD and smaller than or equal to 19 mGy for darkening of 1.8 OD.

#### **1.8.2 Image quality**

##### **1.8.2.1 Spatial (high-contrast) resolution:**

In both directions the resolution should be over 12 lp/mm for measurement with test object placed 4 cm above the supporting breast plate (on top of PMMA phantom), and on midline, 6 cm in from chest-wall side of film.

##### **1.8.2.2 Threshold contrast visibility:**

For measurements of contrast of large details with a test object inside a 45 mm thick PMMA phantom, the limiting value should be smaller than 1.5 % contrast for a 5-6 mm detail.

In digital mammography, the threshold contrast should be smaller than 0.85 % for a 5-6 mm detail, smaller than 2.35 % for a 0.5 mm detail and smaller than 5.45 % for a 0.25 mm detail.

#### **1.8.3 Exposure time:**

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

## **APPENDIX 4**

### **Additional criteria for the application of devices intended for computed tomography**

In addition to the criteria applicable to X-ray machines in diagnostics and the image receptor processing system, the image receptor, the image viewing conditions, computerised

---

<sup>††</sup> For a transitional period of 3 years from the date of entry into force of this Rulebook, the brightness per unit area of the viewing box may be at least 1700  $\text{cd/m}^2$ .

radiography readers, the direct digital radiography system, diagnostic monitors, printers and film scanners prescribed by the provisions of this Rulebook, which also apply to X-ray machines intended for computed tomography, the latter should fulfil the following criteria:

**1. Image noise:**

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

**2. CT number values:**

The deviations of the values of CT numbers in consistent image positions should be less than  $\pm 10$  HU for water and less than  $\pm 20$  HU for other materials in respect of the reference (baseline) value.

**3. 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 reference (baseline) value.

**4. CT dose index:**

The measurements of CT dose index for a single slice for each available beam collimation and for each available slice thickness should not deviate more than  $\pm 20\%$  from the reference (baseline) value.

**5. Irradiated slice thickness:**

The full width at half maximum of the dose profile should not differ more than  $\pm 20\%$  from the reference (baseline) value.

**6. Spatial (high-contrast) resolution:**

The measurements of full width at half maximum of the spread function describing the system response to screening a dotted object or an edge should not differ more than  $\pm 20\%$  from the reference (baseline) value.

**7. Low-contrast resolution:**

Polystyrene ball of 0.35 cm diameter inserted in an appropriate water phantom should be visible in the image.

## APPENDIX 5

*Table 1. Additional criteria to be met by therapeutic kilovoltage X-ray machines*

Parameter:	Permitted deviations:
<b>1. Mechanical</b>	
1.1 Light and X-ray beam congruence	$\pm 5$ mm
1.2 Field uniformity	$\pm 5$ %
1.3 Timer accuracy	$\pm 2$ %
1.4 Semi-thinning measurement	$\pm 10$ %
<b>2. Dosimetric</b>	
2.1 Radiation output constancy	$\pm 5$ %
2.2 Radiation output calibration	$\pm 3$ %
<b>3. Safety</b>	
3.1 Safety switch/door interlock	functional
3.2 Audiovisual monitor	functional
3.3 Emergency switches	functional
3.4 Safety switch/filter interlock, applicators	functional
3.5 Light warning safety devices	functional

## APPENDIX 6

*Table 1. Additional criteria to be met by therapy accelerators*

Parameter:	Permitted deviations:
<b>1. Mechanical</b>	
1.1 Distance indicator (telemeter)	$\pm 2$ mm
1.2 Laser placement	$\pm 2$ mm
1.3 Gantry angle indicator	$\pm 1^\circ$
1.4 Collimator angle indicator	$\pm 1^\circ$
1.5 Field size indicator	$\pm 3$ mm or 1,5 %
1.6 Positioning of multi-leaf collimators	$\pm 3$ mm or 1,5 %
1.7 Blend symmetry	$\pm 2$ mm
1.8 Treatment table positioning indicators	$\pm 2$ mm
1.8.1 Longitudinal and lateral movements	$\pm 2$ mm
1.8.2 Vertical movement	$\pm 1^\circ$
1.8.3 Isocentric rotation	
1.9 Light and X-ray field	
1.9.1 Light and X-ray field congruence	$\pm 2$ mm or 1%
1.9.2 Light and X-ray field centres congruence	$\pm 2$ mm or 1%
1.10 Light field brightness	functional
1.11 Fixation of handle, tube, filter	functional
1.12 Electronic imaging device	functional
1.13 Variation of mechanical isocentre by rotation	
1.13.1 Collimator rotation	2 mm diameter
1.13.2 Gantry rotation	2 mm diameter

1.13.3	Treatment table rotation	2 mm diameter
1.14	Congruence of collimator, gantry and treatment table axes with the isocentre	2 mm diameter
1.15	Congruence of radiation and mechanical isocentre	2 mm diameter
1.16	Treatment table sag	2 mm
2.	<b>Dosimetric</b>	
2.1	Constancy of radiation output for photon beams	3 % or 2 %
2.2	Constancy of radiation output for electron beams	3 % or 2 %
2.3	Radiation fields uniformity	
2.3.1	Photon beam evenness	3 %
2.3.2	Photon beam symmetry	3 %
2.3.3	Electron beam evenness	3 %
2.3.4	Electron beam symmetry	3 %
2.4	Energy constancy	3 %
2.5	Properties of depth dose	
2.5.1	Photon beams	
2.5.1.1	Constancy of dosimetric parameters (PDD, TAR) of the central axis	2 %
2.5.1.2	Penetration quality/Quality index	2%
2.5.2	Electron beams	
2.5.2.1	Constancy of dosimetric parameters (PDD) of the central axis	2 mm in therap. depth
2.5.2.2	Relation of practical range to the 80% isodose range	1.6
2.5.2.3	Penetration quality/Quality index	3% or 2mm
2.6	Monitoring system/dose monitoring	
2.6.1	Linearity	±1% or 1MU
2.6.2	Repeatability	± 1 %
2.6.3	Proportionality	± 2 %
2.6.4	Variations to gantry angle	± 2 %
3.	<b>Safety</b>	
3.1	Safety switch/door interlock	functional
3.2	Emergency switches	functional
3.3	Safety switch/handle interlock, applicators	functional
3.4	Light warning safety devices	functional

**Table 1. Additional criteria to be met by X-ray simulation devices in radiotherapy**

	Parameter:	Permitted deviations:
<b>1.</b>	<b>Mechanical</b>	
1.1	Distance indicator (telemeter)	$\pm 2$ mm
1.2	Laser positioning	$\pm 2$ mm
1.3	Field size indicator	$\pm 2$ mm
1.4	Collimator angle indicator	$\pm 1^\circ$
1.5	Gantry angle indicator	$\pm 1^\circ$
1.6	Cross centring (collimator cross-hairs)	2 mm diameter
1.7	Light and X-ray field congruence	$\pm 2$ mm or 1%
1.8	Focus-film distance indicator	$\pm 2$ mm
1.9	Isocentre	
1.9.1	Collimator rotation	2 mm diameter
1.9.2	Gantry rotation	2 mm diameter
1.9.3	Treatment table rotation	2 mm diameter
1.10	Congruence of collimator, gantry and treatment table axes with the isocentre	2 mm diameter
1.11	Congruence of contrary radiation fields	$\pm 1$ mm
1.12	Vertical movement of simulation table	$\pm 2$ mm
1.13	Simulation table sag from an equally distributed weight of 80 kg	5 mm
<b>2.</b>	<b>Safety</b>	
2.1	Safety switch/door interlock	functional
2.2	Audiovisual monitor	functional
2.3	Emergency switches	functional
2.4	Light warning safety devices	functional
2.5	Safety switch/rotation interlock	functional

**Table 2. Additional criteria to be met by the computed tomograph intended for simulation in radiotherapy**

Parameter:	Permitted deviations:
<b>1. Mechanical</b>	
<b>1.1</b> CT gantry laser positioning	
1.1.1 In relation to slice (scan) plane	± 2 mm
1.1.2 Parallel and perpendicular along laser projection	± 2 mm
<b>1.2</b> Wall laser positioning	
1.2.1 Distance to scanned plane	± 2 mm
1.2.2 In relation to a slice along laser projection	± 2 mm
1.3 Ceiling laser positioning	
1.3.1 Perpendicular to slice plane	± 2 mm
1.4 Orientation of scanner table	
<b>1.4.1</b> Perpendicular to screening plane	± 2 mm
1.5 Reading the longitudinal position of the table	± 1 mm
1.6 CT number / electronic density verification	± 5 HU water ± 10 HU air
1.7 Simulation table sag	± 20 HU lungs, bones 2 mm
<b>2. Safety</b>	
2.1 Emergency switches	functional
2.2 Light warning safety devices	functional

## APPENDIX 8

*Table 1. Criteria for the application of calibrators and gamma cameras in nuclear medicine*

Ordinal number	Parameter	Permitted deviation	
1.	<b>Calibrator</b>	Linearity	$\pm 5\%$ of activities practiced
		Repeatability	$\pm 5\%$
		Accuracy	< 5% for gamma emitters with energy > 100 keV <10 % for beta emitters and low-energy gamma radiation
2.	<b>Gamma camera (high-resolution <math>^{99m}\text{Tc}</math> collimator)</b>	Uniformity	Variation smaller than $\pm 10\%$ for the field being used
		Sensitivity	< 20% from reference (baseline) value
		Deviation of rotation centre	Stable within half a pixel
	<b>Multi-headed camera</b>	Difference in the sensitivity of any two heads	< 20%
		Geometry	The congruence of successive pixels of opposite images should be within half a pixel

*Table 1. Additional criteria for the application of a Cobalt-60 device for teletherapy*

Ordinal number	Parameter	Permitted deviations	
1.	<b>Mechanical</b>	Collimator rotation	2 mm diameter
		Gantry rotation	3 mm diameter
		Treatment table rotation	2 mm diameter
		Congruence of collimator, gantry and treatment table axes with the isocentre	2 mm diameter
		Congruence of mechanical isocentre and radiation field	2 mm diameter
		Treatment table sag from an equally distributed weight of 80 kg	5 mm
		Vertical movement of treatment table	2 mm
		Laser positioning	2 mm
		Optical distance indicator (ODI)	2 mm
		Light and X-ray field congruence	3 mm
		Field size indicator (collimator setting)	2 mm
		Gantry and collimator angle indicator	1°
		Cross centring (collimator cross-hairs)	2 mm
		Light field brightness	functional
		Fixing (blocking) wedges and handles	functional
		Source position check	3 mm

2.	<b>Dosimetric</b>	Radiation output constancy	2%
		Radiation output constancy vs. gantry angle	2%
		Radiation output constancy vs. SSDL	2%
		Dependence of field size on radiation output constancy	2%
		Constancy of the dosimetric parameters (PDD, TAR) of the central axis	2%
		Transmission factor constancy for all standard accessories	2%
		Wedge transmission factor constancy	2%
		Beam uniformity vs. gantry angle	3%
		Timer linearity and error	1%
		Off axis points measurements with or without wedges	3%
3.	<b>Safety</b>	Safety switch/door interlock	functional
		Audiovisual monitor	functional
		Room dose rate monitor	functional
		Emergency switches	functional
		Safety switch / wedge interlock	functional