

Translation. Original text in Finnish.

Acceptability requirements for X-ray equipment used in health care

Radiography and fluoroscopy equipment, computed tomography equipment and bone densitometry equipment

According to the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000, Section 30), the procedures involving exposure to radiation shall be performed by using equipment suited for the said purpose. Furthermore, the decree specifies that the requirements and criteria of acceptability for specific equipment functions to be considered from the point of view of radiation safety shall be confirmed by the Radiation and Nuclear Safety Authority (STUK).

This decision confirms the criteria of acceptability (acceptability requirements) for radiography and fluoroscopy equipment, computed tomography equipment and bone densitometry equipment as set out in the appendix. These acceptability requirements do not apply to dental radiography equipment or radiotherapy equipment.

This decision replaces the previous decision 12/310/06 issued on the matter on 17 August 2006.

This decision is valid as of 1 June 2014 until further notice.

Director General

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Appendix

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1. Introduction

The acceptability requirements denote the minimum requirements or acceptability limits that are imposed on the performance characteristics of the equipment when it is used. No later than at the time the equipment no longer meets an acceptability limit, the equipment must be repaired in a way that restores its performance characteristics to comply with the acceptability limit. Otherwise, it must be decommissioned. If necessary, it is possible to continue the use of such equipment temporarily provided that the use is restricted in a way that enables the operation of the equipment according to the acceptability requirements.

The acceptability requirements typically concern the precision of the settings and the operating condition of the equipment. They are not limit values for optimal equipment performance. As responsible parties (parties running a radiation practice) purchase new equipment, perform acceptance tests and inspect the quality of the equipment during use, they should apply stricter requirements, which may be based, for example, on equipment specifications or the performance tolerances presented in the equipment standards.

When evaluating the results of performance measurements, it should be considered that the conditions of the measurement and the methods used may impact the results. More information on appropriate procedures for determining the performance characteristics is available in bibliographic references 2 and 3, for example.

The X-ray equipment used in health care as well as the accessories and instruments related to its use shall meet the acceptability requirements presented in this decision (see also the Decree of the MSAH 423/2000 [9], Section 30, and Guide ST 3.3 [10]). However, this decision does not apply to dental radiography equipment, whose acceptability requirements are set out in Guide ST 3.1 [11], or radiotherapy equipment, which are subject to decision 20/3020/2010 [12].

2. Suitability and operation of X-ray equipment

Medical X-ray equipment introduced to the market after 13 June 1998 must bear the CE mark (Directive 93/42/EEC) in accordance with the Finnish Medical Devices Act (629/2010). The CE mark is the manufacturer's statement that the equipment meets the safety requirements for equipment set out in the Directive of the European Communities.

The X-ray-equipment and any related accessories, such as a display monitor, must be suitable for the intended use.

The X-ray equipment, its accessories and the location of use must enable the safe operation of the equipment. The unit (including its indicator lights, switches and automatic functions) as well as any accessories and safety equipment related to the unit or its use must be undamaged and function as intended.

The equipment must enable the use of the instruments necessary for the radiation protection of the persons assisting the patient and for keeping the patient motionless. If the equipment is also intended for examining children, it must have appropriate functional and performance characteristics.

3. Dose display

X-ray equipment introduced after 1 April 2006 must include a display that indicates the patient's radiation exposure based on dose¹ measurement or a calculated estimate. The dose display shall indicate the value of the parameter presented in Table 1. For radiography equipment, excluding fluoroscopy equipment, the value indicated on the dose display must not deviate from the actual value of the parameter by more than 25%. For fluoroscopy equipment, the value indicated on the dose display must not deviate from the actual value by more than 35%.²

Table 1. Parameter indicated on the dose display.

Type of equipment		Date of introducing the equipment	
		Before 1 June 2014	After 1 June 2014
Conventional radiography equipment	Radiography equipment mainly used in paediatric examinations	Dose-area product (DAP, KAP ³) or another appropriate dose parameter.	
	Other equipment	Exposure factors that enable assessing the patient's radiation exposure.	Dose-area product (DAP, KAP) or another appropriate dose parameter.
Bone densitometry equipment		Exposure factors that enable assessing the patient's radiation exposure.	
Fluoroscopy equipment	Equipment that is only used in fluoroscopy of limbs	Exposure factors that enable assessing the patient's radiation exposure.	Dose-area product (DAP, KAP) or another appropriate dose parameter.
	Other fluoroscopy equipment	Dose-area product (DAP, KAP) or another appropriate parameter.	
Mammography equipment		Exposure factors that enable assessing the patient's radiation exposure.	Mean glandular dose (MGD)
CT equipment		Weighted dose-length product (DLP) and CT dose index (CTDI _{vol}) ⁴	

4. Filtration of primary radiation

The X-ray equipment must bear a mark concerning the total filtration of radiation. If the filtration is adjustable, the fixed filtration must be marked on the protective housing of the X-ray tube and the selected additional filtration must be verifiable.

For X-ray equipment other than that used in mammography, the total filtration of primary radiation must correspond to a minimum of 2.5 mm Al. This requirement is considered to be met also if the half-value layer (HVL) of primary radiation is at least equivalent to the minimum value presented in Table 2.

¹ The dose specified here may be measured as air kerma.

² The requirement applies throughout the normal operating range of the equipment.

³ This decision uses the acronyms DAP (Dose-Area Product) and KAP (Air Kerma-Area Product).

⁴ The size of the phantom used for determining the dose must be specified.

Table 2. Minimum acceptable half-value layer for primary radiation of non-mammography equipment (IEC 60601-1-3:2008).

X-ray tube voltage (kV)	Minimum half-value layer (mm Al)
50	1.8
60	2.2
70	2.5
80	2.9
90	3.2
100	3.6
110	3.9
120	4.3
130	4.7
140	5.0
150	5.4

For mammography equipment, the total filtration of primary radiation must, at the minimum, correspond to the values presented in Table 3. For anode/filter combinations not included in Table 3, the total filtration must meet the half-value layer criterion $HVL \geq U \cdot (0.01 \text{ mmAl/kV})$, where U is the X-ray tube voltage.

Table 3. Minimum total filtration values for the most commonly used X-ray tube anode/filter combinations in mammography.

Anode material/ filter material	Mo/Mo	Mo/Rh	W/Mo	W/Rh	Rh/Rh	W/Ag
Minimum total filtration	30 μm Mo	25 μm Rh	60 μm Mo	50 μm Rh	25 μm Rh	50 μm Ag

5. X-ray tube voltage

The X-ray tube voltage must not deviate from the set or indicated value by more than 10%. Furthermore, when adjusting the value of the voltage, the change in actual voltage must be at the minimum 0.5 times and at the maximum 1.5 times the difference between the set voltages.

For mammography equipment, the X-ray tube voltage must not deviate from the set or indicated value by more than 2 kV.

6. Current-time product

The current-time product, i.e. the product of the X-ray tube current and exposure time, must not deviate from the set value by more than $20\% + 0.2 \text{ mAs}$.⁵

7. X-ray tube current

The X-ray tube current must not deviate from the set value by more than 20%.⁵

8. Exposure time

The exposure time must not deviate from the set value by more than 20% + 1 ms.

When using mammography equipment with an automatic exposure control unit for conventional projection imaging of a typical breast with a thickness of 45 mm, the exposure time must be less than 2 s.

9. X-ray tube radiation output

When using fixed exposure factors (manual values) that correspond to the clinical use of the equipment, the standard deviation of the doses measured in the radiation beam must not exceed 10%. At least five repeated measurements are used for calculating the standard deviation.

When using manual values, the dose measured in the radiation beam of the X-ray equipment must be proportional to the set current-time product as follows:

$$\frac{\left| \frac{K_1}{Q_1} - \frac{K_2}{Q_2} \right|}{\left(\frac{K_1}{Q_1} + \frac{K_2}{Q_2} \right)} \leq 0,1$$

where K_1 is the dose corresponding to the current-time product Q_1 , K_2 is the dose corresponding to the current-time product Q_2 and $Q_1 < Q_2 < 2 \cdot Q_1$.

10. Radiation beam indicators and alignment

The guide lights and light fields that are used for aligning the radiation beam must be clearly visible in normal working light.

The deviation between the guide lights or other radiation beam indicators and the edges of the radiation beam on the image receptor must not exceed 1% of the distance between the X-ray tube focus and the image receptor on any edge of the radiation field. For mammography equipment, the requirement is 2%.

The radiation beam must be aligned on the image receptor as appropriate and intended by the equipment manufacturer. For conventional radiography and fluoroscopy equipment, the deviation between the radiation beam edge and the intended location on the image receptor must not exceed 2% of the distance between the focus and the image receptor.

⁵Direct measurement of the current-time product or the X-ray tube current is not always necessary in practice, and compliance with the requirement may instead be monitored based on the constancy and linearity of radiation output. If the measured radiation output deviates from the radiation output reference value that was determined during the equipment acceptance test by more than the action level specified in the quality control programme (see Guide ST 3.3 [10]), or if the dose as a function of current-time product does not meet the linearity requirement of Section 9, it may also be necessary to verify the absolute accuracy of the current-time product .

If the radiography or fluoroscopy equipment uses an automatic collimator system that automatically limits the radiation beam up to the size of the image receptor, the operator must be able to reduce the size of the automatically adjusted image field.

In fluoroscopy, the ratio of the radiation field size and the active area of the image receptor must not exceed 1.25. The radiation field must not exceed the primary radiation shield of the equipment.⁶

For mammography equipment, the radiation beam must not reach more than 5 mm beyond the edge of the patient table at the side of the patient's chest. In the other directions, the beam must not reach beyond the primary radiation shield of the equipment.

When the patient table for CT equipment moves a distance of approximately 30 cm, the actual distance travelled must not deviate by more than 3 mm from the value on the table's movement indicator. The indicated starting point of a CT scan must not deviate from the actual starting point by more than 3 mm.

11. Compression force in mammography equipment

Mammography equipment must include an instrument for compressing the breast. When the breast is compressed by motor, the maximum compression force must be between 130 and 200 N. When the breast is compressed manually, the compression force must not exceed 300 N.

12. Display monitors

The functionality of the display monitor must not reduce the quality of the displayed image in a way that essentially hinders the accuracy of the diagnosis. It must be taken into account that the performance of the display monitor is affected by the lighting of the operating environment. Therefore, the lighting in the operating environment must not be so bright that it hinders identifying differences in contrast. There must not be any disturbing glare from light sources when the monitor is off.

13. Image quality and digital imaging receptors

The image quality must meet the clinical requirements for X-ray examinations.⁷

⁶ It is good practice to limit the radiation beam entirely on the image receptor with the edges of the radiation field visible in the image.

⁷ In addition to continuous image quality monitoring during the normal use of equipment, it is good practice to assess the image quality systematically, at least for some of the most common examination types, by using images taken from patients [10]. The person performing the assessment should be a medical specialist in the field. When defining the criteria for image quality, the quality criteria published by the European Union, for example, may be used as a reference. The images included in the assessment should be a representative sample of the patients' images according to which the radiation exposure is determined. The assessment must be carried out according to the local clinical practice in terms of the methods and conditions of viewing the images.

N.B. No detailed *technical* acceptability requirements are presented for image quality in this decision because compliance with technical requirements does not demonstrate clinical acceptability and because the required clinical image quality essentially depends on the medical indications that justify the X-ray examination. The control of the operating condition and performance characteristics of equipment should employ a phantom suited to the technical assessment of image quality as well as appropriately selected performance levels (e.g. resolution and contrast sensitivity) (see Guide ST 3.3 [10]).

Clinical images must not show any traces of previous images.

Images taken from a homogeneous subject must not display any imaging errors that might interfere with making a diagnosis based on the patient images.

The exposure index⁸ value in digital imaging must be repeatable in such a way that the dose determined based on the exposure index value of an individual image must not deviate from the average value of repeated measurements by more than 20%.

14. Functionality of the automatic exposure control unit

The automatic exposure control unit must function as intended by the equipment manufacturer.

The automatic exposure control unit must be able to display the current-time product or exposure time used in imaging afterwards.

When using the automatic exposure control unit, the maximum current-time product of the radiographic equipment must not exceed 600 mAs or correspond to an energy value higher than 60 kWs. For mammography equipment, the maximum value is 800 mAs.

When the imaging of the same applicable subject is repeated five times, the automatic exposure control unit must be able to duplicate the irradiation in such a way that the measurements of the dose or a corresponding parameter deviate from the average by less than $\pm 10\%$.

15. Fluoroscopy equipment

In the normal operating mode of the equipment, the air kerma rate at the reference point⁹ must not exceed 88 mGy/min.

If the equipment has an operating mode that enables an even higher dose rate, it may be approved subject to the following requirements:

- The air kerma rate at the reference point must not exceed 176 mGy/min. (In C-arm units, the requirement applies to a 30-cm distance from the external surface of the image receptor shield instead of the reference point.)
- The equipment must include a switch that the operator has to keep continuously activated in order to use a dose rate higher than in the normal operating mode.
- The use of a dose rate higher than in the normal operating mode is indicated by an uninterrupted audible signal.

⁸ In English literature, this parameter is denoted by the terms exposure index, detector dose index, sensitivity index and sensitivity value, for example, while Finnish literature often uses the term 'annosindikaattori'.

⁹ The reference point is specified in the standards [5, 8] as a point that describes the typical distance between the patient's skin and the focus of the X-ray tube. Its location must be described in the operating instructions of the equipment. When the X-ray tube is located below the examination table, the reference point is located 1 cm above the surface of the patient table. When the X-ray tube is located above the examination table, the reference point is located 30 cm above the surface of the patient table. When the C-arm unit has an isocenter (around which the X-ray tube is rotated), the reference point is located 15 cm from the isocenter towards the focus of the X-ray tube. In C-arm units in which the distance between the X-ray tube focus and the image receptor is under 45 cm, the reference point is located at the minimum focus distance. In other types of X-ray equipment, the reference point is located at a manufacturer-specified distance from the focus of the X-ray tube that corresponds to the distance from the patient's skin.

In the normal operating mode of the equipment, the automatic dose rate level¹⁰ must not exceed 0.8 µGy/s.

If the person who performs the examination has to work near the patient, the equipment or its accessories must provide adequate radiation shielding for the operator that attenuates the scattered radiation from the patient.

The digital image receptor of fluoroscopy equipment are considered to correspond to the image intensifier as referred to in the Decree of the MSAH, Section 30.

The fluoroscopy equipment must be able to display the latest fluoroscopic image.

Literature

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9. Decree of the Ministry of Social Affairs and Health on the medical use of radiation 423/2000.
10. X-ray examinations in health care, Guide ST 3.3, STUK 20 March 2006.
11. Dental X-ray examinations in health care, Guide ST 3.1, STUK 20 August 2011.
12. Acceptability requirements for radiotherapy equipment, decision 20/3020/2010.

¹⁰ The automatic dose rate level refers to the air kerma rate measured at the surface of the image receptor entrance plate as regulated by the automatic system. The phantom used in the measurement is a 2 mm thick copper plate or a 20 mm thick aluminium plate fastened to the X-ray tube collimators. If the anti-scatter grid cannot be removed, the measured result shall be adjusted in such a way that the measured air kerma rate corresponds to the conditions behind the grid.