

Criteria for medical X-ray system

(March 22, 2001)

(MHLW Ministerial Announcement No. 75)

In accordance with provisions in Article 42, Paragraph 2 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), the criteria for medical X-ray system (MHW Announcement No. 238 of August 1976) shall be thoroughly revised as follows and applied from April 1, 2001.

Criteria for medical X-ray system

- 1 A medical X-ray system is an X-ray system that is used for diagnosis or treatment, has the rated tube voltage of ≥ 10 and ≤ 400 kV, and consists of an X-ray generator (refers to X-ray tube device and its attached apparatus, high-voltage generator and X-ray control device as well as integrated X-ray generator), X-ray mechanical device (refers to a retainer, fluoroscopic table, radiographic table, X-rays treatment table, etc.), X-ray imaging device (image intensifier, photofluorographic equipment, X-ray television, etc.), and other devices necessary for the medical X-ray system.
 - (1) The X-ray tube container and irradiation tube shall be shielded so that the X-ray dose other than that of useful beams falls within the air-kerma rate in free air (hereinafter referred to as “air-kerma rate”) as follows.
 - A For a therapeutic X-ray system with the rated tube voltage of ≤ 50 kV, the X-ray dose 5 cm apart from the accessible surface of the X-ray system is ≤ 1.0 mGy/hr.
 - B For a therapeutic X-ray system with the rated tube voltage of > 50 kV, the X-ray dose 1 m apart from the X-ray tube focus is ≤ 10 mGy/hr, and that 5 cm apart from the accessible surface of the X-ray system is ≤ 300 mGy/hr.
 - C For an X-ray system for intraoral radiography with the rated tube voltage of ≤ 125 kV not intended to be HAND-HELD, the X-ray dose 1 m apart from the X-ray tube focus is ≤ 0.25 mGy/hr.
 - D For an X-ray system for intraoral radiography with the rated tube voltage of ≤ 125 kV intended to be HAND-HELD, the X-ray dose at any point on the outer surface of the equipment is ≤ 0.05 mGy.
 - E For X-ray systems other than ones listed in A to D, the X-ray dose 1 m apart from the X-ray tube focus is ≤ 1.0 mGy/hr.
 - F For a capacitor-discharge high-voltage generator, when charged and not used for irradiation, the X-ray dose 5 cm apart from the accessible surface is ≤ 20 μ Gy/hr.
 - (2) To the medical X-ray system, an additional filter shall be attached to ensure total filtration of useful beams as follows.
 - A For an X-ray system for intraoral radiography with the rated tube voltage of ≤ 70 kV, the total filtration is ≥ 1.5 mm aluminum equivalent.
 - B For an X-ray system for mammography with the rated tube voltage of ≤ 50 kV, the total filtration is ≥ 0.5 mm aluminum equivalent or ≥ 0.03 mm molybdenum equivalent.

- C For an X-ray system for irradiation of blood for transfusion, therapeutic X-ray system as well as X-ray systems other than those listed in A and B, the total filtration is ≥ 2.5 mm aluminum equivalent.
(partially revised by MHLW Announcement No. 114 of 2022)
- 3 The fluoroscopic apparatus must have not only measures stipulated in the preceding paragraph but also the following preventive ones against damages in place.
- (1) The incident dose rate on a patient undergoing fluoroscopy shall be adjusted so that the air-kerma rate of core useful beams at the patient's incidence plane will be ≤ 50 mGy/min. For a system that works only through continuous manual operations and has a high-dose fluoroscopy control function to issue an alarm continuously during the operation, the incident dose rate shall be adjusted to ≤ 125 mGy/min.
 - (2) A timer shall be installed so that fluoroscopy time can be integrated, and an alarm can be issued when a certain time has passed during fluoroscopy.
 - (3) A device designed to control the distance between the X-ray tube focus and skin at ≥ 30 cm or an inter-lock designed to prevent irradiation with the distance between the focus and skin < 30 cm shall be installed. For the X-ray system intended for use during surgery, the distance between the X-ray tube focus and skin may be adjusted to ≥ 20 cm.
 - (4) In the distance between the X-ray tube focus in use and image receptor, a device narrowing the X-ray irradiation field shall be installed to prevent X-ray from reaching beyond the image reception area. In the following cases, the X-ray irradiation field may be beyond the image reception area.
 - A The rectangular X-ray irradiation field is not beyond the field circumscribing the circular image reception area.
 - B With respect to two straight lines intersected at right angles on an image reception area perpendicular to the irradiation direction, the sum of distances between the intersection of each straight line with the edge of the X-ray irradiation field and that with the edge of the image reception area (hereinafter referred to as "distances between the points of intersection") does not exceed 3% of the distance between the focus and image receptor, and the total sum of distances between the points of intersection does not exceed 4%.
 - (5) The air-kerma rate of X-rays passing through an image receptor such as a fluorescent screen and image intensifier of useful beams shall be ≤ 150 μ Gy/hr at a point 10 cm apart from the accessible surface of the image receptor such as a fluorescent screen and image intensifier of useful beams.
 - (6) The air-kerma rate of X-rays that have passed through any section exceeding 3.0 cm from the maximum image reception area during fluoroscopy shall be ≤ 150 μ Gy/hr at a point 10 cm apart from the accessible surface of the section.
 - (7) To shield X-rays other than useful beams, appropriate means shall be taken.
(partially revised by MHLW Announcement No. 126 of 2002)
- 4 X-ray systems for radiography (except for X-ray systems for chest mass surveys) must have not only the means as stipulated in Paragraph 2 but also the following preventive measures against damages (except for ones listed in (1) for CT X-ray systems or in (2) for X-ray systems for bone mineral density analysis) in place.

- (1) In the distance between the X-ray tube focus in use and image receptor, a device narrowing the X-ray irradiation field shall be installed to prevent X-ray from reaching beyond the image reception area. In the following cases, an X-ray irradiation field beyond the image reception area may be allowed, or for an X-ray system for intraoral radiography, the diameter of the X-ray irradiation field at the edge of the irradiation tube shall be ≤ 6.0 cm or for an X-ray system for mammography, the X-ray irradiation field shall neither spread > 5 mm beyond the edge of the patient retainer close to the patient's chest wall nor spread $> 2\%$ of the distance between the focus and image receptor beyond the image reception area.
 - A The rectangular X-ray irradiation field is not beyond the field circumscribing the circular image reception area.
 - B With respect to two straight lines intersected at right angles on an image reception area perpendicular to the irradiation direction, the sum of distances between the points of intersection does not exceed 3% of the distance between the focus and image receptor, and the total sum of distances between the points of intersection does not exceed 4%.
 - (2) The distance between the X-ray tube focus and skin shall be as follows: This, however, does not apply to radiographic magnification cases (except for one listed in F).
 - A For an X-ray system for intraoral radiography with the rated tube voltage of ≤ 70 kV, the distance is ≥ 15 cm.
 - B For an X-ray system for intraoral radiography with the rated tube voltage of > 70 kV, the distance is ≥ 20 cm.
 - C For a dental panoramic/tomographic system, the distance is ≥ 15 cm.
 - D For a mobile or portable X-ray system, the distance is ≥ 20 cm.
 - E For a CT X-ray system, the distance is ≥ 15 cm.
 - F For an X-ray system for mammography (only in radiographic magnification cases), the distance is ≥ 20 cm.
 - G For X-ray systems other than ones listed in A to F, the distance is ≥ 45 cm.
 - (3) Mobile or portable X-ray systems as well as ones used during surgery shall have such a structure that the system can be operated at a position ≥ 2 m apart from the X-ray tube focus and the patient.
 - (4) For a X-ray system for intraoral radiography intended to be HAND-HELD of a portable X-ray system shall include a means with a shield which cannot be removed and contains a minimum of 0.25 mm lead equivalence at a nominal x-ray tube voltage of 70 kV.
(partially revised by MHLW Announcement No. 126 of 2002 , No. 127 of 2002 and No. 114 of 2022)
- 5 The X-ray system for chest mass surveys must have the following preventive measures against damages in place other than ones stipulated in Paragraph 2.
- (1) Useful beams shall be formed into a pyramid shape, and in the distance between the X-ray tube focus in use and image receptor, a device narrowing the X-ray irradiation field shall be installed to prevent X-ray from reaching beyond the image reception area. In the following cases, however, the X-ray irradiation field may be beyond the image reception area: With respect to two straight lines intersected at right angles on an image reception area perpendicular to the irradiation direction, the sum of distances between the points of

intersection does not exceed 3% of the distance between the focus and image receptor, and the total sum of distances between the points of intersection does not exceed 4%.

- (2) The primary protection shielding of the image receptor shall be installed so that the air kerma in free air (hereinafter referred to as “air-kerma”) 10 cm apart from the accessible surface of the system will be $\leq 1.0 \mu\text{Gy}$ per irradiation.
- (3) Around the irradiated object, a box-shaped shielding shall be installed so that the air-kerma at a point 10 cm apart from the shielding will be $\leq 1.0 \mu\text{Gy}$ per irradiation. This, however, does not apply to cases where operators of the X-ray system and those engaged in the other works can readily leave the room during irradiation.

(partially revised by MHLW Announcement No. 126 of 2002)

- 6 Therapeutic X-ray systems (except for systems for brachytherapy) must have not only preventive measures against damages stipulated in Paragraph 2 in place but also an interlock mechanism to intercept X-ray generation that would occur upon removal of a filtration plate.

Revised text (Excerpt) (MHLW Ministerial Announcement No. 127 of March 27, 2002)
It shall be applied from October 1, 2002.

Revised text (Excerpt) (MHLW Ministerial Announcement No. 114 of March 31, 2022)
It shall be applied from April 1, 2025.

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