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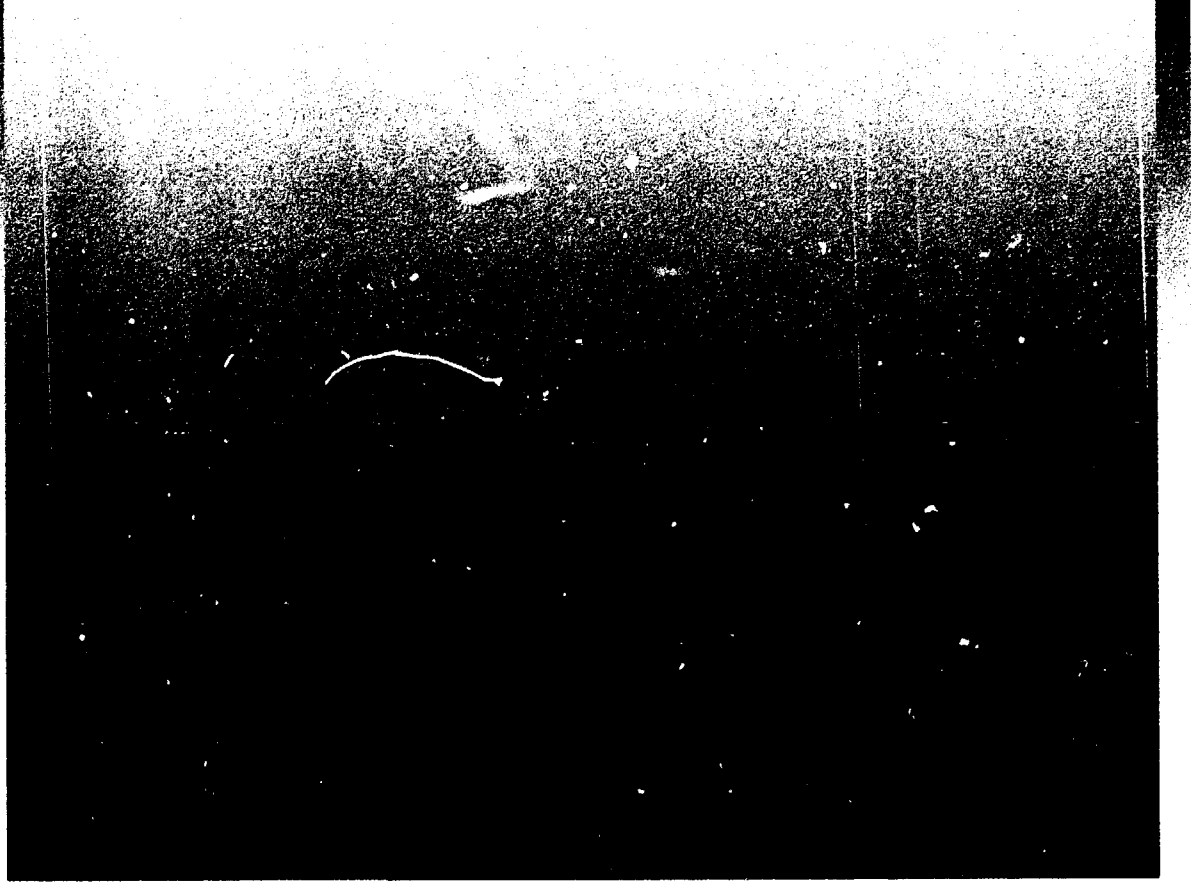
Diagnostic X-ray equipment and its use



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FINNISH CENTRE FOR RADIATION
AND NUCLEAR SAFETY
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Diagnostic X-ray equipment and its use

This ST Guide takes effect on 1 November 1992 and will remain in force until further notice.

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Erweko Painotuote
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Authorization

Under section 70, paragraph 2, of the Radiation Act (592/91), the Finnish Centre for Radiation and Nuclear Safety issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

The instructions given in the ST Guides on actions and procedures are not absolutely binding, but if the responsible party intends to use a procedure or method differing from those presented in an ST Guide, he must be able to prove that the procedure or method chosen ensures the same level of safety as that specified in the ST Guide.

Radiation Protection Guides (SS Guides) issued before 1992 and listed at the end of this guide remain in force until further notice. SS Guides will be replaced by ST Guides whenever the need arises to alter their contents.

Translation. Original text in Finnish.

1 General

Medical use of radiation means in this context any operation in which ionizing radiation is intentionally directed at a person for the diagnosis or treatment of a illness or for the purposes of some other medical examination or intervention. The patient's radiation exposure shall be no more than is necessary for the examination being performed. The operation shall be arranged so that the operating staff's radiation exposure is kept as low as reasonably achievable. This optimisation principle can be considered fulfilled when the X-ray equipment and its accessories satisfy the radiation safety requirements placed on them, when they are used by qualified staff, and when the equipment is subject to adequate quality control.

This guide contains the requirements for the use, structure and operation of diagnostic X-ray equipment necessary to ensure the radiation safety of workers and patients. The guide is intended for the party responsible for operating the X-ray units, the staff operating, installing and maintaining X-ray examination equipment, and companies manufacturing and selling such equipment. Special requirements for mammographic and dental X-ray equipments are given in separate ST Guides.

Other requirements concerning diagnostic X-ray equipment and its use are listed at the end of this guide.

2 Requirements for operation

A safety license shall be required for using, installing, repairing and maintaining X-ray equipment.

X-ray equipment, the room in which it is installed and all accessories shall be such that the X-ray equipment can be used safely.

The licensee shall arrange the control of the functioning of medical X-ray equipment and all accessories and facilities. A separate guide has been published regarding the implementation of quality control (see the list of ST Guides).

During an X-ray examination, the only persons apart from the patient permitted in the examination room shall be those whose presence is essential for the examination or for the safety of the patient. They shall be adequately protected against radiation, and no part of their body shall be liable to primary radiation beam.

Every person working in the examination room shall wear a lead rubber apron or other protective shield during the examination and avoid unnecessary immediate proximity to the patient and the X-ray tube.

The radiation doses of persons in radiation work shall be monitored with personal dosimeters and, when necessary, with radiation meters which show the dose in real time.

The number of exposures, the size of the radiation field and the fluoroscopy time shall be kept as low as possible for the examination in question.

The patient and the X-ray equipment shall be kept under control during the examination. An area-kerma product meter or some other method is recommended for the monitoring of patient dose.

If necessary, the patient shall be helped to remain immobile during the examination. The assisting person shall be adequately instructed in his or her duty. In certain situations, for instance in children's X-ray examinations, it is feasible to use a regular assisting person. It is the duty of the party responsible for the operations to provide training for these persons and to organize individual monitoring of their radiation doses. The operator performing the examination shall ensure that the assisting person is adequately protected.

The gonads of individuals with reproductive potential should be adequately protected, especially when the primary beam is near to the gonads. Instructions* concerning diagnostic examinations of women of reproductive capasity are given by the National Agency for Welfare and Health**.

Data giving exposure factors, projections and combinations of intensifying screen and film, for each type of X-ray examination should be available in X-ray departments for subsequent assessment of the patient dose. The type of X-ray examination performed is recorded in the patient's file using the examination terminology of the Finnish Hospital League. The irradiation time for fluoroscopy examinations is also recorded. For examinations requiring high doses of radiation such as interventional radiology and angiography examinations the dose received by the patient should also be recorded, e.g. as a reading of an area-kerma product. The systematic recording of the patient doses of other X-ray examinations is also recommended.

3 Requirements concerning equipment

According the Radiation Act the X-ray equipment shall be type approved unless it is exempted from type approval. Exemption from type approval is usually granted to equipment inspected on-site. Once EEA Agreement takes effect procedures of the treaty are adopted.

In setting the demands concerning the structure and operation of diagnostic X-ray equipment presented in this guide, the following standards now in effect were taken into account: the International Electrotechnical Commission (IEC) standards, the Harmonization Documents (HD), The European Standards (EN) and the standards of the Finnish Standards Association (SFS). The standards to be taken into account are listed in section 3.1, and other radiation safety requirements concerning the structure and operating of equipment are listed in item 3.2.

The requirements of item 3.2, based mainly on new draft standards, differ somewhat from the requirements of standards now in effect. The requirements of item 3.2 shall take precedence; they will be replaced by the requirements stated in new standards as the new standards are adopted.

3.1 Standards

IEC 407: Radiation protection in medical X-ray equipment 10 kV to 400 kV.

HD 379 S1 (IEC 580): Area exposure product meter.

EN 60601-1: Medical electrical equipment. Part 1: General requirements for safety.

HD 395.2.7 S1 (IEC 601-2-7): Medical electrical equipment. Part 2: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators.

HD 395.2.15 S1 (IEC 601-2-15): Medical electrical equipment. Part 2: Particular requirements for the safety of capacitor discharge X-ray generators.

IEC 637: Marking of and accompanying documents for X-ray tube and X-ray tube assemblies for medical use.

3.2 Other requirements

Radiation quality and filtration

The first half-value layer (HVL) attended in the primary radiation shall be not less than the appropriate value given in Table I.

* Previous the "Ten day rule" was repealed with effect from 1 January 1992 by the Radiation Act.

** The Finnish Centre for Radiation and Nuclear Safety (Ammendment (1102/92) to the Radiation Act).

Table I. Minimum requirement for half-value layer (HVL).

X-ray tube voltage (kV)	HVL (mm Al)
70	2.1
80	2.3
90	2.5
100	2.7
110	3.0
120	3.2
130	3.5
140	3.8
150	4.1

N.B.: The HVL requirements for special diagnostic equipment are presented in the ST guides concerning such equipment.

The X-ray tube housing shall bear a marking indicating the total filtration of the radiation beam. If the additional filtration is removable, the irremovable filtration shall be indicated on the tube housing, and the additional filtration shall be readily attestable.

The total filtration of primary beam shall be no less than 2.5 mm Al.

Indication and limitation of the radiation beam

All radiographic X-ray equipment and fluoroscopic equipment with an image reception area of the image intensifier exceeding 300 cm^2 shall have light field-indicators showing the size, shape and location of the radiation field if there is no patient support or table between the X-ray tube and the patient. Light field-indicator is not required if its absence does not adversely affect radiation safety and if the radiation beam can be otherwise defined, e.g. as with the variable aperture beam limiting device in skull unit.

The average illumination of light field-indicators shall be not less than 100 lux, measured at the greatest film-focal distance in use; however, if this distance exceeds 100 cm, a measuring distance of 100 cm shall be used.

The deviation of the light field-indicators or other radiation beam indicators from the edges of the radiation beam shall be not more than 1 % of the focal distance. It is recommended that the deviation is less than 0.5 %.

Distance between focal spot and skin

Means to prevent the focal spot to patient skin distance from being less than 30 cm shall be provided. If the image intensifier's reception area is less than 300 cm^2, the focal spot to skin distance may be shorter, but not less than 20 cm.

Material between patient and image receptor

The attenuation equivalent of the material situated between the patient and the image receptor shall not exceed the values given in Table II. This demand does not apply to grids, radiographic intensifing screens and cassettes. The attenuation equivalent in mm Al shall be measured using an X-ray tube voltage of 100 kV (percentage ripple less than 10 %) and an HVL of 2.7 mm Al.

Table II. Maximum attenuation equivalent of material between patient and image receptor.

Item	Maximum attenuation equivalent (mm Al)
Front panel of cassette holder	1.0
Front panel of film changer	1.0
Stationary patient support	1.0
Movable patient support (including protective structures)	1.5

Leakage radiation of capacitor discharge X-ray generators

For capacitor discharge X-ray generators, the leakage of primary radiation from the X-ray tube for reasons other than the irradiation of a patient shall be prevented.

The air kerma caused by discharge or standby state of the capacitor shall not exceed 1 mGy in one hour at 1 m from the focal spot when the maximum loading factors specified by the manufacturer of the equipment are used.

When the X-ray equipment is fully charged and the beam limiting device is totally open, the air kerma in one hour at 5 cm from any accessible surface shall not exceed 20 μGy.

Dose rate and image quality of fluoroscopy equipment

The maximum dose rate (air kerma rate) at the skin of the patient on the side facing the X-ray tube shall not be more than 100 mGy/min. The measurement geometry is shown in Figure 1.

If the image quality, examination, or intervention requires a dose rate greater than 100 mGy/min, the equipment can be approved for this type of boosted operation on the following conditions:

1. In normal operation, the dose rate at the patient's skin on the side facing the X-ray tube is no more than 50 mGy/min;

2. The boosted operation shall only be operable with continuous manual activation by the operator;

3. A continuous audible or visible signal shall signify to the examining physician that boosted operation is being employed;

4. The equipment shall include an area-kerma product meter, the readings of which shall be recorded separately for each examination;

5. Protective shielding equivalent to no less than 1 mm Pb shall be available for the operator in the immediate proximity of the equipment.

The dose rate controlled by the automatic dose rate control shall be no more than 0.8 μGy/s on the surface of the front plate of the image intensifier. The measurement shall be carried out according to ST Guide 3.4, using the most commonly employed size of the image intensifier input field. This stipulation shall not apply to the boosted operation defined in the preceding paragraph, in which the dose rate at the patient's skin exceeds 100 mGy/min.

Assessed from the TV monitor image, the resolution of the II-TV chain shall be at least 0.7 line pairs per mm. In the spot image, the resolution shall be at least 2.0 line pairs per mm. The determination shall be performed as in ST Guide 3.4.

The contrast threshold estimated from the TV monitor image shall be 0.6 mm Al or less. The determination shall be performed as in ST Guide 3.4.

Equipment intended for examining children

The imaging performance and functioning of X-ray equipment shall make it possible to use sensitive radiographic intensifying screens and films also for examining of small children without problem.

The patient supports shall be designed in such a way that accessories necessary for the protection of the patient and staff and for the immobilization of the patient is possible.

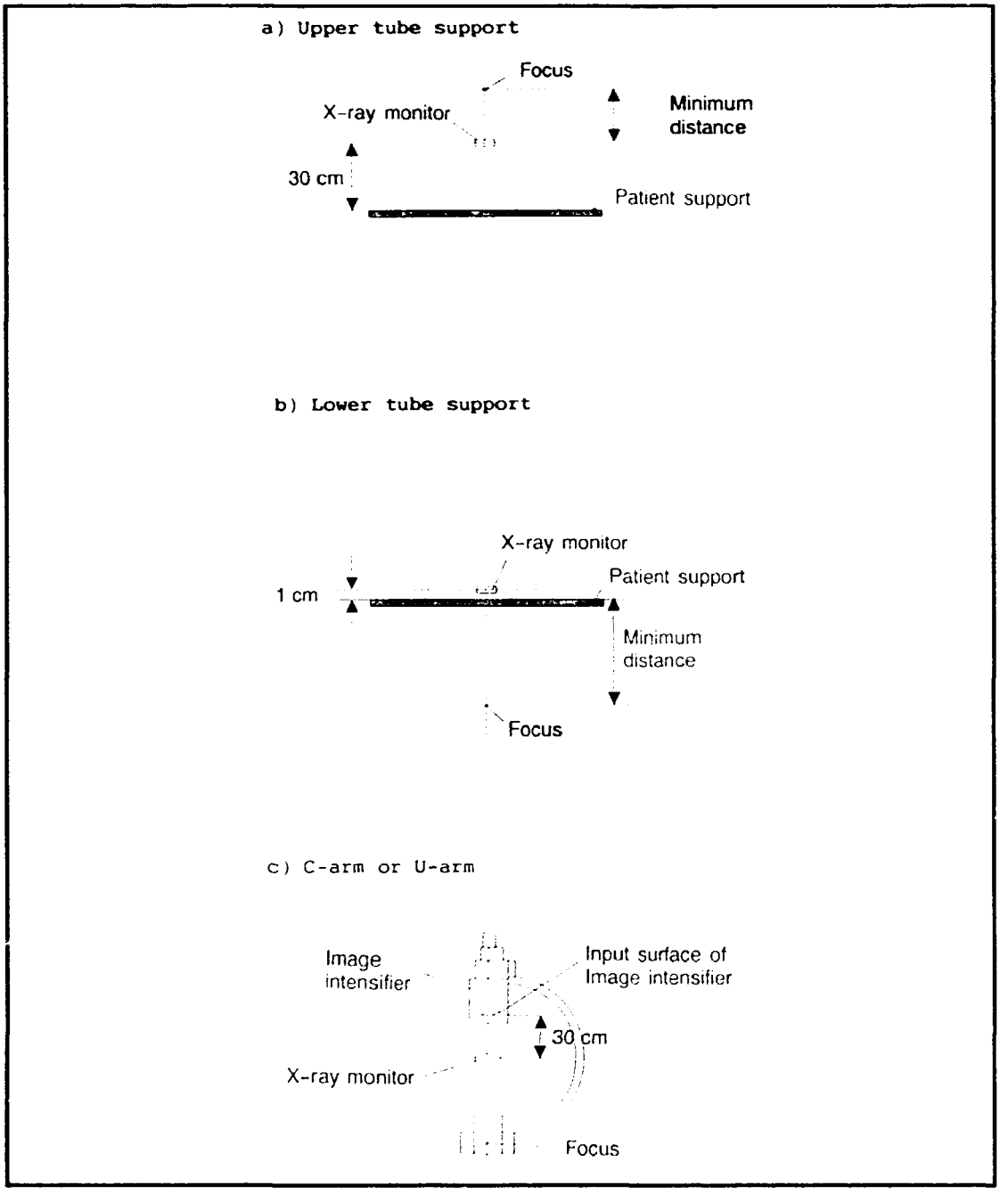

Figure 1. *Measurement geometry for the maximum entrance dose rate.*

4 Entry into force

The guide shall apply to new X-ray equipment taken into use after the effective date and, as applicable, to X-ray equipment taken into use before that date. Old equipment, taken into use before the effective date of the Radiation Act (592/91), may be used according to earlier provisions, unless otherwise specified by the Finnish Centre for Radiation and Nuclear Safety.

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ST 12.1 Radiation safety in mining and underground excavation, 27 August 1992 (in Finnish and Swedish)

ST 12.2 Radioactivity of building materials, fuel peat and peat ash, 2 February 1993 (in Finnish)

SS Guides will be converted into ST Guides wherever necessary.

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