SLOVENSKI STANDARD
oSIST prEN IEC 61267:2024

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Medicinska diagnostična rentgenska oprema - Sevalni pogoji pri ugotavljanju karakteristik

Medical diagnostic x-ray equipment - Radiation conditions for use in the determination of characteristics

Medizinische diagnostische Röntgeneinrichtung - Bestrahlungsbedingungen zur Bestimmung von Kenngrößen

Equipement de diagnostic médical à rayonnement x - Conditions de rayonnement pour utilisation dans la détermination des caractéristiques

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL DIAGNOSTIC X-RAY EQUIPMENT - RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS –

FOREWORD

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IEC 61267 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2005. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) removing former Annex C “Measurement of the practical peak voltage”;
b) inserting of an informative Annex B “Tabulated values for the squared signal-to-noise ratio per air kerma (SNR_{in}^2)” and a normative Annex C “Additional X-ray radiation conditions as used in mammography and determination of the corresponding nominal first and second aluminium half-value layers”;
c) revision of X-ray radiation conditions;
d) new method for verification of X-ray radiation conditions;
e) change of term definitions.

The text of this International Standard is based on the following documents:

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

In this standard, the following print types are used:

- requirements proper: roman type;
- *test specifications: italic type;*
- notes and explanatory matter: small roman type.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at ww.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,

- withdrawn, or
- revised.

INTRODUCTION

To establish characteristics, aspects or properties of (associated equipment (3.2.9)) or to have available radiation beam (3.2.32) for physical and medical investigations, sets of well-defined X-ray radiation condition (3.1.6) can offer an important tool in many situations.

From a regulation and standardization point of view there is a need:

- to have available well-defined X-ray radiation condition (3.1.6) that can be used internationally to specify standards of operation of X-ray equipment (3.2.46) ;
- to provide a basis for the harmonization of existing national standards;
- to provide uniform sets of X-ray radiation condition (3.1.6) (a dictionary of X-ray radiation condition (3.1.6)) to describe and judge the performance of X-ray equipment for the benefit of manufacturer (3.2.22) , user (3.2.45) , patient (3.2.25) and health protection authorities;
- to solve communication problems between manufacturer (3.2.22) , user (3.2.45) and regulatory authorities, stemming from a lack of internationally accepted definitions and test methods.

From an application point of view, commonly accepted sets of X-ray radiation condition (3.1.6) would in general find use in:

- quality control (3.2.29) tests by manufacturer (3.2.22) ;
- installation and acceptance test (3.2.1) ;
- calibration of test instrumentation;
- type approval tests (where required);
- inspection and tests by regulatory authorities and testing institutes;
- physical and medical studies in physical laboratories and medical facilities;
- determination of characteristics of associated equipment (3.2.9) .

Standardized X-ray radiation condition (3.1.6) can benefit a range of potential user (3.2.45) , such as:

- manufacturer (3.2.22) of X-ray equipment (3.2.46) ;
- manufacturer (3.2.22) of X-ray test instrumentation;
- research laboratories;
- testing institutes;
- user (3.2.45) ;
- government regulatory authorities;
- service organizations;
- standardization organizations.

In the development of the second edition of this standard, efforts were made to set up procedures that give a high degree of equivalence of X-ray radiation condition (3.1.6) realized on different X-ray machines. The procedure by which the X-ray radiation condition (3.1.6) are realized consists of setting the X-ray tube voltage (3.1.8) to the prescribed value and determining the amount of additional filtration (3.2.5) needed to produce the required half-value layer (3.2.18) and homogeneity coefficient. The nature of this process implies that there is a certain maximum inherent filtration (3.2.20) beyond which a given X-ray tube (3.2.52) assembly may no longer be used to produce a given X-ray radiation condition. In order not to exclude what are considered as standard X-ray tube (3.2.52) assemblies, the half-value layer (3.2.18) have been chosen in such a way that it is possible to establish all X-ray radiation condition (3.1.6) in this standard with an X-ray tube (3.2.52) assembly with a permanent filtration of 2,5 mm Al and with anode angles down to 9°.

The procedure to be followed for producing the X-ray radiation condition (3.1.6) of the RQR series does require a certain amount of additional effort. In contrast to this, the procedure for the heavily filtered X-ray radiation condition (3.1.6) was simplified. The great advantage of the method lies in a much higher degree of equivalence of a given X-ray radiation condition (3.1.6) with X-ray tube (3.2.52) assemblies having different inherent filtration (3.2.20) .

The second edition of this standard included the X-ray radiation condition (3.1.6) RQR-M and RQA-M which were considered as being representative for mammography beams. However, since the publication of the second edition in 2005 many additional X-ray radiation condition (3.1.6) have emerged. Due to the large number of this X-ray radiation condition (3.1.6) in mammography, it is impractical to list their nominal first aluminium half-value layer (3.2.18) . This third edition of this standard introduces a systematic procedure for the characterization and description of X-ray radiation condition (3.1.6) for these additional X-ray radiation condition (3.1.6) , as well as a method for the verification of the associated half-value layer (3.2.18) .

MEDICAL DIAGNOSTIC X-RAY EQUIPMENT - RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS –

1 Scope and object

This International Standard applies to test procedures which, for the determination of characteristics of systems or components of medical diagnostic X-ray equipment (3.2.46) , require well-defined X-ray radiation condition (3.1.6) .

Except for mammography, this standard does not apply to conditions where discontinuities in radiation absorption of elements are deliberately used to modify properties of the radiation beam (3.2.32) (for example by rare earth filters).

X-ray radiation condition (3.1.6) for screen-film sensitometry are not covered in this standard.

NOTE: Screen-film sensitometry is the subject of the ISO 9236 series.

This standard deals with methods for generating X-ray beams characterized by X-ray radiation conditions which can be used under test conditions typically found in test laboratories or in manufacturing facilities for the determination of characteristics of medical diagnostic X-ray equipment (3.2.46) .

Examples of such are X-ray beams emerging through the filtration from an X-ray source assembly (3.2.51) whereby the radiation field (3.2.34) includes only an insignificant amount of scattered radiation (3.2.38) . X-ray radiation condition (3.1.6) can also represent the more general case, where scattered radiation (3.2.38) emerges from an exit surface (3.1.4) of a patient (3.2.25) or a phantom (3.2.27) .

The attempt to define an X-ray radiation condition (3.1.6) just by means of the X-ray tube voltage (3.1.8) , the first and possibly the second half-value layer (3.2.18) is a compromise between the mutually conflicting requirements of avoiding excessive efforts for establishing a X-ray radiation condition (3.1.6) and of the complete absence of any ambiguity in the definition of a X-ray radiation condition (3.1.6) . Due to differences in the design and the age of X-ray tube (3.2.52) in terms of anode angle, anode roughening and inherent filtration (3.2.20) , two X-ray radiation condition (3.1.6) produced at a given X-ray tube voltage (3.1.8) having the same first half-value layer (3.2.18) can still have quite different spectral distributions. Given the inherent ambiguity in the characterization of X-ray radiation condition (3.1.6) , it is essential that further tolerances introduced by allowing certain ranges of values, e.g. for X-ray tube voltage (3.1.8) and first half-value layer (3.2.18) , must be sufficiently small not to jeopardise the underlying objective of this standard. This standard is to ensure that measurements of the properties of medical diagnostic equipment should produce consistent results if X-ray radiation condition (3.1.6) in compliance with this standard are used.

To achieve this objective, certain degrees of freedom in the way in which an X-ray radiation condition (3.1.6) could be established in the framework of the first edition of this standard had been removed in the second edition. The essential restriction introduced in the second edition was that the X-ray tube voltage (3.1.8) is measured and set to its prescribed value. The second step was to attempt to establish the prescribed first half-value layer (3.2.18) by adding into the beam the necessary amount of additional filtration (3.2.5) . If the inherent filtration (3.2.20) provided by the X-ray tube (3.2.52) assembly alone is so strong that the half-value layer (3.2.18) of the radiation beam (3.2.32) emerging from the X-ray tube (3.2.52) assembly as such is larger than that to be established, the X-ray tube (3.2.52) assembly used is not suited for producing the desired X-ray radiation condition (3.1.6) . This may occur if the anode angle of the X-ray tube (3.2.52) assembly is too small and/or in the case of excessive anode roughening due to tube ageing. In the framework of what is physically feasible, differences in tube design and ageing are considered by adding or removing the appropriate amount of additional filtration (3.2.5) .

In the approach outlined in the two preceding paragraphs the X-ray tube voltage (3.1.8) plays a decisive role. It is therefore essential that the prescribed X-ray tube voltage (3.1.8) is chosen irrespective of the type of high voltage generator connected to the X-ray tube (3.2.52) . The way in which this is realized in this standard is by measuring the X-ray tube voltage (3.1.8) in terms of the practical peak voltage. This quantity is a weighted mean of all values of the X-ray tube voltage (3.1.8) occurring during an exposure. The weighting is done in such a way that identical values of the practical peak voltage give identical values of the low-level contrast on a radiograph irrespective of the waveform supplied by the generator.

This standard describes both X-ray radiation condition (3.1.6) , which to a good approximation are free of scattered radiation (3.2.38) (RQR, RQA, RQC, RQT, RQR-M and RQA-M) and, for patient (3.2.25) simulation, X-ray radiation condition (3.1.6) containing scattered radiation (3.2.38) (RQN, RQB, RQN-M and RQB-M). It is crucial to be aware that in the presence of scattered radiation (3.2.38) the characteristics of X-radiation in terms of fractions of air kerma (3.2.7) associated with the primary radiation (3.2.28) and the scattered radiation (3.2.38) depend on the position and nature of any added filter (3.2.4) or phantom (3.2.27) . It is therefore obvious that air kerma (3.2.7) measurements in such radiation beam (3.2.32) need careful consideration.

Clause 5 to Clause 9 deal with X-ray radiation condition (3.1.6) which are essentially free of scattered radiation (3.2.38) . Due to the spatial homogeneity of the corresponding X-ray radiation condition (3.1.6) , the application distance (3.1.1) does not influence the linked X-ray radiation condition (3.1.6) to a significant extent.

- Clause 5 deals with X-ray radiation condition (3.1.6) for the radiation beam (3.2.32) emerging from the X-ray source assembly (3.2.51) . Such X-ray radiation condition (3.1.6) can be used for determining attenuation (3.2.11) properties of associated equipment (3.2.9) .
- Clause 6 deals with X-ray radiation condition (3.1.6) for the radiation beam (3.2.32) emerging from an irradiated object that simulates a patient (3.2.25) under the conditions that:
  - the contribution of scattered radiation (3.2.38) in the radiation beam (3.2.32) is not significant;
  - exact simulation of the spectral distribution of the radiation beam (3.2.32) emerging from the patient (3.2.25) is not a prerequisite.

- Clause 7 and Clause 8 deal with X-ray radiation condition (3.1.6) from those dealt with in Clause 6 in view of special applications like automatic exposure and automatic exposure rate control systems and computed tomography. The radiation transmitted through the irradiated object has properties similar to those of the radiation transmitted through a patient (3.2.25) under the conditions that:
  - the contribution of scattered radiation (3.2.38) in the radiation beam (3.2.32) is not significant;
  - exact simulation of the spectral distribution of the radiation beam (3.2.32) emerging from the patient (3.2.25) is not a prerequisite.
- Clause 9 and Clause 10 deal with X-ray radiation condition (3.1.6) where scattered radiation (3.2.38) is taken into account. This is done either by limiting the amount of scattered radiation (3.2.38) by appropriate means and/or providing additional information.
- Clause 9 deals with measuring arrangements primarily intended in combination with X-ray radiation conditions RQB of Clause 10 to be used for those measurements where the contribution of scattered radiation (3.2.38) to the detected signal is minimal and is known as narrow beam condition (3.2.23) .
- Clause 10 deals with X-ray radiation condition (3.1.6) to be used for measurements where the contribution of scattered radiation (3.2.38) to the detected signal is significant and is known as broad beam condition (3.2.13) .

For the X-ray radiation condition (3.1.6) specified in Clause 5 to Clause 10 it is assumed that an X-ray tube (3.2.52) is available with an anode angle of not less than about 9°. For X-ray tube (3.2.52) with smaller anode angles it may not be possible to realize some or all X-ray radiation condition (3.1.6) of Clause 5. If some or all X-ray radiation condition (3.1.6) of the RQR series cannot be realized with a given X-ray tube (3.2.52) due to a too strong inherent filtration (3.2.20) , some special provisions have been made to establish nevertheless the more heavily filtered X-ray radiation condition (3.1.6) in Clause 6 and Clause 8 which are in principle based on the X-ray radiation condition (3.1.6) of the RQR series.

In order to make allowance for the use of X-ray tube (3.2.52) with anode angles down to 9°, the half-value layer (3.2.18) of X-ray radiation condition (3.1.6) RQR 4 to RQR 10 have been increased with respect to the values specified in the first edition of this standard (1994).

Clause 11 to Clause 14 deal with X-ray radiation condition (3.1.6) applicable to mammography.

- Clause 11 deals with X-ray radiation condition (3.1.6) for the radiation beam (3.2.32) emerging from the X-ray tube (3.2.52) assembly. Such X-ray radiation condition (3.1.6) can be used for determining attenuation (3.2.11) properties of associated equipment (3.2.9) .
- Clause 12 deals with X-ray radiation condition (3.1.6) transmitted through an irradiated object that simulates a patient (3.2.25) under the conditions that:
  - the contribution of scattered radiation (3.2.38) in the radiation beam (3.2.32) is not significant;
  - exact simulation of the spectral distribution of the radiation beam (3.2.32) emerging from the patient (3.2.25) is not a prerequisite.
- Clause 13 deals with X-ray radiation condition (3.1.6) to be used for studies in mammography under narrow beam condition (3.2.23) . These X-ray radiation condition (3.1.6) are achieved by applying a special tissue-equivalent phantom (3.2.27) .
- Clause 14 deals with X-ray radiation condition (3.1.6) to be used for studies in mammography under broad beam condition (3.2.13) . These X-ray radiation condition (3.1.6) are achieved by applying a special tissue-equivalent phantom (3.2.27) .

The test instrumentation as required in this standard partly comprises specific components or a series of equivalent components out of which the most suitable should be chosen in order to provide test conditions required to achieve prescribed test parameters. However, these provisions in terms of hardware may not be available at user (3.2.45) facilities. As an example, clinical mammography units are not suited for producing the X-ray radiation condition (3.1.6) in Clause 11 to Clause 14 without modification. In order to adapt them the patient support (3.2.24) needs to be removed to allow for the measurement geometry required by this standard.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 61674, *Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676, *Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 61674 and IEC 61676 and the following definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1 Terms defined in this document

3.1.1
application distance
distance from the effective focal spot to the application plane

3.1.2
application plane
plane perpendicular to the central beam axis, where the X-ray radiation condition is defined

3.1.3
central beam axis
line from the focal spot through the centre of the diaphragm

3.1.4
exit surface
<radiology (3.2.36)> plane or curved surface through which the radiation beam emerges from an irradiated object