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

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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 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 informative Annex C "Tabulated values for the squared signal-to-noise ratio per air kerma (SNR^2_{in})" and normative Annex D "Additional X-ray radiation conditions as used in mammography and determination of the corresponding nominal 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
62C/958/FDIS	62C/965/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.

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– withdrawn, or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 or to have available radiation beams for physical and medical investigations, sets of well-defined X-ray radiation conditions 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 conditions that can be used internationally to specify standards of operation of X-ray equipment,
– to provide a basis for the harmonization of existing national standards,
– to provide uniform sets of X-ray radiation conditions (a dictionary of X-ray radiation conditions) to describe and judge the performance of X-ray equipment for the benefit of manufacturers, users, patients and health protection authorities, and
– to solve communication problems between manufacturers, users 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 conditions would in general find use in

– quality control tests by manufacturers,
– installation and acceptance tests,
– 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, and
– determination of characteristics of associated equipment.

Standardized X-ray radiation conditions can benefit a range of potential users, such as

– manufacturers of X-ray equipment,
– manufacturers of X-ray test instrumentation,
– research laboratories,
– testing institutes,
– government regulatory authorities,
– service organizations, and
– standardization organizations.

The X-ray radiation conditions defined in this document are intended to represent the range of typical X-ray radiation beams encountered in medical diagnostic X-ray equipment. This includes X-ray radiation beams passing through the filtration of an X-ray source assembly whereby the radiation field includes only an insignificant amount of scattered radiation. It also includes the more general case, where scattered radiation emerges from an exit surface of a patient or a phantom. An overview of the X-ray radiation conditions defined in this document and of possible applications can be found in Annex E.

Potential applications include studies for devices used in specific imaging modalities such as mammography. However, the clauses of this document are not intended to represent specific imaging modalities in general. For example, the X-ray radiation conditions described in Clause 5 can be useful for examinations of equipment found in dental radiography but also for examinations of equipment related to chest radiography. In addition, some X-ray radiation conditions can only partially cover the range of equipment for a particular imaging task. Therefore, imaging modalities are not explicitly included or excluded from the scope of this document.

1 Scope

This document applies to test procedures which, for the determination of characteristics of systems or components of medical diagnostic X-ray equipment, require well-defined X-ray radiation conditions.

This document deals with methods for generating 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.

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*

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[1] IEC 60731:2011, *Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy*

[2] IEC 61676:2023, *Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

[3] IEC TR 60788:2004, *Medical electrical equipment - Glossary of defined terms*

[4] ICRU Report 60, Fundamental Quantities and Units for Ionizing Radiation

[5] IEC 61267:2005, *Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics*

[6] IEC 62220-1-1, *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging*

[7] IEC 62220-1-3, *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*

[8] ISO/IEC Guide 98-3:2008/Suppl 1:2008, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995) — Supplement 1: Propagation of distributions using a Monte Carlo method*

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