IEC 60601-1-3

Edition 2.0 2008-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

Appareils électromédicaux –
Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:
Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,…). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:
Email: csc@iec.ch
Tél.: +41 22 919 02 11
Fax: +41 22 919 03 00

IEC 60601-1-3

Edition 2.0 2008-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

Appareils électromédicaux –
Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50; 13.280

ISBN 2-8318-9541-3

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-1-3 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

This document cancels and replaces the first edition of IEC 60601-1-3, published in 1994 (which replaced IEC 407 issued in 1973). It constitutes a technical revision. This edition has been restructured and aligned to IEC 60601-1(2005) and focussed on general requirements for RADIATION PROTECTION that apply to all diagnostic X-RAY EQUIPMENT. Requirements particular to specific equipment have been removed and will be covered in particular standards. For a description of the changes, see the mapping in Annex C.

The text of this collateral standard is based on the following documents:

FDIS	Report on voting
62B/673/FDIS	62B/683/RVD

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. RADIOLOGICAL equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

– requirements and definitions: roman type.
– *test specifications: italic type.*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the thirteen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this edition and the base publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended

INTRODUCTION

The requirements in this collateral Standard concern protective measures to be taken by the MANUFACTURER in the design and construction of medical diagnostic X-RAY EQUIPMENT and its subassemblies. They relate to the application of the X-RADIATION generated, both deliberately and incidentally, in fulfilling the medical purpose of the EQUIPMENT. Additional measures are necessary to regulate the generation processes themselves. These are described in the general requirements for safety, IEC 60601-1, and, where appropriate, in particular requirements for the EQUIPMENT concerned. The second edition of this collateral standard is focused on general requirements for RADIATION PROTECTION. The aim of the revision was to restrict to those requirements that apply to all diagnostic X-RAY EQUIPMENT. In consequence, most of the clauses have been reduced compared with the first edition of this standard, owing to the exclusion of content specific to projection RADIOGRAPHY and RADIOSCOPY. Implementation shall be considered in the RISK MANAGEMENT process or by using particular standards.

The recommended principles governing the use of RADIATION for medical purposes, as stated in Publication 60 of the International Commission on Radiological Protection (ICRP)[17][1)], Chapter 4, have been taken into account. The implementation of these principles is essentially determined in the prevailing circumstances at the point of use. It requires judgements to be made by the user and the establishment of measures and working practices part of which are connected with the construction of EQUIPMENT. The requirements in this collateral Standard are intended to be consistent with generally accepted good practice in the administration of X-RADIATION in medicine.

In some cases, the formulation of the requirements is deliberately designed to provide scope for accommodating local laws and regulations at the time of installation and commissioning. Several of the requirements include provisions for relevant technical information to be included in ACCOMPANYING DOCUMENTS.

RESPONSIBLE ORGANIZATIONS for medical diagnostic X-RAY EQUIPMENT should be aware that effective protection against IONIZING RADIATION requires the consideration of many aspects additional to the construction of the EQUIPMENT. Among these are the following:

- compatibility of components and correct installation of EQUIPMENT;
- the protective properties of rooms where X-RAY EQUIPMENT is installed;
- measures for monitoring and maintaining the safety and effectiveness of EQUIPMENT throughout its life, with particular attention to components that can deteriorate progressively with time and use;
- the need in appropriate circumstances for PROTECTIVE CLOTHING to be worn by staff and for suitable devices to be used to protect PATIENTS;
- the keeping of appropriate records concerning the usage of the EQUIPMENT and the results of tests, with systematic review and the application of corrective action when necessary;
- the training of staff in the principles of RADIATION PROTECTION and in the correct use of EQUIPMENT, including any PROTECTIVE DEVICES provided.

Further advice on these aspects can be found in ICRP Publications 33[15], 34[16], 60[17], 73[18], 85[21], 87[22] and 93[23].

Readers of this collateral standard are reminded that, in accordance with IEC 60601-1, Clause 5, all the test procedures described are TYPE TESTS, intended to be carried out in a dedicated testing environment in order to determine compliance. Tests to be carried out by MANUFACTURERS to ensure compliance during production or installation and tests for detecting non-compliance subsequently to delivery, are not included.

---

1) Figures in square brackets refer to the Bibliography.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

1 Scope, object and related standards

1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to X-RAY EQUIPMENT and to subassemblies of such equipment, where RADIOLOGICAL IMAGES of a human PATIENT are used for diagnosis, planning or guidance of medical procedures.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

The object of this collateral standard is to establish general requirements for protection against X-RADIATION in X-RAY EQUIPMENT, in order that the IRRADIATION of the human PATIENT, the OPERATOR, staff and members of the public can be kept as low as reasonably achievable, without jeopardizing the benefit of the RADIOLOGICAL procedure. Particular standards may specify their appropriate values and/or measures for general requirements specified in this collateral standard. The implementation of the general requirements or the reference to the particular standard instead, shall be justified in the RISK MANAGEMENT process.

This collateral standard considers RADIATION PROTECTION aspects related to X-RADIATION only.

Requirements for the control of the electrical energy used to generate X-RADIATION, which is also an important aspect of RADIATION PROTECTION, are included in IEC 60601-1 and in particular standards for the safety and ESSENTIAL PERFORMANCE of the EQUIPMENT concerned.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-3 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following referenced documents are indispensable for the application 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 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis-Characteristics of focal spots*

IEC 60522:1999, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

ISO 497, *Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60788:2004 and the following apply.

NOTE An index of defined terms is found beginning on page 45.

3.1
ACCESSIBLE SURFACE
surface of EQUIPMENT or of an EQUIPMENT part that can be easily or accidentally touched by persons without the use of a TOOL

3.2
ADDED FILTER
removable or irremovable FILTER positioned in the RADIATION BEAM to provide part or all of the ADDITIONAL FILTRATION

3.3
ADDITIONAL FILTRATION
QUALITY EQUIVALENT FILTRATION due to ADDED FILTERS and other removable materials in the RADIATION BEAM which are between the RADIATION SOURCE and the PATIENT or a specified plane

3.4
AIR KERMA
K
quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg^{-1}

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60) [20]

[IEC 60580:2000, definition 3.2, modified] [8]

3.5
AIR KERMA RATE
$\dot{K}$
quotient of dK by dt, where dK is the increment of AIR KERMA in the time interval dt, thus

$$\dot{K} = \frac{dK}{dt}$$

Unit: J kg^{-1} s^{-1}

If the special name gray is used, the unit of AIR KERMA RATE is gray per second (Gy s^{-1}) (ICRU 60) [20]

[IEC 60580:2000, definition 3.3] [8]

3.6
AMBIENT DOSE EQUIVALENT
H*(d)
at a point in a RADIATION FIELD, the DOSE EQUIVALENT that would be produced by corresponding expanded and aligned field, in the ICRU sphere at a depth, d, on the radius opposing the direction of the aligned field

Unit: J kg^{-1}

The special name for the unit of AMBIENT DOSE EQUIVALENT is sievert (Sv) (ICRU 51)[19]

3.7
ATTENUATION
reduction of a RADIATION QUANTITY upon passage of the RADIATION through matter resulting from all types of interaction with this matter

NOTE The RADIATION QUANTITY may be, for example, the particle flux density or the energy density. ATTENUATION does not include the geometric reduction of the RADIATION QUANTITY with distance from the RADIATION SOURCE.

3.8
ATTENUATION EQUIVALENT
δ
thickness of a layer of reference material which, if substituted for the material under consideration in a beam of specified RADIATION QUALITY and under specified geometrical conditions, gives the same degree of ATTENUATION. ATTENUATION EQUIVALENT is expressed in suitable submultiples of the metre together with the reference

3.9
AUTOMATIC CONTROL SYSTEM
in an X-RAY EQUIPMENT, system in which the control or limitation of the electric energy delivered to an X-RAY TUBE ASSEMBLY depends upon the measurement of one or more RADIATION QUANTITIES or corresponding physical quantities

3.10
AUTOMATIC EXPOSURE CONTROL
in an X-RAY EQUIPMENT, MODE OF OPERATION in which one or more LOADING FACTORS are controlled automatically in order to obtain at a pre-selected location a desired quantity of RADIATION

3.11
BEAM LIMITING DEVICE
device to limit the RADIATION FIELD

3.12
BEAM LIMITING SYSTEM
entirety of parts and their geometrical configuration contributing to the limitation of the RADIATION BEAM

3.13
CONTINUOUS ANODE INPUT POWER

specified highest ANODE INPUT POWER which can be applied to the ANODE continuously

Unit: W

3.14
CONTROL PANEL
part of EQUIPMENT for the purpose of controlling all, or some, of the functions of the EQUIPMENT. The CONTROL PANEL may contain devices for indicating and displaying operating factors

3.15
CONTROLLED AREA
defined area which is part of an area under surveillance and for which access, occupancy and working conditions are regulated and controlled in order to protect persons against IONIZING RADIATION

3.16
CURRENT TIME PRODUCT
in MEDICAL RADIOLOGY, quantity of electricity resulting from the LOADING of an X-RAY TUBE, expressed in milliampere seconds, as the product of the mean X-RAY TUBE CURRENT in milliamperes and the duration of the LOADING in seconds

3.17
DIAPHRAGM
BEAM LIMITING DEVICE with either a fixed or an adjustable aperture in one plane

3.18
DOSE EQUIVALENT
H
is the product of Q and D, at a point in tissue, where D is the ABSORBED DOSE and Q is the quality factor at that point, thus

$$H = Q\,D.$$

Unit: J kg^{-1}

The special name for the unit of DOSE EQUIVALENT is sievert (Sv) (ICRU 51)[19]

3.19
EDGE FILTER
FILTER whose ABSORPTION characteristic as a function of RADIATION ENERGY shows a discontinuity in the useful photon energy range

3.20
EFFECTIVE IMAGE RECEPTION AREA

part of the IMAGE RECEPTION AREA that is configured to receive an X-RAY PATTERN that can be processed for display or storage

NOTE 1 In accordance with this convention, the IMAGE RECEPTION AREA of a multi-field X-ray image intensifier tube is considered to be restricted by the selection of magnification modes, to exclude any portion of the input screen from which the X-RAY PATTERN is not electronically processed.

NOTE 2 For X-RAY EQUIPMENT based on scanning that varies the position for receiving an X-RAY PATTERN during the exposure, the EFFECTIVE IMAGE RECEPTION AREA at a certain time during the scan is the area of the image receptor that is receiving and processing an X-RAY PATTERN at that very moment.

3.21
ENTRANCE SURFACE
in RADIOLOGY, plane or curved surface through which the RADIATION enters an irradiated object

3.22
EXTRA-FOCAL RADIATION
in an X-RAY SOURCE ASSEMBLY, X-RADIATION emitted from the RADIATION SOURCE other than that emitted from the ACTUAL FOCAL SPOT

3.23
FILTER
in RADIOLOGICAL EQUIPMENT, material or device provided to effect FILTRATION of the RADIATION BEAM

3.24
FILTRATION
modification of characteristics of IONIZING RADIATION on passing through matter

NOTE FILTRATION may be:

– preferential ABSORPTION of certain components of polyenergetic X-RADIATION accompanying its ATTENUATION;

– a modification of the distribution of RADIATION intensity over the cross-section of a RADIATION BEAM

3.25
FOCAL SPOT TO IMAGE RECEPTOR DISTANCE
distance from the REFERENCE PLANE of an EFFECTIVE FOCAL SPOT to the point at which the REFERENCE AXIS intersects with the image receptor plane

3.26
FOCAL SPOT TO SKIN DISTANCE
in MEDICAL DIAGNOSTIC RADIOLOGY, distance from the REFERENCE PLANE of an EFFECTIVE FOCAL SPOT to a plane normal to the REFERENCE DIRECTION and containing the point on the PATIENT surface nearest to the RADIATION SOURCE

3.27
HALF-VALUE LAYER
thickness of a specified material, which attenuates under NARROW BEAM CONDITIONS X-RADIATION with a particular spectrum to an extent such that the AIR KERMA RATE, EXPOSURE RATE or ABSORBED DOSE rate is reduced to one half of the value that is measured without the material. The HALF-VALUE LAYER (HVL) is expressed in suitable submultiples of the metre together with the material.

3.28
IMAGE RECEPTION AREA
in RADIOLOGY, surface on which an X-RAY PATTERN is received

3.29
IONIZING RADIATION
RADIATION consisting of directly or indirectly ionizing particles or a mixture of both. By convention, ultraviolet radiation is excluded

3.30
IRRADIATION
exposing of a living being or matter to RADIATION. In RADIOLOGY, exposing of a living being or matter to IONIZING RADIATION

Thus: X-IRRADIATION