



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN 60601-1-3:2008+A2:2021, incorporating corrigenda March 2010 and May 2014. It is derived from IEC 60601-1-3:2008, incorporating amendments 1:2013 and 2:2021. It supersedes BS EN 60601-1-3:2008+A11:2016, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association and is intended to support essential requirements of the EU legislation detailed in the European foreword. Annex ZA/ZZ describes how the publication relates to the legislation.

For the Great Britain market (England, Scotland and Wales), if the UK Government has designated this publication for conformity with UKCA marking legislation and has not amended the essential requirements of that legislation, Annex ZA/ZZ and any references to EU law in the publication should be read in accordance with the designation as applying to UK legislation in the same way as to EU law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. References to EU legislation are therefore still valid.

More information on legislation can be found at www.gov.uk.

© The British Standards Institution 2021
Published by BSI Standards Limited 2021

ISBN 978 0 539 14144 3

ICS 11.040.50; 13.280

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2008.

Amendments/corrigenda issued since publication

Date	Text affected
31 July 2010	Implementation of CENELEC corrigendum March 2010: date of withdrawal added to European foreword
31 July 2013	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2013 and Annex ZA updated
30 June 2014	Implementation of CENELEC corrigendum May 2014: date of withdrawal updated in the European foreword and foreword to amendment A1
31 December 2016	Implementation of CENELEC amendment A11:2016: Annexes ZA and ZZ replaced
31 March 2021	Implementation of IEC amendment 2:2021 with CENELEC endorsement A2:2021 and Annex ZA updated

English Version

**Medical electrical equipment - Part 1-3: General requirements for
basic safety and essential performance - Collateral Standard:
Radiation protection in diagnostic X-ray equipment
(IEC 60601-1-3:2008)**

Appareils électromédicaux - Partie 1-3: Exigences
générales pour la sécurité de base et les performances
essentiels - Norme collatérale: Radioprotection dans les
appareils à rayonnement X de diagnostic
(IEC 60601-1-3:2008)

Medizinische elektrische Geräte - Teil 1-3: Allgemeine
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale - Ergänzungsnorm:
Strahlenschutz von diagnostischen Röntgengeräten
(IEC 60601-1-3:2008)

This European Standard was approved by CENELEC on 2008-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62B/673/FDIS, future edition 2 of IEC 60601-1-3, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-3 on 2008-03-01.

The following date was fixed:

- | | |
|---|------------------|
| – latest date by which the EN has to be implemented | (dop) 2008-12-01 |
| at national level by publication of an identical | |
| national standard or by endorsement | (dow) 2008-12-31 |

This European Standard supersedes EN 60601-1-3:1994. However, EN 60601-1-3:1994 remains valid until all the Parts 2 that are used in conjunction with it have been withdrawn. No date of withdrawal of conflicting national standards (dow) has therefore been fixed. However, when Part 1-3 is used for appliances not covered by a Part 2, EN 60601-1-3:1994 is not to be used after 2009-09-12.

This EN 60601-1-3 has been restructured and aligned to EN 60601-1:2006 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.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

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: in roman type;
- *test specifications: in 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: IN 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 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 (*).

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-3:2008 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-7	NOTE	Harmonized as EN 60601-2-7:1998 (not modified).
IEC 60601-2-28	NOTE	Harmonized as EN 60601-2-28:1993 (not modified).
IEC 60601-2-29	NOTE	Harmonized as EN 60601-2-29:1999 (not modified).
IEC 60601-2-32	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
IEC 60601-2-43	NOTE	Harmonized as EN 60601-2-43:2000 (not modified).
IEC 60601-2-44	NOTE	Harmonized as EN 60601-2-44:2001 (not modified).
IEC 60601-2-45	NOTE	Harmonized as EN 60601-2-45:2001 (not modified).
IEC 60580	NOTE	Harmonized as EN 60580:2000 (not modified).
IEC 60627	NOTE	Harmonized as EN 60627:2001 (not modified).
IEC 61262	NOTE	Harmonized in EN 61262 series (not modified).
IEC 62220	NOTE	Harmonized in EN 62220 series (not modified).
IEC 62220-1	NOTE	Harmonized as EN 62220-1:2003 (not modified).

Foreword to amendment A1

The text of document 62B/895/CDV, future amendment 1 to edition 2 of IEC 60601-1-3, prepared by SC 62B "Diagnostic imaging equipment" of IEC TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-3:2008/A1:2013.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2014-02-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of the International Standard IEC 60601-1-3:2008/A1:2013 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A11

This document (EN 60601-1-3:2008/A11:2016) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2017-11-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-11-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Foreword to amendment A2

The text of document 62B/1176/CDV, future IEC 60601-1-3/A2, prepared by SC 62B “Diagnostic imaging equipment” of IEC/TC 62 “Electrical equipment in medical practice” was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-3:2008/A2:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2021-12-02 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2024-03-02 document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 60601-1-3:2008/A2:2021 was approved by CENELEC as a European Standard without any modification.

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60336		Medical electrical equipment - X-ray tube assemblies for medical use - Characteristics of focal spots	EN 60336	2005
IEC 60522	1999	Determination of the permanent filtration of X-ray tube assemblies	EN 60522	1999
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar. 2010	
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		-	-
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		

Annex ZZ

(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretionary choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1 – Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and Clauses and subclauses of this standard

No.	Essential Requirements	Coverage of EN 60601-1-3:2008 + A1:2014 + A11:2016
I.	GENERAL REQUIREMENTS	
1.	General Guidance notes 1 to 6 shall be observed	
1	<p>The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.</p> <p>This shall include:</p>	<p>If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to general ¹⁾ X-ray radiation-related aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to Clauses 4 to 13 of this collateral standard).</p>
	<ul style="list-style-type: none"> - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and 	Covered in respect of aspects contained in Clauses 5 and 6.
	<ul style="list-style-type: none"> - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 	Covered in respect of aspects contained in 5.2.4
2.	General Guidance notes 1, 2, 3, 4, 5, 6 shall be observed	
2	<p>The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.</p> <p>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:</p>	<p>1st paragraph covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account.</p> <p>2nd paragraph, including the following 3 bullets, are covered for radiation protection in x-ray equipment and in subassemblies of such equipment, where radiological images of a human patient are used for diagnosis, planning or guidance of medical procedures, in respect to aspects contained in the Clauses 5 to 13, under the condition that the manufacturer implements</p> <ul style="list-style-type: none"> - EN ISO 14971 (2012) including its Annex ZA.

1) This standard is intended to provide a set of general specifications to be complemented by existing particular/device specific standards, or by other means, such as risk management.

No.	Essential Requirements	Coverage of EN 60601-1-3:2008 + A1:2014 + A11:2016
	- eliminate or reduce risks as far as possible (inherently safe design and construction),	
	- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	
	- inform users of the residual risks due to any shortcomings of the protection measures adopted.	
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	Covered in respect of aspects contained in 6.7
4	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Not covered.
11	Protection against radiation	
General Guidance notes 1, 2, 3, 4, 5, 6 shall be observed		
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Covered for X-ray equipment in respect to aspects contained in Clauses 5 to 13.
11.2	Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Covered for X-ray equipment with respect to aspects contained in Clause 6
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Covered for X-ray equipment with respect to aspects contained in 6.4

No.	Essential Requirements	Coverage of EN 60601-1-3:2008 + A1:2014 + A11:2016
11.3	Unintended radiation	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Covered for X-ray equipment with respect to aspects contained in Clauses 5 to 13
11.4	Instructions	
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Covered in respect to aspects contained in 5.2.4
11.5	Ionizing radiation	
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Covered for X-ray equipment with respect to aspects contained in Clauses 6 to 8
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Covered for X-ray equipment with respect to aspects contained in 6.7
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	Not covered.
13	Information supplied by the manufacturer	
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Covered in respect to accessories, components and subassemblies of X-ray equipment in respect to Clause 5

CONTENTS

FOREWORD	5
INTRODUCTION	8
INTRODUCTION to Amendment 1	9
INTRODUCTION to Amendment 2	9
1 Scope, object and related standards	10
1.1 Scope	10
1.2 Object	10
1.3 Related standards	10
1.3.1 IEC 60601-1	10
1.3.2 Particular standards	10
2 Normative references	11
3 Terms and definitions	11
4 General requirements	21
4.1 Statement of compliance	21
4.2 Composition of reference materials	21
5 ME EQUIPMENT identification, marking and documents	21
5.1 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	21
5.1.1 General	21
5.1.2 Marking requirements in subclauses	21
5.2 ACCOMPANYING DOCUMENTS	21
5.2.1 References in subclauses	22
5.2.2 Dosimetric calibration	22
5.2.3 General requirements for the reference of subassemblies and ACCESSORIES	22
5.2.4 Instructions for use	23
6 RADIATION management	24
6.1 General	24
6.2 Initiation and termination of the IRRADIATION	25
6.2.1 Normal initiation and termination of the IRRADIATION	25
6.2.2 Safety measures against failure of normal termination of the IRRADIATION	25
6.3 RADIATION dose and RADIATION QUALITY	25
6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY	25
6.3.2 Reproducibility of the RADIATION output	25
6.4 Indication of operational states	26
6.4.1 Indication of the X-RAY SOURCE ASSEMBLY selected	26
6.4.2 Indication of LOADING STATE	26
6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION	26
6.4.4 Indication of automatic modes	26
6.4.5 Dosimetric indications	27
6.5 AUTOMATIC CONTROL SYSTEM	27
6.6 SCATTERED RADIATION reduction	27
6.7 Imaging performance	27
6.7.1 General	27
6.7.2 System performance	27
6.7.3 Nominal focal spot value	28

6.7.4	RADIATION DETECTOR or X-RAY IMAGE RECEPTOR	28
7	RADIATION QUALITY	28
7.1	HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT	28
7.2	Waveform of the X-RAY TUBE VOLTAGE	29
7.3	Indication of FILTER properties	29
7.4	Test for FILTRATION by irremovable materials	30
7.5	Test for ADDED FILTERS and materials	30
7.6	Test for HALF-VALUE LAYER	30
8	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA	30
8.1	General	30
8.2	Enclosure of X-RAY TUBES	30
8.3	Limiting DIAPHRAGM in X-RAY TUBE ASSEMBLIES	31
8.4	Confinement of EXTRA-FOCAL RADIATION	31
8.5	Relationship between X-RAY FIELD and IMAGE RECEPTION AREA	31
8.5.1	General	31
8.5.2	* FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	31
8.5.3	Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	31
8.5.4	Positioning of the PATIENT and restriction of the irradiated area	32
9	FOCAL SPOT TO SKIN DISTANCE	32
9.1	General	32
9.2	Information in the ACCOMPANYING DOCUMENTS	32
10	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	32
10.1	General	32
10.2	Information in the ACCOMPANYING DOCUMENTS	32
11	Protection against RESIDUAL RADIATION	33
12	* Protection against LEAKAGE RADIATION	33
12.1	General	33
12.2	Mounting of X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS	33
12.3	Statement of reference LOADING conditions	34
12.4	LEAKAGE RADIATION in the LOADING STATE	34
12.5	LEAKAGE RADIATION when not in the LOADING STATE	35
13	Protection against STRAY RADIATION	35
13.1	General	35
13.2	Control of X-RAY EQUIPMENT from a PROTECTED AREA	35
13.3	Protection by distance	36
13.4	* Designated SIGNIFICANT ZONES OF OCCUPANCY	36
13.5	Handgrips and control devices	37
13.6	* Test for STRAY RADIATION	37
	Annex A (informative) General guidance and rationale	39
	Annex B (normative) Values of the series R'10 and R'20, ISO 497	41
	Annex C (informative) Mapping between this Edition 2 of IEC 60601-1-3 and Edition 1	42
	Bibliography	44
	Index of defined terms used in this collateral standard	46

Figure 1 – Example of presentation of data on STRAY RADIATION

Table 1 – Subclauses containing requirements for marking 21

Table 2 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS 22

Table 3 – HALF-VALUE LAYERS in X-RAY EQUIPMENT 29

Table B.1 – Values of the series R'10 and R'20, ISO 497 41

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