ELEKTRILISED MEDITSIINISEADMED. OSA 1-3: ÜLDISED NÕUDED ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE. KOLLATERAALSTANDARD: KIIRGUSKAITSE NÕUDED DIAGNOSTILISTELE RÖNTGENSEADMETELE

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 + IEC 60601-1-3:2008/A1:2013 + IEC 60601-1-3:2008/A2:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-3:2008 +A1+A11+A2:2021 sisaldab Euroopa standardi EN 60601-1-3:2008 ja selle muudatuste A1:2013, A11:2016 ja A2:2021, paranduse AC:2010 ja muudatuse A1 paranduse AC:2014 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-3:2008 +A1+A11+A2:2021 consists of the English text of the European standard EN 60601-1-3:2008 and its amendments A1:2013, A11:2016 and A2:2021; corrigendum AC:2010 and amendment A1 corrigendum AC:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.04.2008, muudatused A1 14.06.2013, A11 18.11.2016 ja A2 05.03.2021.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 24.04.2008, for A1 14.06.2013, A11 18.11.2016 and A2 05.03.2021.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1] ⟨A1⟩. Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A11] ⟨A11⟩. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A2] ⟨A2⟩. Parandusega AC lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [AC] ⟨AC⟩. Muudatuse A1 parandusega AC lisatud või muudetud teksti algus ja lõpp on tähistatud püstkriipsuga teksti vasakul veerisel. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A1] ⟨A1⟩. The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags [A11] ⟨A11⟩. The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags [A2] ⟨A2⟩. The start and finish of text introduced or altered by corrigendum AC is indicated in the text by tags [AC] ⟨AC⟩. The start and finish of text introduced or altered by amendment A1 corrigendum AC is indicated by a vertical line in the left margin of the text. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50; 13.280

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-3 + A1 + A11 + A2

April 2008, June 2013, November 2016, March 2021

ICS 11.040.50; 13.280

Supersedes EN 60601-1-3:1994

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 + IEC 60601-1-3:2008/A1:2013 + IEC 60601-1-3:2008/A2:2021)

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 (CEI 60601-1-3:2008 + CEI 60601-1-3:2008/A1:2013 + IEC 60601-1-3:2008/A2:2021)

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 + IEC 60601-1-3:2008/A1:2013 + IEC 60601-1-3:2008/A2:2021)

This European Standard was approved by CENELEC on 2008-03-01. Amendment A2 was approved by CENELEC on 2021-03-02. Amendment A1 was approved by CENELEC on 2013-05-24. Amendment A11 was approved by CENELEC on 2016-11-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendments the status of a national standard without any alteration.

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This European Standard and its amendments A1, A11 and A2 exist 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN 60601-1-3:2008 E + EN 60601-1-3:2008/A1:2013 E + EN 60601-1-3:2008/A11:2016 E + EN 60601-1-3:2008/A2:2021 E

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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 at national level by publication of an identical national standard or by endorsement	(dop)	2008-12-01
▌AC〉 latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2012-06-01 〈AC▐

This European Standard supersedes EN 60601-1-3:1994. ▌AC〉 *deleted text* 〈AC▐

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.

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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).

A1 Amendment A1 foreword

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

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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. A1

⟨A11⟩ Amendment A11 European foreword

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

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For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document. ⟨A11⟩

A2 Amendment A2 European foreword

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

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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. A2

IEC 60601-1-3

Edition 2.2 2021-01
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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 60601-1-3:2008-01+AMD1:2013-04+AMD2:2021-01 CSV(en-fr)

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IEC 60601-1-3

Edition 2.2 2021-01
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

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colour inside

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50; 13.280

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
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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

⟨A1⟩ AMENDMENT A1 FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

CDV	Report on voting
62B/895/CDV	62B/907/RVC

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability 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. ⟨A1⟩

AMENDMENT A2 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.
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Amendment 2 to IEC 60601-1-3:2008 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

Draft	Report on voting
62B/1176/CDV	62B/1227/RVC

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 Amendment 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 www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications/.

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- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended. 〈A2〉

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.

INTRODUCTION to Amendment 2

The purpose of this second amendment to IEC 60601-1-3:2008 is to introduce changes to reference the second amendment (2020) to IEC 60601-1:2005.

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:

- ▌A2⟩ "the general standard" designates IEC 60601-1:2005+A1:2012+A2:2020; ⟨A2▐
- ▌A2⟩ "this collateral standard" designates IEC 60601-1-3:2008+A1:2013+A2:2021; ⟨A2▐
- "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

[A1] The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. [A1]

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*

[A2] IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020 [A2]

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 [A2] IEC 60601-1:2005+A1:2012+A2:2020 [A2], IEC 60788:2004 and the following apply.

NOTE An index of defined terms is found beginning on page 54.

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

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