BS EN 60601-1-3:2008+A2:2021
Incorporating corrigenda March 2010 and May 2014

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

bsi.

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 It supersedes BS EN 60601-1-3:2008+A11:2016, which is withdrawn.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.

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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-3:2008 +A2

March 2021

ICS 11.040.50; 13.280

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 essentielles - 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

EN 60601-1-3:2008+A2:2021

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 at national level by publication of an identical national standard or by endorsement	(dop)	2008-12-01
	(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).

EN 60601-1-3:2008+A2:2021

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 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

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.

CONTENTS

IEC 60601-1-3:2008+A2:2021

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.

INTRODUCTION to Amendment 1

The purpose of the first amendment to IEC 60601-1-3:2008 is to introduce changes to reference the first amendment (2012) to IEC 60601-1:2005.

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.

IEC 60601-1-3:2008+A2:2021

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 A2 IEC 60601-1:2005+A1:2012+A2:2020 A2;
- "this collateral standard" designates A2 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.