ELEKTRILISED MEDITSIINISEADMED. OSA 2-68: ERINÕUDED ELEKTRONKIIRENDITEL, KERGETE IOONIDEGA JA RADIONUKLIIDALLIKAGA VÄLISKIIRITUSRAVISEADMETEL KASUTATAVATE RÖNTGENKUJUTISJUHITAVATE KIIRITUSRAVISEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60601-2-68:2025 sisaldab Euroopa standardi EN IEC 60601-2-68:2025 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60601-2-68:2025 consists of the English text of the European standard EN IEC 60601-2-68:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 25.04.2025.	Date of Availability of the European standard is 25.04.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	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 11.040.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-68

April 2025

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Supersedes EN 60601-2-68:2015

English Version

Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment (IEC 60601-2-68:2025)

Appareils électromédicaux - Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides
(IEC 60601-2-68:2025)

Medizinische elektrische Geräte - Teil 2-68: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von röntgenstrahlungsbasierten Geräten für die bildgesteuerte Strahlentherapie zur Verwendung mit Elektronenbeschleunigern, Leichtionen-Strahlentherapiesystemen und Radionuklid-Strahlentherapiesystemen
(IEC 60601-2-68:2025)

This European Standard was approved by CENELEC on 2025-03-11. 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.

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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 62C/927/FDIS, future edition 2 of IEC 60601-2-68, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-68:2025.

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) 2026-04-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-04-30

This document supersedes EN 60601-2-68:2015 and all of its amendments and corrigenda (if any).

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.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-68:2025 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 standard indicated:

IEC 60336:2020	NOTE	Approved as EN IEC 60336:2021 (not modified)
IEC 60364-7-710:2021	NOTE	Approved as HD 60364-7-710:—[1] (not modified) + A11:—[2]
IEC 60601-1-9	NOTE	Approved as EN 60601-1-9
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-2-4:2010	NOTE	Approved as EN 60601-2-4:2011 (not modified)
IEC 60601-2-8	NOTE	Approved as EN 60601-2-8
IEC 60601-2-11:2013	NOTE	Approved as EN 60601-2-11:2015 (not modified)
IEC 60601-2-17	NOTE	Approved as EN 60601-2-17
IEC 60601-2-28:2017	NOTE	Approved as EN IEC 60601-2-28:2019 (not modified)
IEC 60601-2-44:2009	NOTE	Approved as EN 60601-2-44:2009 (not modified) + A11:2011

[1] Under preparation. Stage at the time of publication: HD 60364-7-710:2025.

[2] Under preparation. Stage at the time of publication: HD 60364-7-710:2025/A11:2025.

IEC 60601-2-44:2009/A1:2012	NOTE	Approved as EN 60601-2-44:2009/A1:2012 (not modified)
IEC 60601-2-44:2009/A2:2016	NOTE	Approved as EN 60601-2-44:2009/A2:2016 (not modified)
IEC 60601-2-54	NOTE	Approved as EN IEC 60601-2-54
IEC 60601-2-64:2014	NOTE	Approved as EN 60601-2-64:2015 (not modified)
IEC 60731:2011	NOTE	Approved as EN 60731:2012 (not modified)
IEC 60976:2007	NOTE	Approved as EN 60976:2007 (not modified)
IEC 61223-3-5:2019	NOTE	Approved as EN IEC 61223-3-5:2019 (not modified)
IEC 61262-7:1995	NOTE	Approved as EN 61262-7:1995 (not modified)
IEC 61674	NOTE	Approved as EN IEC 61674
IEC 62083:2009	NOTE	Approved as EN 62083:2009 (not modified)
IEC 62220-1-1:2015	NOTE	Approved as EN 62220-1-1:2015 (not modified)
IEC 62274:2005	NOTE	Approved as EN 62274:2005 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)

IEC 60601-2-68

Edition 2.0 2025-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
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IEC 60601-2-68:2025-02(en-fr)

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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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IEC 60601-2-68 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This second edition cancels and replaces the first edition published in 2014. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) alignment with the new editions of the relevant standards:
   – IEC 60601-2-1:2020;

  - IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016;
  - IEC 60601-2-64:2014;

b) clarification of the use of IEC 60601-2-68 for CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY used in the same room with an EXTERNAL BEAM EQUIPMENT (EBE);

c) introduction of updated requirements related to MECHANICAL HAZARDS, RADIATION HAZARDS, PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS), ACCOMPANYING DOCUMENTATION of an ME SYSTEM, and REMOTE OPERATION.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/927/FDIS	62C/941/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the seventeen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

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

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

Modern RADIOTHERAPY practices utilize information from various imaging modalities, acquired prior to initiating administration of the therapy, to plan the TREATMENT. The imaging provides information about the location of the TARGET VOLUME and other anatomical features so that a TREATMENT PLAN can be developed that provides an optimal dose distribution to have the best chance of achieving the intended effect of TREATMENT while minimizing side effects.

However, difficulties arise when trying to administer the RADIATION, since TARGET VOLUMES/critical structures are constantly moving within the body. For example, in parts of the body moving with respiration, the TARGET VOLUMES/critical structures may change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy can extend over many days, during which the TARGET VOLUME/PATIENT can shrink or grow or move. Hence, the exact location of the TARGET VOLUME/critical structures can change between the time of TREATMENT PLANNING imaging and the actual administration of a TREATMENT.

IMAGE-GUIDED RADIOTHERAPY (IGRT) combines planar or volumetric imaging during the course of RADIOTHERAPY to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. This enables the OPERATOR or EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the imaging information, such as the position of the TARGET VOLUME, critical organs or other reference features, to compensate for anatomical changes including internal organ motions or TREATMENT setup uncertainties. The increased accuracy and precision achieved allows higher doses of RADIATION to be delivered to the TARGET VOLUME and a reduction in the margin of healthy cells affected by the RADIATION. This is often used in conjunction with other monitoring equipment.

This document establishes requirements to be complied with by MANUFACTURERS in the design and construction of X-RAY IGRT EQUIPMENT (X-IGRT).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with an EXTERNAL BEAM EQUIPMENT such as an ELECTRON ACCELERATOR, LIGHT ION BEAM MEDICAL ELECTRICAL EQUIPMENT or RADIONUCLIDE BEAM THERAPY EQUIPMENT, for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, the IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1:2009). However, since IGRT usage does not necessarily have such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

This document deals with the safety aspect of image acquisitions, image analysis, data transfer and TREATMENT replanning or EBE/PATIENT repositioning.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT, and REAL-TIME X-IGRT.

X-IGRT EQUIPMENT is also related to the following current publications:

– IEC 60601-2-1
– IEC 60601-2-44
– IEC 60601-2-64
– IEC 62083
– IEC 61217
– IEC 62274

This document will focus on the safety aspects of the primary function of X-IGRT. It will not focus on emerging technologies within the field so as to not hinder progress, yet it will define a safe way of achieving X-IGRT.

MEDICAL ELECTRICAL EQUIPMENT –

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201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-ray based IMAGE-GUIDED RADIOTHERAPY equipment for use with EXTERNAL BEAM EQUIPMENT (EBE).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices integrated in a specified geometrical relationship with EBE for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT EBE SYSTEM. For example, in the case of ONLINE X-IGRT, the MANUFACTURER will provide an interactive interface for user interaction with the correction suggested by the system.

This document does not apply to CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY, and X-RAY EQUIPMENT for RADIOSCOPY, that are not intended for use for IGRT.

Requirements that are being tested according to another standard can be identified by the manufacturer. If these requirements are equivalent, retesting is not required, but instead evidence can refer to the CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY for RADIOSCOPY manufacturer's compliance statements or test reports.

If the X-IGRT EQUIPMENT is combined with an MEE, any requirement that is the same for the X-IGRT EQUIPMENT and the MEE, such as a PATIENT POSITIONER, is not required to be tested twice, but can be accepted as tested by the MEE.

This document applies to X-RAY EQUIPMENT for RADIOGRAPHY, RADIOSCOPY, and COMPUTER TOMOGRAPHY used for IGRT.

If a clause or subclause is specifically intended to be applicable to X-IGRT EBE SYSTEMS, the content of that clause or subclause will say so. Where that is not the case, the clause or subclause applies only to X-IGRT EQUIPMENT.

This document, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of X-IGRT EBE SYSTEMS intended to be

- for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS having the required skills for a particular medical application, for particular specified clinical purposes, e.g., STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE In this document, all references to installation refer to the installation in the RESPONSIBLE ORGANIZATION'S premises.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-IGRT EQUIPMENT and X-IGRT EBE SYSTEMS.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-3 and IEC 60601-1-6 apply as modified in Clause 203 and Clause 206 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Replacement:

IEC 60601-1-3:2008, *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/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-1:2020, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-4:2010, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

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

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3 : Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61217:2011, *Radiotherapy equipment – Coordinates, movements and scales*

IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-2-1:2020, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020, and IEC TR 60788:2004 apply, except as follows:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp