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# ELEKTRILISED MEDITSIINISEADMED. OSA 2-65: ERINÕUDED INTRAORAALSE DENTAALSE RÖNTGENSEADME ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

# Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment (IEC 60601-2-65:2012 + IEC 60601-2-65:2012/A1:2017 + IEC 60601-2-65:2012/A2:2021)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| See Eesti standard EVS-EN 60601-2-65:2013 +A1+A2:2021 sisaldab Euroopa standardi EN 60601-2-65:2013 ja selle muudatuste A1:2020 ja A2:2021 ingliskeelset teksti. | This Estonian standard EVS-EN 60601-2-65:2013 +A1+A2:2021 consists of the English text of the European standard EN 60601-2-65:2013 and its amendments A1:2020 and A2:2021. |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.<br><br>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.01.2013, muudatused A1 03.04.2020 ja A2 18.06.2021. | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.<br><br>Date of Availability of the European standard is 11.01.2013, for A1 03.04.2020 and A2 18.06.2021. |
| Sellesse standardisse on muudatus A1 sisse viidud ja tehtud muudatused tähistatud püstkriipsuga lehe välisveerisel.<br><br>Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A2] ⟨A2⟩.<br><br>Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest. | The amendment A1 has been incorporated into this standard and changes have been marked by a vertical line on the outer row of the page.<br><br>The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags [A2] ⟨A2⟩.<br><br>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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 60601-2-65 + A1 + A2

January 2013, April 2020, June 2021

ICS 11.040.50

Supersedes EN 60601-2-7:1998 (partially), EN 60601-2-32:1994 (partially)

English Version

## Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment (IEC 60601-2-65:2012 + IEC 60601-2-65:2012/A1:2017 + IEC 60601-2-65:2012/A2:2021)

Appareils électromédicaux - Partie 2-65: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires intra-oraux
(IEC 60601-2-65:2012 + IEC 60601-2-65:2012/A1:2017 + IEC 60601-2-65:2012/A2:2021)

Medizinische elektrische Geräte - Teil 2-65: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von intraoralen zahnärztlichen Röntgeneinrichtungen
(IEC 60601-2-65:2012 + IEC 60601-2-65:2012/A1:2017 + IEC 60601-2-65:2012/A2:2021)

This European Standard was approved by CENELEC on 2012-10-24. Amendment A1 was approved by CENELEC on 2020-01-01. Amendment A2 was approved by CENELEC on 2021-06-07. 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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Ref. No. EN 60601-2-65:2013 E
+ EN 60601-2-65:2013/A1:2020 E
+ EN 60601-2-65:2013/A2:2021 E

## Foreword

The text of document 62B/889/FDIS, future edition 1 of IEC 60601-2-65, prepared by IEC/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 60601-2-65:2013.

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) | 2013-07-24 |
| • latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2015-10-24 |

This document supersedes EN 60601-2-7:1998 (PART) and EN 60601-2-32:1994 (PART).

EN 60601-2-65:2013 includes the following significant technical changes with respect to EN 60601-2-7:1998 and EN 60601-2-32:1994:

Within its specific scope, the clauses of EN 60601-2-65:2012 supersede and replace those of EN 60601-2-7:1998 and EN 60601-2-32:1994.

This standard is to be read in conjunction with EN 60601-1:2006.

In this 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 PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular 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.

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.

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.

## Endorsement notice

The text of the International Standard IEC 60601-2-65:2012 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 60601-2-7:1998 | NOTE | Harmonised as EN 60601-2-7:1998 [1)] (not modified). |
| IEC 60601-2-28:2010 | NOTE | Harmonised as EN 60601-2-28:2010 (not modified). |
| IEC 60601-2-32:1994 | NOTE | Harmonised as EN 60601-2-32:1994 [1)] (not modified). |
| IEC 60601-2-43:2010 | NOTE | Harmonised as EN 60601-2-43:2010 (not modified). |
| IEC 60601-2-44:2009 | NOTE | Harmonised as EN 60601-2-44:2009 (not modified). |
| IEC 60601-2-45:2011 | NOTE | Harmonised as EN 60601-2-45:2011 (not modified). |
| IEC 60601-2-54:2009 | NOTE | Harmonised as EN 60601-2-54:2009 (not modified). |
| IEC 60601-2-63 | NOTE | Harmonised as EN 60601-2-63. |



1) Superseded by EN 60601-2-54:2009 (IEC 60601-2-54:2009, not modified).

## Amendment A1 European foreword

The text of document 62B/1006/CDV, future IEC 60601-2-65/A1, 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 60601-2-65:2013/A1:2020.

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) 2020-10-03
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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, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s), see informative Annex ZZ, included in EN 60601-2-65:2013.

## Endorsement notice

The text of the International Standard IEC 60601-2-65:2012/A1:2017 was approved by CENELEC as a European Standard without any modification.

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| | | |
|---|---|---|
| IEC 60601-1-10 | NOTE | Harmonized as EN 60601-1-10 |
| IEC 60601-1-11 | NOTE | Harmonized as EN 60601-1-11 |
| IEC 60601-1-12 | NOTE | Harmonized as EN 60601-1-12 |

## A2 Amendment A2 European foreword

The text of document 62B/1233/FDIS, future IEC 60601-2-65/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 60601-2-65:2013/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) 2022-03-07
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-06-07

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## Endorsement notice

The text of the International Standard IEC 60601-2-65:2012/A2:2021 was approved by CENELEC as a European Standard without any modification. A2

# IEC 60601-2-65

Edition 1.2 2021-05
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD



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## Medical electrical equipment –
## Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

IEC 60601-2-65:2012-09+AMD1:2017-05+AMD1:2021-05 CSV(en)

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# IEC 60601-2-65

Edition 1.2 2021-05
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD



colour inside

## Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral 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 60601-2-65 has been prepared by IEC subcommittee 62B: Diagnostic Imaging Equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

| FDIS | Report on voting |
|---|---|
| 62B/889/FDIS | 62B/897/RVD |

Full information on the voting for the approval of this particular 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 this 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 PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular 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.

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.

The committee has decided that the contents of this 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

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## 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/1006/CDV | 62B/1039/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 website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- amended.

## AMENDMENT A2 FOREWORD

This second 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:

| FDIS | Report on voting |
|---|---|
| 62B/1233/FDIS | 62B/1238/RVD |

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 website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
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# INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 and its collaterals, a complete set of BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for DENTAL INTRA-ORAL X-RAY EQUIPMENT. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard addresses the system level of DENTAL INTRA-ORAL X-RAY EQUIPMENT. Components and their functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of DENTAL INTRA-ORAL X-RAY EQUIPMENT.

The minimum safety requirements for DENTAL EXTRA-ORAL X-RAY EQUIPMENT are specified in a separate particular standard IEC 60601-2-63 to simplify and improve the readability

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for safety and essential performance*, hereinafter referred to as the general standard.

Within its specific scope, the clauses of this particular standard supersede and replace those of IEC 60601-2-7, *Medical electrical equipment* – Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators. Requirements particular to DENTAL X-RAY-EQUIPMENT which were included in previous editions of the collateral standard IEC 60601-1-3 or the particular standard IEC 60601-2-28, IEC 60601-2-7 or IEC 60601-2-32 have been extracted and moved into this particular standard.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard. Therefore IEC 60601-2-28 does not apply to equipment in the scope of this International Standard.

## INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-65:2012 is to introduce changes to reference the Amendment 1 (2012) to IEC 60601-1:2005. As neither IEC 60601-2-65:2012 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed.

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment



## 201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

### 201.1.1 Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL INTRA-ORAL X-RAY EQUIPMENT and its main components, hereafter also called ME EQUIPMENT.

The scope of this standard is restricted to X-RAY EQUIPMENT where the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

DENTAL EXTRA-ORAL X-RAY EQUIPMENT is excluded from the scope of this standard

NOTE 1 The X-RAY GENERATOR in DENTAL INTRA-ORAL X-RAY EQUIPMENT always comprises an X-RAY MONOBLOCK ASSEMBLY. Therefore in this particular standard the concept of X-RAY TUBE ASSEMBLY is replaced by that of X-RAY MONOBLOCK ASSEMBLY.

NOTE 2 Main components may be for instance the X-RAY MONOBLOCK ASSEMBLY and an ELECTRONIC X-RAY IMAGE RECEPTOR.

NOTE 3 Photostimulated phosphor plates and their readers (hardware and software) are excluded from the scope of this particular standard, since they have no electrical APPLIED PARTS in the PATIENT ENVIRONMENT, and are not ME EQUIPMENT.

ME EQUIPMENT and ME SYSTEMS in the scope of IEC 60601-2-63, IEC 60601-2-44, IEC 60601-2-54, IEC 60601-2-45 or IEC 60601-2-43 are excluded from the scope of this particular standard. The scope of this International Standard also excludes RADIOTHERAPY SIMULATORS and equipment for bone or tissue absorption densitometry. Excluded from the scope is also ME EQUIPMENT intended to be used for DENTAL RADIOSCOPY.

Within its specific scope, the clauses of this particular standard supersede and replace those of IEC 60601-2-7, *Medical electrical equipment – Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* and of IEC 60601-2-32, *Medical electrical equipment – Particular requirements for the safety of associated equipment of X-ray equipment*.

NOTE 4 Requirements for X-RAY GENERATORS and for ASSOCIATED EQUIPMENT, which were previously specified in IEC 60601-2-7 and IEC 60601-2-32, have been included in either IEC 60601-1:2005 (Ed3) or in this particular standard. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the IEC 60601-1 3rd edition scheme for DENTAL INTRA-ORAL X-RAY EQUIPMENT.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard. Therefore IEC 60601-2-28 does not apply to ME EQUIPMENT in the scope of this International Standard.

[1] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT for DENTAL INTRA-ORAL RADIOGRAPHY.

### 201.1.3 Collateral standards

*Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-10[2], IEC 60601-1-11[3] and IEC 60601-1-12[4] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE OPERATORS of DENTAL INTRA-ORAL X-RAY EQUIPMENT are used to audible signals as required in this particular standard rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

### 201.1.4 Particular standards

*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard or 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 the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.



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2 IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

3 IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

4 IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard 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, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

## 201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 43.

Clause 2 of the general standard applies, except as follows:

*Replacement:*

*deleted text*

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

*Addition:*

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

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

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

IEC 62220-1:2003, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*