

**SINGAPORE STANDARD**

## **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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### **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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## National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on IEC SC62D MT20 appointed by the Technical Committee on Medical Devices under the direction of the Biomedical and Health Standards Committee.

This standard is identical with IEC 60601-1-3:2008+A1:2013, “Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment”, published by the International Electrotechnical Commission.

Attention is drawn to the following:

1. Where appropriate, the words “International Standard” shall be read as “Singapore Standard”.
2. Where reference to a particular part of IEC 60601 is made, the appropriate Singapore Standard (which is an identical adoption of that part of IEC 60601) shall be referenced.
3. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

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

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1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.*
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3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

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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**This consolidated version of IEC 60601-1-3 consists of the second edition (2008) [documents 62B/673/FDIS and 62B/683/RVD] and its amendment 1 (2013) [documents 62B/895/CDV and 62B/907/RVC]. It bears the edition number 2.1.**

**The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.**

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 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 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.

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 the base publication and its amendment will remain unchanged until the maintenance result 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;
- withdrawn;
- replaced by a revised edition, or
- amended

**IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.**

## 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]<sup>1)</sup>, 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].

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<sup>1)</sup> Figures in square brackets refer to the Bibliography.

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.

## 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.

**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.