

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**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**



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INTERNATIONAL  
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## CONTENTS

FOREWORD.....	5
INTRODUCTION.....	8
1 Scope, object and related standards.....	9
1.1 Scope.....	9
1.2 Object.....	9
1.3 Related standards.....	9
1.3.1 IEC 60601-1.....	9
1.3.2 Particular standards.....	9
2 Normative references.....	10
3 Terms and definitions.....	10
4 General requirements.....	20
4.1 Statement of compliance.....	20
4.2 Composition of reference materials.....	20
5 ME EQUIPMENT identification, marking and documents.....	20
5.1 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts.....	20
5.1.1 General.....	20
5.1.2 Marking requirements in subclauses.....	20
5.2 ACCOMPANYING DOCUMENTS.....	20
5.2.1 References in subclauses.....	21
5.2.2 Dosimetric calibration.....	21
5.2.3 General requirements for the reference of subassemblies and ACCESSORIES.....	21
5.2.4 Instructions for use.....	22
6 RADIATION management.....	23
6.1 General.....	23
6.2 Initiation and termination of the IRRADIATION.....	24
6.2.1 Normal initiation and termination of the IRRADIATION.....	24
6.2.2 Safety measures against failure of normal termination of the IRRADIATION.....	24
6.3 RADIATION dose and RADIATION QUALITY.....	24
6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY.....	24
6.3.2 Reproducibility of the RADIATION output.....	24
6.4 Indication of operational states.....	25
6.4.1 Indication of the X-RAY SOURCE ASSEMBLY selected.....	25
6.4.2 Indication of LOADING STATE.....	25
6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION.....	25
6.4.4 Indication of automatic modes.....	25
6.4.5 Dosimetric indications.....	26
6.5 AUTOMATIC CONTROL SYSTEM.....	26
6.6 SCATTERED RADIATION reduction.....	26
6.7 Imaging performance.....	26
6.7.1 General.....	26
6.7.2 System performance.....	26
6.7.3 Nominal focal spot value.....	27
6.7.4 RADIATION DETECTOR or X-RAY IMAGE RECEPTOR.....	27
7 RADIATION QUALITY.....	27

7.1	HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT .....	27
7.2	Waveform of the X-RAY TUBE VOLTAGE.....	28
7.3	Indication of FILTER properties .....	28
7.4	Test for FILTRATION by irremovable materials .....	29
7.5	Test for ADDED FILTERS and materials.....	29
7.6	Test for HALF-VALUE LAYER .....	29
8	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA .....	29
8.1	General .....	29
8.2	Enclosure of X-RAY TUBES .....	29
8.3	Limiting DIAPHRAGM in X-RAY TUBE ASSEMBLIES .....	30
8.4	Confinement of EXTRA-FOCAL RADIATION .....	30
8.5	Relationship between X-RAY FIELD and IMAGE RECEPTION AREA .....	30
8.5.1	General .....	30
8.5.2	* FOCAL SPOT TO IMAGE RECEPTOR DISTANCE .....	30
8.5.3	Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA .....	30
8.5.4	Positioning of the PATIENT and restriction of the irradiated area.....	31
9	FOCAL SPOT TO SKIN DISTANCE.....	31
9.1	General .....	31
9.2	Information in the ACCOMPANYING DOCUMENTS .....	31
10	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR .....	31
10.1	General .....	31
10.2	Information in the ACCOMPANYING DOCUMENTS .....	31
11	Protection against RESIDUAL RADIATION .....	32
12	* Protection against LEAKAGE RADIATION .....	32
12.1	General .....	32
12.2	Mounting of X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS .....	32
12.3	Statement of reference LOADING conditions.....	33
12.4	LEAKAGE RADIATION in the LOADING STATE .....	33
12.5	LEAKAGE RADIATION when not in the LOADING STATE .....	34
13	Protection against STRAY RADIATION .....	34
13.1	General .....	34
13.2	Control of X-RAY EQUIPMENT from a PROTECTED AREA.....	34
13.3	Protection by distance .....	35
13.4	* Designated SIGNIFICANT ZONES OF OCCUPANCY .....	35
13.5	Handgrips and control devices .....	36
13.6	* Test for STRAY RADIATION .....	36
	Annex A (informative) General guidance and rationale.....	38
	Annex B (normative) Values of the series R'10 and R'20, ISO 497 .....	40
	Annex C (informative) Mapping between this Edition 2 of IEC 60601-1-3 and Edition 1 .....	41
	Bibliography.....	43
	Index of defined terms used in this collateral standard .....	45

Figure 1 – Example of presentation of data on STRAY RADIATION..... 37

Table 1 – Subclauses containing requirements for marking..... 20

Table 2 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS ..... 21

Table 3 – HALF-VALUE LAYERS in X-RAY EQUIPMENT..... 28

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## 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

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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

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## 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].

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.

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1) Figures in square brackets refer to the Bibliography.

## 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 IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-3 alone;
- "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

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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*

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

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 IEC 60601-1:2005, IEC 60788:2004 and the following apply.

NOTE An index of defined terms is found beginning on page 45.

### 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

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

Unit: J kg<sup>-1</sup>

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60) [20]

[IEC 60580:2000, definition 3.2, modified] [8]