

Australian/New Zealand Standard™

Medical electrical equipment

Part 1.3: General requirements for basic safety and essential performance— Collateral Standard: Radiation protection in diagnostic X-ray equipment



AS/NZS IEC 60601.1.3:2015

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 August 2015 and on behalf of the Council of Standards New Zealand on 21 August 2015.

This Standard was published on 14 September 2015.

The following are represented on Committee HE-003:

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This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.1.3:2015.

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Part 1.3: General requirements for basic safety and essential performance— Collateral Standard: Radiation protection in diagnostic X-ray equipment

Originated as AS/NZS 3200.1.3:1996.
Jointly revised and redesignated as AS/NZS IEC 60601.1.3:2015.

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ISBN 978 1 76035 239 4

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HE-003 Medical Electrical Equipment, to supersede AS/NZS 3200.1.3:1996, *Approval and test specification—Medical electrical equipment, Part 1.3: General requirements for safety—Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment*.

The objective of this Standard is to specify 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 low as reasonably achievable, without jeopardizing the benefit of the radiological procedure. It considers radiation protection aspects related to X-radiation only. The particular requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015.

This Standard is identical with, and has been reproduced from IEC 60601-1-3 Ed.2.1 (2013), *Medical electrical equipment, Part 1-3: General requirements for basic safety and essential performance—Collateral Standard: Radiation protection in diagnostic X-ray equipment*. This edition 2.1 incorporates Amendment 1 (2013). The text affected by Amendment 1 is indicated in the source document by marginal bars, redline and strikeout.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standards</i>	<i>Australian/New Zealand Standards</i>
IEC	AS/NZS IEC
60601 Medical electrical equipment	60601 Medical electrical equipment
60601-1 Part 1: General requirements for basic safety and essential performance	60601.1 Part 1: General requirements for basic safety and essential performance

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

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IEC FOREWORD

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 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 A.

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.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

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 60601-1:2005+A1:2012-~~alone~~;
- "this collateral standard" designates IEC 60601-1-3:2008+A1:2013-~~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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*
Amendment 1:2012

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+A1:2012, IEC 60788:2004 and the following apply.

NOTE An index of defined terms is found beginning on page 46.

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⁻¹

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

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

3.5**AIR KERMA RATE** $\dot{K}$

quotient of dK by dt , where dK is the increment of AIR KERMA in the time interval dt , thus

$$\dot{K} = \frac{dK}{dt}$$

Unit: $\text{J kg}^{-1} \text{s}^{-1}$

If the special name gray is used, the unit of AIR KERMA RATE is gray per second (Gy s^{-1}) (ICRU 60) [20]

[IEC 60580:2000, definition 3.3] [8]

3.6**AMBIENT DOSE EQUIVALENT** $H^*(d)$

at a point in a RADIATION FIELD, the DOSE EQUIVALENT that would be produced by corresponding expanded and aligned field, in the ICRU sphere at a depth, d , on the radius opposing the direction of the aligned field

Unit: J kg^{-1}

The special name for the unit of AMBIENT DOSE EQUIVALENT is sievert (Sv) (ICRU 51)[19]

3.7**ATTENUATION**

reduction of a RADIATION QUANTITY upon passage of the RADIATION through matter resulting from all types of interaction with this matter

NOTE The RADIATION QUANTITY may be, for example, the particle flux density or the energy density. ATTENUATION does not include the geometric reduction of the RADIATION QUANTITY with distance from the RADIATION SOURCE.

3.8**ATTENUATION EQUIVALENT** δ

thickness of a layer of reference material which, if substituted for the material under consideration in a beam of specified RADIATION QUALITY and under specified geometrical conditions, gives the same degree of ATTENUATION. ATTENUATION EQUIVALENT is expressed in suitable submultiples of the metre together with the reference

3.9**AUTOMATIC CONTROL SYSTEM**

in an X-RAY EQUIPMENT, system in which the control or limitation of the electric energy delivered to an X-RAY TUBE ASSEMBLY depends upon the measurement of one or more RADIATION QUANTITIES or corresponding physical quantities

3.10**AUTOMATIC EXPOSURE CONTROL**

in an X-RAY EQUIPMENT, MODE OF OPERATION in which one or more LOADING FACTORS are controlled automatically in order to obtain at a pre-selected location a desired quantity of RADIATION

3.11**BEAM LIMITING DEVICE**

device to limit the RADIATION FIELD

3.12**BEAM LIMITING SYSTEM**

entirety of parts and their geometrical configuration contributing to the limitation of the RADIATION BEAM

3.13**CONTINUOUS ANODE INPUT POWER**

specified highest ANODE INPUT POWER which can be applied to the ANODE continuously

Unit: W

3.14**CONTROL PANEL**

part of EQUIPMENT for the purpose of controlling all, or some, of the functions of the EQUIPMENT. The CONTROL PANEL may contain devices for indicating and displaying operating factors

3.15**CONTROLLED AREA**

defined area which is part of an area under surveillance and for which access, occupancy and working conditions are regulated and controlled in order to protect persons against IONIZING RADIATION

3.16**CURRENT TIME PRODUCT**

in MEDICAL RADIOLOGY, quantity of electricity resulting from the LOADING of an X-RAY TUBE, expressed in milliamperere seconds, as the product of the mean X-RAY TUBE CURRENT in milliamperes and the duration of the LOADING in seconds

3.17**DIAPHRAGM**

BEAM LIMITING DEVICE with either a fixed or an adjustable aperture in one plane

3.18**DOSE EQUIVALENT*****H***

is the product of *Q* and *D*, at a point in tissue, where *D* is the ABSORBED DOSE and *Q* is the quality factor at that point, thus

$$H = Q D.$$

Unit: J kg⁻¹

The special name for the unit of DOSE EQUIVALENT is sievert (Sv) (ICRU 51)[19]

3.19**EDGE FILTER**

FILTER whose ABSORPTION characteristic as a function of RADIATION ENERGY shows a discontinuity in the useful photon energy range

3.20**EFFECTIVE IMAGE RECEPTION AREA**

part of the IMAGE RECEPTION AREA that is configured to receive an X-RAY PATTERN that can be processed for display or storage

NOTE 1 In accordance with this convention, the IMAGE RECEPTION AREA of a multi-field X-ray image intensifier tube is considered to be restricted by the selection of magnification modes, to exclude any portion of the input screen from which the X-RAY PATTERN is not electronically processed.

NOTE 2 For X-RAY EQUIPMENT based on scanning that varies the position for receiving an X-RAY PATTERN during the exposure, the EFFECTIVE IMAGE RECEPTION AREA at a certain time during the scan is the area of the image receptor that is receiving and processing an X-RAY PATTERN at that very moment.

3.21

ENTRANCE SURFACE

in RADIOLOGY, plane or curved surface through which the RADIATION enters an irradiated object

3.22

EXTRA-FOCAL RADIATION

in an X-RAY SOURCE ASSEMBLY, X-RADIATION emitted from the RADIATION SOURCE other than that emitted from the ACTUAL FOCAL SPOT

3.23

FILTER

in RADIOLOGICAL EQUIPMENT, material or device provided to effect FILTRATION of the RADIATION BEAM

3.24

FILTRATION

modification of characteristics of IONIZING RADIATION on passing through matter

NOTE FILTRATION may be:

- preferential ABSORPTION of certain components of polyenergetic X-RADIATION accompanying its ATTENUATION;
- a modification of the distribution of RADIATION intensity over the cross-section of a RADIATION BEAM

3.25

FOCAL SPOT TO IMAGE RECEPTOR DISTANCE

distance from the REFERENCE PLANE of an EFFECTIVE FOCAL SPOT to the point at which the REFERENCE AXIS intersects with the image receptor plane

3.26

FOCAL SPOT TO SKIN DISTANCE

in MEDICAL DIAGNOSTIC RADIOLOGY, distance from the REFERENCE PLANE of an EFFECTIVE FOCAL SPOT to a plane normal to the REFERENCE DIRECTION and containing the point on the PATIENT surface nearest to the RADIATION SOURCE

3.27

HALF-VALUE LAYER

thickness of a specified material, which attenuates under NARROW BEAM CONDITIONS X-RADIATION with a particular spectrum to an extent such that the AIR KERMA RATE, EXPOSURE RATE or ABSORBED DOSE rate is reduced to one half of the value that is measured without the material. The HALF-VALUE LAYER (HVL) is expressed in suitable submultiples of the metre together with the material.

3.28

IMAGE RECEPTION AREA

in RADIOLOGY, surface on which an X-RAY PATTERN is received

3.29

IONIZING RADIATION

RADIATION consisting of directly or indirectly ionizing particles or a mixture of both. By convention, ultraviolet radiation is excluded

3.30

IRRADIATION

exposing of a living being or matter to RADIATION. In RADIOLOGY, exposing of a living being or matter to IONIZING RADIATION

Thus: X-IRRADIATION

3.31**IRRADIATION SWITCH**

in RADIOLOGICAL EQUIPMENT, control device provided to initiate and/or stop IRRADIATION

3.32**IRRADIATION TIME**

duration of an IRRADIATION determined according to specific methods, usually the time a rate of a RADIATION QUANTITY exceeds a specified level

3.33**LEAKAGE RADIATION**

IONIZING RADIATION which has passed through the PROTECTIVE SHIELDING of a RADIATION SOURCE as well as that which, for some types of X-RAY GENERATORS, has passed through the RADIATION APERTURE before and after LOADING (for example one containing a grid controlled X-RAY TUBE)

3.34**LOADING**

in an X-RAY GENERATOR, act of supplying electrical energy to the ANODE of an X-RAY TUBE

3.35**LOADING FACTOR**

factor influencing by its value the X-RAY TUBE LOAD, for example X-RAY TUBE CURRENT, LOADING TIME, CONTINUOUS ANODE INPUT POWER, X-RAY TUBE VOLTAGE and PERCENTAGE RIPPLE

3.36**LOADING STATE**

for an X-RAY GENERATOR, state from the end of the READY STATE, when the intended function of the generator is initiated, until the end of the LOADING of the X-RAY TUBE

3.37**LOADING TIME**

time determined according to a specific method, during which the ANODE INPUT POWER is applied to the X-RAY TUBE

3.38**MEASURED VALUE**

estimate of the TRUE VALUE of a quantity, derived from the INDICATED VALUE of a meter after applying all relevant CORRECTION FACTORS

3.39**MEDICAL RADIOLOGY**

branch of RADIOLOGY applied to human and veterinary medicine as well as to dentistry and chiropractic

3.40**MODE OF OPERATION**

for X-RAY EQUIPMENT the technical state defined by a configuration of several predetermined LOADING FACTORS and other settings for RADIOLOGY or RADIOGRAPHY, selectable simultaneously by the operation of a single control

NOTE 1 Selection of a particular mode does not necessarily define the values of all the parameters affecting its use.

NOTE 2 Values defined by selection of a particular mode are not necessarily invariable during its use.

3.41**NARROW BEAM CONDITION**

arrangement for the measurement of a RADIATION QUANTITY in a NARROW BEAM of IONIZING RADIATION

3.42**NOMINAL X-RAY TUBE VOLTAGE**

highest permitted X-RAY TUBE VOLTAGE for specific operating conditions

3.43**PATIENT ENTRANCE REFERENCE POINT**

point intended to represent the intersection of the X-RAY BEAM AXIS with the ENTRANCE SURFACE of the PATIENT

NOTE The geometries to be used for various X-RAY EQUIPMENT are given in the particular standards.

3.44**PERCENTAGE RIPPLE**

for a HIGH-VOLTAGE GENERATOR, ratio of the difference between the highest and the lowest values of a rectified voltage waveform during a cycle of the supply to the highest value, expressed as a percentage

3.45**PERMANENT FILTRATION**

the QUALITY EQUIVALENT FILTRATION effected in an X-RAY TUBE ASSEMBLY by permanently fixed materials intercepting the X-RAY BEAM, that are not intended to be removed for any application and are not provided with means for removal in NORMAL USE

3.46**PHANTOM**

device intended to simulate parts of the PATIENT for test purposes

3.47**PRIMARY PROTECTIVE SHIELDING**

PROTECTIVE SHIELDING for attenuating RESIDUAL RADIATION

3.48**PROTECTED AREA**

defined area within an area under surveillance or within a CONTROLLED AREA which is protected by STRUCTURAL SHIELDING or by distance so that the resulting level of RADIATION is lower than the ambient level in the overall area of which it is a part

3.49**PROTECTIVE BARRIER**

PROTECTIVE SHIELDING in the form of attenuating material provided for RADIOLOGICAL protection

3.50**PROTECTIVE DEVICE**

in RADIOLOGY, device for the purpose of RADIOLOGICAL protection

Thus:

- PROTECTIVE CLOTHING;
- PROTECTIVE APRON;
- PROTECTIVE SKIRT;
- PROTECTIVE GLOVE;
- PROTECTIVE GLASSES;
- mobile PROTECTIVE BARRIER