

Australian/New Zealand Standard™

Medical electrical equipment

**Part 2.29: Particular requirements for
safety—Radiotherapy simulators
(IEC 60601-2-29:1999, MOD)**



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Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.29: Particular requirements for safety—Radiotherapy simulators (IEC 60601-2-29:1999, MOD)

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE/003, Medical Electrical Equipment.

This Particular Standard modifies, and has been reproduced from, IEC 60601-2-29:1999, *Medical electrical equipment, Part 2-29: Particular requirements for the safety of radiotherapy simulators* which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998, hereinafter referred to as the General Standard. Additional requirements for Australia and New Zealand are included in Appendix ZZ.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

In the text of this Standard, the following print types are used:

- (a) Requirements, compliance with which can be tested and definitions
.....in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
..... in smaller roman type
- (c) Headings of sub-clauses and text specifications
.....in italic type
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

Some pages of the original, which relate to IEC administrative matters, are omitted from this edition.

As this publication has been reproduced from an international Standard, the following modifications apply:

- (i) its number does not appear on each page of text and its identity is shown on the cover and title page.
- (ii) the words 'this Australian/New Zealand Standard' should replace the words 'this International Standard' wherever they appear.
- (iii) substitute a full point for a comma where it appears as a decimal marker.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

<i>Reference to International Standard</i>		<i>Australian or Australian/New Zealand Standard</i>	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety Amendment 1:1991 Amendment 2:1995	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-1	Part 1: General requirements for safety 1: Collateral Standard: Safety requirements for medical electrical systems	3200.1.1	Part 1.1: General requirements for safety—Collateral Standard: Safety requirements for medical electrical systems

IEC		AS/NZS	
60601-1-2	Part 1: General requirements for safety 2: Collateral Standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests
60601-2-7	Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	3200.2.7	Part 2.7: Particular requirements for safety—High voltage generators of diagnostic X-ray generators
60788	Medical radiology—Terminology	—	
61217	Radiotherapy equipment—Co-ordinates, movements and scales	4495	Radiotherapy equipment—Co-ordinates, movements and scales

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the Appendix or 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.

CONTENTS

	Page
INTRODUCTION	vi
SECTION ONE – GENERAL	
Clause	
1 Scope and object	1
2 Terminology and definitions	3
5 Classification	4
6 Identification, marking and documents	4
SECTION TWO – ENVIRONMENTAL CONDITIONS	
10 Environmental conditions	7
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
16 ENCLOSURES and PROTECTIVE COVERS	7
18 Protective earthing, functional earthing and potential equalization	7
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	8
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS	
22 Moving parts	9
27 Pneumatic and hydraulic power	12
28 Suspended masses	12
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
29 X-RADIATION generated by SIMULATORS	12
36 ELECTROMAGNETIC COMPATIBILITY	15
SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	
52 Abnormal operation and fault conditions	16

Clause	Page
Annexes	
Appendix L (normative) – References – Publications mentioned in this standard	21
Annex AA (normative) – Terminology – Index of defined terms	22
Annex BB (informative) – Bibliography	25
Table	
Table 101 – Clauses and subclauses in this Particular Standard that require the provision of information in the ACCOMPANYING DOCUMENTS, the INSTRUCTIONS FOR USE, and in the technical description.....	6
Figures	
Figure 101 – EQUIPMENT movements and scales – Rotary GANTRY (adapted from IEC 60601-2-1) with identification of axes 1 to 8, directions 9 to 13, and dimensions 14 and 15	17
Figure 102 – EQUIPMENT movements and scales – ISOCENTRIC RADIOTHERAPY SIMULATOR OR TELERADIOTHERAPY EQUIPMENT, with identification of axes 1; 4 to 6; 19, of directions 9 to 12; 16 to 18 and of dimensions 14; 15	18
Figure 103 – EQUIPMENT movements and scales – View from RADIATION SOURCE of TELERADIOTHERAPY RADIATION FIELD OR RADIOTHERAPY SIMULATOR DELINEATED RADIATION FIELD	19

INTRODUCTION

The use of RADIOTHERAPY SIMULATORS may expose PATIENTS to danger if the EQUIPMENT design does not satisfy standards of electrical, mechanical and IONIZING RADIATION safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the IONIZING RADIATION adequately and/or if there are inadequacies in the design of the SIMULATOR room.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of RADIOTHERAPY SIMULATORS; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT; it places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists, for example a component failure, and where an INTERLOCK then operates to prevent continued operation of the EQUIPMENT.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.29:

Particular requirements for safety—Radiotherapy simulators

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

1.1 Scope

Addition:

This Particular Standard applies to RADIOTHERAPY SIMULATORS:

- that use diagnostic X-RAY EQUIPMENT to simulate physically a RADIOTHERAPY RADIATION BEAM, so that the TREATMENT VOLUME to be subjected to IRRADIATION during RADIOTHERAPY can be localized, and the position and size of the RADIOTHERAPY RADIATION FIELD can be confirmed;
- intended exclusively for RADIOTHERAPY simulation as a prelude to intended RADIOTHERAPY, and not for any other purpose such as general diagnostic examinations;
- used within the environmental and electrical supply conditions SPECIFIED in the technical description;
- comprising the following parts:
 - a system for producing an X-RAY BEAM, which simulates the geometry of the RADIOTHERAPY RADIATION BEAM;
 - a system for producing images of the transmitted X-RAY BEAM, for example, either by RADIOGRAPHY or RADIOSCOPY;
 - an assembly to control the size and position of the RADIATION BEAM and to delineate the intended treatment area;
 - a mechanical structure that physically simulates the geometry and movements of the RADIOTHERAPY EQUIPMENT and supports the imaging system;
 - a PATIENT SUPPORT system.

1.2 Object

Addition:

This Particular Standard establishes requirements to ensure the IONIZING RADIATION safety and enhanced mechanical and electrical safety of RADIOTHERAPY SIMULATORS; it identifies geometrical parameters that are critical for the accurate simulation of a RADIOTHERAPY treatment.

1.3 Particular Standards

Additional subclauses:

1.3.101 Relationship to the General Standard.

NOTE – See appendix L for normative references.

The requirements of this Particular Standard take priority over those of all other standards; it is to be read in conjunction with IEC 60601-1 (1988), *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and corrigendum (1995) – hereinafter referred to as the General Standard – which it amends and supplements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard. Unless otherwise stated, all clauses of the General Standard apply.

As in the General Standard, the requirements are followed by compliance tests. The term “this standard” is used throughout to refer to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard (but see 29.1 b)). The changes to the text of the General Standard, or its Collateral Standards, are SPECIFIED by the use of the following words:

“Replacement” means that the clause or subclause of the General/Collateral Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General/Collateral Standard.

“Amendment” means that the clause or subclause of the General/Collateral Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

1.3.102 Relationship to other standards and documents

a) IEC 60601-2-7

This standard applies to HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS used with RADIOTHERAPY SIMULATORS (see 29.1 a)).

b) IEC 61217

This standard gives guidance on the designation of EQUIPMENT movements, the marking of scales, their zero positions, and the direction of movement with increasing value (see 6.3.101 a)).

1.5 Collateral Standards

Additional subclauses:

1.5.101 IEC 60601-1-1

This Collateral Standard does not apply.

1.5.102 IEC 60601-1-2

All clauses and subclauses of this Collateral Standard, together with the additions given in clause 36, apply to RADIOTHERAPY SIMULATORS and their integral INFORMATION TECHNOLOGY EQUIPMENT (ITE).

NOTE – IEC 60601-1-2 applies to EQUIPMENT and ITE used in medical applications. RADIOTHERAPY SIMULATORS and their integral ITE are not excluded from compliance with IEC 60601-1-2; at the date of publication of this standard it has not been possible to determine whether further amendments to its requirements or tests will be necessary.

1.5.103 IEC 60601-1-3

All clauses and subclauses of this Collateral Standard apply, except as amended in clause 29.

1.5.104 IEC 60601-1-4

All clauses and subclauses of this Collateral Standard apply (see 52.1 b)).

2 Terminology and definitions

Addition:

NOTE – Annex AA lists all defined terms alphabetically with their source reference.

Definitions of additional terms used in this Particular Standard.

2.1.101

DELINEATED RADIATION BEAM

that part of the RADIATION BEAM bordered by the shadow cast by the DELINEATORS

2.1.102

DELINEATED RADIATION FIELD

area of the DELINEATED RADIATION BEAM intercepted on a plane perpendicular to the REFERENCE AXIS

2.1.103

DELINEATOR(s)

means for defining the border(s) of the simulated RADIATION FIELD

2.1.104

RADIOTHERAPY SIMULATOR (hereinafter referred to as SIMULATOR)

EQUIPMENT that uses X-RAY EQUIPMENT to simulate geometrically parameters of movements and RADIATION FIELDS of RADIOTHERAPY EQUIPMENT so as to assist with the planning of PATIENT treatments

5 Classification

Replacement:

EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in clause 6. This includes:

- 5.1** According to the type of protection against electric shock:
 - CLASS I EQUIPMENT.
- 5.2** According to the degree of protection against electric shock:
 - TYPE B APPLIED PARTS.
- 5.3** According to the degree of protection against ingress of water detailed in the current edition of IEC 60529 (see 6.1 l)):
 - IPX0, unless otherwise SPECIFIED.
- 5.4** According to the method(s) of sterilization or disinfection recommended in the INSTRUCTIONS FOR USE.
- 5.5** According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE:
 - EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.
- 5.6** According to the mode of operation:
 - Suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for SPECIFIED LOADINGS, unless otherwise SPECIFIED.

6 Identification, marking and documents

6.3 Marking of controls and instruments

Additional subclause:

6.3.101 Provision of scales and indications for moving parts

- a) The following shall be provided:
- a numerical indication of the dimensions of the DELINEATED RADIATION FIELD at a SPECIFIED distance;
 - an indication by light of the RADIATION BEAM and the DELINEATED RADIATION FIELD;
 - an indication of the position of the ISOCENTRE;
 - means for indicating the FOCAL SPOT TO SKIN DISTANCE;
 - an indication of the position of the REFERENCE AXIS on entry to the PATIENT or X-RAY IMAGE RECEPTOR;
 - an indication to the OPERATOR, associated with the angular position of the DELINEATED RADIATION BEAM, of the possible WEDGE FILTER direction(s) for the RADIOTHERAPY EQUIPMENT being simulated;
 - a numerical indication of the distance from the FOCAL SPOT to the IMAGE RECEPTOR PLANE;
 - a numerical indication of the distance from the ISOCENTRE to the FOCAL SPOT when this parameter is adjustable;
 - scale readouts complying with the conventions of IEC 61217, for all available movements of GANTRY, RADIATION HEAD and BLDS, DELINEATORS, X-RAY IMAGE RECEPTOR and PATIENT SUPPORT (see 1.3.102 b)).