Australian/New Zealand Standard™

Medical electrical equipment

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

Standards Australia

STANDARDS NEW ZEALAND

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE/3, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 16 June 2000 and on behalf of the Council of Standards New Zealand on 4 July 2000. It was published on 1 August 2000.

The following interests are represented on Committee HE/3:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Laboratory
Australian Society of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Family Services
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Medical Industry Association of Australia
Ministry of Commerce, New Zealand
Royal Australasian College of Surgeons
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

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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:

Reference to International Standard		*Australian or Australian/New Zealand Standard*	
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

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

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Part 2.29:
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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.