AS/NZS IEC 60601.2.29:2015
IEC 60601-2-29, Ed.3.0 (2008)

AS/NZS IEC 60601.2.29:2015

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

STANDARDS Australia

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PAEREWA AOTEAROA

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 16 November 2015 and on behalf of the Council of Standards New Zealand on 4 November 2015.
This Standard was published on 18 December 2015.

The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board, New Zealand
College of Biomedical Engineering, Engineers Australia
Department of Defence, Australia
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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 or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.29:2015.

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Medical electrical equipment

Part 2.29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

Originated as AS/NZS 3200.2.29:2000.
Jointly revised and redesignated as AS/NZS IEC 60601.2.29:2015.

Jointly published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001 and by Standards New Zealand, Private Bag 2439, Wellington 6140.

ISBN 978 1 76035 348 3

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.29:2000, *Medical electrical equipment,* Part 2.29: *Particular requirements for safety—Radiotherapy simulators (IEC 60601-2-29:1999, MOD)*

The objective of this Standard is to establish particular basic safety and essential performance requirements for radiotherapy simulators.

The 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 60601-2-29, Ed.3.0 (2008), *Medical electrical equipment*, Part 2-29: *Particular requirements for the basic safety and essential performance of radiotherapy simulators*.

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.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

CONTENTS

IEC FOREWORD

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this 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 PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen 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 particular 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.

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

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 ME EQUIPMENT. It places limits on the degradation of ME 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 ME EQUIPMENT.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.29:
Particular requirements for the basic safety and essential performance of radiotherapy simulators

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of RADIOTHERAPY SIMULATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for RADIOTHERAPY SIMULATORS [as defined in 201.3.204].

201.1.3 *Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

The following collateral standard does not apply:

– IEC 60601-1-10.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

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