AS/NZS 3200.2.33:2005
IEC 60601-2-33:2002

AS/NZS 3200.2.33:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.33: Particular requirements for safety—Magnetic resonance equipment for medical diagnosis

STANDARDS Australia

STANDARDS NEW ZEALAND Paerewa Aotearoa

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-008, Diagnostic Ionizing Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 9 August 2005 and on behalf of the Council of Standards New Zealand on 26 August 2005.
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The following are represented on Committee HE-008:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Dental Association
Australian Diagnostic Manufacturers Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian and New Zealand Society of Nuclear Medicine
Department of Defence (Australia)
Department of Human Services, Victoria
Ministry of Economic Development, New Zealand
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National Radiation Laboratory, New Zealand
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The Royal Australian and New Zealand College of Radiologists
United Dental Hospital of Sydney

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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.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-008, Diagnostic Ionizing Imaging Equipment, to supersede AS/NZS 3200.2.33:1996, *Approval and test specification—Medical electrical equipment,* Part 2.33: *Particular requirements for safety—Magnetic resonance equipment for medical diagnosis.*

The objective of this revision is to adopt the 2002 edition of IEC 60601-2-33 which takes account of the rapid progress of magnetic resonance equipment.

This Particular Standard has been reproduced from, and is identical to, IEC 60601-2-33:2002, *Medical electrical equipment,* Part 2-33: *Particular requirements for the safety of magnetic resonance equipment for medical diagnosis,* 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 3200.1.0:1998, *Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard*, and is hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

The General Standard details electrical safety requirements for the design and manufacture of medical electrical equipment, which makes physical or electrical contact with the patient. A Particular Standard details additional safety requirements for a medical device, or related group of medical 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.

It is recommended that, to interpret a Particular Standard or a Collateral Standard, a copy of the General Standard should be readily available.

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, notes, general statements and exceptions ..... in smaller roman type

(c) Test specifications.....*in italic type*

(d) Terms defined in Clause 2 of the General Standard or this Particular Standard .....IN SMALL CAPITALS

As this publication has been reproduced from an International Standard, the following modifications apply.

(i) Its number does not appear on each page 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) The substitution of a full point (.) for a comma (,) when it appears as a decimal marker.

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

Some pages of the original, which relate to IEC administrative matters, do not appear in this version.

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

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-1	Part 1-1: Collateral Standard: Safety requirements for medical electrical systems	3200.1.1	Part 1.1: Collateral Standard: Safety requirements for medical electrical systems
60601-1-4	Part 1-4: Collateral Standard: Programmable electrical medical systems	3200.1.4	Part 1.4: Collateral Standard: Programmable electrical medical systems

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INTRODUCTION

This Particular Standard is written at a moment in which the technical evolution of MAGNETIC RESONANCE EQUIPMENT is in rapid progress and the scientific foundation of its safe use is still expanding.

The standard addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein, related to safety of PATIENTS examined with this system and personnel involved with its operation. Where limits of exposure of PATIENTS and medical staff are stated, these limits do not imply that such levels of exposure can be assumed to be acceptable for the population at large. Rather the implication is that the limits provide for the PATIENT a sensible balance between risk and benefit and for the medical staff a balanced risk, given their responsibility for the wellbeing of the PATIENT.

Organisational aspects of safety are the task of the USER. This task includes adequate training of staff, rules of access to the MR SYSTEM, qualification of staff for decisions that are related to safety, definition of medical responsibility and specific requirements for personnel following from that responsibility when the PATIENT is in or near the MR SYSTEM.

Examples of such organisational aspects are:

– operation in first controlled mode;
– emergency procedures for resuscitation of the PATIENT who is in the MR SYSTEM,
– emergency procedures after a QUENCH of the superconductive magnet when present;
– set-up and maintenance of a protocol for screening the PATIENT for contraindications or for conditions that may affect acceptable exposure;
– rules for ROUTINE MONITORING and for MEDICAL SUPERVISION of the PATIENT during the exam.

Extensive rationale is provided in Annex BB for some of the definitions and requirements in order to provide the USER of this standard with a reasonably complete access to the source material that was used in support of the considerations during drafting.

The relationship of this Particular Standard with IEC 60601-1 (including its amendments) and the Collateral Standards is explained in 1.3.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.33:
Particular requirements for safety—Magnetic resonance equipment for medical diagnosis

SECTION ONE: GENERAL

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

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard applies to MAGNETIC RESONANCE EQUIPMENT as defined in 2.2.101 and MAGNETIC RESONANCE SYSTEMS as defined in 2.2.102.

This Standard does not cover the application of MAGNETIC RESONANCE EQUIPMENT beyond the INTENDED USE.

1.2 Object

Replacement:

This Particular Standard establishes requirements for the safety of MAGNETIC RESONANCE EQUIPMENT to provide protection for the PATIENT.

It establishes requirements to provide information to the OPERATOR, staff associated with MAGNETIC RESONANCE EQUIPMENT and the general public.

It also provides methods for demonstrating compliance with those requirements.

1.3 Particular standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as the "General Standard", consisting of

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, and its amendments 1 (1991) and 2 (1995),

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems,* and

IEC 60601-1-4:1996*, Medical electrical equipment – Part 1: General requirement for safety – 4. Collateral Standard: Programmable electronic medical systems*.