AS/NZS 3200.2.44:2005
IEC 60601-2-44, Ed. 2.1(2002)

AS/NZS 3200.2.44:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.44: Particular requirements for safety—X-ray equipment for computed tomography

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 10 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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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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Medical electrical equipment

Part 2.44: Particular requirements for safety—X-ray equipment for computed tomography

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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 3200.2.44:2000, *Medical electrical equipment,* Part 2.44: *Particular requirements for safety—X-ray equipment for computed tomography.*

The objective of this Standard is to adopt the 2002 edition of IEC 60601-2-44, which incorporates its first Amendment (2002). A vertical line in the margin indicates where the base publication has been modified by Amendment 1.

This Particular Standard has been reproduced from, and is identical to, IEC 60601-2-44, Ed. 2.1(2002), *Medical electrical equipment,* Part 2.44: *Particular requirements for the safety of X-ray equipment for computed tomography,* 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, *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 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.

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 and headings of sub-clauses ..... *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 of text and its identity is shown only on the cover and title page.

(ii) The substitution of a full point (.) for a comma (,) where it appears as a decimal marker.

(iii) The words this ‘Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.

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

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

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	Part 1:General requirements for safety—Parent Standard
60601-1-2	Part 1-2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: Collateral Standard: Electromagnetic compatibility—Requirements and tests
60601-1-3	Part 1-3: General requirements for safety—Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment	3200.1.3	Part 1.3: General requirements for safety—Collateral Standard:General requirements for radiation protection in diagnostic X-ray equipment
60601-2-28	Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	3200.2.28	Part 2.28: Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis
60601-2-32	Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment	3200.2.32	Part 2.32: Particular requirements for safety—Associated equipment of X-ray equipment
60664	Insulation coordination for equipment within low-voltage systems	—	
60664-1	Part 1: Principles, requirements and tests	—	
60788	Medical radiology—Terminology	—	
ISO			
2092	Light metals and their alloys—Code of designation based on chemical symbols	—	

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AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.44:
Particular requirements for safety—X-ray equipment for computed tomography

SECTION 1: 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 X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT SCANNERS).

It includes safety requirements for the X-RAY GENERATOR, and those where HIGH VOLTAGE GENERATORS are integrated with an X-RAY TUBE ASSEMBLY.

1.2 Object

Replacement:

The object of this standard is to establish particular requirements to ensure safety, and to specify methods for demonstrating compliance with those requirements, for CT SCANNERS.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the ICRP as stated in ICRP 60, 1990, paragraph 112,[1)] namely:

"(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

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1) ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No 1-3, 1990)*. Published by Pergamon Press.