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AS/NZS 3200.1.3:1996
IEC 601-1-3:1994

Australian/New Zealand Standard®

Approval and test specification—Medical electrical equipment

Part 1.3: General requirements for safety—Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/23, Medical Diagnostic Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 20 June 1996 and on behalf of the Council of Standards New Zealand on 20 June 1996. It was published on 5 September 1996.

The following interests are represented on Committee HT/23:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Academy of Dento-Maxillo-Facial Radiologists
Australian and New Zealand Society of Nuclear Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Dental Industry Association
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This Standard was issued in draft form for comment as DR 95243.

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PUBLISHED JOINTLY BY:

STANDARDS AUSTRALIA
1 The Crescent,
Homebush NSW 2140 Australia

STANDARDS NEW ZEALAND
Level 10, Standards House,
155 The Terrace,
Wellington 6001 New Zealand

ISBN 0 7337 0678 9

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PREFACE

This Standard was prepared by the Joint Standards Australian/Standards New Zealand Committee HT/23 on Medical Diagnostic Imaging Equipment, as a Joint Standard.

This Standard is technically equivalent to and has been reproduced from IEC 601-1-3:1994, *Medical electrical equipment*, Part 1: *General requirements for safety—3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*.

This Standard is one of a series of approval and test specifications issued by Standards Australia and Standards New Zealand for various categories of medical equipment. It is supplementary to AS 3200.1.0 (NZS 6150):1990, *Approval and test specification—Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard*.

The international Standard IEC 601-1-3:1994 is a collateral standard to IEC 601-1:1988, *Medical electrical equipment*, Part 1: *General requirements for safety* which has been adopted as AS 3200.1.0 (NZS 6150) hereinafter referred to as the General Standard. Collateral Standards specify safety requirements for groups of equipment (for example, radiology equipment) or for a characteristic common to all medical electrical equipment not covered by the General Standard.

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*

(d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index . . . . . IN SMALL CAPITALS

(e) Marginal bars are added to the text wherever the requirements of the Standard have been varied to meet Australian and New Zealand requirements; these variations are detailed in Appendix ZZ.

Under arrangements made between Standards Australia, Standards New Zealand and the IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover and title page.

For the purposes of this Standard the IEC text should be modified as follows:

(i) *Terminology* The words 'this Australian/New Zealand Standard' should replace the words 'this International Standard' wherever they appear.

(ii) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

(iii) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*
IEC		AS/NZS
406	Radiographic cassettes	—
522	Inherent filtration of an X-ray tube assembly	—
601	Medical electrical equipment	3200(NZS 6150) Approval and test specification—Medical electrical equipment

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IEC		AS/NZS	
601-2-7	Part 2-7: 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
601-2-15	Part 2-15: Particular requirements for the safety of capacitor discharge X-ray generators	3200.2.15	Part 2.15: Particular requirements for safety—Capacitor discharge X-ray generators
601-2-28	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
601-2-29	Part 2-29: Particular requirements for the safety of radiotherapy simulators	—	
601-2-32	Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment	3200.2.32	Particular requirements for safety—Associated equipment of X-ray equipment
627	Characteristics of anti-scatter grids used in X-ray equipment	—	
637	Marking of and accompanying documents for X-ray tubes and X-ray tube assemblies for medical use	—	
658	Radiographic intensifying screens for medical use—Dimensions	—	
788	Medical radiology—Terminology	—	
878	Graphical symbols for electrical equipment in medical practice	4334	Graphical symbols for use on medical electrical equipment
ICRP			
Publication 33	Protection against ionizing radiation from external sources used in medicine	—	
Publication 34	Protection of the patient in diagnostic radiology	—	
Publication 60	Recommendations of the International Commission on Radiological Protection	—	

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