Australian/New Zealand Standard™

Medical electrical equipment

Part 2.43: Particular requirements for safety—X-ray equipment for interventional procedures (IEC 60601-2-43:2000, MOD)

Standards Australia

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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The following are represented on Committee HE-008:

Australian College of Physical Scientists and Engineers in Medicine
Australasian and New Zealand Society of Nuclear Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Department of Defence (Australia)
Department of Human Services, Vic.
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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-008, Diagnostic Ionizing Imaging Equipment.

This Particular Standard has been reproduced with national modifications, from IEC 60601-2-43:2000, *Medical electrical equipment,* Part 2.43; *Particular requirements for the safety of X-ray equipment for interventional procedures,* and supplements the corresponding Clauses of IEC 60601-1:1998, *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 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 electrical 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.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-43. These changes are indicated by a rule in the margin against each Clause affected.

In the text of this Standard, the following fonts are used:

(a) Requirements, compliance with which can be tested, and definitions .....in large roman type

(b) Explanations, advice, introductions, general statements, exceptions, references ..... in smaller roman type

(c) Headings, of sub-clauses and test specifications ..... *in italic type*

(d) Terms used throughout the Standard, which have been defined in Clause 2 or the Index of Defined Terms [see Annex AA]. ..... 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 (,) where it appears as a decimal marker.

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 only for information and guidance.

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 references to the following Australian/New Zealand Standards:

Reference to International Standard or other publication[1]		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60529	Degrees of protection provided by enclosures for electrical equipment (IP code)	1939	Degrees of protection provided by enclosures for electrical equipment (IP code)
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-2-7	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
60601-2-28	Part 2-28 Particular requirements for the safety of associated equipment 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 diagnostic generators
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 for X-ray equipment

[1] Only IEC documents adopted in Australia/New Zealand appear in this list.

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INTRODUCTION

In recent years, there have been major developments in the use of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. These procedures may involve prolonged IRRADIATIONS and may subject PATIENTS and OPERATORS to higher levels of risk than those which normally prevail.

A consequence is the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas on the PATIENT. Another consequence is the large contribution to the stochastic risk for the RADIATION induced cancers etc. collectively to the PATIENT.

This Particular Standard deals with these additional risks and thereby complements the General Standard with special provisions for this particular domain. Interventional procedures of the type envisaged are well established in clinical fields such as:

– invasive cardiology;
– interventional RADIOLOGY;
– interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.43:

Particular requirements for safety—X-ray equipment for interventional procedures (IEC 60601-2-43:2000, MOD)

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 declared by the MANUFACTURER to be suitable for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;
– equipment for COMPUTED TOMOGRAPHY;
– ACCESSORIES intended to be introduced into the PATIENT;
– mammographic X-RAY EQUIPMENT.

NOTE 1 Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of EQUIPMENT complying with this standard is recommended, are given in annex BB.

NOTE 2 The particular requirements of this standard are not essential for EQUIPMENT used in all RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Examples of procedures, for which the use of EQUIPMENT complying with this standard is considered not to be essential, are given in annex BB.

EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this standard.

1.2 Object

Replacement:

The object of this standard is:

– to establish safety requirements for the design and manufacture of X-RAY EQUIPMENT for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES;
– to specify information which is to be provided with such EQUIPMENT for the assistance of the USER and OPERATOR in managing the RADIATION risk arising from these procedures which could affect PATIENTS and staff.