

AS/NZS 3200.1.4:1997
IEC 601-1-4:1996

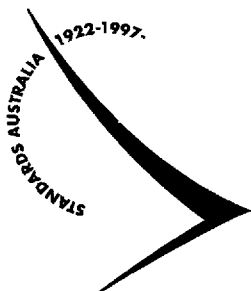
AS/NZS 3200.1.4

Australian/New Zealand Standard[®]

**Approval and test specification—
Medical electrical equipment**

**Part 1.4: General requirements
for safety—Collateral Standard:
Programmable electrical medical
systems**

[ISO title: Medical electrical equipment, Part 1: General requirements
for safety—4. Collateral Standard: Programmable electrical medical
systems]



**LEADING AUSTRALIA
INTO THE FUTURE**



AVA Documents
Document Sharing Hub

AS/NZS 3200.1.4:1997

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/3, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 9 May 1997 and on behalf of the Council of Standards New Zealand on 23 June 1997. It was published on 5 July 1997.

The following interests are represented on Committee HT/3:

Australasian College of Physical Scientists and Engineers in Medicine
 Australian and New Zealand College of Anaesthetists
 Australian Private Hospitals Association
 Canterbury Health, New Zealand
 College of Biomedical Engineering, Australia
 Commonwealth Department of Health and Family Services
 Department of Defence, Australia
 Department of Public Works and Services N.S.W.
 Ministry of Commerce, New Zealand
 Monash Medical Centre
 N.S.W. Health Department
 Queensland Health
 Society For Medical and Biological Engineering, Australia
 Testing and Certification Australia
 Wellington Area Health Board, New Zealand

Review of Standards. To keep abreast of progress in industry, Joint Australian/New Zealand Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto.

Full details of all Joint Standards and related publications will be found in the Standards Australia and Standards New Zealand Catalogue of Publications; this information is supplemented each month by the magazines 'The Australian Standard' and 'Standards New Zealand', which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.

Suggestions for improvements to Joint Standards, addressed to the head office of either Standards Australia or Standards New Zealand, are welcomed. Notification of any inaccuracy or ambiguity found in a Joint Australian/New Zealand Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

This Standard was issued in draft form for comment as DR 96553.



Documents

Document Sharing Hub

AS/NZS 3200.1.4:1997

Australian/New Zealand Standard®

**Approval and test specification—
Medical electrical equipment**

**Part 1.4: General requirements
for safety—Collateral Standard:
Programmable electrical medical
systems**

First published as AS/NZS 3200.1.4:1997.

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

PREFACE

This Joint Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/15, Medical Electrical Equipment General Safety Aspects.

This Collateral Standard is identical to and has been reproduced from IEC 601-1-4:1996, *Medical electrical equipment, Part 1: General requirements for safety—4. Collateral Standard: Programmable electrical medical systems*, which modifies and supplements the corresponding Clauses of IEC 601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS 3200.1/NZS 6150, hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for all types of medical electrical equipment. 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.

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

The even numbered pages of the original publication are in French and are omitted from this edition. Some pages of the original, which relate to IEC administrative matters, are omitted from this edition.

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 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) Substitute a full point for a comma where it appears as a decimal marker.

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

<i>Reference to International Standard or other publication</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS/NZS	
513	Fundamental aspects of safety standards for medical electrical equipment	4513	Approval and test specification— Medical electrical equipment— Fundamental aspects of safety Standards
		AS	
601	Medical electrical equipment	3200	Approval and test specification— Medical electrical equipment

iii

IEC		AS/NZS	
601-1	Part 1: General requirements for safety	3200.1	Part 1: General requirements for safety
601-1/Amd 1	Amendment 1 (1991)		Amdt 1 December 1992
601-1/Amd 2	Amendment 2 (1995)		Amdt 2 December 1995
601-1-1	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
788	Medical radiology—Terminology	—	
812	Analysis techniques for system reliability—Procedure for failure modes and effects analysis (FMEA)		
880	Software for computers in the safety systems of nuclear power stations Supplements to IEC 880 (45A(Sec)189 CD and 45(UK)98)	—	
1025	Fault tree analysis (FTA)	—	
1508	Functional safety—Safety-related systems (in preparation)	—	
1508.1	Part 1: General requirements		
1508.2	Part 2: Requirements for electrical/electronic/programmable electronic systems		
1508.3	Part 3: Software requirements		
1508.4	Part 4: Definitions and abbreviations of terms		
1508.5	Part 5: Guidelines on the application of Part 1		
1508.6	Part 6: Guidelines on the application of Parts 2 and 3		
1508.7	Part 7: Bibliography of techniques and measures		
ISO/IEC			
12119	Information technology—Software packages—Quality requirements and testing	—	
15026	Systems and software integrity level (in preparation)	—	
ISO		AS	
9000	Quality management and quality assurance	3900	Quality management and assurance Standards
9000.3	Guidelines for the application of ISO 9001 to the development, supply and maintenance of software	3900.3	Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software

ISO		AS	
9001	Quality systems—Model for quality assurance in design, development, production, installation and servicing	9001	Quality systems—Model for quality assurance in design, development, production, installation and servicing
prEN 1441	Medical devices/Risk analysis (in preparation)	—	

© Copyright – STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Users of Standards are reminded that copyright subsists in all Standards Australia and Standards New Zealand publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia or Standards New Zealand may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia or Standards New Zealand. Permission may be conditional on an appropriate royalty payment. Australian requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia. New Zealand requests should be directed to Standards New Zealand.

Up to 10 percent of the technical content pages of a Standard may be copied for use exclusively in-house by purchasers of the Standard without payment of a royalty or advice to Standards Australia or Standards New Zealand.

Inclusion of copyright material in computer software programs is also permitted without royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia or Standards New Zealand at any time.

V

CONTENTS

	<i>Page</i>
INTRODUCTION	vi
Clause	
SECTION 1: GENERAL	
1 Scope, object and relationship to other standards	1
1.201 Scope	1
1.202 Object	1
1.203 Relationship to other standards	1
2 Terminology and definitions	2
2.201 Defined terms	2
2.202 Degrees of requirements and miscellaneous terms	3
6 Identification, marking and documents	4
6.8 ACCOMPANYING DOCUMENTS	4
SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	
52 Abnormal operation and fault conditions	4
52.201 Documentation	4
52.202 Risk management plan	6
52.203 DEVELOPMENT LIFE-CYCLE	6
52.204 Risk management process	6
52.205 Qualification of personnel	8
52.206 Requirement specification	8
52.207 Architecture	9
52.208 Design and implementation	9
52.209 VERIFICATION	9
52.210 VALIDATION	9
52.211 Modification	10
52.212 Assessment	10
Table DDD.1 - Suggested correlation of the documentation requirement to the DEVELOPMENT LIFE-CYCLE phases	23
Figures	
201 Content of RISK MANAGEMENT FILE and RISK MANAGEMENT SUMMARY	5
CCC.1 Risk chart	15
CCC.2 Risk management process	17
DDD.1 DEVELOPMENT LIFE-CYCLE model for PEMS	21
EEE.1 Examples of PEMS/PESS structures	25
Annexes	
AAA Terminology - Index of defined terms	11
BBB Rationale	12
CCC RISK concepts	14
DDD DEVELOPMENT LIFE-CYCLE model	20
EEE Examples for PEMS/PESS structures	24
FFF Bibliography	26

INTRODUCTION

Computers are increasingly used in MEDICAL ELECTRICAL EQUIPMENT, often in critical-safety roles. The use of computing technologies in MEDICAL ELECTRICAL EQUIPMENT introduces a level of complexity which is exceeded only by the biological systems of the PATIENTS the MEDICAL ELECTRICAL EQUIPMENT is intended to diagnose and/or treat. This complexity means that systematic failures can escape practical accepted limits of testing. Accordingly, this safety standard goes beyond traditional testing and assessment of the finished MEDICAL ELECTRICAL EQUIPMENT and includes requirements for the processes by which the MEDICAL ELECTRICAL EQUIPMENT is developed. Testing of the finished product is not, by itself, adequate to address the SAFETY of complex MEDICAL ELECTRICAL EQUIPMENT.

This standard is a Collateral Standard to the General Standard. It requires that a process be followed and that a record of that process be produced to support the SAFETY of MEDICAL ELECTRICAL EQUIPMENT incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS. The concepts of RISK management and a DEVELOPMENT LIFE-CYCLE that are the basis of this standard can also be of value in the development of MEDICAL ELECTRICAL EQUIPMENT that does not include a PROGRAMMABLE ELECTRONIC SUBSYSTEM.

The effective application of the standard will require, subject to the task in hand, competency in the following:

- application of the specific MEDICAL ELECTRICAL EQUIPMENT with emphasis on SAFETY considerations;
- MEDICAL ELECTRICAL EQUIPMENT development process;
- methods by which SAFETY INTEGRITY is assured;
- techniques of RISK analysis and RISK control.

AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment

Part 1.4:

General requirements for safety—Collateral Standard: Programmable electrical medical systems

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 *Scope*

This Collateral Standard applies to the SAFETY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS), hereinafter referred to as PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).

NOTE - Some systems which incorporate software and are used for medical purposes fall outside the scope of this Collateral Standard, e.g. many medical informatics systems. The distinguishing factor/criterion is whether or not the system satisfies the definition of MEDICAL ELECTRICAL EQUIPMENT in 2.2.15 of IEC 601-1 or the definition of MEDICAL ELECTRICAL SYSTEM in 2.203 of IEC 601-1-1.

1.202 *Object*

This Collateral Standard specifies requirements for the process by which a PEMS is designed. This Collateral Standard also serves as the basis of requirements of Particular Standards, including serving as a guide to SAFETY requirements for the purpose of reducing and managing RISK. This Collateral Standard is addressed to:

- a) certification bodies;
- b) MANUFACTURERS;
- c) writers of Particular Standards.

This standard covers:

- d) requirement specification;
- e) architecture;
- f) detailed design and implementation including software development;
- g) modification;
- h) VERIFICATION and VALIDATION;
- j) marking and ACCOMPANYING DOCUMENTS.

Aspects not covered by this standard include:

- k) hardware manufacturing;
- l) software replication;
- m) installation and commissioning;
- n) operation and maintenance;
- o) decommissioning.

1.203 *Relationship to other standards*

1.203.1 *IEC 601-1*

For MEDICAL ELECTRICAL EQUIPMENT, this Collateral Standard complements IEC 601-1 and its amendments.

COPYRIGHT

When referring to IEC 601-1 or to this Collateral Standard, either individually or in combination, the following conventions are used:

- "the General Standard" designates IEC 601-1 alone;
- "this Collateral Standard" designates IEC 601-1-4 alone;
- "this Standard" designates the combination of the General Standard and this Collateral Standard.

1.203.2 *Particular Standards*

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.203.3 *Normative references*

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 601-1: 1988, *Medical electrical equipment - Part 1: General requirements for safety*
Amendment No. 1 (1991)
Amendment No. 2 (1995)

IEC 601-1-1: 1992, *Medical electrical equipment - Part 1: General requirements for safety - 1. Collateral Standard: Safety requirements for medical electrical systems*

IEC 788: 1984, *Medical radiology - Terminology*

ISO 9000-3: 1991, *Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

ISO 9001: 1994, *Quality systems - Model for quality assurance in design, development, production, installation and servicing*

2 Terminology and definitions

2.201 *Defined terms*

In this Collateral Standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard, IEC 601-1-1, this Collateral Standard or IEC 788.

An index of defined terms used in this Collateral Standard is given in annex AAA.

For the purpose of this Collateral Standard, the following additional definitions apply.

2.201.1 *DEVELOPMENT LIFE-CYCLE*: Necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the VALIDATION of the PEMS is complete.

2.201.2 *HAZARD ANALYSIS*: Identification of HAZARDS and their initiating causes.

NOTE - The quantification of HAZARD is not a part of the HAZARD ANALYSIS.

2.201.3 MAXIMUM TOLERABLE RISK : Value of RISK which is specified as the maximum which may be permitted.

NOTE - The value may be specified for the PEMS as a whole or for a particular HAZARD.

2.201.4 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS) : MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEM.

2.201.5 PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) : System based on one or more central processing units, including their software and interfaces.

2.201.6 RESIDUAL RISK : RISK identified by HAZARD ANALYSIS which remains after RISK management has been completed.

2.201.7 RISK : Probable rate of occurrence of a HAZARD causing harm, and the degree of SEVERITY of the harm.

2.201.8 RISK MANAGEMENT FILE : That part of the quality records required by this standard.

2.201.9 RISK MANAGEMENT SUMMARY : Document, which provides traceability for each HAZARD and each cause of the HAZARD to the RISK analysis and to the VERIFICATION that the RISK of the HAZARD is controlled.

NOTE - This document may be held on paper or on electronic media.

2.201.10 SAFETY : Freedom from unacceptable RISK.

2.201.11 SAFETY HAZARD (hereinafter referred to as HAZARD) : Potentially detrimental effect on the PATIENT, other persons, animals, or the surroundings, arising directly from MEDICAL ELECTRICAL EQUIPMENT.

2.201.12 SAFETY INTEGRITY : Likelihood of a safety-related system satisfactorily performing the required SAFETY functions under all the stated conditions within a stated period of time.

2.201.13 SEVERITY : Qualitative measure of the possible consequences of a HAZARD.

2.201.14 VALIDATION : Process of evaluating a PEMS or a component of a PEMS during or at the end of the development process, to determine whether it satisfies the requirements for its intended use.

2.201.15 VERIFICATION : Process of evaluating a PEMS or a component of a PEMS to determine whether the products of a given development phase satisfy the specified requirements imposed at the start of that phase.

2.202 Degrees of requirements and miscellaneous terms

In this Collateral Standard, certain terms (which are not printed in small capitals) have particular meanings, as follows:

- "shall" indicates a requirement that is mandatory for compliance;
- "should" indicates a strong recommendation that is not mandatory for compliance;
- "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;
- "specific" is used to indicate definitive information stated in this Collateral Standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;