AS/NZS 3551:2004
(Incorporating Amendment No. 1)

AS/NZS 3551:2004

Australian/New Zealand Standard™

Technical management programs for medical devices

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 23 February 2004 and on behalf of the Council of Standards New Zealand on 5 March 2004.

This Standard was published on 11 June 2004.

The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Ageing
Department of Defence (Australia)
Medical Industry Association of Australia Inc
Ministry of Economic Development (New Zealand)
Testing Interests (Australia)
The Royal Australian and New Zealand College of Radiologists
Wairarapa District Health Board

Additional Interests:

Auckland Healthcare (New Zealand)
College of Biomedical Engineering Institute of Engineers Australia
Wairarapa District Health Board
N.S.W Dept of Commerce

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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 Subcommittee HE-003-01-02, Technical Management Programs for Medical Equipment, under the responsibility of Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3551:1996.

*This Standard incorporates Amendment No. 1 (*September 2005*). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.*

The following interests played a major role in the preparation of this Standard:

Biomedical Services, New Zealand
New South Wales Department of Public Works and Services
Prince of Wales Hospital, N.S.W.
Queensland Health
Royal North Shore Hospital, N.S.W.

The principal differences between this edition and the previous edition are as follows:

(a) The introduction of a definition for ‘essential safety and performance parameter’.

(b) Detailing information on repair using non-OEM spares, manufacturer approved modification and other modifications.

(c) Amendment of the previous Compliance with Standards section on regulatory compliance to take into account the Therapeutic Goods Act and the Medical Device Directives.

(d) The mains contact current test is required only at acceptance and when the mains isolation barrier is part of a repair.

(e) With regard to frequency of testing, the introduction of risk management principles in assessing risks and hazards. A 12-monthly maximum interval is required if risk assessment is not followed.

The Standard was prepared for users of medical devices who need to —

(i) ensure that the device purchased complies with the Essential Principles of Safety and Performance;

(ii) inspect and test new devices, before commissioning, in order to ensure against manufacturing defects; and

(iii) perform routine inspections or tests on medical devices, or both, during their service life, in order to ensure their continued safety and performance.

The safe application of medical devices depends on a variety of factors. The minimum requirements are as follows:

(A) Medical electrical devices are used only in a patient area provided with appropriate protection and the reticulated mains wiring in accordance with AS/NZS 3003, *Electrical installations—Patient treatment areas of hospitals and medical and dental practices*.

(B) Appropriate equipment is used for each particular application and in accordance with an appropriate set of rules linking the type of procedure with the class of device and the electrical safety facilities provided in the patient area.

(C) Each new item of equipment is —

(1) acceptance tested prior to clinical use;

(2) subjected to routine performance testing during its useable life to detect damage, wear, component failure or changed component value which might render it unsafe; and

(3) maintained with reference to the manufacturer's instructions using formal risk analysis.

(D) The users of the device have to know, not only the medical procedure, but also the safety characteristics and operational details of the device. This can be achieved by learning and training under the supervision of either the manufacturer, the local representative, or users, or in biomedical engineering departments.

(E) Users and, where applicable, the biomedical engineering department or service provider, need to ensure that safety and performance of the device is maintained by an effective maintenance scheme with regular servicing in accordance with this Standard.

Many tests in this Standard are derived from the tests specified in AS/NZS 3200.1.0, *Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard,* and in no case are intended to be more stringent than those in AS/NZS 3200.1.0.

Recommendations linking the type of medical procedures with the appropriate type and class of medical electrical equipment and the type of protective facilities in the reticulated mains wiring are not covered in this Standard but are published as AS/NZS 2500, *Guide to safe use of electricity in patient care*.

Design requirements for type examination and approval of medical electrical devices are not considered in this Standard but are set out in AS/NZS 3200.1.0 and Collateral Standards, and the relevant Part 2 Standards in the AS/NZS 3200 series. In this regard, it is important to note the following:

(1) The test requirements of the AS/NZS 3200 Part 2 Standards can be applied to a sample of the device to verify that the basic design and manufacture complies with these Standards before the device is introduced to the market.

(2) Many of the tests in the AS/NZS 3200 Part 2 Standards are too extensive to be applied on a routine basis to each item of equipment delivered to a hospital or health care facility. Some inspection and testing requirements of the AS/NZS 3200 Part 2 Standards are potentially destructive of the device or its components. Some of those type tests, if applied to each item of equipment purchased, would render the device inoperative or unsafe for use.

(3) Few organizations and health care facilities have the resources to carry out type testing to the full requirements of the AS/NZS 3200 Part 2 Standards.

(4) For the reasons outlined above, it is not appropriate, nor would it be cost effective, to carry out all the inspection and testing required in the AS/NZS 3200 Part 2 Standards on every item of equipment to be commissioned.

(5) The AS/NZS 3200 Part 2 Standards modify the Parent Standard and are totally dependent on AS/NZS 3200.1.0 for the bulk of requirements.