

Australian/New Zealand Standard™

Management programs for medical equipment



AS/NZS 3551:2012

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Australian Dental Association
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Management programs for medical equipment

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3551:2004.

This Standard incorporates Amendment No. 1 (October 2013) and Amendment No. 2 (September 2016). 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 principal differences between this edition and the previous edition are as follows:

- (a) Principles from quality management and risk management standards have been incorporated throughout the document.
- (b) Introduction of the requirements for hire and loan equipment.
- (c) Introduction of the term ‘performance verification’ which encompasses physical, functional, and electrical testing.
- (d) Change in earth leakage current tests to align with IEC 60601-1, Ed. 3.0.
- (e) Addition of touch current testing to align with IEC 60601-1, Ed. 3.0.
- (f) Addition of the medical electrical systems section (Section 7) to align with IEC 60601-1, Ed. 3.0.
- (g) Management of medical equipment configurations during medical equipment maintenance.
- (h) Introduction of test requirements for non-medical equipment used in a patient environment.
- (i) Introduction of terms ‘service entity’ and ‘responsible organization’.
- (j) Introduction of requirements for management of medical equipment used in the home.

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

- (i) ensure that medical equipment used in the responsible organization perform as intended by the manufacturer and is safe for clinical use;
- (ii) ensure that the medical equipment complies with the essential principles of safety and performance;
- (iii) inspect and test new medical equipment, before commissioning, in order to ensure against manufacturing defects; and
- (iv) perform maintenance, routine inspections or tests on medical equipment during its service life, in order to ensure its continued safety and performance.

This Standard is intended to provide a practical approach and application of the testing philosophies of AS/NZS 3200.1.0 and associated Part 2 Standards, along with other essential performance verification principles, to ensure that medical equipment, in clinical use in the responsible organization, performs as intended by the manufacturer and does not compromise the safety of the patient, the operator or the environment.

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 equipment 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:

- (A) The test requirements of the AS/NZS 3200 Part 2 Standards can be applied to a sample of the medical equipment to verify that the basic design and manufacture complies with these Standards before the medical equipment is introduced to the market.
- (B) 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 healthcare facility. Some inspection and testing requirements of the AS/NZS 3200 Part 2 Standards are potentially destructive of the medical equipment or its components. Some of those type tests, if applied to each item of equipment purchased, may render some or all of them inoperative or unsafe for use.
- (C) Few organizations and healthcare facilities have the resources to carry out type testing to the full requirements of the AS/NZS 3200 Part 2 Standards.
- (D) For these reasons, 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.
- (E) 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.

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

Statements expressed in mandatory terms in notes to tables and figures are deemed to be requirements of this Standard.

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FOREWORD

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

- (a) Medical electrical equipment is used only in a patient area provided with appropriate protection and the reticulated mains wiring in accordance with AS/NZS 3003, *Electrical installations—Patient areas*.
- (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 medical equipment and the electrical safety facilities provided in the patient area.
- (c) Each new item of equipment is—
 - (i) acceptance tested prior to clinical use;
 - (ii) subjected to routine performance verification during its useable life to detect damage, wear, component failure or changed component value which might render it unsafe; and
 - (iii) maintained with reference to the manufacturer's instructions using formal risk analysis within a risk management framework.
- (d) The users of the medical equipment must know, not only the medical procedure, but also the safety characteristics and operational details of the medical equipment. This can be achieved by learning and training under the supervision of the manufacturer, the local representative, experienced users, or staff from biomedical engineering departments or the service entity.
- (e) The responsible organization needs to ensure that safety and performance of the medical equipment is maintained by an effective maintenance scheme with regular assessment, testing and maintenance in accordance with this Standard.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard
Management programs for medical equipment

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard outlines procedures required to develop management programs for medical equipment. These include protocols and procedures for procurement, acceptance, maintenance activities throughout the service life of the medical equipment, and finally disposal of medical equipment.

This Standard applies to non-electrical medical equipment, such as ventilators, which may be solely pneumatic or fluidic in operation, as well as medical electrical equipment. Also included in the scope are products that are not generally considered to be medical equipment, but are used in the patient environment, such as computers, imaging cameras and recorders.

This Standard applies whether the medical equipment is owned by the responsible organization, privately owned, on loan, on hire, on trial or donated, and includes medical equipment provided by a responsible organization as part of a pool of medical equipment for hire. It does not apply to the electrical commissioning requirements of permanently installed medical electrical devices as specified in AS/NZS 3003.

Although this Standard is focused on the management of medical equipment within an organization, it is acknowledged that some responsible organizations may choose to use many of the protocols and procedures of this document to manage medical equipment in other areas, for example laboratories. In such circumstances, the organization, or its service entity, will have to consider the relevance of some of the requirements outlined in this document.

In developing this Standard, reference has been made to manufacturer's specifications for a wide range of commercially available medical equipment. It is not possible in this Standard to address every type of medical equipment, particularly since new treatment modalities and medical equipment will be marketed during the life of the Standard. It is therefore important to make reference to manufacturer's specifications for the operation, performance testing and calibration of any new medical equipment, and to balance this with a knowledge of professional biomedical engineering practice for similar equipment.

Where the acceptance values of an AS/NZS 3200 Part 2 Standard for a particular type of medical electrical equipment are not in agreement with the requirements of AS/NZS 3200.1.0:1998 or IEC 60601-1, Ed. 3.0 (2005), the requirements of the Part 2 Standard override these documents. For example, the normal limit (specified in AS/NZS 3200.1.0) for mains contact current is 50 μA per Applied Part, while AS/NZS 3200.2.4 specifies an allowable current of 100 μA for Type CF defibrillator Applied Parts. It should also be noted that, in some instances, allowable limits applicable for acceptance testing may be more stringent than for ongoing performance verification.

1.2 APPLICATION

This Standard is intended for use by persons with management responsibility for medical equipment to ensure that it is safe and suitable for its intended clinical use. The Standard is intended to guide the in-house biomedical engineering service, and external contract service entities responsible for the procurement, testing, installation, maintenance, calibration and operation of medical equipment for use within the organization. It is meant to address the disparate needs of teaching hospitals, small hospitals, biomedical engineering service groups and other healthcare providers. While the operational modes of these groups may differ widely, the overall perspective is one of keeping medical equipment safe and functional.

The principles and provisions contained in this Standard have been framed in a manner considered suitable for application by public and private hospitals, healthcare centres and clinics, and service entities responsible for supporting the safe use of medical equipment.

1.3 REFERENCED DOCUMENTS

This Standard has been designed, as far as practicable, as a stand-alone document capable of implementation without reference to other Standards. However, the following documents are referred to in this Standard:

AS	
2125	General conditions of tendering and form of tender
AS/NZS	
2500	Guide to the safe use of electricity in patient care
3003	Electrical installations—Patient areas
3112	Approval and test specification—Plugs and socket-outlets
3200	Medical electrical equipment (series)
3200.1.0	Part 1.0 General requirements for safety—Parent Standard
3200.2.4	Part 2.4: Particular requirements for safety—Cardiac defibrillators
3760	In-service safety inspection and testing of electrical equipment
4513	Medical electrical equipment—Fundamental aspects of safety Standards
60320	Appliance couplers for household and similar general purposes
60320.1	Part 1: General requirements (IEC 60320-1, Ed. 2.0 (2001) MOD)
AS ISO	
13485	Medical devices—Quality management systems—Requirements for regulatory purposes
AS/NZS ISO	
31000	Risk management—Principles and guidelines
ISO	
14971	Medical devices—Application of risk management to medical devices
IEC	
60601	Medical electrical equipment
60601-1	Part 1: General requirements for basic safety and essential performance

1.4 DEFINITIONS

For the purpose of this Standard, the definitions below apply.

1.4.1 Accessory

An additional part for use with the medical equipment in order to—

- (a) achieve the intended purpose of the medical equipment;
- (b) adapt it to some special use;
- (c) facilitate its use;
- (d) enhance its performance; or
- (e) enable its functions to be integrated with those of other equipment.

NOTES:

- 1 An accessory should not be confused with a spare part to medical equipment. An accessory is an additional item of equipment intended to adapt, enhance or interconnect medical equipment and provide additional functionality, whereas a spare part (see Clause 1.4.56) is intended to replace an element of the medical equipment, where the presence and correct operation of that element is essential to safe and correct operation of the medical equipment.
- 2 Medical equipment may rely on consumable items for correct operation, e.g. fluid chambers for humidification, infusion sets for pumps, and covers and sleeves for thermometers. For the purposes of this Standard, these are considered accessories to the medical equipment.

1.4.2 Acceptance procedure

A set of processes, both administrative and technical, required to be performed before new medical equipment is released for clinical use.

1.4.3 Appliance inlet

Part of an appliance socket either integrated in or fixed to medical electrical equipment—commonly referred to as a mains inlet connector.

1.4.4 Applied Part

1.4.4.1 General definition

Part of medical equipment that in normal use necessarily comes into physical contact with the patient for the medical equipment or medical electrical system to perform its function.

Excluded are other parts that are only likely to be contacted following an unnecessary action by the patient. For the purpose of this definition, the medical equipment includes those accessories that are necessary for the intended use of the equipment.

NOTES:

- 1 For some medical equipment, AS/NZS 3200 Part 2 Standards may also consider parts in contact with the operator as Applied Parts.
- 2 Identification of Applied Parts only relates to medical electrical equipment. AS/NZS 3200.1.0 requires all Applied Parts be classified by the manufacturer as B, BF or CF (see Clauses 1.4.4.2, 1.4.4.3, 1.4.4.4, 1.4.4.5 and 1.4.4.6) and marked accordingly. Individual Applied Parts of the same item of medical equipment may be classified differently.
- 3 A detailed explanation of how the term Applied Part is used in this Standard is given in Appendix L.

1.4.4.2 Type B Applied Parts

Those marked with the symbol 

1.4.4.3 Type BF Applied Parts

Those marked with the symbol 

1.4.4.4 Type BF Applied Parts defibrillator proof

Those marked with the symbol 

1.4.4.5 Type CF Applied Parts

Those marked with the symbol 

1.4.4.6 Type CF Applied Parts defibrillator proof

Those marked with the symbol 

1.4.5 Class I electrical equipment

Medical electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed.

1.4.6 Class II electrical equipment

Medical electrical equipment in which protection against electric shock does not rely on basic insulation only but in which additional safety precautions, such as double insulation or reinforced insulation, are provided, there being no provision for protective earthing or reliance upon installation conditions.

NOTE: Class II electrical equipment does not utilize a protective earthing conductor in the power supply cord but may have a functional earth.

1.4.7 Corrective maintenance

Maintenance carried out after fault recognition and intended to restore an item into a state in which it can safely perform its specified function.

1.4.8 Earth leakage current

Current flowing from the mains part through or across the insulation into the protective earth conductor.

1.4.9 Essential performance parameter

Any function, alarm, protective equipment, part or parameter that needs to perform accurately and reliably to achieve freedom from unacceptable risk and for the continued safe use of the medical equipment for both the patient and the operator.

NOTE: Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk. Refer to Appendix E for guidance on parameters.

1.4.10 Expected service life

Maximum period of useful operational life of the medical equipment, as defined by the manufacturer.

1.4.11 Fixed equipment

Equipment that is fastened or otherwise secured at a specific location in a building or a vehicle and can only be detached by means of a tool.

1.4.12 Functional earth

A terminal directly connected to a circuit or a screening part, which is intended to be earthed for functional purposes.

1.4.13 Harm

Physical injury or damage to the health of people, or damage to property or the environment.

1.4.14 Hazard

Potential source of harm.

1.4.15 Hazardous situation

Circumstance in which people, property or the environment are exposed to one or more hazards.

1.4.16 Intended use/Intended purpose

Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer.

NOTE: Intended use should not be confused with normal use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose for which the equipment is used, while normal use incorporates not only the medical purpose, but maintenance, service, transport, and other influences as well.

1.4.17 Mains part

Electrical circuit that is intended to be connected to the supply mains.

NOTES:

- 1 The mains part includes all conductive parts that are not separated from the supply mains by at least one means of protection.
- 2 For the purpose of this definition, the protective earth connector is not regarded as a part of the mains part.

1.4.18 Maintenance

Combination of all technical and administrative actions including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform its specified function.

1.4.19 Measuring equipment (MD)

An electrical current to voltage converter, as defined in Appendix C, used to perform current measurements described in this Standard.

1.4.20 Medical electrical system

Combination of either medical equipment or multiple medical devices, which may also include other non-medical equipment, having a specified function and connected by either a physical connection or an electrical interconnection. A multiple socket-outlet is an example of an electrical connection.

NOTES:

- 1 The medical electrical system includes those accessories that are needed for operating the system.
- 2 The medical electrical system may also include devices that are not within the patient area, e.g. external printer, computer etc.

1.4.21 Medical equipment/Medical device

Any instrument, apparatus or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation, that makes physical or electrical contact with the patient, or transfers energy to or from the patient, or detects such energy transfer to or from the patient, or is intended to diagnose, treat or monitor a patient.

NOTES:

- 1 Items of equipment that were not originally designed as medical equipment, but which are supplied as part of, or interfaced with, other medical equipment, are considered to be themselves part of a medical electrical system, and subject to the requirements of this Standard.
- 2 Although this Standard relates to medical equipment, some institutions may use many of the same procedures for the management of equipment used in other areas such as laboratories. In such circumstances, the responsible organization, or the service entity, will have to consider the relevance of some of the requirements outlined in this document.

1.4.22 Mobile

Term referring to moveable equipment intended to be relocated from one location to another, while being supported by its own wheels or equivalent means, by one or more persons.

1.4.23 Network/data coupling

Any means to transmit or receive information to or from other equipment in accordance with the manufacturer's specifications.

1.4.24 Normal condition

Condition in which all means provided for protection against hazards are intact.

1.4.25 Normal use

Operation, including routine inspection and adjustments by any operator, and stand-by, according to the instructions for use.

NOTE: Normal use should not be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose for which the equipment is used, while normal use incorporates not only the medical purpose, but maintenance, service, transport and other possible influences.

1.4.26 Patient

Living being (person) undergoing medical or dental investigation or treatment.

NOTE: A person under treatment for cosmetic purposes may be considered as a patient.

1.4.27 Patient area

Locations where it is intended that low-voltage medical electrical equipment will be used on a patient. This does not include areas such as corridors and lifts where such equipment is only used in an emergency.

1.4.28 Patient connection

Every individual part of an Applied Part from which a current may flow through the patient with the equipment in the normal condition or single fault conditions.

NOTE: This includes those conducting parts of an Applied Part that make direct electrical contact with the patient or with liquid that in turn enters the patient.

1.4.29 Patient environment

The space shown in Figure 1 extending 1500 mm around all possible patient locations.

Where adjacent patient environments overlap, the combined area is deemed one patient environment.

The patient environment does not extend through walls.

A patient environment may contain one or more patient locations.

NOTES:

A2

- 1 The patient environment is intended to embrace all patient locations in which intentional or unintentional electrical contact could occur between the patient and any other object, directly or via another person touching the patient and the object.
- 2 Every possible location of the patient should be considered when determining the extent of the patient location. Refer to Clause 1.4.31.

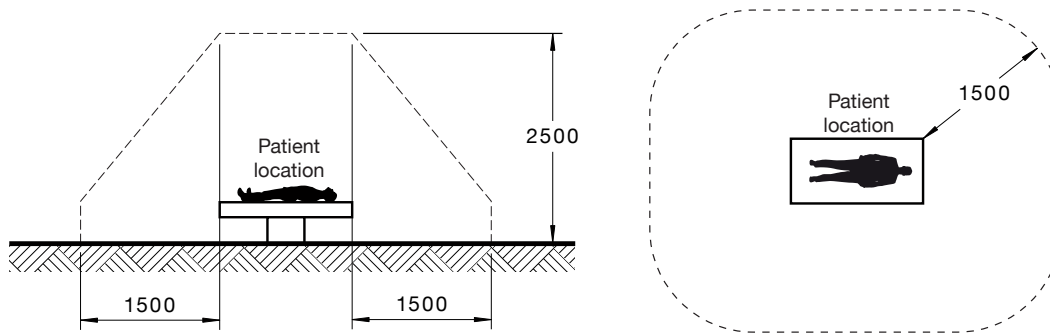


FIGURE 1 PATIENT ENVIRONMENT AND PATIENT LOCATION

NOTE: The patient environment is the area enclosed by dashed line.

1.4.30 Patient leakage current

That current flowing from the patient connections via the patient to earth, or originating from the unintended appearance of a voltage from an external source on the patient and flowing from the patient via the patient connections of an Applied Part to earth.

1.4.31 Patient location

Any intended location of the bed, table or seating arrangement for a patient, whether or not occupied by the patient.

Where the location of a patient undergoing a body-type or cardiac-type procedure is likely to vary for different occasions (e.g. in some operating theatres) the patient location extends to the entire room. This includes locations for incubators or cribs in delivery suites.

1.4.32 Performance verification

Testing the essential performance parameters of the medical equipment. This will require a range of physical, functional and electrical tests to confirm it is capable of performing safely and as intended by the manufacturer.

1.4.33 Permanently installed equipment

Term meaning electrically connected to the supply mains by means of a permanent connection that can only be detached by the use of a tool.

1.4.34 Portable

Term referring to equipment intended to be carried from one location to another by one or more persons.

1.4.35 Power supply cord

Flexible cord, fixed to, or assembled with electrical equipment, for connection to the supply mains.

1.4.36 Preventive maintenance

Maintenance carried out at predetermined intervals, or according to prescribed criteria, and intended to reduce the probability of failure or the degradation of the functioning of an item.

1.4.37 Protective earth conductor

A conductor to be connected between the protective earth terminal and an external protective earthing system.

1.4.38 Protective earth connection

A connection within the medical equipment to the protective earth terminal provided for protective purposes.

1.4.39 Protective earth terminal

A terminal connected to conductive parts of Class I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a protective earth conductor.

1.4.40 Protectively earthed

An arrangement in which the medical equipment is connected to the protective earth terminal for protective purposes.

NOTE: The terms 'protective earthing', 'earth' or 'earthing' used without qualification in this Standard are intended to mean an earth that is incorporated to provide protection from electric shock (as distinct from a 'functional earth' which may be provided to ensure proper functioning of the equipment, but is not deliberately included to provide protection against electric shock).

1.4.41 Residual risk

The risk remaining after risk treatment measures have been taken.

1.4.42 Responsible organization

The entity accountable for the use and maintenance of medical equipment or a medical electrical system.

NOTES:

- 1 The accountable entity may be, for example, a hospital, an individual clinician or a layperson. In home use applications, the patient, operator and responsible organization can be one and the same person.
- 2 Education and training is included in 'use'.

1.4.43 Risk

The combination of the probability of occurrence of harm and the severity of that harm.

1.4.44 Risk analysis

The systematic use of available information to identify hazards and to estimate the risk.

1.4.45 Risk assessment

The overall process comprising a risk analysis and risk evaluation.

1.4.46 Risk control

Process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels.

1.4.47 Risk evaluation

A judgement, on the basis of risk analysis, of whether a risk that is acceptable has been achieved in a given context based on the current values of society.

1.4.48 Risk management

The systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risk.

1.4.49 Risk management file

The set of records and other documents, not necessarily contiguous, that are produced by a risk management process.

1.4.50 Routine maintenance

See Clause 1.4.36.

1.4.51 Safety

A condition in which there is freedom from unacceptable risk.

1.4.52 Service entity

Entity, person or persons accountable to the responsible organization for providing the medical equipment management services outlined in this Standard.

NOTE: The accountable entity may be, for example, an in-house biomedical engineering group, a medical equipment manufacturer or authorized representative, an independent organization, or a combination of these entities engaged by the responsible organization to deliver the requirements of the medical equipment management program to the responsible organization.

1.4.53 Severity

A measure of the possible consequences of a hazard.

1.4.54 Signal input/signal output part

Medical electrical equipment parts, excluding Applied Parts or circuits operating above extra-low voltage that are intended to receive or deliver signal voltages or currents (e.g. for display, recording or data processing).

1.4.55 Single fault condition

A condition in which a single means for reducing a risk is defective or a single abnormal condition is present.

1.4.56 Spare part

A substitute item, intended to replace an original component, assembly or subassembly of medical equipment, where the item is either—

- (a) a direct replacement (generally supplied, or specified, by the original equipment manufacturer (OEM)); or
- (b) an equivalent assessed by the service entity as being a suitable replacement for the original component contained in the medical equipment (which is not necessarily sourced from the OEM), and which is essential for the safe and correct operation of the medical equipment.

NOTES:

- 1 A spare part should not be confused with an accessory (see Clause 1.4.1) to medical equipment. A spare part is intended to replace an element of the medical equipment, where its presence and correct operation is essential to safe and correct operation, whereas an accessory is an additional item of equipment intended to adapt, enhance or interconnect medical equipment and provide additional functionality for the medical equipment.
- 2 Examples of an equivalent spare part include a replacement halogen globe that has been in a theatre or examination light, which has been confirmed as having the same spectral characteristics as the original, and battery packs that are confirmed as having the same capacity, characteristics and protective/safety measures as the OEM assembly.

1.4.57 Supply mains

Source of electrical energy not forming part of the medical equipment or medical electrical system.

1.4.58 Touch current

Leakage current flowing from the enclosure or from parts thereof, excluding patient connections, accessible to any operator or patient in normal use, through an external path other than the protective earth conductor, to earth or to another part of the enclosure.

NOTE: The meaning of this term is the same as that of 'enclosure leakage current' in the first and second editions of IEC 60601-1. The term has been changed to align with IEC 60950-1 (adopted in New Zealand and Australia as AS/NZS 60950.1:2011) and to reflect the fact that the measurement now applies also to parts that are normally protectively earthed.

A1

1.4.59 Hiree

The person or business that receives the equipment from the hirer or lessee.

1.4.60 Hirer

The person or business that offers the equipment for hire or lease.

SECTION 2 MEDICAL EQUIPMENT MANAGEMENT PROGRAM

2.1 GENERAL

A program shall be implemented for the management of the medical equipment in the responsible organization's inventory, used within its premises, under its jurisdiction or in conjunction with patients under its care.

The medical equipment management program should consider, at least, the following:

- (a) Establishment of risk criteria to guide the medical equipment program.
- (b) Criteria for selecting and acquiring medical equipment.
- (c) High level policies on maintenance strategies.
- (d) Provision of sufficient resources for implementing the requirements of this Standard.
- (e) Criteria for replacing/upgrading medical equipment.
- (f) Safe disposal of obsolete medical equipment.
- (g) Ongoing evaluation of the effectiveness of the program.

2.2 PROGRAM SUPPORT FUNCTIONS

2.2.1 Responsibility, authority and communication

The responsibilities and authorities for operating the medical equipment management program shall be defined, documented and communicated within the responsible organization.

Responsibility for the medical equipment management program shall be assigned to an individual or committee from the staff responsible for the use and application of the medical equipment, biomedical engineering staff employed within the organization, or a qualified and experienced biomedical engineering consultant engaged by the organization.

A staff member from the responsible organization shall be designated with the responsibility and management authority to—

- (a) identify the processes needed for the medical equipment management program;
- (b) determine the timing, sequence and interaction of these processes;
- (c) determine the criteria and methods required to ensure the effective operation of the medical equipment management program;
- (d) ensure the availability of information necessary to support the operation and monitoring of the processes;
- (e) measure, monitor and review the processes and implement action necessary to ensure effective operation of the medical equipment management program; and
- (f) measure monitor and review a plan for cyclical long term replacement of medical equipment.

2.2.2 Resources

2.2.2.1 General

The resources required to implement, maintain and monitor the medical equipment management program in compliance with the requirements of this Standard shall be provided.

NOTE: These resources would usually be provided by the responsible organization.

Criteria shall be defined for reviewing the suitability of the existing service entity or any potential new service entity of medical equipment management services.

Review criteria should include—

- (a) formal qualifications in engineering or technological disciplines;
- (b) training in areas of medical equipment technology;
- (c) expertise in the maintenance of a particular category of medical equipment;
- (d) knowledge of relevant standards, legislation, regulations and codes of practice;
- (e) ability to provide loan medical equipment;
- (f) access to spare parts and medical equipment documentation;
- (g) capability to manage an ongoing medical equipment maintenance program;
- (h) capability to respond quickly when required, e.g. 'on call' service;
- (i) contacts, resources and availability of reference to appropriate expertise;
- (j) eligibility for membership of relevant professional groups;
- (k) references from other customers; and
- (l) cost of proposed services.

2.2.2.2 *Human resources*

Personnel engaged in implementing the requirements of the medical equipment management program shall be adequately trained in biomedical engineering and suitably qualified in engineering, and have the necessary knowledge and training to manage and maintain the medical equipment specific to the organization.

Attention needs to be paid to any local statutory requirements involving registration or licensing—when, for example, working on medical equipment using or emitting ionizing/non-ionizing radiation, lasers and pressure vessels.

2.2.2.3 *Technical training*

Training of personnel is a key element in ensuring safe and effective maintenance and repair of medical equipment. All personnel shall be trained to understand the basic principles on which the medical equipment works (generic training). In addition, repair and maintenance of particular brands/models of medical equipment in use in the institution should only be undertaken by appropriately trained staff (specific training).

2.2.2.4 *Training records*

As part of the management program, records of staff training shall be kept. This may be as part of the central record keeping, or records held by user departments. The records shall include the date and details of the training, persons participating, instructors and medical equipment covered by the training.

2.2.2.5 *Work environment*

Requirements for health, cleanliness and clothing of personnel shall be established and documented if contact between such personnel and the work environment could adversely affect either the health of personnel or the safety of the medical equipment, for example when work on medical equipment is undertaken in environmentally controlled areas such as operating theatres or controlled laboratory environments.

Where applicable, all personnel who are required to work temporarily under special environmentally controlled conditions within the work environment shall be appropriately trained or supervised by a trained person.

If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated medical equipment in order to prevent contamination of the work environment, personnel or other medical equipment in the area.

2.2.2.6 Infrastructure

The support infrastructure required for effective implementation of the medical equipment management program shall be identified, documented, provided and maintained, and shall include the following, as appropriate:

- (a) Adequate accommodation, workspace and storage areas that comply with relevant occupational health and safety regulations.
- (b) Test equipment and related technical resources (both hardware and software), including any specialized testing equipment, as required to meet the specific provisions of this Standard.
- (c) Supporting services such as transport and communication as required.
- (d) Specialized facilities if staff are required to perform equipment decontamination, work with lasers or work with devices emitting ionizing radiation.
- (e) Containment areas if hazardous substances are encountered.

2.3 TEST EQUIPMENT

2.3.1 General

Test equipment used in the medical equipment management program shall, as appropriate, be maintained within a calibration program. If required to be calibrated, it shall be traceable to appropriate reference standards.

The prescribed regularity of performance verification/calibration of any test equipment used for certification of medical equipment will vary according to the equipment, and should not be less than required by the manufacturer. In the absence of guidance from the medical equipment manufacturer, annual performance verification should be taken as a general guideline. Some test equipment may require more regular performance verification/calibration if particularly sensitive to usage conditions, or if damage or maltreatment is suspected.

In some cases, extreme stability of some test equipment may also lead calibration agencies to advocate repeated performance verification or calibration of test equipment less frequently than annually, subject to the performance of in-house verification test procedures utilizing secondary standards. In such cases, the service entity shall have documented protocols and procedures to ensure compliance, along with appropriate record keeping of equipment calibration status.

Advice on the traceability of measurement and suitable test organizations appropriate to various measurements is available from the following:

- (a) The equipment supplier.
- (b) The National Association of Test Authorities Australia.
- (c) National Measurement Institute.
- (d) International Accreditation New Zealand.
- (e) Equivalent overseas organizations.

2.3.2 Traceability of test equipment in use

Records shall be established and maintained to enable the service entity to identify the test equipment maintained within the calibration program and used for acceptance testing or performance verification, and sufficient to identify which test equipment was used for each entry recorded in the medical equipment database.

2.4 DOCUMENTATION REQUIREMENTS

2.4.1 Control of documentation

Documents used in the delivery of the medical equipment management program shall be controlled.

A document control procedure shall be established to define the controls needed to—

- (a) review and approve documents for adequacy prior to issue;
- (b) review and update as necessary, and re-approve documents;
- (c) ensure that changes and current revision status of documents are identified;
- (d) ensure that relevant versions of applicable documents are available for use;
- (e) ensure documents remain legible and readily identifiable;
- (f) ensure documents of external origin are identified and their distribution controlled; and
- (g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

2.4.2 Operations manual

The management program shall be supported by an operations manual which includes, at least, the following:

- (a) The scope of the medical equipment management program, including details of any medical equipment or medical equipment categories excluded from the medical equipment management system, including rationale for the exclusion(s).
- (b) Description of the structure of the documentation used in support of the medical equipment management program.
- (c) The documented procedures established to implement the management program.

These procedures will include both high level procedures, such as overarching policymaking decision processes, and lower level documents, such as specific test procedures for particular models of medical equipment.

2.4.3 Supporting documentation

Documents such as standards, user guides, technical manuals and other supporting publications shall be identified, stored, issued and updated in a controlled manner.

2.4.4 Hazard and recall notices

Records of published recalls and hazard notification should be included in each device documentation file, although a register of each may be kept centrally with details of action taken. Records of any amendment or modification to individual devices as a result of such notifications shall be kept in the individual device record in the equipment database.

2.5 EQUIPMENT DATABASE

2.5.1 General

Records shall be established and maintained to provide evidence of adequate and effective operation of the medical equipment management program. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and ultimate disposal of records.

Generally, these records will consist of a medical equipment database comprising a record for each item of medical equipment, implemented and maintained by adding a new record for each new item of medical equipment, and supplemented by the responsible organization and/or service entity(ies) performing a periodic stocktake of equipment. This database shall assign a unique identifying number to each device to facilitate individual medical equipment identification.

Attention should be paid to the backing up of records.

2.5.2 Medical equipment details

The database shall contain sufficient information to individually identify each piece of equipment. Typically this will consist of, at least—

- (a) the unique identifying number assigned to each item of medical equipment to facilitate individual medical equipment identification;
- (b) nomenclature code identifying medical equipment type (Typically GMDN or UMDNS);
- (c)
- (d) medical equipment description (based on nomenclature code);
- (e) identification and contact details of manufacturer;
- (f) identification and contact details of supplier;
- (g) medical equipment model number and/or family name;
- (h) medical equipment serial number;
- (i) software version details;
- (j) support contract details;
- (k) department in which the medical equipment is located;
- (l) service entity;
- (m) purchase date and cost; and
- (n) warranty details (if relevant).

2.5.3 History

The database shall contain a history for each item of medical equipment that includes the dates, details and results of the following:

- (a) Acceptance testing.
- (b) Corrective maintenance, including—
 - (i) a description of the problem necessitating remedial action;
 - (ii) details of the work performed (including supplier modifications);
 - (iii) labour details;
 - (iv) details and cost of parts; and
 - (v) dates of removal and return to service.
- (c) Performance verification tests.
- (d) Preventive maintenance activities undertaken.
- (e) Corrective action as a result of recall notification or field modification notices.
- (f) Identification of personnel performing work for each activity.
- (g) Date of permanent removal from service.

NOTE: Identification of test equipment used in performance of acceptance checking and performance verification is only required for test equipment maintained within the calibration program cited in Clause 2.3.1.

Depending on acceptance and maintenance procedures, these records may be contained in one or more separate databases. However, in such circumstances there shall be a means to identify the individual records for a piece of medical equipment from the different databases.

2.5.4 Recording of medical electrical systems

To support ongoing testing and assessment activities, the medical equipment database shall contain a record for each medical electrical system in use. That record shall detail the individual medical equipment constituting the system.

The individual items of equipment that constitute the medical electrical system shall also be recorded separately in the database.

Further explanation of medical electrical systems is provided in Section 7.

2.5.5 Document control

Documents required by the medical equipment management program shall be controlled. The retention period should take into account the expected in-service life of the medical equipment within the organization to which the document refers and the record keeping policies of the organization.

In establishing retention times for medical equipment specific records, consideration needs to be given to statutory requirements for medical records associated with patient treatment delivery.

Where medical equipment management activities are contracted by the responsible organization to an external service entity, the following shall be clarified and documented:

- (a) the ownership of, and access to, the records;
- (b) responsibility for maintenance of the records; and
- (c) in the event of termination of the commercial relationship with the service entity, ongoing access to these records.

Retention of numerical values of tests and inspection results by the responsible organization using the medical equipment is an important component of responsible medical equipment management and is essential to provide continuity in the event of a change in the service entity, with copies retained by the service entity undertaking the acceptance testing. Results of previous testing should also be available for future reference by maintenance or testing staff to assist in the conduct of subsequent tests.

2.6 MAJOR PROGRAM FUNCTIONS

Procurement, acceptance procedures, safety and performance verification, maintenance procedures during the service life and the final disposition of the medical equipment are the major processes within a medical equipment management program.

These processes are, in turn, supported by high level policies relating to implementation of risk management, resource planning and allocation, maintenance scheduling and the keeping of records relating to implementation of the management program.

Specific requirements for each of these functions are detailed in the following sections:

- (a) Regulatory compliance—Section 3.
- (b) Procurement—Section 4.
- (c) Acceptance procedures—Section 5.

- (d) Performance verification and maintenance—Section 6.
- (e) Application of risk management principles—Appendix A.
- (f) Recall management—Clause 6.9.

SECTION 3 REGULATORY COMPLIANCE

3.1 GENERAL EVIDENCE OF REGULATORY COMPLIANCE

Evidence of compliance with regulatory requirements allowing supply in the relevant jurisdiction shall be obtained before placing medical equipment into clinical use.

NOTE: This should be performed by the responsible organization.

3.2 MARKETING AUTHORIZATION

In Australia, evidence of regulatory compliance shall include a copy of the ARTG Inclusion Certificate provided to the sponsor by the Australian Therapeutic Goods Administration (TGA) at the time of inclusion of the medical equipment on the Australian Register of Therapeutic Goods (ARTG).

In New Zealand this evidence shall include a copy of the sponsor's entry of the medical equipment into the WAND database operated by Medsafe, providing the inclusion number, and a copy of one of the following:

- (a) The ARTG Inclusion Certificate.
- (b) The Declaration of Conformity, in accordance with the requirements of the European Council Directive 93/42/EEC on medical devices.
- (c) The Declaration of Conformity, in accordance with the requirements of the European Council Directive 90/385/EEC on Active Implantable Medical Devices.
- (d) The Declaration of Conformity, in accordance with the requirements of the European Council Directive 98/79/EEC on In Vitro Diagnostic Medical Devices.

In both Australia and New Zealand, regulatory compliance is the responsibility of the sponsor of the medical equipment. Both the TGA and Medsafe require the product sponsor to be a person or organization that is resident in Australia or New Zealand respectively.

3.3 ELECTROMAGNETIC COMPATIBILITY

In Australia, electromagnetic compatibility (EMC) of medical equipment is regulated by the TGA and in most instances a copy of the ARTG Inclusion Certificate is sufficient evidence of compliance.

However, for medical equipment incorporating radio transmission elements, e.g. Bluetooth communications, that element of the equipment shall comply with the EMC framework requirements of the Australian Communications and Media Authority (ACMA).

NOTE: Usually the sponsor is required to provide evidence of compliance.

For such medical equipment, evidence of compliance consists of two documents—

- (a) a copy of the ARTG Inclusion Certificate provided to the sponsor by the TGA at the time of inclusion of the medical equipment on the ARTG; and
- (b) a copy of the Supplier's Declaration of Conformity, drawn up and maintained by the medical equipment supplier under the ACMA EMC Regulatory Arrangements.

In New Zealand, electromagnetic compatibility for all equipment, including medical equipment, is regulated by the Radio Spectrum Management Group within the Ministry of Economic Development.

For all medical equipment in New Zealand, evidence to demonstrate compliance consists of a Supplier's Declaration of Conformity, prepared and signed by the New Zealand supplier or New Zealand based agent of the overseas manufacturer.

3.4 MEDICAL EQUIPMENT FOR CLINICAL TRIAL

Human clinical trials for medical equipment are one element of product development undertaken by a manufacturer prior to general release for marketing. Where these trials are undertaken within an organization, the sponsor/manufacturer will not be able to demonstrate full regulatory compliance as required by this Standard.

In undertaking clinical trials, users should ensure that the supplier has complied with appropriate regulatory requirements for the medical equipment. For example, in Australia, if the medical equipment is not formally approved for supply by the TGA, it will be necessary to gain approval from the Institutional Ethics Committee to undertake the trial, and notification made to the TGA of the conduct of the trial. In New Zealand, it will be necessary to gain approval from the Institutional Ethics Committee to undertake the trial.

In Australia, a copy of the letter from the TGA acknowledging receipt of such notification shall be required prior to use of the medical equipment within the organization.

In New Zealand, a copy of the acknowledgement from the Institutional Ethics Committee shall be provided prior to use of the medical equipment within the organization.

NOTE: Clinical trial in the context of this Clause (3.4) refers to clinical trial of medical equipment that is not approved for general marketing, where the trial is being undertaken to gather safety and effectiveness data to support an application for marketing approval.

It does not include evaluations, undertaken by an organization or user, to determine product acceptance, useability or suitability within the organization where marketing approvals already allow for general distribution. In these circumstances the requirements of Clause 3.2 apply.

SECTION 4 PROCUREMENT

4.1 SCOPE

This Section describes the procedures to be followed when procuring medical equipment to ensure that it complies with the relevant regulatory requirements, fulfils the needs of the intended users, and is of a quality appropriate to their proposed use. Some aspects are also relevant to the pre-purchase trialling of medical equipment.

4.2 PROCUREMENT PROCEDURES

4.2.1 General

The procurement process required for medical equipment acquisition should be documented. For major acquisitions this process will, most likely, establish a formal project specific committee.

The process should draw on the expertise of relevant personnel. The procurement process shall include—

- (a) clinical users;
- (b) supply services if appropriate;
- (c) administrative or financial services;
- (d) medical equipment engineering support services; and
- (e) others as appropriate, e.g. staff responsible for infection control, cleaning, OHS, ICT and radiation safety.

NOTE: In some organizations, external consultants may be engaged to provide advice in these, or other, specific areas.

This group should be responsible for developing guidelines covering all aspects of the procurement process.

In doing so, it should consider—

- (i) the circumstances under which tenders may, or may not, be required;
- (ii) the nature of any tender documents;
- (iii) the grounds on which tenders may be awarded; and
- (iv) any applicable statutory or regulatory requirements associated with the tendering process.

4.2.2 Regulatory compliance

The medical equipment shall be in compliance with the requirements outlined in Section 3 of this Standard.

4.2.3 Medical equipment devices on loan, lease or hire

All medical equipment on loan, lease or hire shall be subject to a written agreement which defines and clearly assigns all aspects of its management and operational requirements, responsibilities and liabilities. Delivery, receipt and pre-use procedures for such medical equipment shall be the same as those for purchased medical equipment unless specified otherwise in writing.

4.2.4 Pre-purchase evaluation

Pre-purchase evaluation of medical equipment may include clinical evaluation, reference to other users of similar medical equipment, statements of clinical efficacy, and evaluation of published reports and hazard alerts. The primary goal is to ensure that the user's requirements are met. However, all relevant factors should be considered.

Pre-purchase evaluation of medical equipment is used by an organization to assess currently available equipment to ensure the medical equipment will meet the clinical needs of its users.

The evaluation process should include the following:

- (a) Development of an understanding of the clinical requirements of the user.
- (b) An assessment of the human factors, useability and ongoing safety of the medical equipment, e.g. functionality of alarms, drug management software, quality of construction, operator interface, and adequacy of design to maintain acceptable accuracy.
- (c) An assessment of the whole-of-life cost of the system—including purchase cost, consumables, parts, maintenance, risk, availability of software/hardware upgrades and installation costs. In the case of larger items of equipment, this may include building modifications, requirement and availability of specialized test equipment, provision of suitable power supplies, air-conditioning, reticulated water supplies and similar.

NOTE: Assessment of the maintenance cost provides information towards setting up the maintenance and performance verification schedules at the time of medical equipment acceptance.
- (d) The service life expectancy, e.g. quality of construction, availability of parts, upgrades, obsolescence, and technology maturity.
- (e) Availability and accessibility of necessary documentation and support—operator and maintenance manuals and training, proof of compliance with relevant standards and published efficacy evidence.
- (f) Warranty duration and coverage.
- (g) Supplier support—availability of service support, e.g. fault analysis software, error log download capabilities, service contracts, loan medical equipment and consumable items.
- (h) Assessment of the ability to adequately and easily clean and decontaminate the medical equipment.
- (i) Compatibility with other medical equipment likely to be used during the same clinical procedures or during patient care.
- (j) Compatibility of individual components that may not be considered medical equipment in their own right, within a medical system.
- (k) Merits of medical equipment standardization.

4.2.5 Tenders and quotations

If the purchase of medical equipment is subject to tendering requirements, a written request for quotations or tenders will be necessary.

This should include medical equipment performance, purchasing, contractual, and delivery requirements and any other information likely to influence costs to both the potential supplier and the organization purchasing the medical equipment.

NOTE: Attention is drawn to the tendering protocols specified in AS 2125 for further guidance on tendering processes and suggested documentation.

Typically, these should include confirmation from the supplier of the following:

- (a) Medical equipment and equipment accessories will be—
 - (i) suitable for the intended application;
 - (ii) suitable for use in the available patient treatment areas; and
 - (iii) compatible with other medical equipment likely to be used during the same clinical procedures.
- (b) Medical equipment will meet documented performance standards outlined in the tender documentation.
- (c) Supporting technical documentation will be supplied, including any special delivery and installation instructions, commissioning procedures, operating instructions, technical descriptions, comprehensive technical documentation consistent with the level of intended support, maintenance and repair instructions, and calibration procedures.
- (d) Availability of technical training and, if required, specialized software for in-service inspection, preventive maintenance and repair of the medical equipment.
- (e) Instructions for use will include operating instructions and user maintenance procedures.
- (f) Details of the nature and extent of warranty and, as required, cost and availability of spare parts, service manuals, service calls and service contract will be provided.
NOTE: Clarification of the commencement date of the warranty period is essential.
- (g) All necessary specifications to demonstrate compliance with the published purchasing requirements.
- (h) A Declaration of Conformity confirming that the medical equipment offered meets all regulatory requirements in Australia and/or New Zealand (see Clause 3.1).

In the assessment of tender submissions, consideration should also be given to—

- (i) the ability of the medical equipment supplier to support the medical equipment;
- (ii) any special costs or processes involved in installation and commissioning of the medical equipment, including building modifications, provision of suitable power supplies, air-conditioning, reticulated water supplies and similar; and
- (iii) the continuing cost of ownership of the medical equipment, including projected maintenance and service costs, consumable and support services required and the expected service life of the medical equipment.

NOTE: Reference to other owners of similar medical equipment can also provide useful information concerning the likely performance of the medical equipment and technical support services available.