Australian/New Zealand Standard™

Guide to the safe use of electricity in patient care

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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 29 March 2004 and on behalf of the Council of Standards New Zealand on 30 April 2004.
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The following are represented on Committee HE-003:

Auckland District Health Board, New Zealand
Australian College of Physical Scientists and Engineers in Medicine
Australian Society for Ultrasound in Medicine
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, New Zealand
College of Biomedical Engineering, Institution of Engineers Australia
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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 Sub-Committee HE-003-09, Safe Use of Electricity in Patient Care, under the responsibility of HE-003, Medical Electrical Equipment, to supersede AS/NZS 2500:1995. It sets out guidelines for the safe use of electricity in patient care.

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

Biomedical Services, New Zealand
Department of Human Services, S.A.
Institute of Hospital Engineering, Australia
Queensland Health
Royal Melbourne Hospital

The main differences between this edition and the 1995 edition are as follows:

(a) All patient areas are now required to be at least body protected. (Refer AS/NZS 3003.)

(b) A recommendation for colour coding has been included to distinguish essential, non-essential, UPS and cleaners socket-outlets.

(c) Inclusion of requirements for medical electrical systems and upgrading of mobile communications.

(e) Upgrading of defibrillator requirements.

Safe use of medical electrical equipment (i.e. electrically operated medical equipment) depends on a variety of factors as follows:

(i) The users have to know, not only the medical procedure, but also the safety characteristics and operational details of the equipment. This can be achieved by learning and training under the supervision of either the manufacturer, his local representative, or the user's own biomedical engineering department.

(ii) The equipment has to be safe, i.e. manufacture in accordance with relevant essential principles of safety and performance.

(iii) The installations have to be safe, i.e. electrical wiring in accordance with the requirements of AS/NZS 3003.

(iv) The instructions for use have to be available at the site of use. Such instructions should be in English and written in terms acceptable to the user.

(v) Users and, where available, the biomedical engineering department have to ensure that safety and performance of the equipment are maintained by an effective maintenance scheme with regular servicing in accordance with AS/NZS 3551.

This Standard emphasizes the responsibility of the management of health care facilities to ensure selective purchasing, installation, inspection, maintenance, training and coordination of all aspects necessary to ensure adherence to safe procedures.

Building design, equipment design, purchasing specifications, inspection procedures, preventive maintenance schedules and training programs; each contributes to safety. While primary dependence is placed on the electrical distribution system and equipment, because these are most amenable to specification and control, the safety of patients and operators is equally dependent on the proper maintenance of the installation and all equipment, together with adequate education of all staff in the safe use of equipment.

Some terms, when used in medical electrical safety documents, which have a special significance, are printed in SMALL CAPITALS. An index is provided at the end of this document which indicates where substantive material can be found on these terms and other major topics discussed in the document.

The term ‘informative’ has been used in this Standard to define the application of the appendix to which it applies. An ‘informative’ appendix is only for information and guidance.

Commonly accepted terms (such as ‘earth wire’) are used throughout this document while the product Standard may use a more precise term (such as ‘protective earthing conductor’).

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FOREWORD

The greatly increasing use of electrically operated medical equipment and the introduction of new appliances for diagnosis, therapy and monitoring, and the acceptance of techniques that bypass the body's natural barriers to injury, have resulted in a complexity of circumstances wherein the dangers to patient and staff are increased.

Examples of hazards involved in the use of medical electrical equipment include the following:

(a) When electric current flows in the human body, the likelihood of cardiac arrest or severe tissue damage depends on the amount of current which flows, the time for which it flows and the path it takes through the body. The applications of medical electrical equipment are such as to be significantly more hazardous than other electrical equipment.

(b) When unintended current flows in a patient, a visible reaction to electric shock or heat may be lacking because the patient is unconscious, anaesthetized, under the influence of muscle relaxing drugs or fastened to the equipment. The patient may not, therefore, be disconnected quickly from the source of current by an involuntary response.

(c) The high electrical resistance of the intact skin, which normally limits the flow of current in casual contact with a live conductor, is considerably reduced when physiological electrodes are applied to a patient or when parts of the equipment breach the skin and contact internal tissue. In an electric shock under these conditions, the current which may flow is often much greater than that during casual contact.

(d) Both patient and staff are at increased risk in many clinical situations involving medical electrical equipment because of the coincident use of medical electrical equipment and electrolyte solutions, such as blood or saline.

(e) Some clinical procedures involve placing an insulated conductor, in the form of an electrode or a tube filled with electrically conducting liquid, into direct contact with the heart. Under such conditions, the flow of current directly through the heart at minute current levels, that would normally flow quite undetected in the intact body, may result in electrocution.

(f) Some procedures which have been carried out quite safely using one item of equipment connected to the patient may not be safe when the patient is also connected to other equipment. Different items of equipment can interact together to produce a hazardous situation.

(g) Problems can arise when equipment is designed to intentionally deliver current to the patient. Accidents resulting from misuse or failure of this equipment can produce severe burns or electrocution of the patient or the operator.

(h) The flow of electric current through living tissue stimulates nerve and muscle, and heats the tissue through which it passes. While all these effects are put to useful purposes in clinical medicine, each can also have pathological results, including cardiac arrest, respiratory arrest, burns and damage to nerve and muscle.

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S E C T I O N 1 S C O P E A N D G E N E R A L

1.1 SCOPE

This Standard provides a guide to the safe use and application of electrically operated equipment used in health care.

Although the Standard is concerned primarily with the electric shock hazard to patients and staff, provisions to safeguard against other hazards, e.g. thermal, radiant or mechanical, are included.

Measures required to provide and maintain patient and operator safety, including specification of the class of equipment and electrical installation to be employed for particular medical procedures, are also included.

Separate sets of guidelines are included as appendices for certain specific types of equipment where particular methods or potential hazards are recognized.

NOTE: Appendices are limited to equipment in common use by the broad spectrum of people in the health care industry.

1.2 APPLICATION

1.2.1 Establishments

The Standard is intended for application to all patient care areas where electrical equipment is used for medical diagnosis or therapy, surgery, dentistry and other related applications. All such areas (referred to as 'PATIENT AREAS'), including operating theatres, intensive care and coronary care units, diagnostic imaging units, cardiac catheterization laboratories, physiotherapy facilities and dental surgeries, are covered. Requirements for home equipment used for dialysis procedures are also included.

This Standard does not apply to areas, such as laboratories, offices, darkrooms, storage areas and plant equipment areas, from which a patient is normally excluded.

The Standard deals mainly with the safe application of medical electrical equipment in rooms or areas where both the equipment and the installation comply with the relevant Australian/New Zealand Standards. Some guidance is also given in the application of medical electrical equipment in existing areas or rooms where electrical installations do not yet fulfil the requirements of the relevant Australian/New Zealand Standards.

NOTE: It is emphasized that all new installations (and alterations or additions thereto) and equipment should comply with the relevant Australian/New Zealand Standards.

1.2.2 Personnel

The Standard is intended for use by the governing body, the administration, physicians, surgeons, nurses, engineers and all personnel concerned with the application of electrical appliances to the patient or the use of electrical appliances in the vicinity of the patient.