AS/NZS 2500:2020

Australian/New Zealand Standard™

Safe use of medical electrical equipment in health care

AS/NZS 2500:2020

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 1 June 2020 and by the New Zealand Standards Approval Board on 3 June 2020.

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The following are represented on Committee HE-003:

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Originated as AS 2500—1982.
Previous edition AS/NZS 2500:2004.
This edition 2020.

Preface

This Standard was prepared by the joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 2500:2004, *Guide to the safe use of electricity in patient care*.

This Standard sets out guidelines for the safe use of electrical medical equipment in patient care.

The major changes in this edition are as follows:

(a) The removal of all appendices.

(b) Inclusion of Clauses 3.8 to 3.11.

(c) Alignment of this Standard with the requirement of AS/NZS 3003 that all patient areas be at least body-protected.

(d) Alignment of this Standard with the requirement of AS/NZS 3003 for socket-outlets to be colour coded in order to distinguish between essential, non-essential, UPS and cleaners' socket-outlets.

(e) Recommendations for medical electrical systems and upgrading of mobile communications.

(f) Upgrading of defibrillator recommendations.

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).

Contents

Introduction

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 where 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 ventricle. 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 medical electrical equipment connected to the patient may not be safe when the patient is also connected to other equipment. Different items of medical electrical equipment can interact together to produce a hazardous situation.

(g) Problems can arise when medical electrical 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, heating 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.

(i) A hazard exists if medical electrical equipment is not maintained correctly to manufacturer's specifications and may result in a failure of a medical or surgical procedure, tissue damage or misdiagnosis of a patient condition.

(j) Failure to follow the manufacturer's operating procedures for a medical electrical device can result in both a hazard to the patient and personnel caring for the patient.

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Section 1 Scope and general

1.1 Scope

This Standard provides guidance on the correct function, safe use and application of electrically operated medical equipment used in healthcare.

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

Recommended measures 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.

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

1.2 Application

1.2.1 Setting

The Standard is intended for application to all patient care areas where medical 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, dental surgeries, mobile facilities, residential and domestic situations where long-term patient care is delivered, are covered.

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

This Standard mainly deals with the safe application of medical electrical equipment in rooms or areas where both the equipment and the installation conform to 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 meet the requirements of the relevant Australian/New Zealand standards.

NOTE AS/NZS 3003 contains the requirements for all new installations and alterations or additions thereto and equipment.

1.2.2 Personnel

This Standard is intended for use by the responsible organization, administration, physicians, surgeons, nurses, engineers, and all personnel concerned with the application of medical electrical equipment to a patient or the use of electrical equipment in the vicinity of a patient.

1.3 Normative references

There are no normative references in this document.

NOTE Documents for informative purposes are listed in the Bibliography.