AS/NZS 4815:2006

Australian/New Zealand Standard™

Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment

STANDARDS Australia

STANDARDS NEW ZEALAND PAEREWA AOTEAROA

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments. It was approved on behalf of the Council of Standards Australia on 13 March 2006 and on behalf of the Council of Standards New Zealand on 24 March 2006.
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The following are represented on Committee HE-023:

Australian Association of Practice Managers
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association
Australian General Practice Accreditation
Australian Health Industry
Australian Infection Control Association
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Australian/New Zealand Standard™

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments and Equipment, to supersede AS/NZS 4815:2001, *Office-based health care facilities not involved in complex patient procedures and processes—Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of the associated environment.*

The Standard has been prepared for office-based health care facilities to implement procedures for cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and the maintenance of associated environments as applicable to their own professions.

Where complex patient procedures and sterilizing processes, such as low temperature sterilization are performed in office-based health care facilities, reference to AS/NZS 4187 *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities* is required.

Persons having responsibility for the safe provision of sterile health care products should be aware of available sterilization processes, methods of control, and physical characteristics of the product to be sterilized. Unless products are produced under controlled conditions, they will have microorganisms on them and are, by definition, non-sterile. The purpose of sterilization is to destroy these microbiological contaminants.

Certain processes used in the manufacture of health care products are considered to be 'special' (as described in the AS/NZS ISO 9000 series of quality management system standards) in that the result cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because efficacy cannot be verified by inspection or testing of the product. For this reason, sterilization processes must be validated before use, the process routinely monitored and the equipment maintained.

There are many references in this Standard to using the manufacturer's written instructions. However, there are occasions when such instructions may still be inadequate and it is recommended that on-site testing be undertaken. Further clarification of these instructions should be sought from the manufacturer.

Reprocessing of items that may be contaminated with prions, capable of causing diseases such as Transmissible Spongiform Encephalopathies (TSEs), e.g. Creutzfeldt-Jakob Disease (CJD), is still being researched. Current knowledge indicates that these TSEs resist the processes specified in this Standard.

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.

Mandatory statements in footnotes to Tables are deemed to be requirements of this Standard.

The principal differences between this edition and the 2001 edition are as follows:

(a) New definitions have been added.

(b) Requirements regarding the use of sheaths/sleeves/protective barriers for instruments and equipment without these items first being cleaned, disinfected or sterilized, as appropriate, have been added.

(c) Table 7.1 has been modified to assist in a clearer understanding of the relationship between monitoring and validation.

(d) Performance tests for small steam sterilizers that use mechanical air removal systems e.g. Type B and some Type S cycles have been clarified.

(e) Validation requirements (Appendix F) have been upgraded.

(f) Measurement of temperature and pressure in steam sterilizers, or temperature only in dry heat sterilizers (Appendix G) has been modified.

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FOREWORD

This Standard reflects the conscientious efforts of health care professionals representing office-based practice, New Zealand health interests, State health authorities in Australia, professional associations and interested manufacturers in Australia, to develop minimum standards in the processing of items that are required to be clean, disinfected or sterile. It is intended that the principles of this Standard be taken as universally applicable, although it is understood that some requirements contained herein may not be immediately achievable. Therefore, this Standard should be used as a basis by those responsible for sterilizing items in office-based health care facilities to work towards a situation of excellence and adapt it to the special needs of their particular facility.

There are two agents available to office-based health care facilities to free items from viable organisms. They are the following:

(a) *Moist heat*—steam under pressure.

(b) *Dry heat*—hot air sterilization.

Office-based health care facilities that may use other methods of sterilization should refer to AS/NZS 4187, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.*

Currently, moist heat, in the form of steam under pressure, is the most dependable, economical and quickest medium known for the destruction of microbial life.

In the 1930s, with the advent of thermometers being added to steam sterilizer drain lines, sterilization ceased to be the unscientific guesswork it had been previously. ‘Pressure’ was the only indication of control with no means for measuring the temperature developed by the steam or the degree of air elimination.

Since then, a clear understanding of the scientific principles of sterilization has emerged with the result that supplies in health care facilities can now be sterilized with greater economy, increased safety, and a higher degree of precision than ever before. The process, by which microorganisms are destroyed when subjected to this form of heat, is closely linked to the alteration by coagulation of the protein matter in the microbial cell.

Dry heat sterilization, using hot dry air, has been used since the latter part of the nineteenth century. Sterilizers of today are made with specially designed perforated convection chambers with heating elements and fans. The process by which microorganisms are destroyed, when subjected to this form of heat, is by oxidation.

Filters are not sterilizing agents; however, they are used to remove microorganisms and particles from liquids and gases, thus rendering them sterile. Filters are also used on air intake lines following the sterilizing process to return chambers back to atmospheric pressure.

The production of items required to be sterile for use depends not only on the correct medium being selected for the item to be processed and the validation of the sterilization process itself, but also on cleaning and disinfection processes, facility design/workflow, prevention of contamination, and effective quality control, prior to, during and after the sterilizing process.

Management should ensure that personnel involved in the cleaning, disinfecting, sterilization, storage and distribution of items are trained and educated to enable them to correctly undertake any task that they will be required to perform. For those who are charged with the responsibility of quality control and supervision, it is essential to be familiar with risk management, safe work practices, malpractice and duty of care.

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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 sets out procedures and process development which can be validated for the cleaning, disinfection and sterilization of reusable medical and surgical instruments and equipment, and maintenance of associated environments in office-based health care facilities not involved in complex patient procedures and processes.

The Standard is suitable for medical, dental and allied health facilities and skin penetration establishments. The Standard may also be suitable for application to the instruments and equipment used exclusively on animals in veterinary practice.

The Standard does not apply to the reprocessing of items intended by the manufacturer for single use only.

Goods such as dressings and bandages should be obtained sterile from commercial sources, ready for use. This Standard also encompasses the environmental conditions for sterility maintenance of both in-house produced and commercially supplied sterile items.

Reference to AS/NZS 4187 is required for complex cleaning, disinfecting and sterilizing processes, such as those involving anaesthetic equipment processing, endoscopy equipment processing and processes involving low temperature sterilizing systems.

This Standard does not apply to day surgical or day procedures centres, and reference should be made to AS/NZS 4187.

The Standard also does not apply to items that may be contaminated with prions capable of causing Transmissible Spongiform Encephalopathies (TSEs), e.g. Creutzfeldt-Jakob Disease (CJD). Reference should be made to the ‘Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting’ for advice on reprocessing of these items.

NOTE: These ‘Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting’ are available at www.icg.health.gov.au.

1.2 REFERENCED DOCUMENTS

A list of the documents referred to in this Standard is given in Appendix A.

1.3 DEFINITIONS

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

1.3.1 Autoclave

Colloquial term for a steam-under-pressure sterilizer.

1.3.2 Batch principle

Made in one designated cycle of manufacture.

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