Australian/New Zealand Standard™

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

Standards Australia

STANDARDS NEW ZEALAND

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-002, Medical and Surgical Equipment. It was approved on behalf of the Council of Standards Australia on 30 December 2000 and on behalf of the Council of Standards New Zealand on 12 January 2001. It was published on 9 February 2001.

The following interests are represented on Committee HE-002:

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 Care Association
Australian Health Industry
Australian Infection Control Association
Australian Nursing Federation
Commonwealth Dept of Health and Aged Care
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New Zealand Sterile Services Association
N.S.W. Health Department
Queensland Health
Royal Australasian College of Surgeons
Royal Australian College of General Practitioners
Rural Doctors Association of Australia
South Australian Health Commission

Additional interests participating in the preparation of this Standard:

Australian Association of Practice Managers
Australian Chemical Specialty Manufacturers Association
Australian Medical Association
Australian Podiatry Council
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Australian/New Zealand Standard™

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

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Sub-committee HE-002-07, Processing of Medical and Surgical Instruments and Equipment, under the responsibility of Committee HE-002, Medical and Surgical Equipment.

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 more complex patient procedures and sterilizing processes, such as low temperature sterilization, are performed by some office-based health care facilities, reference to AS 4187 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 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.

Sterilization of items that may be contaminated with unconventional infectious agents, e.g. Creutzfeldt-Jakob, is currently being investigated. Current knowledge suggests that these unconventional agents resist 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.

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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 which 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 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.

Although filters are not sterilizing agents, 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. For those who are charged with the responsibility of quality control and supervision, it is essential to be thoroughly familiar with all aspects of safe work practices, malpractice and the laws of negligence, as these are never more important than when considering requests to re-process items that manufacturers have deemed ‘single use’. There are existing Federal and State Government policies pertaining to this matter. These policies universally condemn this practice.

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.

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SECTION 1 SCOPE AND GENERAL

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, surgical 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 items intended by the manufacturer for single use only, or complex cleaning, disinfecting and sterilizing processes, such as those involving anaesthetic equipment processing, endoscopy equipment processing and processes involving low temperature sterilizing systems. For these processes, reference to AS 4187 is required.

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

A colloquial term for steam-under-pressure sterilizer.

1.3.2 Batch principle

Refers to one designated cycle of manufacture and enables retrieval of items in the event of a recall or the tracing of problems to their source.

1.3.3 Benchtop steam sterilizer

A self-contained, portable, electrically-heated machine that has an integral water storage reservoir, generates saturated steam at selected temperatures up to 134°C by an electrical heating unit within or on the sterilizing chamber, and may be designed to dry wrapped items.

1.3.4 Bioburden

The number and the types of microorganisms present on an item prior to sterilization.

1.3.5 Biofilm

A layer of material on the surface of an instrument or device which contains biological materials and in which microorganisms may be embedded.

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