Australian/New Zealand Standard™

Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities

Standards Australia

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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Australian Dental Association
Australian Dental Industry Association
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Australian Health Care Association
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Additional interests participating in the preparation of this Standard:

Australian Association of Practice Managers
Infection Control Review and Certification Service, N.S.W.

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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 4187—1998, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.*

The objective of this Standard is to ensure that items intended for reprocessing are cleaned, disinfected or sterilized so that they can be safely reused without risk of infection transmission.

The principal differences between this edition and the 1998 edition are as follows:

(a) Table 7.1 has been modified.

(b) A new appendix (Appendix A) has been included to provide a rationale for some of the requirements of the Standard. Relevant clauses are indicated by a footnote to the clause title.

(c) An appendix on validation protocol for moist heat sterilization process has been included (Appendix H) as well as a new appendix on handwashing (Appendix J).

(d) The appendix on care and handling of flexible and rigid endoscopes has been rewritten.

(e) The appendix on the method for measurement of temperature and pressure in steam sterilizers, or temperature only in any heat sterilizers, has been expanded.

Persons having responsibility for the safe delivery of sterile health care products should be aware of available sterilization processes, methods of control, and physical characteristics of the product to be sterilized. Even when 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. After sterilization, however, there is always a finite probability that a microorganism could survive regardless of the treatment applied. As a consequence, sterility of a processed item is defined in terms of the probability of the occurrence of a single viable microorganism surviving on the item.

Quality system requirements covering the various aspects for design, development, production, supply, installation and servicing are given in AS/NZS ISO 9001:2000, *Quality management systems—Requirements*, and these requirements can be applied to health care products.

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 or 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 controlled, 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.

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

In addition to the referenced documents appearing in Clause 1.2, Appendix K lists additional documents which are considered useful sources of information on the subject of this Standard.

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

CONTENTS

Page

FOREWORD

This Standard reflects the conscientious efforts of health care professionals representing national and state health authorities, professional associations and interested manufacturers in Australia and New Zealand, 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. Therefore, this Standard should be used as a basis by those responsible for sterilizing items in health care facilities to work towards a situation of excellence and adapt it to the special needs of their particular facility.

There are a number of agents available to health care facilities to free items from viable organisms. They include the following:

(a) Moist heat—steam under pressure.

(b) Dry heat—hot air sterilization.

(c) Chemical—ethylene oxide gas and other low temperature sterilizing processes, e.g. hydrogen peroxide plasma peracetic acid.

(d) Filtration—filter treatment.

Moist heat, in the form of steam under pressure, is the most dependable, quickest and most economical 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.

Chemical sterilization, involving ethylene oxide gas, has been used as a fumigant since its discovery in the latter part of the nineteenth century. However, it was not until the late 1930s that it was used as an effective sterilizing agent.

Due to its high toxicity, the use of ethylene oxide gas in health care facilities is restricted (see Federal and State regulations). The process by which microorganisms are destroyed, when subjected to this medium, is by alkylation of the protein matter in the microbial cell.

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 of steam and ethylene oxide gas sterilizers back to atmospheric pressure. Filters may be used in environmental control of airborne particulate contamination.

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. The routine use of instrument (‘flash’) sterilization for the provision of sterile instruments is an example of situations where many of these factors cannot be achieved, and is therefore not recommended.

It should be noted that more stringent requirements for loan set processing and tracking systems are included in this Standard.

For those who are charged with 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 national and state Government policies pertaining to this matter.

It is imperative that all staff involved in the management and operation of sterilizing department activities encompassing cleaning, disinfecting and sterilizing be trained and educated to national training curriculum standards to enable them to correctly undertake any task they will be required to perform in the department.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

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SECTION 1 SCOPE AND GENERAL

1.1 SCOPE*

This Standard sets out procedures and process development which may be validated for the cleaning, disinfection and sterilization of reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

The Standard may 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, nor to items that may be contaminated with unconventional infective agents, e.g. Creutzfeldt-Jakob, nor to goods such as dressings and bandages which should be obtained sterile from commercial sources, ready for use.

NOTE: Reference should be made to current national guidelines relating to Creutzfeldt-Jakob disease and other transmissible spongiform encephalopathies.

1.2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS	
1079	Packaging of items (sterile) for patient care
1079.2	Part 2: Non-reusable papers—For the wrapping of goods undergoing sterilization in health care facilities
1079.4	Part 4: Flexible packaging systems—For single use in hospitals
1079.5	Part 5: Non-reusable, non-woven wrapping materials—For goods undergoing sterilization in health care facilities
1410	Sterilizers—Steam—Pre-vacuum
1668	The use of ventilation and airconditioning in buildings
1668.2	Part 2: Ventilation design for indoor air containment control
2182	Sterilizers—Steam—Benchtop
2192	Sterilizers—Steam—Downward displacement
2437	Flusher/sanitizers for bed pans and urine bottles
2487	Dry heat sterilizers
2514	Drying cabinets for medical equipment

* Appendix A, which should be read in conjunction with this Clause, gives a rationale that is useful in gaining more comprehensive understanding of these requirements.