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

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments and Equipment. It was approved on behalf of the Council of Standards Australia on 9 December 2002 and on behalf of the Council of Standards New Zealand on 13 December 2002. It was published on 28 January 2003.

---

The following are represented on Committee HE-023:

Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association
Australian General Practice Accreditation Ltd
Australian Health Care Association
Australian Health Industry Inc.
Australian Infection Control Association
Australian Medical Association
Australian Nursing Federation
Commonwealth Department of Health and Ageing
Dental Assistants Association of Australia
Department of Defence
Department of Human Services, Vic.
Federation of Sterilizing Research and Advisory Councils of Australia
Gastroenterological Nurses College of Australia
Health Department of Western Australia
Medical Industry Association of Australia
Ministry of Health, New Zealand
New Zealand Nurses Organisation
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
Infection Control Review and Certification Service, N.S.W.

---

**Keeping Standards up-to-date**

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Australia web site at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

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.

---

*This Standard was issued in draft form for comment as DR 01114.*

Australian/New Zealand Standard™

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

Originated as AS 4187—1994.
Previous edition 1998.
Jointly revised and designated as AS/NZS 4187:2003.





Jointly published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 5024 9

# 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 ..... 7

SECTION 1 SCOPE AND GENERAL
1.1 SCOPE ..... 9
1.2 REFERENCED DOCUMENTS ..... 9
1.3 DEFINITIONS ..... 11
1.4 PROCESSING ENVIRONMENT ..... 16
1.5 REPROCESSING OF INSTRUMENTS AND EQUIPMENT ..... 16

SECTION 2 CLEANING AND HANDLING OF USED ITEMS
2.1 WATER QUALITY FOR CLEANING ..... 17
2.2 INITIAL TREATMENT OF USED ITEMS ..... 17
2.3 COLLECTION PROCEDURES ..... 18
2.4 COLLECTION EQUIPMENT ..... 18
2.5 CLEANING AREA ..... 18
2.6 SORTING OF ITEMS IN THE STERILIZING PROCESSING FACILITY PRIOR TO CLEANING ..... 19
2.7 CLEANING PRECAUTIONS ..... 19
2.8 CLEANING AGENTS ..... 20
2.9 CLEANING METHODS ..... 21
2.10 DRYING OF ITEMS ..... 26
2.11 MONITORING OF CLEANING PROCESSES ..... 27

SECTION 3 PACKAGING AND WRAPPING OF ITEMS PRIOR TO STERILIZATION
3.1 GENERAL ..... 28
3.2 PACK SIZE ..... 28
3.3 LABELLING OF PACKS AND BAGS PRIOR TO STERILIZATION ..... 28
3.4 SPECIFIC PACKAGING AND WRAPPING REQUIREMENTS ..... 28
3.5 METHODS OF WRAPPING ..... 30
3.6 SEALING OF PACKS AND BAGS ..... 33

SECTION 4 STERILIZING EQUIPMENT
4.1 GENERAL ..... 35
4.2 STEAM STERILIZERS ..... 35
4.3 DRY HEAT STERILIZERS ..... 39
4.4 LOW TEMPERATURE STERILIZERS AND LIQUID STERILANTS ..... 39

SECTION 5 LOADING OF STERILIZERS
5.1 FOR STEAM STERILIZATION ..... 41
5.2 FOR DRY HEAT STERILIZATION ..... 41
5.3 FOR ETHYLENE OXIDE GAS STERILIZATION ..... 42
5.4 FOR HYDROGEN PEROXIDE PLASMA STERILIZATION ..... 42
5.5 FOR PERACETIC ACID LIQUID CHEMICAL STERILIZATION ..... 42
5.6 EFFECT OF LOAD CONTENT AND MANNER OF LOADING ..... 42

SECTION 6 UNLOADING OF STERILIZERS
6.1 STEAM STERILIZERS ..... 43
6.2 DRY HEAT STERILIZERS ..... 43
6.3 ETHYLENE OXIDE STERILIZERS ..... 43

6.4 HYDROGEN PEROXIDE PLASMA STERILIZERS....44
6.5 PERACETIC ACID LIQUID CHEMICAL STERILIZATION SYSTEM....44
6.6 MONITORING OF THE UNLOADING PROCEDURE....45

SECTION 7 PURCHASING, VALIDATION, MONITORING AND MAINTENANCE OF STERILIZERS AND ASSOCIATED EQUIPMENT
7.1 GENERAL....46
7.2 PURCHASING STERILIZERS AND ASSOCIATED EQUIPMENT....46
7.3 VALIDATION....46
7.4 RECOMMISSIONING AND PERFORMANCE REQUALIFICATION OF THE STERILIZER....48
7.5 CALIBRATION OF STERILIZER....48
7.6 MONITORING OF STERILIZERS....49
7.7 MAINTENANCE OF STERILIZERS....57
7.8 ASSOCIATED EQUIPMENT....57

SECTION 8 QUALITY MANAGEMENT
8.1 STERILIZING PROCESSING FACILITY MANAGEMENT....61
8.2 DOCUMENTATION....61
8.3 PERFORMANCE MANAGEMENT....61
8.4 EDUCATION AND TRAINING....62
8.5 MATERIALS MANAGEMENT....63
8.6 MONITORING STERILIZING CYCLES....65
8.7 VALIDATION PROCESSES....69
8.8 CRITERIA FOR RELEASE OF PROCESSED ITEMS....69
8.9 MONITORING OF PACKAGING FOLLOWING STERILIZATION....70
8.10 OCCUPATIONAL HEALTH AND SAFETY....70
8.11 ENVIRONMENTAL CONTROL....71
8.12 EVALUATION, FEEDBACK AND OUTCOMES....71
8.13 OFF-SITE REPROCESSING....71

SECTION 9 STORAGE AND HANDLINGOF PROCESSED ITEMS
9.1 GENERAL....72
9.2 STORAGE AREAS FOR STERILE ITEMS....72
9.3 PLASTIC DUST COVERS....73
9.4 TRANSPORTATION/DISTRIBUTION OF STERILE ITEMS....73
9.5 COMMERCIALLY PREPARED ITEMS....74
9.6 SHELF-LIFE/ROTATION OF STOCK....74

SECTION 10 DISINFECTION
10.1 GENERAL....75
10.2 MEANS OF DISINFECTION....75

SECTION 11 CLEANING OF THE STERILIZING PROCESSING FACILITY AND ASSOCIATED EQUIPMENT
11.1 GENERAL....77
11.2 EQUIPMENT....77
11.3 WASTE DISPOSAL....77

SECTION 12 SELECTION AND CARE OF INSTRUMENTS
12.1 GENERAL ..... 78
12.2 GENERAL CONSIDERATIONS ..... 78
12.3 SPECIAL CONSIDERATIONS ..... 79
12.4 SPECIALIZED INSTRUMENTS ..... 80
12.5 USE OF INSTRUMENT SHEATHS/SLEEVES ..... 82

SECTION 13 USE OF OPERATING ROOM TEXTILES
13.1 GENERAL ..... 83
13.2 SPECIFIC CONSIDERATIONS ..... 83
13.3 INSPECTION ..... 83
13.4 MENDING ..... 83
13.5 EQUIPMENT ..... 84

APPENDICES
A RATIONALE ..... 85
B CARE AND HANDLING OF POWERED TOOLS ..... 100
C CARE AND HANDLING OF FLEXIBLE AND RIGID ENDOSCOPES, ACCESSORY ITEMS AND ASSOCIATED EQUIPMENT ..... 102
D GUIDE TO THE SELECTION OF CLEANING AGENTS ..... 111
E SELECTION AND USE OF RIGID REUSABLE STERILIZATION CONTAINERS ..... 112
F HEAT SEALING EQUIPMENT ..... 115
G GUIDELINES FOR THE SELECTION OF PORTABLE (‘BENCHTOP’) STERILIZERS IN HEALTH CARE FACILITIES ..... 116
H VALIDATION PROTOCOL FOR MOIST HEAT STERILIZATION PROCESS ..... 117
I METHOD FOR MEASUREMENT OF TEMPERATURE AND PRESSURE IN STEAM STERILIZERS, OR TEMPERATURE ONLY IN DRY HEAT STERILIZERS ..... 121
J HANDWASHING ..... 125
K BIBLIOGRAPHY ..... 127

# 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

# Australian/New Zealand Standard

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

## 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.

AS/NZS 4187:2003 Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities