

Australian/New Zealand Standard™

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



AS/NZS 4815:2006

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Australian/New Zealand Standard™

Office-based health care facilities— Reprocessing of 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 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.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard

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

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 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.

1.3.3 Benchtop steam sterilizer (see also small steam sterilizer)

Self-contained, portable, bench top electrically-heated machine that generates saturated steam within the unit at selected temperatures up to, and including, 136°C.

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.

1.3.6 Biological indicator

Inoculated carrier, contained within its primary pack, ready for use, that provides a defined resistance to the specified sterilization process.

1.3.7 Calibration

The comparison of a measurement system or device of unknown accuracy to a measurement system or device of a known accuracy to detect, correlate, report, or eliminate by adjustment, any variation from the required performance limits of the unverified measurement system or device.

1.3.8 Chemical indicator

Dye, which can be impregnated into materials or contained within a device, and which changes colour when subjected to the sterilizing process.

1.3.9 Cleaning

The removal of soil and reduction in the number of microorganisms from a surface, by a process such as washing with water and detergent without prior processing.

1.3.10 Commissioning

Obtaining and documenting of evidence that equipment has been provided and installed in accordance with its specification and that it functions within pre-determined limits when operated in accordance with the manufacturer's instructions.

NOTE: Commissioning comprises installation qualification (IQ) and operational qualification (OQ).

1.3.11 Condensate

Water formed when steam condenses during the steam sterilization process.

1.3.12 Contamination

The introduction of microorganisms or foreign matter (or both) to sterile or non-sterile materials or living tissues.

1.3.13 Critical medical device

A device which enters, or is capable of entering, tissue that would be sterile under normal circumstances, or the vascular system.

1.3.14 Cytotoxic

Chemicals that are toxic to the cells, e.g. preparations that are used in the treatment of leukaemia.

1.3.15 Disinfection

The inactivation of non-spore-forming organisms using either heat and water (thermal) or by chemical means.

1.3.16 Drying cycle

NOTE: See Clause 1.3.17.

1.3.17 Drying stage (drying cycle)

The stage in the sequence of the function of a steam sterilizer during which the items in the chamber are dried. This stage occurs immediately following the sterilization stage whilst the sterilizer chamber remains sealed.

1.3.18 Endotoxins

Heat-stable substances in the cell walls of gram-negative bacteria that cause a febrile reaction if introduced into the blood or tissues.

1.3.19 Enzymatic cleaner

Enzymatic cleaning solutions containing enzymes which are capable of breaking down biological soils (containing proteins, lipids, carbohydrates and mucopolysaccharides).

1.3.20 Enzymatic indicator

An indicator that utilizes detection of spore-derived enzyme, rather than the conventional observation of visible organism growth in culture media.

1.3.21 Health care facility

A hospital, nursing home or other facility, e.g. office-based practice, which provides health care services.

1.3.22 Holding time

The time at a given temperature that has been established to destroy all microorganisms.

1.3.23 Hollow load type A

An object whose ratio of length of cavity to diameter is greater than 1 and greater than 5. (See also Appendix E)

1.3.24 Hollow load type B

An object whose ratio of length of cavity to diameter is greater than 1 and less than 5. (See also Appendix E)

1.3.25 Implantable item

Any item which remains *in situ* after surgery and does not dissolve.

1.3.26 Installation qualification (IQ)

Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.

1.3.27 Instruments on loan (loan instruments)

Instruments which are provided by the commercial supplier to the office-based health care facility, or from other health care facilities and individual clinicians.

1.3.28 Item

An individual device or several devices grouped together as one, in a package or set.

1.3.29 Low temperature sterilization

Sterilization achieved by low temperature systems such as ethylene oxide, hydrogen peroxide plasma or peracetic acid.

1.3.30 May

Indicates the existence of an option.

1.3.31 Monitoring

A programmed series of challenges and checks, repeated periodically, and carried out according to a documented protocol which demonstrates that the process being studied is both reliable and repeatable.

1.3.32 Non-critical medical device

A device which comes into contact with intact skin.

1.3.33 Office-based health care facility (office-based practice)

The provision of health care services in sites outside routine hospital in-patient and operating room settings. Such sites include private consulting rooms and health clinics.

1.3.34 Operational qualification (OQ)

Obtaining and documenting evidence that installed equipment operates within pre-determined limits when used in accordance with its operational procedures.

1.3.35 Parametric release

Declaring a product as sterile, based on the records demonstrating that the process parameters were delivered within specified tolerances.

1.3.36 Pathogenic organism

An organism capable of initiating infection in a susceptible host.

1.3.37 Penetration time (equilibration time)

The time required for every part of a load to reach the selected sterilizing temperature after that temperature has been reached in the sterilizing chamber.

1.3.38 Performance qualification (PQ)

Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with pre-determined criteria, and thereby yields a product meeting its specification.

1.3.39 Performance requalification

Procedure to confirm data recorded during performance qualification, conducted annually or when significant changes are made to any aspect of reprocessing activities, e.g. changes to packaging materials, loading configurations and sterilization process parameters.

1.3.40 Pre-vacuum air removal

A colloquial term for air removal from the chamber and load by mechanical means.

1.3.41 Process challenge device (PCD)

A device which simulates the worst-case conditions for the attainment of the specified sterilizing conditions within items to be sterilized.

NOTE: The device is so constructed that a biological or chemical indicator can be placed within the device in the position which is the most difficult for the sterilizing agent to reach. The design of the process challenge device depends on the nature of the items to be sterilized and the sterilization procedure.

1.3.42 Process recorder

A device intended to record all stages of the sterilization cycle.

NOTE: The operator is required to check the sterilization parameters recorded at the completion of each cycle.

1.3.43 Processing time

The total time of the sterilization stage, that equals penetration time plus holding time. (See also Clause 1.3.22.)

1.3.44 Recommissioning

Repetition of part or all of the commissioning test requirements for the purpose of reconfirming process reliability.

1.3.45 Reprocessing

All steps necessary to make a contaminated reusable medical device ready for its intended use. The steps may include cleaning, functional testing, packaging, labelling, disinfection or sterilization.

1.3.46 Reusable device

A device designated or intended by the manufacturer as suitable for reprocessing and reuse. It is *not* a device that is designated or intended by the manufacturer for single use only.

1.3.47 Revalidation

Repetition of part or all of the validation test requirements for the purpose of reconfirming process reliability.

1.3.48 Semi-critical medical device

Device which comes into contact with intact mucous membranes and does not normally enter sterile areas of the body.

1.3.49 Shall

Indicates that a statement is mandatory.

1.3.50 Should

Indicates a recommendation.

1.3.51 Small steam sterilizer (see also benchtop steam sterilizer)

Sterilizer with a chamber volume not exceeding 60 L or one that is unable to accommodate a sterilization module with the dimensions of 300 mm × 300 mm × 600 mm. These types of sterilizers may be capable of generating their own steam or may be attached to external steam generators.

1.3.52 Soil

Dirt or debris which may protect, harbour or assist the growth of microorganisms. Includes inorganic matter and organic matter, such as blood and body substances.

1.3.53 Standard Precautions

Work practices which require everyone to assume that all blood and body substances are potential sources of infection, independent of perceived risk. Such precautions involve the use of safe work practices and protective barriers and the safe disposal of body substances and soiled material.

1.3.54 Sterile

The state of being free from viable microorganisms.

NOTE: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

1.3.55 Sterility assurance level (SAL)

The probability of a viable microorganism being present on an item after sterilization.

NOTE: SAL is normally expressed as 10^{-n} .

1.3.56 Sterilization

Validated process used to render a product free of all forms of viable microorganisms.

NOTE: In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

1.3.57 Sterilization cycle

Defined sequence of operational steps, designed to achieve sterilization, that are carried out in a sealed chamber.

1.3.58 Sterilizing agent

The medium used for the sterilizing process.

1.3.59 Store pack

A pack containing one or more smaller packs that contain a number of unit packs.

1.3.60 Superheated steam

Steam whose temperature, at any given pressure, is higher than that indicated by the vaporization curve of water.

NOTE: Superheated steam is not suitable for sterilization.

1.3.61 Tape

A combination of backing material and suitable adhesive applied to one side only, with or without the application of a chemical indicator.

1.3.62 Type B cycle

A cycle capable of sterilizing all wrapped (single or double) or unwrapped items, including porous and cannulated items that do not exceed the specifications of Hollow load Type A.

1.3.63 Type N cycle

A cycle capable of sterilizing unwrapped, solid items.

1.3.64 Type S cycle

A cycle capable of sterilizing unwrapped items and *at least* one of the following load types: porous items, small porous items, Hollow load Type A, Hollow load Type B, single layer wrapped items, double wrapped items.

1.3.65 Unit pack

A pack containing a single unit.

1.3.66 Validation

Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with pre-determined specifications.

1.3.67 Washer/disinfector

Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

NOTES:

- 1 Instrument washer/disinfectors are intended to process loads containing surgical instruments, anaesthetic accessories, hollowware, utensils, glassware and similar items. They are also known as batch-type washer/disinfectors and can have doors on two sides for separate loading and unloading.
- 2 Bed pan washer/disinfectors are intended to be used for the emptying, flushing, cleaning and thermal disinfecting of human waste containers. They are also known as flusher/sanitizers for bed pans and urine bottles.

1.3.68 Wet steam

Steam that contains minute drops of water due to condensation.

NOTE: An excess of 3% wetness in steam prevents further penetration of steam in the item to be sterilized. Therefore, wet steam cannot be used for sterilization.

1.4 REPROCESSING ENVIRONMENT

The planning and construction of any new reprocessing area of an office-based health care facility or major refurbishment to an existing reprocessing area of an office-based health care facility, incorporating pack preparation and loading of sterilizers, shall incorporate the principles of environmental control to minimize particulate contamination and bioburden. Consideration shall be given to workflow and surface finishes.

NOTES:

- 1 Existing sterilizing facilities should make every endeavour to conform to the requirements of this Clause.
- 2 A suggested layout for a reprocessing area is given in Figure 1.1.

1.5 REPROCESSING OF INSTRUMENTS AND EQUIPMENT

Prior to use or reuse, the item shall be cleaned, cleaned and disinfected, or cleaned and sterilized, as appropriate to its intended use.

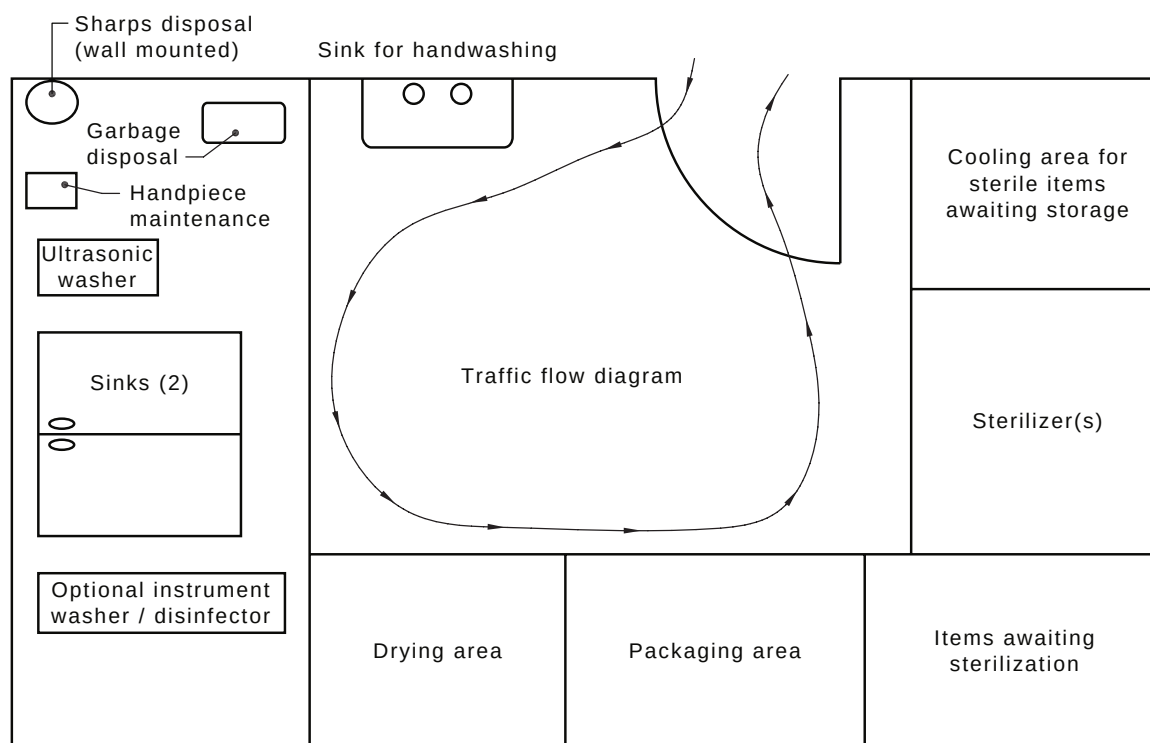
Any critical medical device shall be sterile at the point of use.

Semi-critical devices shall be sterilized between uses unless they are incapable of withstanding a sterilization process. In this case, semi-critical medical devices shall be subjected to high level disinfection process using either a thermal disinfection process or an instrument grade disinfectant between patient uses.

Items incapable of being disinfected or sterilized may require the use of an instrument sheath or sleeve or protective barrier to create a sterile barrier for use of that item during procedures. Such items shall be reprocessed to the highest level possible for that item between reuses (see also Clause 12.5).

WARNING: DO NOT REPROCESS EX-PLANTED MEDICAL/DENTAL DEVICES.

Implantable items should be purchased in a sterile condition.



NOTES:

- 1 Arrow direction indicates the flow of instruments and equipment from dirty—clean—sterile.
- 2 Personnel working in the processing area should wash their hands—
 - (a) after handling soiled items and removal of gloves;
 - (b) before handling clean items; and
 - (c) before handling sterile items.
- 3 See also Section 9 for storage and handling of processed items.

FIGURE 1.1 SUGGESTED LAYOUT FOR A REPROCESSING AREA

(Modified from Cleaning, Disinfection, Sterilisation. A guide for Office-Based Practice (Lohead, L (2006))

SECTION 2 CLEANING AND HANDLING OF USED ITEMS

2.1 WATER QUALITY FOR CLEANING

There shall be a clean water supply of good quality. Water suitable for drinking should be suitable for cleaning. Information on the quality of water may be obtained from the local water authority.

NOTE: Water with high mineral content is unsuitable for the rinsing of instruments due to mineral deposits permanently damaging and seriously shortening the life of the instruments and equipment. High mineral content may also interfere with the efficacy of cleaning agents.

2.2 INITIAL TREATMENT OF USED ITEMS

Gross residual soil shall be removed as soon as practicable.

WARNING: TO PREVENT EXPOSURE TO BLOOD AND BODY SUBSTANCES WHEN CLEANING AND HANDLING USED ITEMS, FOLLOW STANDARD PRECAUTIONS.

STANDARD PRECAUTIONS INVOLVE TREATING BLOOD AND BODY SUBSTANCES OF ALL PERSONS AS POTENTIAL SOURCES OF INFECTION INDEPENDENT OF DIAGNOSIS OR PERCEIVED RISK.

WEAR APPROPRIATE PERSONAL PROTECTION, SUCH AS UTILITY/HOUSEHOLD GLOVES, SPECIFICALLY DESIGNED FLUID REPELLENT MASKS/EYE PROTECTION/ FACESHIELDS AND FLUID-RESISTANT APRONS OR GOWNS.

NOTES:

- 1 Removal of gross residual soil may be achieved by procedures such as dry wiping, damp wiping and rinsing. Cold water will congeal fatty substances. Hot water will coagulate protein in blood and body fluids.
- 2 A written description of the procedures should be available.
- 3 All single use items should be discarded appropriately after use, according to local regulations.
- 4 Drapes should be placed in designated containers and returned to the laundry service.

2.3 COLLECTION PROCEDURES

Procedures for the collection of used reusable items from treatment areas shall be formulated by each office-based health care facility to suit its individual needs.

2.4 COLLECTION EQUIPMENT

Used reusable items shall be collected in containers made of material that is able to be cleaned. The containers shall be puncture resistant and leak resistant. They may require a lid or inner liner that can be closed.

The containers intended for the collection of used items shall be maintained in a clean and dry condition.

The office-based health care facility shall have separate systems for the containment of used items and the delivery of sterile items.

2.5 REPROCESSING AREA

All used items shall be cleaned in a designated area to prevent possible contamination of processed items. There shall be a written policy on the methods, and frequency, of cleaning of the area and the equipment. To facilitate this function, equipment in the area should ideally include the following:

- (a) Separate handwashing facilities.
- (b) Adequate bench space.
- (c) Smooth surfaces without crevices.
- (d) Good lighting.
- (e) Efficient ventilation.
- (f) Adequate storage space for materials and equipment.
- (g) Bins or other containers for disposal of waste.
NOTE: Storage and disposal of waste should be in accordance with regulatory authorities and AS/NZS 3816 and NZS 4304.
- (h) Non-slip flooring.
- (i) Sink suitable for the disposal of liquid waste.
- (j) Cleaning sinks.
- (k) Drying facilities.
- (l) Work surfaces made of non-porous materials which allow for efficient cleaning.
- (m) Directed traffic flow from reception to final distribution of clean products.

Where mechanical or other instrument processing equipment such as ultrasonic cleaners is used, such equipment should be selected to meet the user's need for efficient use and ease of maintenance.

NOTE: AS 2773.2 and AS 2945 specify requirements for bench top ultrasonic cleaners for health care facilities, and washer/disinfectors for health care facilities, respectively.

2.6 SORTING OF ITEMS IN THE REPROCESSING AREA PRIOR TO CLEANING

On receipt at the reprocessing area, items should be sorted according to type and corresponding cleaning method.

All instruments and equipment that have been unwrapped are considered to be contaminated whether they have been used or not, and shall be subjected to the full cleaning process.

A check for completeness and defects shall be made during sorting (e.g. whether multi-part instruments or sets are present).

There shall be written procedures for handling specialized items if used.

Care and handling of powered instruments shall be in accordance with Appendix B.

2.7 CLEANING PRECAUTIONS

Techniques of cleaning should be designed to avoid generation of aerosols.

Reusable tubing poses a particular challenge to the cleaning process and has the potential to generate infectious aerosols. Where practicable, single use tubing should be used.

Cleaning agents shall not be allowed to come into contact with personnel. If accidental exposure does occur, the affected area should be immediately washed with copious amounts of clean water and treated in accordance with Material Safety Data Sheets.

Abrasive cleaners (e.g. steel wool or abrasive cleaning powders and pastes) shall not be used. These cleaners may damage the surfaces of instruments or leave residues.

2.8 CLEANING AGENTS

Cleaning agents shall be used to remove residual soil and organic matter from instruments and equipment. Only those intended by the manufacturer for use in cleaning medical devices shall be used.

NOTES:

- 1 Appendix C gives information on the selection of cleaning agents.
- 2 A Standard for the performance of cleaning agents is currently under development.

Staff shall be trained in application, handling and safe use of cleaning agents for instrument cleaning.

Product Data Bulletins and Material Safety Data Sheets for all cleaning agents shall be obtained, read and their requirements implemented.

Common household detergents shall not be used due to their high foaming properties and the difficulties involved in rinsing items free of residue.

Cleaning agents shall be packaged and be able to be dispensed in a manner which is safe for the operator and which does not promote contamination of the contents. Cleaning agents shall not leave any residue after rinsing.

NOTES:

- 1 Mild alkaline detergents in the pH range 8.0 to 10.8 are preferred over neutral pH detergents in most applications. Although neutral detergents may be quite effective in a number of applications, they may not prove as effective as built alkaline detergents in many of the dirtier applications. However, some instruments and equipment may be made of materials where the use of neutral detergents may be more appropriate.
- 2 Acid-based agents should only be used for stainless steel surfaces and then only for intermittent de-scaling or brightening. Items with different metallurgic compositions should not be cleaned in the same acid-based solution as this may cause galvanic corrosion.
- 3 Care should be taken when using cleaning agents containing perfume as even small amounts of residue can cause allergic reaction in some individuals.

Cleaning agents for manual cleaning should be—

- (a) biodegradable;
- (b) non-corrosive;
- (c) non-toxic;
- (d) non-abrasive;
- (e) low foaming;
- (f) free rinsing;
- (g) preferably liquid; and
- (h) of mild alkali formulations.

Cleaning agents for mechanical cleaning should be—

- (i) biodegradable;
- (ii) non-abrasive;
- (iii) low foaming;
- (iv) free rinsing; and
- (v) preferably liquid.

Labelling of cleaning agents by the manufacturer shall include—

- (A) the name of the product;
- (B) the name and address of the manufacturer;
- (C) the description and purpose of the product;
- (D) the directions for dilution and use;
- (E) the batch number;
- (F) the expiry date;
- (G) the advice not to mix the cleaning agent with other chemicals;
- (H) safety and first aid instructions;
- (I) specific storage requirements; and
- (J) statement of Hazardous Nature.

In addition, labelling of cleaning agents shall comply with any statutory regulations.

2.9 CLEANING METHODS

2.9.1 General

Thorough cleaning of all instruments and equipment is an essential prerequisite in disinfection and sterilization processes. The effectiveness of sterilization is dependent on a low bioburden; therefore care shall be taken to ensure that the cleaning process does not add to the bioburden.

WARNING: IF THE ITEM IS NOT CLEAN, STERILIZATION MAY BE COMPROMISED.

Cleaning methods shall be appropriate to the design of the instruments and equipment being cleaned. It is imperative that cleaning protocols be devised for modern instruments made of various materials (polymers and metals). Cleaning protocols should ensure the removal of adherent soils, proteins and biofilm.

Some instruments and equipment such as acupuncture needles and endodontic reamers, files and fillers are extremely difficult and hazardous to clean. Such items shall be single-use unless a validated cleaning method is used, which is safe for the operator.

Effective cleaning ensures that instruments and equipment are clean to the naked eye (macroscopic) and free from any protein residues and other stains. The most commonly used practice for the monitoring of cleaning is by visual inspection. Technology is now available that allows for the detection of protein residues or for monitoring of washer-disinfector efficacy via the use of simulated soil tests. Consideration should be given to the inclusion of protein residue testing or simulated soil tests as part of validation and routine monitoring for cleaning processes.

Many instruments are now so designed that soiling may occur internally where it cannot be seen. The narrow lumens, joints and complex valves may become coated with a biofilm because of the inability to be cleaned physically and to be dried thoroughly. The problem of biofilm also extends to cleaning machines.

2.9.2 Manual cleaning

2.9.2.1 General

The use of mechanical methods may be contraindicated for washing certain delicate or complex instruments. These instruments shall be carefully hand-washed and rinsed. Alternatively, single-use instruments should be used.

Cleaning equipment shall be non-abrasive and maintained in good condition. Cleaning equipment should be free from visible debris before re-use. The equipment shall be thermally disinfected or sterilized at the end of each cleaning session, or at least daily when in use. When not in use, such equipment shall be stored clean and dry.

2.9.2.2 *Cleaning agents and equipment for manual cleaning*

The following are recommended:

- (a) Water (see also Clause 2.1).
- (b) Two dedicated sinks large and deep enough for practical use.
NOTES:
 - 1 A bowl may be used for cleaning only if a second sink is not yet available.
 - 2 Any sink that is used for the disposal of contaminated liquids should not be used for handwashing without prior cleaning.
- (c) Small brush with firm plastic bristles, capable of withstanding cleaning agents.
- (d) Light grade nylon or similar non-abrasive scouring pad.
- (e) Cleaning agent.
- (f) Wire dental bur brush.
- (g) Lint free cloths or disposable low-lint cloths, in sufficient supply to allow for frequent changing.

2.9.2.3 *Method of cleaning*

The method for manual cleaning should be as follows:

- (a) Flush the item in warm running water to remove gross visible blood and body substances.
- (b) Fill a sink or bowl with warm water and detergent to the concentration recommended by the manufacturer.
- (c) Dismantle or open all items for cleaning prior to placement in the cleaning solution.
- (d) Hold the items low in the sink to limit the generation of aerosols during scrubbing. Wash all surfaces of the items, including lumens and valves. Remove stubborn staining by using the non-abrasive scouring pad or soaking in an approved stain-removing solution.
- (e) Rinse the item finally in warm-to-hot running water.
- (f) Dry in a drying cabinet or with lint-free cloths or disposable low-lint cloths.
NOTE: Items should not be dried in ambient air.
- (g) Visually inspect the cleanliness of all items.

2.9.2.4 *Manual cleaning of respiratory equipment*

All items shall be thoroughly cleaned in detergent and water, followed by thorough rinsing in clean running water to remove any detergent residue.

Where thermal disinfection or sterilization processes are not available for semi-critical items, single-use devices shall be used.

The manufacturer's instructions for cleaning and reprocessing of respiratory equipment should be considered.

Procedures for manual cleaning of various items of respiratory equipment shall be as follows:

- (a) *Re-breathing bags and self-inflating resuscitator sets* Components, including valves and flanges, shall be dismantled according to the manufacturer's instructions, or as far as practicable, before being cleaned in detergent and water and thoroughly rinsed prior to thermal disinfection or sterilization.

- (b) *Nebulizers, ventilators, masks and reusable accessories* There are varying types of nebulizers, ventilators, associated masks and reusable accessories.

NOTE: The manufacturer's instructions for cleaning and disinfection or sterilization should be followed.

- (c) *Spacers* Special reprocessing procedures are required for these items. However, many of these items are single patient use.

NOTE: Reference should be made to the 'Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting' or the manufacturer's instructions for cleaning and disinfection or sterilization should be followed.

2.9.3 Mechanical cleaning

2.9.3.1 General

Mechanical cleaning of instruments and utensils may be accomplished with either an instrument washer (usually referred to as a washer/disinfector) or an ultrasonic cleaner.

NOTE: Residue should not be present at the end of the cleaning process.

WARNING: INSTRUMENT WASHERS NEED TO BE REGULARLY CLEANED AND MAINTAINED TO PREVENT COLONIZATION AND FORMATION OF BIOFILMS WHICH COULD CONTAMINATE THE INSTRUMENTS PROCESSED THEREIN.

2.9.3.2 Instrument washers

Instrument washers have closed cabinets which are linked to the water supply and drainage system. The machines are loaded with the soiled instruments/utensils and the doors closed before the cycle commences.

Washer cycles shall include the following:

- (a) Pre-rinse, with water.
- (b) Wash, in warm water with cleaning agent added, in accordance with the manufacturer's recommendations.
- (c) One or more rinses with hot (80°C–86°C) water with a drying agent added, in accordance with the manufacturer's recommendations.
- (d) Drain, leaving the contents at a temperature for quick drying.
- (e) Drying.

Instruments/utensils shall be positioned to ensure surfaces are exposed to the action of the water spray without dislodgement, and to allow drainage.

2.9.3.3 *Ultrasonic cleaners*

Ultrasonic cleaners may be used to effectively clean jointed and serrated stainless steel instruments. Cannulated instruments may be cleaned in an ultrasonic cleaner provided that the manufacturer's instructions are followed. Plastics and other similar materials may not be successfully processed by this method. Cemented glass syringes, mirrors and lenses will be damaged if repeatedly subjected to this process.

NOTES:

- 1 The instructions provided by the manufacturer of the medical device (instrument) to be cleaned, should be considered in relation to the suitability of the medical device for ultrasonic cleaning.
- 2 Some ultrasonic cleaners have mechanisms within the cleaning tank to circulate cleaning solutions through cannulated instruments (see Item (v) below).
- 3 Ultrasonic cleaners work by subjecting instruments to high frequency, high energy sound waves, causing soil to be dislodged or sufficiently loosened, to enable removal during the rinsing process.

The process for ultrasonic cleaning shall be as follows:

- (a) Fill the water tank with cold or tepid water and add a measured amount of recommended detergent intended for ultrasonic use. Operate the machine to degas the solution.
- (b) Rinse off blood and other visible soil before immersing the instruments in the water tank.
- (c) After degassing, place the opened instruments in the machine's basket and submerge the basket in the water tank, close the lid and commence the cycle.
- (d) After the specified time, remove the instrument basket and rinse the instruments in clean, running, warm to hot water, dry and visually inspect the cleanliness of all items.

WARNING: ULTRASONIC CLEANERS CLEAN BUT DO NOT DISINFECT INSTRUMENTS.

Specific considerations on the use of ultrasonic cleaners are as follows:

- (i) Lack disinfecting properties.
- (ii) Detergent has to be added after tank is filled with water, and only detergents approved by the manufacturer should be used.
- (iii) Degassing is necessary after each fill before instruments are processed.
- (iv) Blood and gross debris should be rinsed off instruments prior to immersion in the water tank.
- (v) Cleaning the ultrasonic cleaner and replacement of the cleaning solution is necessary at least daily (where the cleaner is used daily) or more frequently, depending on how many and what type of instruments are being cleaned in the machine, and the effectiveness of the initial rinsing process to which instruments are subjected to prior to ultrasonic cleaning.
- (vi) Tests are necessary to establish the efficiency of the transducers (see Section 7).
- (vii) Precautions for occupational health and safety are as follows:
 - (A) Ultrasonic cleaners shall be operated with lids closed, to prevent emission of aerosols and reduce exposure to high sound frequency.
 - (B) No part of the operator's body should be submerged into the water tank during operation, as this is thought to cause long-term arthritic conditions.

The manufacturer's handbook should be consulted for further information on the use and limitations of ultrasonic cleaning.

NOTE: Mechanical shaking can blunt fine points by impaction.

2.10 RINSING OF INSTRUMENTS

Where manual cleaning methods are used, thorough rinsing in clean, running, warm to hot water is required to ensure that instruments and equipment are free from detergent residues after the cleaning process.

Where an instrument washer-disinfector is used, documented daily checks for detergent or rinse additive residue are necessary to establish the efficacy of the final rinse process.

Chemical residues are capable of causing tissue irritation and instrument damage and shall not be present at the end of the cleaning process.

2.11 DRYING OF INSTRUMENTS

2.11.1 General

Drying reduces the risk of contamination during inspection and assembly of instruments. Residual moisture may impede the sterilization process, and can damage instruments.

2.11.2 Drying methods

Drying shall be by means of a drying cabinet or lint free cloths or disposable low-lint cloths.

SECTION 3 PACKAGING AND WRAPPING OF ITEMS PRIOR TO STERILIZATION

3.1 GENERAL

The purpose of packaging and wrapping of items for sterilization is to provide an effective barrier against sources of potential contamination in order to maintain sterility and to permit aseptic removal of the contents of the pack (see also Section 9).

Packaging and wrapping materials shall permit the removal of air from the pack, penetration of the sterilizing agent into the pack and removal of the sterilizing agent and water vapour.

Materials, including materials used for inner wraps, shall be compatible with the item being packed and the sterilizing method selected.

Sharp instruments shall be packaged in such a way that the tips of these instruments are exposed to the sterilizing agent but will not perforate the packaging material.

Drapes shall be laundered prior to re-use. Single-use wrapping materials shall be used once only and discarded.

NOTES:

- 1 AS/NZS 4146 outlines laundering practice.
- 2 AS 3789.2 specifies requirements for theatre linen and pre-packs.
- 3 In New Zealand, the Ministry of Health 'Laundry Guidelines for Rest Homes and Small Hospitals', should also be consulted.

3.2 PACK SIZE

The basic principle determining the size, mass and contents of instrument and hollowware packs is that the contents are sterile and dry immediately on completion of the sterilization cycle and removal of the pack from the sterilizer chamber. Large packs may inhibit effective sterilization and, in the case of steam sterilization, drying. If a pack or its contents are wet, the pack shall be deemed unsterile and shall not be used.

The density of porous items and the maximum size and mass of packs determines the ability of the sterilizing agent to penetrate the load. The efficiency of the sterilization process shall be established during validation procedures (see Section 8).

3.3 LABELLING OF PACKS AND BAGS PRIOR TO STERILIZATION

Prepared labelling systems or non-toxic, water resistant, felt-tipped marking pens and rubber stamps, using similar ink, shall be used for labelling packs prior to sterilization. Labelling shall include batch control data on both packs and bags (see also Clause 8.5.2.1) and the contents if not visible through the pack or bag.

Sharp-tipped, water-based or ball-type pens shall not be used as these pens may compromise pack integrity.

3.4 SPECIFIC PACKAGING AND WRAPPING REQUIREMENTS

3.4.1 Instruments

Instruments with hinges or ratchets shall remain open and unlocked. Multiple-part instruments for sterilization shall be disassembled or sufficiently loosened prior to packaging to permit the sterilizing agent to come into contact with all parts of the instrument.

Instrument sets should be packaged in a manner that prevents damage to delicate items. Trays used for assembly of instrument sets for steam sterilization shall be perforated.

3.4.2 Hollowware

Hollowware i.e. gallipots, bowls or kidney dishes when packaged in sets shall be assembled to minimize the risk of air entrapment and pooling of condensate. All openings shall face the same direction and be assembled so that the contents cannot be dislodged.

Hollowware items packaged together shall be separated by non-porous spacers to permit effective steam circulation (see also Clause 5.1.2).

3.4.3 Types of packaging and wrapping materials

3.4.3.1 Paper

Paper materials intended for specific use as sterilization wrapping materials shall be used.

3.4.3.2 Woven and non-woven

Woven and non-woven materials intended for specific use as sterilization wrapping materials shall be used.

3.4.3.3 Flexible packaging

These materials consist of paper or non-woven materials combined with a clear laminate to form pouches or continuous reels and are commonly used in office-based health care facilities.

This form of packaging is best positioned in the sterilizer chamber on its side or flat with the paper surface downwards to allow egress of air and condensate and ingress of the steam.

Hollowware shall be placed with the opening against the paper side of flexible packaging materials. If packaged incorrectly into a sterilizer, hollow items such as gallipots may entrap air or condensate in the gusset or against the plastic surface when laid flat, thus defeating the sterilizing process.

WARNING: DUE TO THE RISK OF INCOMPLETE SEALING, USE SELF SEALING POUCHES STRICTLY IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS

3.4.3.4 Rigid reusable sterilization containers

Containers used for sterilization shall allow penetration and removal of the sterilizing agent, and shall maintain sterility following the process.

For steam sterilization, the container used for packaging instrument sets shall be perforated to ensure penetration of the sterilizing agent and efficient drying.

If required to be stored sterile, perforated metal or plastic containers and trays shall be wrapped, or have the appropriate filter in place, prior to sterilization.

On-site physical, chemical and biological testing shall establish that the loaded rigid reusable sterilization containers will achieve sterilization of their contents (see Clause 8.7).

NOTE: Containers differ in performance characteristics and should be demonstrated to be effective for the specific sterilization method and cycle to be used, and checked for seal integrity after each use.

3.4.3.5 Nylon packaging material

Impervious packaging material, e.g. 100% nylon packaging material, shall not be used as a packaging material for steam sterilization, as it is impervious to air and inhibits penetration of the sterilizing agent.

3.4.4 Selection of packaging materials

Outer packaging and wrapping materials for the different sterilization processes should be selected as outlined in Table 3.1.

TABLE 3.1
PACKAGING MATERIALS

Material	Steam	Dry heat
Paper bags and wrapping materials	Yes*	Yes†
Flexible packaging systems —		
(i) cellulose based	Yes†	No
(ii) porous non-cellulose based	Yes	No
(iii) non-porous, non-cellulose based (e.g. nylon)	No	(depends on the grade)
Cellulose based, non-woven wrapping materials	Yes	Yes†
Non-cellulose based, non-woven wrapping materials	Yes	No
Rigid reusable sterilization container‡	Yes	No
Sealed metal or glass containers	No	Yes
Aluminium foil	No	Yes
Polyethylene film	No	No

* Correct loading will facilitate appropriate movement of air, steam and condensate.

† These wrapping materials are prone to embrittlement during sterilization.

‡ Applies to rigid reusable sterilization containers with an inbuilt filter and locking device

NOTE: Cotton and cotton polyester wrapping materials have been shown to be much less effective than non-woven wrapping materials as a microbial barrier. 100% polyester wrapping materials require specialized laundering processes and cycles to retain barrier fabric capabilities. Tightly woven 100% polyester limits the penetration of the steam in the sterilization process.

3.5 METHODS OF WRAPPING

Methods of wrapping are illustrated in Figures 3.1 and 3.2.

3.6 SEALING OF PACKS AND BAGS

3.6.1 General

The purpose of sealing is to maintain pack integrity, and is achieved by the use of heat sealers, self-sealing pouches or sterilizing indicator tape. Methods which compromise pack integrity shall not be used.

NOTE: String, non-adhesive tape, staples and elasticized bands are not suitable as they can cause compression within the pack, damage or compromise pack integrity.

Where sterilizing indicator tape is used to seal a pouch the open edge of the pouch should be sequentially folded over two to three times prior to taping across the entire folded edge with one continuous piece of tape extending across at least 25 mm around the back of the pouch on both sides. Figure 3.3 illustrates correct procedures for sealing pouches with adhesive tape.

The use of sterilizing indicator tape for sealing both ends of continuous reel packaging should only be made in the event of breakdown or absence of heat-sealing equipment.

NOTE: The use of sterilizing indicator tape to seal flexible packaging materials should be avoided as maintenance of sterility and aseptic opening of the package may be compromised.

3.6.2 Heat sealing

Sterilizing bags and laminated pouches should be sealed using suitable heat-sealing equipment.

Following the heat sealing of packs, checks shall be made to ensure that the seal is complete, especially over the gusset folds of bags or pouches.

NOTE: Appendix D gives information on heat sealing and associated equipment.

3.6.3 Sterilizing indicator tape

Users shall select the type of indicator tape specific to the mode of sterilization selected. The tape shall be heat stable, moisture stable and permeable to the sterilizing agent. The colour change of the indicator tape after exposure to the sterilizing agent shall be clear, distinct and uniform and be markedly different to the unprocessed indicator tape.

NOTE: Sterilizing indicator tape or other Class 1 chemical indicators are used to indicate that the item has been exposed to the sterilization process. However, the indicator tape can also change colour in relation to other conditions, e.g. poor storage, expired dates and sterilizer chamber heat.

The indicator tape shall have an adhesive system that is compatible with the wrapping material used, especially for non-woven or treated paper surfaces. The tape adhesive should be pressure sensitive, non-toxic and adhere to clean surfaces.

The tape shall have the name of the manufacturer, batch number and date (month and year) of manufacture or expiry clearly marked on the core.