

Australian/New Zealand Standard™

# Reprocessing of reusable medical devices in health service organizations



## **AS/NZS 4187:2014**

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments. It was approved on behalf of the Council of Standards Australia on 18 November 2014 and on behalf of the Council of Standards New Zealand on 26 November 2014. This Standard was published on 15 December 2014.

---

The following are represented on Committee HE-023:

Australasian College for Infection Prevention and Control  
Australian Chamber of Commerce and Industry  
Australian College of Operating Room Nurses  
Australian Day Surgery Nurses Association  
Australian Dental Association  
Australian Dental Industry Association  
Australian Industry Group  
Australian Institute of Packaging  
Australian Nursing and Midwifery Federation  
Department of Health, SA  
Department of Human Services Victoria  
Department of Health, WA  
Federation Sterilizing Research and Advisory Council of Australia  
Gastroenterological Nurses College of Australia  
Institute of Hospital Engineering Australia  
Medical Technology Association of Australia  
New Zealand Nurses Organisation  
New Zealand Sterile Services Association  
NSW Ministry of Health  
Queensland Health  
Royal College of Pathologists of Australasia  
Therapeutic Goods Administration

---

### **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 Standards may also be withdrawn.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 Web Shop at [www.saiglobal.com](http://www.saiglobal.com) or Standards New Zealand web site at [www.standards.govt.nz](http://www.standards.govt.nz) and looking up the relevant Standard in the on-line catalogue.

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 Standards Australia or the New Zealand Standards Executive at the address shown on the back cover.

---

*This Standard was issued in draft form for comment as DR 100397.*

## Australian/New Zealand Standard™

# Reprocessing of reusable medical devices in health service organizations

Originated in Australia as AS 4187—1994.  
Previous and first joint edition AS/NZS 4187:2003.  
Fourth edition 2014.  
Reissued incorporating Amendment No. 1 (July 2015).  
Reissued incorporating Amendment No. 2 (May 2019).

### **COPYRIGHT**

© Standards Australia Limited

© The Crown in right of New Zealand, administered by the New Zealand Standards Executive

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Australia) or the Copyright Act 1994 (New Zealand).

## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments, to supersede AS/NZS 4187:2003, Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

*This Standard incorporates Amendment No. 1 (July 2015) and Amendment No. 2 (May 2019). The changes required by the Amendments are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.*

Prevention of health care associated infection in patients undergoing dental, medical or surgical procedures is an essential component of patient safety in the delivery of high quality health care. It avoids unnecessary pain and suffering for patients and lessens health care costs. Effective and safe reprocessing of reusable medical devices (RMDs) in health service organizations (HSOs) is a critical aspect in the prevention of health care associated infection.

The objective of this Standard is to ensure that HSOs correctly clean, disinfect and sterilize RMDs prior to and between patient uses in order to produce RMDs that are able to be used safely without risk of transmission of infectious agents.

There are significant differences in the structure, content and terminology of this edition of the Standard and that of the previous 2003 edition, as follows:

- (a) The structure and clause headings of this Standard mirror that of the International Organization for Standardization, Technical Committee 198 (ISO/TC 198), Sterilization of health care products, suite of Standards.
- (b) It is necessary to read this Standard in conjunction with relevant national and International Standards and guideline documents (see Clause 1.3, normative references).
- (c) This Standard does not reiterate all the technical requirements already identified in national or International Standards. For example, this Standard refers directly to ISO 17665-1, Sterilization of health care products—Moist heat, Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, for the requirements concerning moist heat sterilization processes.
- (d) This Standard is not written as a procedural document. Therefore, it is necessary for HSOs to develop their own workplace procedures based on the requirements of this Standard.

Committee HE-023 recommends that HSOs implement the requirements of this Standard within 2 years of date of publication.

Statements expressed in mandatory terms in notes to tables are deemed to be requirements of 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.

## CONTENTS

|                                                                          | <i>Page</i> |
|--------------------------------------------------------------------------|-------------|
| FOREWORD.....                                                            | 5           |
| <br>SECTION 1 SCOPE AND GENERAL                                          |             |
| 1.1 SCOPE.....                                                           | 7           |
| 1.2 EXCLUSIONS.....                                                      | 7           |
| 1.3 NORMATIVE REFERENCES .....                                           | 8           |
| 1.4 ABBREVIATIONS .....                                                  | 10          |
| 1.5 DEFINITIONS.....                                                     | 11          |
| <br>SECTION 2 QUALITY MANAGEMENT                                         |             |
| 2.1 GENERAL.....                                                         | 21          |
| 2.2 DOCUMENTATION.....                                                   | 21          |
| 2.3 MANAGEMENT RESPONSIBILITY .....                                      | 23          |
| 2.4 PRODUCT REALIZATION.....                                             | 24          |
| 2.5 MEASUREMENT, ANALYSIS AND IMPROVEMENT .....                          | 27          |
| <br>SECTION 3 REPROCESSING AGENT CHARACTERIZATION                        |             |
| 3.1 GENERAL.....                                                         | 30          |
| 3.2 CLEANING AGENTS.....                                                 | 31          |
| 3.3 DISINFECTANTS.....                                                   | 31          |
| 3.4 STERILIZING AGENTS.....                                              | 32          |
| 3.5 MICROBICIDAL EFFECTIVENESS .....                                     | 32          |
| 3.6 EFFECTS ON RMD MATERIALS .....                                       | 32          |
| 3.7 PERSONNEL AND ENVIRONMENTAL SAFETY.....                              | 33          |
| <br>SECTION 4 PROCESS CHARACTERIZATION AND EQUIPMENT<br>CHARACTERIZATION |             |
| 4.1 GENERAL.....                                                         | 34          |
| 4.2 PROCESS CHARACTERIZATION.....                                        | 34          |
| 4.3 EQUIPMENT CHARACTERIZATION .....                                     | 35          |
| <br>SECTION 5 PRODUCT DEFINITION                                         |             |
| 5.1 GENERAL.....                                                         | 37          |
| 5.2 PRODUCT FAMILIES.....                                                | 39          |
| 5.3 LIMITING VALUES.....                                                 | 40          |
| 5.4 PRE-DISINFECTION AND PRE-STERILIZATION CLEANLINESS OF RMDs.....      | 40          |
| 5.5 PACKAGING SYSTEM.....                                                | 40          |
| 5.6 REPROCESSING ENVIRONMENT.....                                        | 40          |
| <br>SECTION 6 PROCESS DEFINITION                                         |             |
| 6.1 GENERAL.....                                                         | 43          |
| 6.2 CLEANING PROCESS DEFINITION .....                                    | 44          |
| 6.3 DISINFECTING PROCESS DEFINITION .....                                | 45          |
| 6.4 PACKAGING PROCESS DEFINITION .....                                   | 46          |
| 6.5 STERILIZING PROCESS DEFINITION .....                                 | 47          |

## SECTION 7 VALIDATION

|     |                                        |    |
|-----|----------------------------------------|----|
| 7.1 | GENERAL.....                           | 51 |
| 7.2 | INSTALLATION QUALIFICATION (IQ).....   | 53 |
| 7.3 | OPERATIONAL QUALIFICATION (OQ) .....   | 56 |
| 7.4 | PERFORMANCE QUALIFICATION (PQ) .....   | 56 |
| 7.5 | REVIEW AND APPROVAL OF VALIDATION..... | 59 |

## SECTION 8 ROUTINE MONITORING AND CONTROL

|     |                                                                                                                             |    |
|-----|-----------------------------------------------------------------------------------------------------------------------------|----|
| 8.1 | GENERAL.....                                                                                                                | 61 |
| 8.2 | ROUTINE MONITORING AND CONTROL OF CLEANING PROCESSES .....                                                                  | 61 |
| 8.3 | ROUTINE MONITORING AND CONTROL OF MANUAL CHEMICAL<br>DISINFECTION WITH HIGH LEVEL INSTRUMENT GRADE DISINFECTANT             | 63 |
| 8.4 | ROUTINE MONITORING AND CONTROL OF WASHER DISINFECTORS<br>EMPLOYING CHEMICAL DISINFECTION FOR THERMOLABILE<br>ENDOSCOPE..... | 64 |
| 8.5 | MICROBIOLOGICAL SURVEILLANCE OF FLEXIBLE ENDOSCOPES WITH<br>CHANNELS .....                                                  | 64 |
| 8.6 | ROUTINE MONITORING AND CONTROL OF PACKAGING PROCESSES .....                                                                 | 65 |
| 8.7 | ROUTINE MONITORING AND CONTROL OF STERILIZING PROCESSES .....                                                               | 65 |

## SECTION 9 RELEASE OF RMDS FOLLOWING REPROCESSING

|     |                                                                      |    |
|-----|----------------------------------------------------------------------|----|
| 9.1 | GENERAL.....                                                         | 71 |
| 9.2 | RMD RELEASE CRITERIA .....                                           | 73 |
| 9.3 | RMD RELEASE .....                                                    | 75 |
| 9.4 | RECORDS OF RMD RELEASE .....                                         | 75 |
| 9.5 | HANDLING, TRANSPORT AND STORAGE OF RELEASED REPROCESSED<br>RMDS..... | 75 |

## SECTION 10 MAINTAINING PROCESS EFFECTIVENESS

|      |                                |    |
|------|--------------------------------|----|
| 10.1 | GENERAL.....                   | 76 |
| 10.2 | CALIBRATION .....              | 76 |
| 10.3 | MAINTENANCE OF EQUIPMENT ..... | 76 |
| 10.4 | REQUALIFICATION.....           | 80 |
| 10.5 | ASSESSMENT OF CHANGE.....      | 81 |

## APPENDICES

|   |                    |     |
|---|--------------------|-----|
| A | GUIDANCE .....     | 82  |
| B | BIBLIOGRAPHY ..... | 110 |

## FOREWORD

Reusable medical devices (RMDs) are used for diagnostic and/or treatment purposes for multiple patients and are intended by the manufacturer for reprocessing and reuse.

When an RMD is used for diagnostic or treatment purposes it can contact the patient's sterile tissues, mucous membranes or skin, or it might be used in a non-critical area around a patient without direct patient contact, e.g. a suction canister. As a result, there is potential for the RMD to become contaminated with microorganisms, blood, tissue and other biological material.

Correct, effective and safe reprocessing of RMDs is essential to protect patients and staff. Failure to correctly and effectively reprocess RMDs risks the transmission of infectious agents or an adverse reaction from residual cleaning, disinfecting or sterilizing agents.

Reprocessing of RMDs is a multistep process that includes cleaning, disinfection (if applicable), inspection and assembly, testing (if applicable), packaging and sterilization (if applicable) of used items to render them safe for reuse:

- (a) Manual or automated cleaning removes visible soil from RMDs. Thorough cleaning is an essential prerequisite prior to disinfection (thermal or chemical) or sterilization of RMDs as residual inorganic and organic soil on the surfaces of used items interferes with, or has the potential to interfere with, the effectiveness of these processes.
- (b) Disinfection (thermal or chemical) of RMDs kills many microorganisms, including human pathogens. Unlike sterilization, disinfection is not effective against high numbers of bacterial spores. Many factors affect the efficacy of a disinfecting process (presence of soil, nature and level of microbial contamination, RMD design, concentration of disinfectant, temperature, pH and exposure time and presence of biofilm).

Disinfectants differ significantly in their spectrum of antimicrobial activity and in their speed of action. Low-level instrument grade disinfectants kill vegetative bacteria, some fungi and some viruses. Intermediate-level instrument grade disinfectants kill vegetative bacteria, mycobacteria, viruses and most fungi but do not kill bacterial spores. High-level instrument grade disinfectants kill all microorganisms with the exception of high numbers of bacterial spores. Some disinfectants used as high-level instrument grade disinfectants are actually chemical sterilizing agents that kill high numbers of bacterial spores with prolonged exposure under controlled and defined conditions.

- (c) Sterilization destroys microorganisms on RMDs rendering them free from viable microorganisms. Moist heat sterilization, low temperature sterilization (e.g. hydrogen peroxide gas or plasma, liquid peracetic acid, low temperature steam formaldehyde and ethylene oxide) and dry heat sterilization are the principal processes used by HSOs to sterilize RMDs. Moist heat sterilization is the preferred process for sterilization of RMDs where the item to be reprocessed (including its packaging, if used) is able to withstand this process. Where an item cannot withstand a moist heat sterilizing process, a suitable, alternative sterilizing process will be necessary, e.g. a low temperature gas or plasma, or liquid chemical sterilizing process.

It is not necessary to sterilize all RMDs. The Spaulding Classification System provides a system to determine the level of reprocessing necessary for an RMD based on its intended use:

- (i) Critical RMDs require cleaning followed by sterilization.
- (ii) Semi-critical RMDs require cleaning followed by high-level disinfection at a minimum; however, sterilization of these items is strongly recommended.

- (iii) Non-critical RMDs require cleaning and this can be followed by low or intermediate level disinfection.

Critical and semi-critical RMDs are typically reprocessed in designated reprocessing environments in HSOs. However, non-critical RMDs, particularly non-invasive, non-critical RMDs are frequently reprocessed at the point of use.

Appropriate validation and control of cleaning, disinfecting, packaging and sterilizing processes reduces the risk of transmission of infectious agents associated with the use of RMDs. This requires a HSO to strive towards development of a state of the art reprocessing facility in which the requisite infrastructure and necessary resources are available to undertake effective and safe reprocessing activities, including, for example, the provision of water and steam of the specified quality. In this regard, the HSO needs to ensure that its reprocessing staff are educated and trained, that they adhere strictly to defined work practices and have demonstrated competency in reprocessing and associated activities.

Surgical techniques and diagnostic procedures are continually evolving. Developments in materials science and engineering, are resulting in an increasingly wide array of RMDs of varying design and complexity. These advances can pose significant challenges to the effective reprocessing of RMDs. The design of an RMD needs to ensure that the RMD is able to be effectively cleaned and disinfected, and sterilized. In this regard it is imperative that the design requirements for a RMD no longer only focus on clinical need and medical device functionality, but also on reuse considerations. Prior to purchasing an RMD, it is imperative that HSOs consider carefully the manufacturer's instructions for reprocessing of the RMD and evaluate their in-house capability to reprocess the RMD effectively and safely.

This Standard reflects the conscientious efforts of health care professionals representing national and regional health authorities, professional associations and industry associations in Australia and New Zealand, to develop minimum requirements for the effective and safe reprocessing of RMDs in HSOs.

The requirements of this Standard are applicable to all HSOs. It is necessary for individual HSOs to develop their own work place procedures based on the requirements of this Standard to ensure that their reprocessing activities result in a safe RMD that is able to be used for diagnostic or treatment purposes and that is not hazardous to either staff or to the environment.

## STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

---

**Australian/New Zealand Standard****Reprocessing of reusable medical devices in health service organizations**

---

## SECTION 1 SCOPE AND GENERAL

**1.1 SCOPE**

This Standard specifies the requirements and practices necessary for the effective and safe reprocessing, storage, handling and transportation of reusable medical devices (RMDs) in human health care.

The application of the principles of this Standard recognizes and acknowledges that there are similarities and differences between different types of HSOs (e.g. hospitals, and dental general and podiatry practices).

The similarities are the common need for quality systems, staff training, and compliance with reprocessing procedures. The major difference relates to the unique physical and organizational conditions in different types of HSO (e.g. reprocessing equipment and ability to physically segregate the reprocessing environment).

The principles of this Standard are also applicable to processing of single use medical devices supplied to HSOs by the manufacturer in a non-sterile state and which require sterilization in accordance with the medical device manufacturer's processing instructions prior to use.

This Standard is applicable wherever RMDs are reprocessed in HSOs, including the reprocessing of RMDs used in post-mortem examinations.

Infection prevention and control practices preclude the interchange of RMDs between post-mortem examinations and live patient health care. Infection prevention and control practices also preclude the interchange of RMDs between veterinary and human health care, including RMDs used in preclinical training on animal tissue.

The principles of this Standard may be applicable to the reprocessing of RMDs in veterinary practice.

**1.2 EXCLUSIONS**

This Standard does not include requirements for the following:

- (a) The reprocessing of medical devices that are intended for single use only and that have been in contact with blood, tissue or body substances. Reprocessing of these medical devices is a manufacturing activity that is regulated by national regulatory authorities (e.g. in Australia, the Therapeutic Goods Administration).
- (b) The reprocessing of RMDs potentially contaminated with Transmissible Spongiform Encephalopathies (TSEs) [e.g. Creutzfeldt Jakob Disease (CJD)]. The 'Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting' include specific recommendations in relation to the reprocessing of RMDs potentially contaminated with these agents.

- (c) The sterilization of bandages and dressings in HSOs. Sterilization of these single use medical devices requires the estimation of the presterilization bioburden to ensure that performance qualification of the sterilizing process delivers product with the necessary sterility assurance level (SAL).
- (d) Items not intended to be used as medical devices (e.g. sterilizing empty plastic water bottles, rubber bands, cardboard cut from store-packs, dessert spoons and paper clips).
- (e) The manufacture of chemical indicators (CI) or biological indicators (BI). Requirements for the manufacture of these indicators are specified in relevant International Standards.
- (f) The manufacture of reprocessing equipment. Requirements for the manufacture of this equipment are specified in relevant international and national standards.

### 1.3 NORMATIVE REFERENCES

The following are the normative documents referenced in this Standard:

NOTE: Documents referenced for informative purposes are listed in the Bibliography in Appendix C.

#### AS

- 1668 The use of ventilation and airconditioning in buildings
- 1668.2 Part 2: Mechanical ventilation in buildings
- 2514 Drying cabinets for medical equipment
- 2773 Ultrasonic cleaners for health care facilities
- 2773.1 Part 1: Benchtop
- 2773.2 Part 2: Non-portable
- 2774 Drying cabinets for respiratory apparatus
- 3789 Textiles for healthcare facilities and institutions
- 3789.8 Part 8: Textiles for health care facilities and institutions—Recyclable barrier fabrics

#### ISO

- 10993 Biological evaluation of medical devices
- 10993-7 Part 7: Ethylene oxide sterilization residuals
- 11135 Sterilization of health care products—Ethylene oxide—Requirements for development, validation and routine control of a sterilization process for medical devices
- 11138 Sterilization of health care products—Biological indicators (series)
- 11140 Sterilization of health care products—Chemical indicators (series)
- 11607 Packaging for terminally sterilized medical devices
- 11607-1 Part 1: Requirements for materials, sterile barrier systems and packaging systems
- 11607-2 Part 2: Validation requirements for forming, sealing and assembly processes
- 13485 Medical devices—Quality management systems—Requirements for regulatory purposes
- 14937 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

|                                                                              |                                                                                                                                                                                            |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO                                                                          |                                                                                                                                                                                            |
| 15882                                                                        | Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results                                                                        |
| 15883                                                                        | Washer-disinfectors                                                                                                                                                                        |
| 15883-1                                                                      | Part 1: General requirements, terms and definitions and tests                                                                                                                              |
| 15883-2                                                                      | Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. |
| 15883-3                                                                      | Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers                                                                           |
| 15883-4                                                                      | Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes                                                                         |
| 15883-6                                                                      | Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment                              |
| 17664                                                                        | Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices                                                       |
| 17665                                                                        | Sterilization of health care products—Moist heat                                                                                                                                           |
| 17665-1                                                                      | Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices                                                                    |
| 20857                                                                        | Sterilization of health care products—Dry heat—Requirements for the development, validation and routine control of a sterilization process for medical devices                             |
| 25424                                                                        | Sterilization of medical devices—Low temperature steam and formaldehyde—Requirements for development, validation and routine control of a sterilization process for medical devices        |
| EN                                                                           |                                                                                                                                                                                            |
| 285                                                                          | Sterilization—Steam Sterilizers—Large Sterilizers                                                                                                                                          |
| 867                                                                          | Non-biological Systems For Use in Sterilizers                                                                                                                                              |
| 867-5                                                                        | Part 5: Specification For Indicator Systems and Process Challenge Devices For Use in Performance Testing For Small Sterilizers Of Type B and Type S                                        |
| NOTE: EN 867-5 is expected to be superseded by ISO 11140-6 (in preparation). |                                                                                                                                                                                            |
| 868                                                                          | Packaging For Terminally Sterilized Medical Devices                                                                                                                                        |
| 868.10                                                                       | Part 10: Adhesive Coated Nonwoven Materials Of Polyolefines—Requirements And Test Methods                                                                                                  |
| 1422                                                                         | Sterilizers for Medical Purposes—Ethylene Oxide Sterilizers—Requirements and Test Methods                                                                                                  |
| 13060                                                                        | Small Steam Sterilizers                                                                                                                                                                    |
| 14180                                                                        | Sterilizers for Medical Purposes—Low Temperature Steam Formaldehyde Sterilizers—Requirements and Testing                                                                                   |
| A2   16442                                                                   | Controlled environment storage cabinet for processed thermolabile endoscopes                                                                                                               |
| TGO                                                                          |                                                                                                                                                                                            |
| 54                                                                           | Therapeutic goods order No. 54—Standard for disinfectants and sterilants                                                                                                                   |

## 1.4 ABBREVIATIONS

For the purposes of this Standard, the following abbreviations apply:

|            |                                                                           |
|------------|---------------------------------------------------------------------------|
| AER        | Automated endoscope reprocessor (aka WD for thermo labile endoscopes)     |
| ARTG       | Australian Register of Therapeutic Goods                                  |
| BI         | Biological indicator                                                      |
| CDC        | Centers for Disease Control and Prevention                                |
| CI         | Chemical indicator                                                        |
| CJD        | Classical Creutzfeldt Jacob Disease                                       |
| EO         | Ethylene oxide                                                            |
| GESA/GENSA | Gastroenterological Society of Australia                                  |
| HLD        | High level disinfection                                                   |
| HSO        | Health service organization                                               |
| IAP        | Inspection and packaging                                                  |
| IFU        | Instructions for use                                                      |
| IQ         | Installation qualification                                                |
| MPQ        | Microbiological performance qualification                                 |
| MRC        | Minimum recommended concentration                                         |
| OQ         | Operational qualification                                                 |
| PCD        | Process challenge device                                                  |
| PPE        | Personal protective equipment (e.g. gloves, visors, aprons)               |
| PPQ        | Physical performance qualification                                        |
| PQ         | Performance qualification                                                 |
| PSBS       | Preformed sterile barrier system                                          |
| RMD        | Reusable medical device                                                   |
| RO         | Reverse osmosis                                                           |
| SAL        | Sterility assurance level                                                 |
| SBS        | Sterile barrier system                                                    |
| SDS        | Safety data sheet                                                         |
|            | NOTE: An SDS was previously known as a Material Safety Data Sheet (MSDS). |
| TGA        | Therapeutic Goods Administration                                          |
| TGO        | Therapeutic Goods Order                                                   |
| WD         | Washer-disinfector                                                        |

## 1.5 DEFINITIONS

For the purposes of this Standard, the following definitions apply:

### 1.5.1 A0

Equivalent time in seconds at 80°C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K.

[ISO 15883-1]

### 1.5.2 Aeration

Part of the sterilization process during which the sterilization gas and/or its reaction products desorb from the medical device until predetermined levels are reached.

NOTE: This may be performed within the sterilizer and/or in a separate chamber or room.

[ISO 11135]

### 1.5.3 Australian Register of Therapeutic Goods (ARTG)

The reference database of the Therapeutic Goods Administration (TGA) that provides information on therapeutic goods that can be supplied in Australia.

NOTE: The ARTG is a record of the contents and classification details of therapeutic goods. It is not intended to provide guidance, advice or recommendations on those goods.

### 1.5.4 Batch

Defined quantity of product, intended or purported to be uniform in character and quality, which has been produced during a defined cycle of manufacture.

[ISO/TS 11139]

### 1.5.5 Bioburden

Population of viable microorganisms on or in product and/or sterile barrier system.

[ISO/TS 11139]

### 1.5.6 Biofilm

Accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.

[CDC]

### 1.5.7 Biological indicator (BI)

A test system containing viable microorganisms providing a defined resistance to a specified sterilization process.

[ISO/TS 11139]

### 1.5.8 Calibration

A set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

[ISO/TS 11139]

### 1.5.9 Change control

Assessment and determination of the appropriateness of a proposed alteration to product or procedure.

[ISO/TS 11139]

**1.5.10 Chemical indicator (CI)**

A non-biological indicator test system that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process.

[ISO/TS 11139]

**1.5.11 Cleaning**

The removal of contamination from an item to the extent necessary for further processing or for intended use.

[ISO/TS 11139]

**1.5.12 Cleaning agent**

A product added to water to aid the removal of contaminants from RMD and equipment used for processing RMD.

**1.5.13 Competent person**

A person who has, through a combination of training, education and experience, acquired knowledge and skills enabling that person to correctly perform a specific task.

**1.5.14 Condensate**

The liquid that forms when a gas or vapour changes to a liquid during the process of condensation.

NOTE: For example, water is formed when steam condenses.

**1.5.15 Containment devices**

Device used inside the SBS to facilitate organization, drying and aseptic presentation of the RMD (e.g. instrument stringer, instrument organizer tray, tray liners or cassettes).

**1.5.16 Contamination**

The presence of microorganisms or foreign matter.

**1.5.17 Corrective action**

An action to eliminate the cause of a detected nonconformity or other undesirable situation.

[ISO/TS 11139]

**1.5.18 Critical medical device**

A medical device that comes into contact with the vascular system or sterile tissue and that must be sterile at the time of use.

NOTE: A critical medical device contaminated with microorganisms confers a high risk of transmission of infectious agents.

[NHMRC 2010 (modified)]

**1.5.19 Disinfectant**

A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms.

[TGO 54]

NOTE: See also definitions for high level (1.5.25), hospital grade (1.5.28), instrument grade (1.5.33), intermediate level (1.5.34) and low level (1.5.38) disinfectants.

**1.5.20 Disinfection**

Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

### 1.5.21 Drying phase

The phase in the sequence of the function of a WD or sterilizer during which the items in the chamber are dried. This phase occurs immediately following the disinfection or sterilization phase whilst the chamber remains sealed.

### 1.5.22 Exposure time

The period for which the process parameters are maintained within their specified tolerances.

[ISO/TS 11139]

### 1.5.23 Fault

One or more of the process parameters lying outside of its/their specified tolerance(s).

[ISO/TS 11139]

### 1.5.24 Health service organization (HSO)

A separately constituted health service that is responsible for the clinical governance, administration and financial management of a service unit(s) providing health care.

NOTE: A service unit involves a grouping of clinicians and others working in a systematic way to deliver health care to patients and can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms.

[Australian Commission on Safety and Quality in Health Care (ACSQHC) (2011), National Safety and Quality Health Service Standards, ACSQHC, Sydney.]

### 1.5.25 High level disinfectant

A disinfectant that kills all microbial pathogens, except large numbers of bacterial endospores when used as recommended by its manufacturer.

### 1.5.26 Holding time

Sterilization period for which the temperatures at the reference measurement point and at all points within the sterilization load are continuously within the sterilization temperature band.

[ISO 17665-1]

### 1.5.27 Hollowware

Items such as bowls, flasks, jugs and containers.

### 1.5.28 Hospital grade disinfectant

A disinfectant that is suitable for general purpose disinfection of building and fitting surfaces, and purposes not involving instruments or surfaces likely to come into contact with broken skin.

### 1.5.29 Immediate use sterilization

A process in which sterilized RMDs are transferred aseptically to the sterile field in the shortest practicable time after removal from the sterilizer.

### 1.5.30 Implantable medical device

A medical device (other than an active implantable medical device) that is intended by the manufacturer to—

- (a) be, by surgical intervention, wholly introduced into the body of a human being and to remain in place after the procedure;

- (b) replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being and to remain in place after the procedure; or
- (c) be, by surgical intervention, partially introduced into the body of a human being and to remain in place for at least 30 days after the procedure.

[TGA Acronyms and Glossary]

NOTE: This also applies to medical devices implanted by endoscopic means.

### **1.5.31 Infectious agents**

An infectious agent (also called a pathogen or germ) is a biological agent that causes disease or illness to its host.

NOTE: Infectious agents include prions, bacteria, viruses, fungi and parasites, etc.

[NHMRC, 2010]

### **1.5.32 Installation qualification (IQ)**

A process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

[ISO/TS 11139]

### **1.5.33 Instrument grade disinfectant**

- (a) A disinfectant that is used to reprocess reusable therapeutic devices.
- (b) When associated with the words 'low', 'intermediate' or 'high' means 'low', 'intermediate' or 'high' level disinfectant respectively.

### **1.5.34 Intermediate level disinfectant**

A disinfectant that kills all microbial pathogens except bacterial endospores, when used as recommended by the manufacturer. It is bactericidal, tuberculocidal, fungicidal (against asexual spores but not necessarily dried chlamydospores or sexual spores), and virucidal.

### **1.5.35 Labile**

An RMD that is damaged when exposed to conditions outside of the manufacturer's processing specifications, e.g. heat, moisture.

### **1.5.36 Liquid chemical sterilizing agent**

A chemical agent that kills all microorganisms and which is used to sterilize a critical medical device with the result that the theoretical probability of there being a microbial survivor is equal to or less than  $1 \times 10^{-6}$ .

NOTE: A liquid chemical sterilizing agent is a sterilizing agent (see Clause 1.5.85).

[TGO 54 (modified)]

### **1.5.37 Loan or trial reusable medical device**

A reusable medical device that is not owned by the HSO but that is supplied to the HSO by a commercial supplier or other HSO, or individual clinician.

### **1.5.38 Low level disinfectant**

A disinfectant that rapidly kills most vegetative bacteria as well as medium sized lipid containing viruses, when used according to labelling. It cannot be relied upon to destroy, within a practical period, bacterial endospores, mycobacteria, fungi, or all small non-lipid viruses.

### **1.5.39 Manufacturer's instructions**

Instructions for use (IFU) provided by the manufacturer of the medical device and/or accessories (e.g. sterile barrier systems, RMD or WD).

#### 1.5.40 Medical device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of—

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
- (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- (c) investigation, replacement, modification, or support of the anatomy or of a physiological process;
- (d) supporting or sustaining life;
- (e) control of conception;
- (f) disinfection of medical devices;
- (g) providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

[ISO 13485]

#### 1.5.41 Microbicidal

Destructive to microorganisms.

#### 1.5.42 Minimum recommended concentration (MRC)

The minimum concentration of a biocidal agent as recommended by the manufacturer for use. The MRC is not necessarily equivalent to the minimum effective concentration (MEC) as determined by dose response testing.

NOTE: The user often refers to MRC testing as an MEC test.

#### 1.5.43 Monitoring

A programmed series of challenges and checks, repeated periodically, and carried out according to a documented protocol to demonstrate that a process is reproducible and reliable.

NOTE: This involves but might not be limited to measurement of process variables, and comparison of the values obtained with the values specified for the process.

#### 1.5.44 Nonconforming product

The non-fulfilment of a requirement (not meeting specification).

[AS/NZS ISO 9000]

#### 1.5.45 Non-critical medical device

A medical device that only comes into contact with intact skin and not mucous membranes.

NOTE: Some non-critical medical devices might not come into direct contact with a patient, e.g. a suction canister where the outer casing is reusable. However, as the item is used within the patient environment there is potential for the item to become contaminated.

[NHMRC 2010 (modified)]

**1.5.46 Non-invasive medical device**

A medical device which does not penetrate inside the body, either through a body orifice or through the surface of the body.

[ISO 15883-6]

**1.5.47 Office based practice (office based health care facility)**

The provision of health care services in sites not involved in complex patient procedures and processes. Such sites include private consulting rooms and health clinics.

**1.5.48 Open-but-unused medical device**

A single use medical device where the packaging has been damaged or opened but the medical device has not been used and/or did not come into contact with blood, tissue or body fluids.

[TGA Acronyms and Glossary]

**1.5.49 Operational qualification (OQ)**

A process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

[ISO/TS 11139]

**1.5.50 Overkill approach**

Approach using sterilization process that delivers a minimum of 12 Spore Log Reduction (SLR) to a biological indicator having a resistance equal to or greater than the product bioburden.

[ISO 11135]

**1.5.51 Packaging system**

A combination of the sterile barrier system and protective packaging.

[ISO/TS 11139]

**1.5.52 Penetration time**

The time taken to attain the specified parameters on or in all parts of a reusable medical device after those conditions have been attained in the sterilizer chamber.

**1.5.53 Performance qualification (PQ)**

A process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

[ISO/TS 11139]

**1.5.54 Preformed sterile barrier system**

A sterile barrier system that is supplied partially assembled for filling and final closure or sealing.

NOTE: Examples—

- (a) pouches;
- (b) bags; and
- (c) open reusable containers.

[ISO/TS 11139]

**1.5.55 Pre-treatment**

The initial treatment of a used RMD performed at the point of use prior to reprocessing.

### 1.5.56 Preventive action

An action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

NOTES:

- 1 There can be more than one cause for a potential nonconformity.
- 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

[AS/NZS ISO 9000]

### 1.5.57 Process challenge device (PCD)

An item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

[ISO/TS 11139]

### 1.5.58 Process parameter

The specified value for a process variable.

NOTE: The specification for a sterilization process includes the process parameters and their tolerances.

[ISO/TS 11139]

### 1.5.59 Process variable

A condition within a sterilization process, changes in which alter microbicidal effectiveness, e.g. time, temperature, pressure, concentration, humidity.

[ISO/TS 11139]

### 1.5.60 Processing

The process carried out on a new medical device in order to allow its safe use. This can include cleaning, disinfection, sterilization and related procedures.

### 1.5.61 Processing category

Group of different product that can be processed together.

[ISO/TS 11139]

### 1.5.62 Product family

Groups or subgroups of product characterized by similar attributes such as mass, material, construction, shapes, lumens, SBS or packaging system and which present a similar challenge to the cleaning, disinfecting and/or sterilizing processes.

[ISO 17665-1 modified]

### 1.5.63 Product

The result of a process.

[AS/NZS ISO 9000]

NOTES:

- 1 For the purposes of sterilization standards, a product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies) and health care product(s).
- 2 For the purposes of this Standard, the term 'product' is synonymous with reusable medical device.

### 1.5.64 Protective packaging

The configuration of materials designed to prevent damage to the sterile barrier system and its contents until the point of use.

[ISO/TS 11139]

### 1.5.65 Reprocessing

All of the activities required to ensure that a used RMD is safe for its intended purpose.

NOTE: This is a multi-step process that includes cleaning, inspection and assembly, functional testing (if applicable), disinfection (if applicable), packaging and labelling, and sterilization (if applicable).

### 1.5.66 Requalification

The repetition of part of validation for the purpose of confirming the continued acceptability of a specified process.

[ISO/TS 11139]

### 1.5.67 Reusable container

Rigid sterile barrier system designed to be repeatedly used.

[ISO 11607-1]

### 1.5.68 Reusable medical device (RMD)

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

NOTES:

- 1 An RMD is presented for use either as an individually packaged RMD or as more than one RMD assembled and packaged together as a group or set.
- 2 For the purposes of this Standard, the term RMD includes a loan RMD and a trial RMD (see Clause 1.5.36).

[TGA Acronyms and Glossary]

### 1.5.69 Reverse osmosis (RO)

A process to produce purified water in which pressure is applied to force feed water through a semipermeable membrane across which dissolved inorganic solids, such as salts and impurities, cannot pass.

NOTE: Purified water is collected as the membrane permeate whereas concentrated water containing substances that cannot flow through the membrane is discharged from the process as waste.

### 1.5.70 Safety data sheet (SDS)

A document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely.

### 1.5.71 Saturated steam

Water vapour in a state of equilibrium between condensation and evaporation.

[ISO 17665-1]

### 1.5.72 Semi-critical medical device

A medical device that comes into contact with mucous membranes or non-intact skin.

[NHMRC 2010 (modified)]

### 1.5.73 Shall

Indicates that a statement is mandatory.

### 1.5.74 Should

Indicates a recommendation.

### **1.5.75 Soil**

Visible dirt or debris that can protect, harbour or assist the growth of microorganisms and which includes organic matter, inorganic matter, blood tissue and other biological material.

### **1.5.76 Spaulding Classification System**

Strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semi-critical, or non-critical on the basis of risk to patient safety from contamination on a device. The system also established three levels of microbicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and non-critical) as follows:

- (a) Critical—RMDs require cleaning followed by sterilization.
- (b) Semi-critical—RMDs require cleaning followed by high-level disinfection at a minimum; however, sterilization of these items is strongly recommended.
- (c) Non-critical—RMDs require cleaning and this can be followed by low or intermediate level disinfection.

### **1.5.77 Specify**

Stipulate in detail within an approved document.

### **1.5.78 Standard precautions**

Work practices that constitute the first line approach to infection prevention and control in the health care environment.

[NHMRC 2010]

### **1.5.79 Sterile**

Free from viable microorganisms.

[ISO/TS 11139]

### **1.5.80 Sterile barrier system (SBS)**

Minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use.

[ISO/TS 11139]

### **1.5.81 Sterility**

State of being free from viable microorganisms.

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

[ISO/TS 11139]

### **1.5.82 Sterility assurance level (SAL)**

Probability of a single viable microorganism occurring on an item after sterilization.

[Modified from ISO/TS 11139]

### **1.5.83 Sterilization**

Validated process used to render a product free from viable microorganisms.

NOTE: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an 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. cf. sterility assurance level.

[ISO/TS 11139]

#### 1.5.84 Sterilization process

Series of actions or operations needed to achieve the specified requirements for sterility.

NOTE: This series of actions includes pre-treatment of product (if necessary), exposure under defined conditions to the sterilizing agent and any necessary post treatment. The sterilization process does not include any cleaning, disinfection or packaging operations that precede sterilization.

[ISO/TS 11139]

#### 1.5.85 Sterilizing agent

Physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under defined conditions.

NOTE: See also Clause 1.5.36.

[ISO/TS 11139]

#### 1.5.86 Terminal sterilization

The process whereby a product is sterilized within its sterile barrier system.

[ISO/TS 11139]

#### 1.5.87 Traceability

The ability to trace the history, application or location of that which is under consideration.

NOTES:

- 1 When considering product, traceability can relate to—
  - (a) the origin of materials and parts;
  - (b) the processing history; and
  - (c) the distribution and location of the product after delivery.
- 2 Some professional groups refer to 'traceability' as 'tracking'.

[AS/NZS ISO 9000]

#### 1.5.88 Transmission-based precautions

Extra work practices in situations where standard precautions alone may be insufficient to prevent infection (e.g. for patients known or suspected to be infected or colonized with infectious agents that may not be contained with standard precautions alone).

[NHMRC 2010]

#### 1.5.89 Validation

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

[ISO/TS 11139]

#### 1.5.90 Verify

Confirm through the provision of objective evidence that specified requirements have been fulfilled.

[Modified from AS/NZS ISO 9000:2006, Definition 3.8.4]

#### 1.5.91 Washer-disinfector (WD)

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

[ISO 15883-1]

## SECTION 2      QUALITY MANAGEMENT

### 2.1 GENERAL

This Section specifies the elements of a quality management system that are necessary to ensure the safe and effective reprocessing of RMDs. HSOs shall develop their own workplace procedures based on the requirements of this Standard.

NOTE: HSOs might be required to implement an organization-wide quality management system as part of state, territory or national regulatory requirements.

### 2.2 DOCUMENTATION

#### 2.2.1 General

The requirements for documentation relate to the generation and control of documentation (including specifications and procedures) and records.

NOTE: In other sections of this Standard there is reference to other procedures that will need to be documented.

#### 2.2.2 Policies and procedures

Policies and procedures for reprocessing activities shall be documented and dated. At a minimum these shall include procedures for the following:

- (a) Workplace health and safety including staff health, wellbeing and immunization.
- (b) Purchasing of RMDs and reprocessing equipment and critical consumables, including manufacturer's instructions for use (see Clause 2.4.2).
- (c) Qualification of equipment including RMDs and reprocessing equipment.
- (d) Validation and requalification of cleaning, disinfecting and sterilizing processes including the rationale used to assign a particular RMD to a specific product family and processing category.
- (e) Routine monitoring and control of cleaning, disinfecting and sterilizing processes.
- (f) The initial treatment of used RMDs prior to their return to the designated reprocessing area/facility.
- (g) The collection of used RMDs from point of use or designated holding area.
- (h) Handling of specialized RMDs, including instruments on loan and instruments on trial [see Clause 2.4.2(g)].
- (i) Cleaning of RMDs prior to disinfection and/or sterilization.
- (j) Inspection, assembly and testing (where applicable) of RMDs prior to disinfection.
- (k) Inspection, assembly and testing (where applicable) and packaging of RMDs prior to sterilization.
- (l) Loading and unloading of equipment used to reprocess RMDs [examples include, but are not restricted to, washer-disinfector (WD), automated endoscope reprocessor (AER) and sterilizer].
- (m) Traceability of reprocessed semi-critical and critical RMDs.
- (n) Disinfection of cleaned RMDs.
- (o) Sterilization of cleaned RMDs.
- (p) Validation and routine control of cleaning, disinfecting processes and sterilizing processes.

- (q) Release of RMDs after reprocessing.
- (r) Handling, transport and storage of reprocessed RMDs.
- (s) Cleaning of reprocessing equipment and the reprocessing facility.
- (t) Periodic preventative maintenance of reprocessing equipment, including the calibration of monitoring instrumentation.
- (u) Action to be taken in the event of a biological or chemical spill or exposure.
- (v) Control of nonconforming RMDs.
- (w) Recall of RMDs.
- (x) Review of deviation reports and other indicators of quality or procedural problems.
- (y) Handling of product complaints.
- (z) Corrective action and preventative action.
- (aa) Staff training and assessment of competency.
- (bb) Contingency planning in the case of an emergency.

### **2.2.3 Records**

Records at a minimum shall include the following:

- (a) Purchasing records of RMDs and reprocessing equipment.
- (b) Monitoring of reprocessing equipment.
- (c) Cleaning process records.
- (d) Sterilizing process records.
- (e) High level disinfection, including chemical and thermal process records.
- (f) Microbiological surveillance testing (where applicable).
- (g) Cleaning of reprocessing equipment.
- (h) Cleaning of the reprocessing facility.
- (i) Staff training and competency to undertake reprocessing activities.
- (j) Staff rosters and allocations.
- (k) Maintenance records for RMDs (where applicable) and reprocessing equipment.
- (l) IQ, OQ and PQ for reprocessing equipment (where applicable).
- (m) Process deviation reports and where applicable, records of corrective action or preventative action.

### **2.2.4 Control of documents and records**

Documents required by this Standard shall be reviewed at defined intervals according to HSO policy and applicable regulatory requirements.

Documents shall be approved by designated personnel.

Documents and records shall be maintained in a designated storage area for a period of time not less than that defined by regulatory authorities or in their absence, HSO policy.

Documents and records shall be controlled and retrievable for the period of time specified.

## 2.3 MANAGEMENT RESPONSIBILITY

### 2.3.1 General

HSO executive management shall ensure organizational structure supports the requirements of this Standard. Responsibilities and authorities shall be defined, documented and communicated within the HSO.

Interrelationships shall be established between all personnel who manage, perform and verify work affecting reprocessing.

Irrespective of where reprocessing of non-critical, non-invasive RMDs occurs, appropriate resources shall be provided to ensure that the principles of this Standard can be followed.

### 2.3.2 Resource requirements

The HSO shall determine and provide the resources necessary to—

- (a) implement the requirements of this Standard, and the applicable requirements of the normative reference documents effectively;
- (b) implement the quality management program and to maintain its effectiveness through review;
- (c) meet regulatory and customer requirements;
- (d) ensure that staffing levels are sufficient to maintain the continuous, safe and efficient operation of the reprocessing facility;
- (e) establish the buildings, workspaces and associated utilities necessary to achieve conformity with requirements for RMD reprocessing;
- (f) procure reprocessing equipment appropriate to purpose;
- (g) maintain buildings, workspaces, associated utilities and process equipment;
- (h) provide supporting services; and
- (i) staff training.

### 2.3.3 Reprocessing facility

The person directly responsible for the reprocessing of RMDs within the facility shall—

- (a) have relevant qualifications and experience in reprocessing of sterilization technology and/or RMD;

#### NOTES:

- 1 Mandatory qualifications apply in some regions.
- 2 Nationally recognized competency-based courses exist in both Australia and New Zealand. Reference to these courses is essential in establishing the specific educational requirements for reprocessing staff.

- (b) have the authority to implement the requirements of this Standard and the applicable requirements of the normative reference documents associated with this Standard wherever reprocessing activities occur throughout the entire organization;
- (c) implement policies and procedures to assure the quality and safety of reprocessed RMDs;
- (d) be directly involved in the supervision of the day to day activities within the reprocessing facility; and

NOTE: Reprocessing of critical and semi-critical RMDs might also occur in separate endoscopy units, day surgery facilities, outpatient clinics, radiology, etc. in some organizations.

- (e) ensure that there is a formal orientation and training program for staff involved in reprocessing activities, that staff are trained and competent to undertake reprocessing activities and there is ongoing periodic assessment of staff competency at intervals defined by the HSO.

#### **2.3.4 Equipment**

HSOs shall consider the total time required to reprocess RMDs correctly as part of operational planning to ensure that sufficient quantities of RMDs and reprocessing resources are available to meet demand.

HSOs shall ensure sufficient reprocessing equipment is available to meet the needs of the reprocessing facility, taking into consideration the volume of RMDs requiring reprocessing.

NOTE: Capacity planning requires knowledge of the available inventory of RMDs, the demand for specific RMDs to be reprocessed for reuse within the same operating session, the average volume of RMDs requiring reprocessing per hour and consideration of the impact of planned and unplanned redundancy on the total turnaround time.

#### **2.3.5 Contracts**

Where any activities encompassed by this Standard are undertaken by an external contractor, HSOs shall ensure that an agreement is in place that identifies the responsibilities of each party, including the requirement to comply with this Standard.

### **2.4 PRODUCT REALIZATION**

#### **2.4.1 General**

The requirements for product realization relate to the product life cycle from the determination of customer/patient requirements, design and development, purchasing, control of production and calibration of monitoring and measuring devices.

#### **2.4.2 Purchasing**

Procedures for purchasing reprocessing equipment, RMDs and accessories to RMDs shall be established by the HSO.

To ensure that the selected product conforms to specified purchasing requirements procedures for purchasing shall include:

- (a) Criteria for product selection and evaluation that are risk based and which address workplace health and safety requirements.
- (b) Involvement of the reprocessing facility manager in the selection process prior to the purchase of an RMD.
- (c) Evaluation to ensure compatibility with the reprocessing systems available for use in the reprocessing facility.
- (d) The requirement for reprocessing equipment to comply with relevant regulatory, equipment and/or safety standards (where applicable).
- (e) For New Zealand, the requirement for RMDs and accessories to RMDs and reprocessing equipment to be entered on the ARTG or equivalent (in New Zealand).
- (f) Provision of operational instructions for use for reprocessing equipment and accessories to medical devices.
- (g) Provision of documented and validated reprocessing instructions in accordance with ISO 17664 for RMDs (including trial and loan RMDs).
- (h) Acceptance criteria when taking delivery.

## NOTES:

- 1 Inclusion of IQ, OQ and PQ and staff training can be considered as part of the purchasing agreement with equipment supplier.
- 2 Accessories to medical devices include but might not be limited to cleaning agents, cleaning utensils, packaging materials and sterile barrier systems.
- 3 Acceptance criteria could include checking of packaging for evidence of tampering or damage, product expiry dates, compliance with purchasing specifications, etc.

**2.4.3 Identification and traceability of product****2.4.3.1 General**

Procedures shall be specified for the identification and traceability of semi-critical RMDs undergoing high level chemical disinfection and critical RMDs including trial and loan RMDs, during reprocessing and subsequent use on patients undergoing surgical or invasive procedures.

At a minimum, the traceability system shall be sufficient to enable the identification of a patient(s) where a nonconforming product has been used in an event that a recall is necessary.

## NOTES:

- 1 In certain circumstances, traceability of an RMD to individual patient use might be required (e.g. those RMD used on high risk tissues).
- 2 Consideration should be given to implementing a means of traceability for semi-critical RMDs that are released for use after thermal disinfection, in particular, for complex RMDs that are stored after processing for later use.
- 3 In the event of recall action procedures should be sufficient to ensure traceability of an implantable RMD that is subject to numerous reprocessing cycles, e.g. screw banks utilized in orthopaedic or plastic surgery. Consideration should be given to incorporating the manufacturer's batch/lot number of a non-sterile, commercially-supplied, implantable component into the unit pack.

**2.4.3.2 Traceability records**

Traceability systems shall require at a minimum, the identification of the following for each RMD:

- (a) High level chemical disinfection—Disinfection process records [see Clause 2.2.3(e)]:
  - (i) Type of RMD, e.g. trans-rectal ultrasound probe, colonoscope, vaginal probe, endoscope.
  - (ii) Unique identification number of the RMD, e.g. the serial number.
  - (iii) Date of cleaning of the RMD and identification of the person responsible.
  - (iv) Identification of the person responsible for connecting the RMD to the AER or for manual immersion of the RMD in the disinfectant.
  - (v) Identification of the automated equipment used to process the RMD, e.g. equipment identification number or code (if there is more than one unit in the reprocessing facility).
  - (vi) Disinfecting process cycle number and date of disinfection.
  - (vii) Other records, including but not limited to the following:
    - (A) Disinfectant Type/brand of the disinfectant, batch number, manufacturer's expiry date, date of decanting/opening of disinfectant and in-use expiry date/date for disposal.

- (B) Test strips Brand/type of test strip, batch number, manufacturer's expiry date, date of decanting/opening of test strips and in-use expiry date/date for disposal, results of any positive/negative controls performed upon opening, results of test strips used for daily MRC or MRC check for each use/cycle; identification of person conducting positive and negative controls and identification of person conducting MRC check.
  - (C) Cycle process record/printout, self-disinfection cycles (where required), water filter pressures and date of chemical and filter changes.
  - (D) Manual immersion into disinfectant, temperature of disinfectant, time of immersion into disinfectant, time removed from disinfectant, final rinse according to chemical disinfectant and RMD manufacturers' instructions.
- (viii) Documented evidence of attainment of process parameters, e.g. process record/printout (where applicable).
- NOTE: Process records can be paper based or electronic. Where electronic records are kept, procedures should be in place to verify attainment of process parameters at the conclusion of every cycle.
- (ix) Identification of the person responsible for release of the RMD.
- (b) Sterilization—Sterilizing process records [see Clause 2.2.3(d)]:
- (i) Date of sterilization and sterilizing process cycle number.
  - (ii) Identification of the sterilizer, e.g. sterilizer identification number or code (if there is more than one unit in the reprocessing facility).
  - (iii) Identification of the RMD (e.g. RMD name or name of a set of RMDs) and the number of these items within the load.
  - (iv) Identification of the person responsible for loading the RMDs into the sterilizer.
  - (v) Other records, including but not limited to the following:
    - (A) Results of any performance tests required to verify functional performance of the equipment prior to use, e.g. leak rate test, Bowie and Dick—type test.
    - (B) Results of chemical and biological monitoring undertaken for individual cycles or on a periodic basis (see also Section 8).
    - (C) Sterilizing agent (where applicable), batch number and expiry date.
  - (vi) Documented evidence of attainment of process parameters, e.g. process record/printout (where applicable).
- NOTES:
- 1 Process records can be paper based or electronic. Where electronic records are kept, procedures should be in place to verify attainment of process parameters at the conclusion of every cycle.
  - 2 Additional information can be linked to an RMD where an electronic traceability system is in place. These systems can assist in other management activities including asset management.
- (vii) Identification of the person responsible for release of the RMD (sterilization load).

## **2.4.4 Control of monitoring and measuring equipment**

### **2.4.4.1 General**

The HSO shall ensure that monitoring and measuring equipment, including that which is used for testing purposes, is calibrated at specified intervals, or prior to use, traceable to international or national measurement standards.

This requirement also applies to monitoring and measuring devices used by external contractors.

Calibration equipment shall be certified by a suitable certification body [e.g. the National Association of Testing Authorities (NATA) in Australia, IANZ].

NOTE: Refer to Sections 8 and 10 for frequency of routine monitoring, calibration and testing.

Monitoring and measuring equipment shall be—

- (a) identified with its calibration status;
- (b) adjusted/re-adjusted as necessary;
- (c) protected from adjustments that would invalidate the measurement result; and
- (d) protected from damage during handling, maintenance and storage.

### **2.4.4.2 Documentation**

A calibration report shall be obtained for calibration tests performed for each piece of monitoring and measuring equipment. Records of calibration and any adjustments shall be kept.

The calibration report shall include the certification number of the calibration device used.

### **2.4.4.3 Nonconformance**

Where equipment is found not to conform to requirements, then the HSO shall take action in relation to the faulty equipment and any product affected. Records of this action shall be kept.

## **2.5 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **2.5.1 Audits**

Regular periodic audits shall be performed to confirm that the requirements of this Standard are being met. The audit findings shall be documented and where applicable, corrective action shall be implemented to rectify deficiencies. Corrective action shall be reviewed to ensure that it has been effective in addressing the deficiency.

### **2.5.2 Nonconforming RMD**

Nonconforming RMD shall include those items that do not meet acceptance criteria after completion of cleaning, disinfecting or sterilizing processes, and packaging, as applicable.

NOTE: Refer to Paragraph A2.5.2 of Appendix A, for examples of nonconforming RMD.

An investigation shall be performed for a nonconforming RMD in accordance with HSO risk assessment policy.

### **2.5.3 Corrective action**

#### **2.5.3.1 General**

Corrective action taken in relation to a nonconforming RMD shall include—

- (a) identification of the nature of the nonconformity (including user concerns or complaints);
- (b) implementation of an action plan to correct the nonconformity;

- (c) documentation of action taken to address the nonconformity;
- (d) evaluation of corrective action taken to verify its effectiveness in resolving the nonconformity; and
- (e) where applicable, implementation of additional corrective action to further resolve the nonconformity.

Where a nonconforming RMD is detected after delivery or use, then the HSO shall take action appropriate to the type and possible effects of the nonconformity.

NOTE: This might include recall of a nonconforming RMD.

#### **2.5.3.2 Recall procedure**

Recall procedures shall—

- (a) identify examples of situations where recall of a distributed RMD is warranted;  
NOTE: The expectation is that timely recall of a released RMD is necessary where there is evidence of failure during the cleaning, disinfecting, packaging or sterilizing processes for that RMD. Recall of a released RMD can also be necessary where problems have been encountered during transport and storage of a reprocessed RMD.
- (b) emphasize that recall activities should be performed in a timely manner;
- (c) identify the person/s responsible for coordinating recall activities;
- (d) identify the persons to be notified in the event of recall within or outside of the HSO;
- (e) identify the person/s responsible for retrieving distributed RMDs, including RMDs that have been distributed off-site;
- (f) identify the person/s responsible for reporting on recall activities;
- (g) identify the critical information to be included in a recall notice [e.g. identify the departments for which the recall notice is intended, identify the RMD and quantity to be recalled, state the reason for recall of the RMD and identify the action to be taken by persons receiving the recall notice (i.e. return of the RMD or holding/quarantining of the RMD pending further instructions)]; and
- (h) include the need to reconcile quantities of recalled RMDs with RMD distribution records.

#### **2.5.3.3 Recall report**

The recall report shall be completed in accordance with HSO policies. At a minimum it shall include the following information:

- (a) Identification of the circumstances that initiated the need for recall of the RMD.
- (b) Identification of the recalled RMD and reconciliation of quantities of the recalled RMD with RMD distribution records.
- (c) Where applicable, identification of patients impacted by the recall activity and follow up action taken.
- (d) Identification of the root causes for the recall.
- (e) Identification of corrective action taken in relation to the recall.
- (f) Identification of the consequences of the recall (e.g. cost and time of reprocessing a recalled RMD, cost of replacing equipment, impact on surgical procedures and where applicable, the need for staff retraining).
- (g) Recommendations to prevent a recurrence of the circumstances that led to the recall.

#### **2.5.4 Preventative action**

The HSO should also identify potential causes of a nonconforming RMD to prevent their occurrence. At a minimum, preventative action should include—

- (a) identification of potential cause/s of nonconforming RMDs;
- (b) implementation of an action plan to prevent the potential for nonconforming RMDs;
- (c) documentation of action taken to address the potential for nonconforming RMDs;
- (d) evaluation of preventative action taken to verify its effectiveness in preventing the potential for nonconforming RMDs; and
- (e) where applicable, implementation of additional preventative action to further prevent the potential for nonconforming RMDs.

## SECTION 3 REPROCESSING AGENT CHARACTERIZATION

### 3.1 GENERAL

#### 3.1.1 Introduction

Reprocessing agent characterization defines the reprocessing (cleaning, disinfecting and sterilizing) agent(s), necessary to demonstrate their microbicidal effectiveness, to identify the factors that influence microbicidal effectiveness, to assess the effects that exposure to the reprocessing agent(s) has on RMDs, and to identify requirements for the safety of personnel and for the protection of the environment. This includes—

- (a) the cleaning agents;
- (b) chemical disinfecting agents;
- (c) physical disinfecting processes;
- (d) physical and chemical sterilizing agent(s); and
- (e) any other agents involved in reprocessing.

This activity also ensures that the HSOs in conjunction with the manufacturer or supplier of cleaning agents, disinfectants and sterilizing agents, will determine—

- (i) the effects exposure to these agents has on RMDs;
- (ii) requirements for safety of personnel and the environment; and
- (iii) microbicidal effectiveness of disinfectants and sterilizing agents and any factors that influence this.

#### 3.1.2 Reprocessing agent selection

Cleaning agents, instrument grade chemical disinfectants and liquid chemical sterilizing agents that are supplied in Australia and which are intended for use on RMDs shall be included in the TGA Australian Register of Therapeutic Goods (ARTG).

##### NOTES:

- 1 Cleaning agents, chemical disinfectants and liquid chemical sterilizing agents that are intended for use on medical devices are regulated by the TGA as accessories to medical devices.
- 2 Cleaning agents are classified as Class I medical devices, Disinfectants and liquid chemical sterilizing agents are classified as Class IIB medical devices.
- 3 For a product to be included on the ARTG it has to comply with the TGA's regulatory requirements.

#### 3.1.3 Reprocessing agent information

The HSO shall obtain the following information for each cleaning agent(s), disinfectant and sterilizing agent (where applicable) from the product manufacturer/or supplier:

- (a) Safety data sheet.
- (b) Regulatory status.
- (c) Active ingredient/s and physical/chemical properties, including stability (shelf life).
- (d) Microbial efficacy (if applicable).
- (e) Toxicity/residues.
- (f) Material effects of the agent on RMDs, including known RMD material compatibilities and known RMD material non-compatibilities.

- (g) Container/packaging.
- (h) Labelling (this shall include shelf life and storage requirements).
- (i) Directions for use and where applicable, and permitted by the manufacturer, reuse.

NOTES:

- 1 Steam quality should be in accordance with Clause 7.2.3.2.
- 2 Some disinfectants or sterilizing agents may be able to be reused multiple times prior to disposal. Where this is permitted, manufacturer's instructions for reuse are to be followed.

### 3.2 CLEANING AGENTS

A cleaning agent shall be used to remove residual soil and organic matter from a used RMD.

The HSO shall obtain a documented specification for each cleaning agent from the manufacturer/supplier that provides the requisite information as detailed in Clause 3.1.3.

NOTE: Different cleaning agents could be required for manual cleaning versus cleaning in a washer-disinfector or ultrasonic cleaner.

Where an RMD manufacturer's instructions for reprocessing recommend against the use of a cleaning agent the RMD manufacturer shall provide evidence of the efficacy of the cleaning process.

Cleaning agents shall be—

- (a) intended for use on medical devices, and where supplied in Australia, shall be included in the ARTG;
- (b) compatible with the RMDs being processed and selected method of cleaning;
- (c) diluted and used in accordance with the manufacturer's instructions;
- (d) compatible with the available water quality;
- (e) preferably biodegradable;
- (f) non-toxic at the in-use dilution;
- (g) non-abrasive;
- (h) low foaming;
- (i) free rinsing; and
- (j) preferably in liquid form.

### 3.3 DISINFECTANTS

A chemical disinfectant used to reprocess an RMD shall be labelled as an 'Instrument grade disinfectant'. The following criteria shall be met in selection of such a disinfecting agent:

- (a) A high-level instrument grade disinfectant shall be the minimum grade disinfectant used for disinfection of a semi-critical RMD (see Section 5).
- (b) An intermediate or low level instrument grade disinfectant shall be the minimum grade disinfectant used for disinfection of a non-critical RMD where required (see Section 5 and the Spaulding Classification System).

Other classes of chemical disinfectants, e.g. hospital grade disinfectant, shall not be used to reprocess an RMD.

### 3.4 STERILIZING AGENTS

The reprocessing facility shall obtain the specification for each sterilizing agent from the manufacturer. At a minimum it shall include the identity of the sterilizing agent, active ingredient(s), shelf life and the storage conditions necessary to maintain the sterilizing agent within specification for the duration of the stated shelf life. It shall also include the requirements to be met for reuse of the sterilizing agent if this is permitted.

NOTE: This requirement is applicable to liquid chemical sterilizing agents, sterilizing gases (other than saturated steam) and other sterilizing agents used in low temperature sterilization processes.

### 3.5 MICROBICIDAL EFFECTIVENESS

The microbicidal effectiveness of disinfectants and sterilizing agents used for reprocessing of RMDs in HSOs has been comprehensively documented. This information is available in the published literature and in the technical monographs provided by the suppliers of disinfectants and sterilizing agents and the equipment in which these agents are used.

Where cleaning agents make claims of microbicidal effectiveness the agent manufacturer is required to provide the evidence of this claim.

Where disinfectants and sterilizing agents are used in disinfecting or sterilizing processes outside of the range of conditions specified by a supplier of a disinfecting or sterilizing system, then the microbicidal effectiveness of the alternative disinfecting or sterilizing process(es) shall be demonstrated by the HSO.

Reference shall be made to the following:

- (a) For disinfectants and liquid chemical sterilizing agents—TGO 54 (in Australia).
- (b) For moist heat sterilization—ISO 17665-1.
- (c) For dry heat sterilization—ISO 20857.
- (d) For ethylene oxide gas sterilization—ISO 11135.  
NOTE: For flexible chamber EO sterilization processes, refer to ISO 14937.
- (e) For low temperature steam formaldehyde—ISO 25424.
- (f) For sterilizing processes where no other standard applies refer to ISO 14937.
- (g) For washer-disinfectors—ISO 15883 (relevant part).

### 3.6 EFFECTS ON RMD MATERIALS

Cleaning agents, disinfectants and sterilizing agents shall be compatible with the RMD to be processed and the associated equipment used to deliver that process.

Assessment of compatibility and the effects on materials shall occur through review of information provided by the RMD or equipment manufacturer (see also Clause 5.3). The outcome of this assessment shall be documented.

Where an HSO chooses to reprocess an RMD using a cleaning agent, disinfectant or sterilizing agent or a cleaning, disinfection or sterilization process that is not consistent with the validated reprocessing instructions provided, then the HSO shall discuss the possible effects of repeated exposure of the RMD to the proposed agent(s) and process with the manufacturer or supplier of the RMD. The outcome of this discussion shall be documented.

NOTE: HSOs can perform this assessment by considering information provided by the manufacturer or supplier of the RMD and by the manufacturer or supplier of the reprocessing agent(s).

### **3.7 PERSONNEL AND ENVIRONMENTAL SAFETY**

#### **3.7.1 Safety information**

A safety data sheet (SDS) or other relevant safety information shall be obtained and applied for each cleaning agent, disinfectant and chemical sterilizing agent, and if applicable, for its precursor(s) and by-products.

NOTES:

- 1 A current SDS is generally available from the product manufacturer or supplier. Checks to ensure the most up-to-date SDS is available should occur at least annually.
- 2 An SDS was previously known as a Material Safety Data Sheet (MSDS).

The HSO shall ensure sufficient information about the safe use, handling and storage of the hazardous chemical is readily accessible to—

- (a) a worker at the workplace; and
- (b) an emergency services worker.

#### **3.7.2 Environmental impact**

The potential impact on the environment of any substance, which could be released during or following the use of a cleaning, disinfectant or sterilizing agent, shall be assessed to ensure compliance with local and national regulatory requirements.

Control measures implemented to mitigate environmental impact shall be established in accordance with national and regional requirements. This assessment, including details of control measures in place, shall be documented.

#### **3.7.3 Health and safety procedures**

Procedures shall be developed for the storage, handling, decanting and disposal of chemicals in accordance with manufacturer's instructions for use/SDS and regulatory requirements.

Chemical containers, including containers holding decanted chemicals shall be labelled in accordance with the applicable local or national regulatory requirements.

Reference shall be made to relevant legislation for work, health and safety.

#### **3.7.4 Health and safety training**

All personnel involved in the handling and use of cleaning agents, disinfectants and chemical sterilizing agents shall be trained in the safe handling, use and storage of these substances, the use of PPE, and procedures for spills and exposure management.