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DR 100397 Reprocessing of reusable medical devices in health service organizations

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DR 100397

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Draft for Public Comment
Australian/New Zealand Standard

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BEGINNING DATE FOR COMMENT: 23 April 2014

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Reprocessing of reusable medical devices in health service organizations

(Revision of AS/NZS 4187:2003)
Draft for Public Comment
Australian/New Zealand Standard

The committee responsible for the issue of this draft comprised representatives of organizations interested in the subject matter of the proposed Standard. These organizations are listed on the inside back cover.

Comments are invited on the technical content, wording and general arrangement of the draft.

The method for submission of comment on this document is to register and fill in an online form via Standards Hub Website. Instructions and examples of comment submission are available on the website. Please use the following link—

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Please place relevant clause numbers beside each comment.

Editorial matters (i.e. spelling, punctuation, grammar etc.) will be corrected before final publication.

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Normally no acknowledgment of comment is sent. All comments received via the Standards Hub Website by the due date will be reviewed and considered by the relevant drafting committee. We cannot guarantee that comments submitted in other forms will be considered along with those submitted via the Standards Hub online form. Where appropriate, changes will be incorporated before the Standard is formally approved.

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Committee HE-023—Processing of Medical and Surgical Instruments

DRAFT

Australian/New Zealand Standard

Reprocessing of reusable medical devices in health service organizations

(Revision of AS/NZS 4187:2003)
(To be AS/NZS 4187:201X)

Comment on the draft is invited from people and organizations concerned with this subject. It would be appreciated if those submitting comment would follow the guidelines given on the inside front cover.

Important: The procedure for public comment has changed—please read the instructions on the inside cover of this document.

This document is a draft Australian/New Zealand Standard only and is liable to alteration in the light of comment received. It is not to be regarded as an Australian/New Zealand Standard until finally issued as such by Standards Australia/Standards 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.*

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 clean, disinfect and sterilize RMDs prior to and between patient uses correctly 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.

Statement 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.
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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 and/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 and/or an adverse reaction from residual cleaning, disinfecting and/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 and/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 and/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 RMD, particularly non-invasive, non-critical RMD 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 be cleaned and disinfected, and/or 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 re-use 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 and/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, for example hospitals, dental practice, general practice and podiatry.

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, for example, 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 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. Creutzfeld 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, for example sterilizing empty plastic water bottles, rubber bands, cardboard cut from store-packs, dessert spoons, 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 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
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 health care facilities and institutions
3789.1 Part 1: General ward linen

AS/NZS ISO
9001 Quality management systems—Requirements

ISO
10993 Biological evaluation of medical devices
10993-7 Part 7: Ethylene oxide sterilization residuals
11135 Sterilization of health care products—Ethylene oxide
11135.1 Part 1: 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)

ISO
14607 Packaging for terminally sterilized medical devices
14607-1 Part 1: Requirements for materials, sterile barrier systems and packaging systems
14607-2 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
15882 Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results
ISO
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, anesthetic 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
15883-5 Part 5: Test soils and methods for demonstrating cleaning efficacy
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

ISO/TS
11135 Sterilization of health care products—Ethylene oxide
11135-2 Part 2: Guidance on the application of ISO 11135-1

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)

EN
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

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

AER  Automated endoscope reprocessor (aka W-D for thermo labile endoscopes)
ARTG  Australian Register of Therapeutic Goods
BI  Biological indicator
CDC  Centers for Disease Control and Prevention
CI   Chemical indicator
cCJD Classical Creutzfeld Jacob Disease
vCJD Variant Creutzfeld Jacob disease
EO   Ethylene oxide
GES/GESA/Gastroenterological Society of Australia
HLD  high level disinfection
HSO  Health service organization
IAP  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 Performed 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
W-D Washer-disinfector

1.5 DEFINITIONS

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

1.5.1 \( t_0 \)

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 pre-determined levels are reached.

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

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

1.5.5 Bioburden

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

1.5.6 Biofilm

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

1.5.7 Biological indicator (BI)

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

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.

1.5.9 Change Control

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

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.

1.5.11 Cleaning

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

1.5.14 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 cassette.

1.5.15 Contamination
The presence of microorganisms or foreign matter.

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

[ISO/TS 11139]

1.5.17 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 conveys a high risk of transmission of infectious agents.

[NHMRC 2010 (modified)]

1.5.18 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 (1.5.24), hospital grade (1.5.27), instrument grade (1.5.31), intermediate level (1.5.32) and low level (1.5.35) disinfectants.

1.5.19 Disinfection
The inactivation of microorganisms using either heat and water (thermal) or by chemical means.

1.5.20 Drying phase
The phase in the sequence of the function of a W-D 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.

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

[ISO/TS 11139]

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

[ISO/TS 11139]
1.5.23 **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.


1.5.24 **High level disinfectant**

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

1.5.25 **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]

1.5.26 **Hollowware**

Items such as bowls, flasks, jugs and containers.

1.5.27 **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.

1.5.28 **'Immediate use'**

Immediate use sterilization is defined as a process in which sterilized RMDs are transferred aseptically to the sterile field in the shortest practicable time after removal from the sterilizer. The method of transfer must minimize exposure to air and environmental contaminants. An RMD sterilized for immediate use must not be stored for future use nor be held for use in another procedure.

1.5.29 **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 devices implanted by endoscopic means.

1.5.30 **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.
1.5.31 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]

1.5.32 Instrument grade disinfectant
(a) A disinfectant which 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.

1.5.33 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.

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

1.5.35 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 SAL of a microbial survivor is less than 10^-6.

NOTE: A liquid chemical sterilizing agent is a sterilizing agent (see Clause 1.5.34).

[TGO 54 (modified)]

1.5.36 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.

1.5.37 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.

1.5.38 Manufacturer's instructions
Instructions for use (IFU) provided by the manufacturer of the medical device and/or accessories, for example sterile barrier systems, RMD, W-D.

1.5.39 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 13485:2003]

NOTE: The ISO 13485:2003 definition was developed by the Global Harmonization Task Force (GHTF 2002).

1.5.40 Microbicidal
Destructive to microorganisms.

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

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

1.5.42 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.

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

[ISO 9000]

1.5.44 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)]

1.5.45 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 15883-6:2011]

1.5.46 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.

1.5.47 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]
1.5.48 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]

1.5.49 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]

1.5.50 Packaging system

A combination of the sterile barrier system and protective packaging.

[ISO/TS 11139]

1.5.51 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.

1.5.52 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]

1.5.53 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]

1.5.54 Pre-treatment

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

1.5.55 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.

[ISO 9000:2005]

1.5.56 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]
1.5.57 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]

1.5.58 Process variable

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

[ISO/TS 11139]

1.5.59 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.

1.5.60 Processing category

Group of different product that can be processed together.

[ISO/TS 11139]

1.5.61 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]

1.5.62 Product

The result of a process.

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) [ISO 9000].

2. For the purposes of this Standard, the term “product” is synonymous with reusable medical device.

[ISO 9000:2005]

1.5.63 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]

1.5.64 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).

1.5.65 Requalification

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

[ISO/TS 11139]
1.5.66 Reusable container
Rigid sterile barrier system designed to be repeatedly used.
[ISO 11607-1]

1.5.67 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]

1.5.68 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.

1.5.69 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.

1.5.70 Saturated steam
Water vapour in a state of equilibrium between condensation and evaporation.
[ISO 17665-1]

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

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

[NHMRC 2010 (modified)]

1.5.72 Shall
Indicates that a statement is mandatory.

1.5.73 Should
Indicates a recommendation.

1.5.74 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.

1.5.75 Spalding classification
Strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also established three levels of microbiocidal
activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical).

1.5.76 Specify
Stipulate in detail within an approved document.

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

[NHMRC 2010]

1.5.78 Sterile
Free from viable microorganisms.

[ISO/TS 11139]

1.5.79 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]

1.5.80 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]

1.5.81 Sterility assurance level (SAL)
Probability of a single viable microorganism occurring on an item after sterilization.

[Modified from ISO/TS 11139]

1.5.82 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]

1.5.83 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]

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

NOTE: See also Clause 1.5.35.

[ISO/TS 11139]
1.5.85 Terminal sterilization
The process whereby a product is sterilized within its sterile barrier system.
[ISO/TS 11139]

1.5.86 Traceability
The ability to trace the history, application or location of that which is under consideration.
NOTE: 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.
[AS/NZS ISO 9000]

1.5.87 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]

1.5.88 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]

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

1.5.90 Washer-disinfector (W-D)
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) Validation and requification of equipment.
(d) The initial treatment of used RMDs prior to their return to the designated reprocessing area/facility.
(e) The collection of used RMDs from point of use or designated holding area.
(f) Handling of specialized RMDs, including instruments on loan and/or instruments on trial [see Clause 2.4.2(e)].
(g) Cleaning of RMDs prior to disinfection and/or sterilization.
(h) Inspection, assembly and testing (where applicable) of RMDs prior to disinfection.
(i) Inspection, assembly and testing (where applicable) and packaging of RMDs prior to sterilization.
(j) Loading and unloading of equipment used to reprocess RMDs (for example, but not restricted to, washer-disinfector (W-D), automated endoscope reprocessor (AER) and sterilizer).
(k) Traceability of reprocessed semi-critical and critical RMDs.
(l) Disinfection of cleaned RMDs.
(m) Sterilization of cleaned RMDs.
(n) Validation and routine control of cleaning, disinfecting processes and sterilizing processes, including the rationale used to assign a particular RMD to a specific product family and processing category.
(o) Release of RMDs after reprocessing.
(p) Handling, transport and storage of reprocessed RMDs.
(q) Cleaning of reprocessing equipment and the reprocessing facility.

(r) Periodic preventative maintenance of reprocessing equipment, including the calibration of monitoring instrumentation.

(s) Action to be taken in the event of a biological or chemical spill and/or exposure.

(t) Control of nonconforming RMDs.

(u) Recall of RMDs.

(v) Review of deviation reports and other indicators of quality or procedural problems.

(w) Handling of product complaints.

(x) Corrective action and preventative action.

(y) Staff training and assessment of competency.

(z) Contingency planning in the case of an emergency and/or disaster.

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 and services to this 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 records and evidence of staff competency to undertake reprocessing activities.

(j) Staff rosters and allocations are kept according to HSO policy and applicable regulatory requirements.

(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 and/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 manager

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

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

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;

NOTE: Reprocessing of critical and semi-critical RMDs might also occur in separate endoscopy units, day surgery facilities, outpatient clinics, radiology, etc. in larger organizations.
(e) ensure that the staff involved in reprocessing activities are trained and competent to undertake these activities; and

(f) ensure that there is a formal orientation and training program for staff and that this program includes periodic assessment of staff performance at intervals defined by HSOs.

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.

NOTE: Refer to Paragraph A2.4.1 for guidance on existing instruments where no reprocessing instructions can be obtained.

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 are risk based and address workplace health and safety requirements.

(b) The reprocessing facility manager shall be involved in the selection process prior to the purchase of the 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) The requirement for RMDs and accessories to RMDs and reprocessing equipment to be entered on the ARTG or equivalent (in New Zealand).

(f) For reprocessing equipment and accessories to medical devices, provision of operational instructions for use.

(g) For RMDs, including trial and loan RMDs, provision of documented and validated reprocessing instructions in accordance with ISO 17664.
(h) Acceptance criteria when taking delivery.

NOTES:
1 Inclusion of IQ, OQ and PQ and staff training may be considered as part of the purchasing agreement with equipment supplier.
2 Accessories to medical devices include but may not be limited to cleaning agents cleaning utensils, packaging materials and sterile barrier systems.
3 Acceptance criteria could include checking 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 and/or invasive procedures.

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

NOTES:
1 In certain circumstances, for example those RMD used on high risk tissues, traceability of RMD to individual patient use might be required.
2 Where semi-critical items are released for use post thermal disinfection, consideration should be given to implementing traceability of these items, particularly in situations where complex devices are being processed and stored for later use.
3 In the event of recall action the procedures should be sufficient to ensure traceability of an implantable RMD that are 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 any unsterile commercially prepared implantable materials 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 2.2.5(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 may not be limited to the following:
      (A) Disinfectant—Type/brand of the disinfectant, batch number, manufacturers expiry date, date of decanting/opening of disinfectant and expiry date/date for disposal.
(B) Test strips—Brand/type of test strip, batch number, manufacturers expiry date, date of decanting/opening of test strips and expiry date/date for disposal, results of any positive/negative controls performed upon opening, results of test strips used for daily MRC or MRC for each use/cycle; identification of person conducting positive and negative controls, identification of person conducting MRC.

(C) AER—Cycle process record/printout, self-disinfection cycles (where required), water filter pressures, dates, chemicals and filters changed.

(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) Identification of the person responsible for release of the RMD.

(ix) 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.

(b) Sterilization—Sterilizing process records [see Clause 2.2.5(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) Identification of the person responsible for release of the RMD (sterilization load).

(vi) Other records, including but may not be 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/or biological monitoring undertaken on a cycle by cycle or periodic basis (see also Section 8).

(C) Sterilizing agent (where applicable), batch number and expiry date.

(vii) 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.

NOTE: 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.

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 Non-conformance

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 on non-conformance according to 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 should—

(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 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/or 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 register

Cleaning agents, instrument grade chemical disinfectants and liquid chemical sterilizing agents that are intended for use on RMDs shall be included on the 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. It is a TGA regulatory requirement that these products be included on the ARTG before they can be supplied in Australia. 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 entered on 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) biodegradable;
(f) non-toxic;
(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 Spaulding’s 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/or 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 and/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 and/or sterilizing process(es) shall be demonstrated by the HSO.

Reference shall be made to the following:

(a) For disinfectants: TGO 54.
(b) For moist heat sterilization: ISO 17665-1.
(c) For dry heat sterilization: ISO 20857.
(d) For ethylene oxide gas sterilization: ISO 11135-1.
   NOTE: EO gas diffusion processes in flexible bags reference should be made to ISO 14937.
(e) For low temperature steam formaldehyde: ISO 25424.
(f) ISO 14937.

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/or the effects on materials shall occur through review of information provided by the RMD manufacturer and/or the equipment manufacturer (see also Clause 4.2.5). 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 validated reprocessing instructions provided, then the HSO shall discuss the possible effects of repeated exposure of the RMD to the proposed agent(s) and/or 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 service 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 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.
SECTION 4 PROCESS CHARACTERIZATION AND EQUIPMENT CHARACTERIZATION

4.1 GENERAL
The purpose of this activity is to define the processes and the equipment used to deliver safe, effective and reproducible cleaning, disinfecting and sterilizing processes. Reprocessing equipment shall be intended for use to process medical devices.

The HSO shall—
(a) obtain process and equipment specifications from the equipment manufacturer;
(b) review the manufacturer’s process and equipment specification and establish that it has the services and infrastructure necessary to safely operate the equipment (see also Clauses 4.2 and 4.3); and
(c) ensure RMDs are compatible with the processes delivered by the selected reprocessing equipment.

NOTES:
1 Manufacturers of reprocessing equipment undertake process and equipment characterization to develop the process and equipment specifications in order to obtain regulatory approval.
2 Many types of reprocessing equipment are considered medical devices and are required to be entered on the Australian Register of Therapeutic Goods.
3 The equipment manufacturer’s process specifications in conjunction with the RMD manufacturer’s reprocessing instructions can be used to determine compatibility of the RMD with the available processes and equipment.

4.2 PROCESS CHARACTERIZATION
The HSO shall obtain from the equipment manufacturer detailed specifications of the processes delivered by the cleaning, disinfecting and sterilizing equipment.

The information provided shall include but may not be limited to the following:
(a) A detailed description of the process cycle.
(b) The process parameters, together with their tolerances.
(c) The means by which the process variables may be monitored and controlled.
(d) The measures to ensure that a failure to achieve specified process parameters shall not result in an ineffective cleaning, disinfecting and/or sterilizing process being recorded as effective.

NOTE: Measures may include the use of independent systems for process control and monitoring, or the use of cross-checks between process control and process monitoring systems to identify discrepancies that might indicate a fault.

(e) Any treatment of product that is required prior to exposure to the process to ensure its effectiveness.
(f) A description of the product families that can be safely and effectively processed.
(g) Any restrictions or limitations relating to the size, mass, configuration, or loading orientation of RMDs being processed.

(h) Post process cycle treatment (if applicable).

NOTE: Reference should be made to the applicable ISO/TC 198 Sterilization of Healthcare Products standard for each specified process for further information.
4.3 EQUIPMENT CHARACTERIZATION

4.3.1 Equipment specifications

The HSO shall obtain from the equipment manufacturer detailed specifications for the equipment used to deliver cleaning, disinfecting and sterilizing processes.

Information provided shall include but may not be limited to—

(a) a description of the equipment and any necessary ancillary items, including the materials of construction;

(b) a specification for the cleaning agent(s), disinfectant or sterilizing agent (as applicable) and the means by which it/they are delivered to the equipment;

(c) a description of the instrumentation used for controlling, monitoring and recording of cleaning, disinfecting and sterilizing processes, including the locations of sensors;

(d) the identification of fault(s) recognized by the equipment, including the means provided to ensure that a failure to achieve specified process parameters will not result in an ineffective process being recorded as effective;

(e) details of safety features;

(f) the requirements for installation, including those for control of environmental emissions (where applicable); and

(g) a description of the software used for monitoring and/or controlling the processes, including the validation demonstrating it meets its design intention.

Changes to software that can affect operation of reprocessing equipment shall be validated.

NOTE: Reference should be made to the applicable ISO process standards and applicable EN ISO equipment standards for information required to be supplied by the manufacturer.

4.3.2 Controlling and/or monitoring software

Software used for controlling and/or monitoring cleaning, disinfecting, packaging and sterilizing processes shall comply with its design intention and shall be validated. Changes to software that can affect operation of reprocessing equipment shall also be validated.

NOTE: Attention is drawn to ISO 13485.

4.3.3 Standards for reprocessing equipment

Equipment used for reprocessing of RMDs shall comply with the applicable Standards as follows:

(a) Washer-disinfectors: ISO 15883 (applicable parts).

(b) Ultrasonic cleaners: AS 2773.1 or AS 2773.2.

(c) Drying cabinets: AS 2514.

(d) Heat sealers.

NOTE: No existing equipment standard. Refer to ISO 11607-2 and ISO/DTS 16675-3 for guidance.

(e) Steam sterilizers—Large: EN 285

(f) Steam sterilizers—Small: EN 13060

(g) Dry heat sterilizers.

NOTE: No existing equipment Standard. Refer to ISO 20857 for guidance.

(h) Ethylene oxide sterilizers: EN 1422.

(i) Steam/formaldehyde Sterilizers: EN 14180.
(j) Peracetic acid sterilizers.
   NOTE: No existing equipment standards. Refer to ISO 14937 for guidance.

(k) Hydrogen peroxide gas/plasma sterilizers.
   NOTE: No existing equipment standard. Refer to ISO 14937 for guidance.

(l) Aeration cabinets.
   NOTE: No existing equipment standard. Refer to ISO 25424 for steam/formaldehyde or
   ISO 11135-1 for ethylene oxide for guidance.

(m) Endoscope storage cabinets.
   NOTE: No existing equipment standard. Refer to EN 16442 controlled environment storage
   cabinet for disinfected thermolabile endoscopes (in draft) for guidance.

(n) Biological indicator incubators.
   NOTE: No existing equipment standard. Refer to ISO 11138-1 or ISO 14161 for guidance.
SECTION 5 PRODUCT DEFINITION

5.1 GENERAL

5.1.1 General

The purpose of this activity is to define the RMDs to be cleaned and disinfected and/or sterilized.

This shall include specifying the microbiological quality of the RMDs prior to disinfection and/or sterilization and any associated materials used to package and present RMDs for sterilization.

Consideration shall be given to the bioburden and other contaminants on the RMD such as tissue, organic and inorganic material and toxic chemicals, prior to the cleaning process. Other contaminants such as inorganic and organic materials and toxic chemicals in addition to bioburden require consideration when defining the microbiological quality of the RMDs to be processed.

Achievement of suitable microbiological quality of RMDs prior to disinfection and/or sterilization can be inferred providing the RMD and processing equipment manufacturer’s instructions for cleaning and disinfection (if appropriate) have been followed by the HSO and there is evidence of this.

NOTES:
1. RMD manufacturer’s reprocessing instructions provided in accordance with ISO 17664 can include requirements for the method of disinfection and/or sterilization in addition to requirements for packaging and presentation for sterilization.
2. Reprocessing equipment manufacturer’s instructions for use should also be considered when defining RMDs to be processed by each method of cleaning, disinfection or sterilization.

5.1.2 Classification for reprocessing

The Spaulding Classification system shall be used to categorize an RMD according to its intended use and the subsequent level of reprocessing required to render the RMD safe for reuse.

RMDs shall be categorized as follows:

(a) Critical.
(b) Semi-critical.
(c) Non-critical.

After cleaning using a validated cleaning process:

(i) Critical RMDs shall be as follows:
   (A) Terminally sterilized by a validated moist heat sterilizing process between uses on individual patients unless the RMD is heat and/or moisture labile and is not able to withstand the process.
   (B) Heat and moisture labile critical RMD’s shall be sterilized using a validated low temperature sterilizing process between uses on individual patients.

(ii) Semi-critical RMD’s shall be as follows:
   (A) Sterilized by a validated thermal moist heat or low temperature sterilizing process between uses on individual patients unless the RMD is heat and/or moisture labile and is not able to withstand the process.
(B) Heat and moisture labile semi-critical RMD shall be subject to a validated thermal disinfecting process between uses on individual patients unless it is not able to withstand the process.

(C) A semi-critical RMD that cannot withstand a thermal disinfecting process shall be subject to a validated high level chemical disinfecting process between uses on individual patients (see Clause 6.5).

(iii) Non-critical RMD's shall be—

(A) subject to a validated cleaning process, and where necessary, a validated disinfecting process, at a frequency defined by the HSO's procedures.

Table 5.1 provides general criteria for use in reprocessing and storage of RMDs in HSOs.

**TABLE 5.1**

<table>
<thead>
<tr>
<th>Level of risk</th>
<th>Process</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical:</td>
<td>Clean as soon as possible after using.</td>
<td>Sterility must be maintained.</td>
</tr>
<tr>
<td></td>
<td>Sterilize by moist heat after cleaning.</td>
<td>Packaged RMDs are to be stored to prevent environmental contamination in a designated storage area to protect RMD.</td>
</tr>
<tr>
<td></td>
<td>If RMD is heat or moisture sensitive, sterilize using an alternative process, e.g., automated low temperature chemical sterilizing process, liquid chemical sterilizing process, or ethylene oxide sterilizing process.</td>
<td>RMDs processed through a liquid chemical sterilizing process are to be used immediately.</td>
</tr>
<tr>
<td>Semi-critical:</td>
<td>Clean as soon as possible after using.</td>
<td>Store to prevent environmental contamination in a designated storage area to protect RMD.</td>
</tr>
<tr>
<td></td>
<td>Sterilize by moist heat after cleaning.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If the RMD will not tolerate moist heat sterilization use a low temperature sterilization process or thermal disinfection or disinfection using a high level instrument grade chemical disinfectant.</td>
<td></td>
</tr>
<tr>
<td>Non-critical:</td>
<td>Clean as necessary with detergent solution.</td>
<td>Store in a clean dry place to minimize environmental contamination.</td>
</tr>
<tr>
<td></td>
<td>If further treatment is necessary, disinfect with compatible low level or intermediate level instrument grade disinfectant after cleaning.</td>
<td></td>
</tr>
</tbody>
</table>

5.1.3 Policies and procedures

The HSO shall develop policies and procedures for reprocessing of RMD's for special circumstances including but not limited to the following:

(a) A new RMD being introduced into circulation, loan RMD's or an RMD being returned from maintenance or repair. These RMD shall be processed at a minimum by a validated cleaning and further processing method per Clause 5.1.1.

(b) RMD's that require off-site repair or maintenance shall be processed at a minimum by a validated cleaning and high level disinfection process in accordance with the RMD manufacturer's instructions. If this is not possible due to the nature of the damage to the RMD, then the RMD manufacturer shall be consulted to ensure the RMD is prepared and packaged for transportation in a manner suitable for safe transportation of the RMD between the HSO and manufacturer's premises.
(c) Prior to its release off-site a loan or trial RMD shall be processed at a minimum by a validated cleaning and high level disinfection process in accordance with the RMD manufacturer’s instructions.

NOTE: Some organizations require loan and trial RMDs to be cleaned and sterilized prior to their release off-site.

(d) RMDs that have been opened for a procedure but not used shall be subjected to the full reprocessing procedures.

NOTE: RMD that have been opened for a procedure and exposed to the perioperative environment should be considered contaminated.

(e) RMDs that come into contact with usually sterile body cavities or are used on the critical aseptic field during invasive procedures shall be considered critical medical devices. These RMDs shall be reprocessed to the highest possible level between uses on individual patients in accordance with the manufacturer’s reprocessing instructions.

Cleaning, disinfection or sterilization, as appropriate, of RMDs shall be performed between uses even if a single use sheath/sleeve/protective barrier is used. Single use sheaths/sleeves/protective barriers for RMDs shall not be used as a substitute for cleaning, disinfection or sterilization.

(f) A single use medical device that is past its’ expiration date or that has been opened-but-unused shall only be reprocessed, if this is permitted by the medical device manufacturer. Reprocessing of the medical device shall be performed in accordance with the validated sterilization instructions provided by the manufacturer of the medical device.

NOTE: The expiry date on some medical devices is related to the loss of functional integrity of the device over time and may not be related to duration of sterility.

Medical devices labelled as or intended for single use that have been used, shall not be reprocessed or reused.

A medical device labelled with any of the following information or symbol in Figure 5.1 shall be deemed to be a medical device intended only for single use.

FIGURE 5.1 INFORMATION AND SYMBOL USED TO DESIGNATE A MEDICAL DEVICE FOR SINGLE USE ONLY

DO NOT REUSE

Synonyms for this are:
• Single-use
• Use only once
5.2 PRODUCT FAMILIES

The classification of an RMD into a product family can assist with the development of processing conditions. When assigning an RMD to a product family and to a method of reprocessing the following shall be considered and documented:

(a) A description of the RMD, including the materials of construction (e.g. metal, non-metal combinations, plastics) and its configuration.

(b) The intended use of the RMD.

(c) The design of the RMD, including design characteristics that can affect selection of a cleaning, disinfecting and/or sterilizing process, e.g. case of disassembly and assembly, tolerance to moisture, heat and chemicals, presence of lumens, moving parts, fibre-optics, electronics.

(d) The physical characteristics of the RMD, including its mass, surface area and thermal conductivity.

(e) Packaging of the RMD, including the SBS for sterilized RMDs.

NOTE: ISO/TS 17665-3 and ISO 17664 provides useful information to assist in assigning an RMD to a product family.

5.3 LIMITING VALUES

The limiting values for each process variable for the cleaning, disinfecting and sterilizing processes to which an RMD is subjected shall be specified to prevent adverse effects on performance of the RMD and/or its packaging. Consultation with the RMD and processing equipment manufacturer will be required. Where limiting values are exceeded, corrective action shall be taken.

NOTE: Examples of process variables include temperature, pressure, humidity, chemical concentration, immersion compatibility, exposure time and rates of change of pressure and/or temperature.

5.4 PRE-DISINFECTION AND PRE-STERILIZATION CLEANLINESS OF RMDs

The HSO shall ensure that the cleanliness of the RMD and/or its packaging (where applicable) presented for disinfection and/or sterilization is controlled and shall not compromise the effectiveness of the process.

5.5 PACKAGING

5.5.1 General

The sterile barrier system for an RMD that is terminally sterilized shall be specified and shall conform to ISO 11607-1 and ISO 11607-2.

5.5.2 Compatibility

The sterile barrier system for an RMD shall be compatible with the sterilizing process. It shall allow the removal of air from the packaging and RMD, ingress and egress of sterilizing agent and removal of water vapour (where applicable).

5.5.3 Protective packaging

Protective packaging if used shall protect the SBS and contents until point of use.

Protective packaging if applied prior to sterilization shall be compatible with the sterilizing process.
5.6 REPROCESSING ENVIRONMENT

5.6.1 General

The HSO shall provide the physical environment and equipment necessary for safe and effective reprocessing activities to ensure delivery of an RMD, including loan and trial RMDs, of the required quality. This shall include requirements for environmental control in areas that can impact the bioburden of an RMD, e.g. control of temperature, humidity, traffic flow, and reprocessing, ventilation and air flow.

5.6.2 Facility design

Reprocessing facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities. Design of the facility shall provide an environment that minimizes the risk from cross contamination of a cleaned, disinfected and sterilized RMD and shall facilitate a unidirectional work flow of dirty to clean.

NOTE: Distinct and separate physical segregation of the cleaning areas from the other reprocessing areas is integral in the development of a reprocessing facility to meet the requirements of this Standard.

5.6.3 Facility finishes

The reprocessing facility shall be free from opening windows. Ledges and areas that are inaccessible for cleaning shall be minimized. The finishes on the walls and other surfaces shall be flush, smooth, non-shedding, water resistant and able to withstand frequent cleaning. The junctions between the walls and floors shall be covered and flush. Fittings shall be flush with wall surfaces (where possible). Floors shall be covered in a sealed, non-slip material that is washable.

5.6.4 Fixtures and finishing

All work surfaces, fittings, fixtures, window treatment, shelving and furniture in the reprocessing facility shall be constructed from robust, non-shedding materials. It shall be easy to clean and shall be maintained in good condition. Shelving shall be designed and installed to enable safe handling practices. It shall have smooth surfaces that will not damage product, packaging and other materials.

5.6.5 RMD cleaning sinks

Dedicated sinks for pre-treatment and/or manual cleaning and rinsing of an RMD shall be provided and shall be of sufficient depth and size to allow an RMD to be completely immersed. Sink workstations shall be ergonomically designed to allow staff to both fully immerse and retrieve an RMD safely from the sink without the potential for injury. Sink workstations shall be designed to provide sufficient bench space to facilitate a unidirectional work flow and to minimize the risk of cross contamination. Cleaning sinks shall not be used for any other purpose, e.g. hand hygiene. Facilities to enable water or air flushing of a lumened RMD shall be provided.

NOTE: The provision of height adjustable cleaning sinks, sink depth and configuration of work stations to allow for ergonomic use and promotion of operator safety are important factors to be considered.

5.6.6 Water

Water of the required quality shall be specified for use in the reprocessing facility (see Section 7).

NOTE: The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process. Softened, filtered, demineralized, distilled or RO water can be required for various stages of the cleaning process. For further information see AAMI TIR 34:2007.
5.6.7 Workstations
There shall be sufficient electricity supply, computer terminal points and ergonomically designed work stations in the reprocessing facility to facilitate safe and effective reprocessing activities. Workstations shall be suitably equipped for the preparation and packaging of RMDs. They shall be of adequate size to accommodate packaging materials to be used and shall be height adjustable. There shall be adequate space between workstations for the safe movement of equipment and staff.

5.6.8 Lighting
The reprocessing facility shall have adequate lighting to enable thorough visual examination of an RMD. Task lighting and magnification shall be in-situ where required.

5.6.9 Storage
Storage facilities for bulk items shall be provided external to the cleaning and packing areas. Safe storage facilities shall be provided for chemicals in accordance with applicable workplace health and safety requirements and regulations.
A dedicated area shall be provided within the sterilizer unloading zone for cooling, and where applicable, aeration of sterilized RMDs.
A dedicated area shall be provided for the storage of reprocessed RMDs that have been released for use.

5.6.10 Facility cleaning
The reprocessing facility shall be cleaned regularly in accordance with a documented procedure and schedule. It shall be maintained in a hygienic condition at all times. Separate, dedicated cleaning equipment shall be provided for both dirty and clean work areas.

5.6.11 Entry to facility
Entry to the reprocessing facility shall be restricted to authorized personnel.

5.6.12 Hand hygiene
There shall be sufficient hand hygiene facilities available and accessible in all work areas. Personal protective equipment (PPE) shall be easily accessible in each of the work areas.
Only alcohol based hand rubs (ABHR) and hand creams approved for use by the HSO in the reprocessing of RMD environment shall be used and appropriate training in their use provided.
Residue from hand hygiene products shall not be transferred to RMD’s or packaging.

5.6.13 Waste disposal
Disposal of waste shall comply with the requirements of the local regulatory authorities.

5.6.14 Ventilation
Ventilation in cleaning areas and sterile storage areas shall be in accordance with AS 1668.2.

NOTE: Further information can be found in Technical series TS11, Engineering Services and Sustainable Development Guidelines, 2008, NSW Health.
SECTION 6 PROCESS DEFINITION

6.1 GENERAL

6.1.1 Introduction

The purpose of this activity is to define a detailed specification for the cleaning, disinfecting, packaging and/or sterilizing processes to be applied to a defined RMD without compromising the safety, quality and performance of that RMD.

AN RMD shall meet its specified requirements for safety, quality and performance following exposure to the specified cleaning, disinfecting, packaging and/or sterilizing processes.

WARNINGS:

1. THE ESSENTIAL PREREQUISITES FOR EFFECTIVE DISINFECTION AND STERILIZATION ARE THAT THE RMD IS CLEAN AND IS ABLE TO WITHSTAND THE PROCESS. IF AN RMD IS NOT CLEAN, THEN THE DISINFECTING AND STERILIZING PROCESSES WILL BE COMPROMISED.

2. DO NOT STORE AN RMD IN DISINFECTANT BEFORE OR AFTER ANY FORM OF PROCESSING.

3. AN RMD THAT HAS BEEN PROCESSED IN A LIQUID CHEMICAL STERILIZING AGENT OR DISINFECTANT IS AT RISK OF CONTAMINATION UNTIL USED.

The process(es) required to reprocess a defined RMD shall be established and specified (see also Clause 5.1). This shall include all applicable cleaning, disinfecting, packaging and sterilizing processes used in the reprocessing of each RMD or product family (see also Clause 5.2).

The HSO shall specify the chemical and/or biological indicators to be used during validation and/or monitoring of the processes. These indicators shall comply with the relevant ISO/EN standards. Refer to Section 7 and 8.

To produce an RMD to the required quality it is essential all steps specified in the reprocessing procedures shall be followed. There is a risk that if any of these procedures are bypassed an adverse patient outcome might result.

Specifications for cleaning, disinfecting, packaging and sterilizing process shall be developed with consideration of the manufacturer's reprocessing instructions for each RMD.

NOTES:

1. Manufacturer's reprocessing instructions should be in accordance with the requirements of ISO-17664.

2. If an HSO chooses to deviate from the manufacturer's reprocessing instructions then validation of the alternative process(es) might be necessary.

6.1.2 Immediate use sterilization

Immediate use sterilization (also known as 'flash', 'emergency' and 'fast track' sterilization) is not referred to specifically in this Standard as it is a process that shall be defined and validated as part of the sterilizing protocols developed by the HSOs.

Immediate use sterilization shall not be used routinely as a convenience where insufficient RMD are available to meet end user need or as a cost saving mechanism.
6.2 CLEANING PROCESS DEFINITION

6.2.1 General

The purpose of this activity is to define a specification for the cleaning process used to reduce the bioburden and to remove other contaminants from a surface of a used RMD to a specified level. These contaminants can include cell and tissue remnants, organic and inorganic material, and toxic chemicals.

A used RMD shall be cleaned after each patient use. The cleaning process shall be compatible with the RMD and shall be performed in accordance with the validated cleaning instructions provided by the RMD manufacturer.

If a reprocessing facility is not able to safely and effectively meet the requirements for cleaning an RMD then that particular RMD shall not be reprocessed by the facility unless suitable reprocessing equipment is specifically purchased and qualified for reprocessing of that RMD. An alternative, such as the purchase of a sterile, single-use medical device, shall be considered.

When defining the specification, reference shall be made to Clause 4.2.

6.2.2 Transportation and pre-treatment

6.2.2.1 Transportation

HSOs shall develop and implement procedures for the transportation of used RMD to the reprocessing facility. Methods used shall protect the RMD, personnel and the environment from contamination and harm.

6.2.2.2 Pre-treatment

HSOs shall develop and implement procedures for pre-treatment of used RMD at the point of use. Procedures for pre-treatment of RMD shall be inclusive of the role of the end user.

Methods used shall—

(a) remove gross soil;
(b) not cause damage to the RMD;
(c) not compromise the subsequent cleaning, disinfecting and/or sterilizing processes; and
(d) minimize risk of drying of contaminants.

The maximum period of time that is permitted to elapse between use of an RMD and subsequent reprocessing shall be specified. Actions to be taken if this period is exceeded shall be specified.

6.2.3 Cleaning

The procedure shall be as follows:

(a) Disassembly of RMD prior to pre-treatment and/or cleaning

Methods shall ensure that the RMD can be adequately cleaned without damage and in accordance with the RMD manufacturer’s instructions.

(b) Segregation of RMD to allocated cleaning pathways

Cleaning pathways include manual cleaning only, manual and/or ultrasonic pre-treatment prior to processing in a WD, cleaning in a WD without any pre-treatment (see Clause 4.2.5).
(c) Manual cleaning of an RMD shall only be used—
   (i) where an RMD manufacturer’s validated cleaning instructions require manual cleaning of the RMD; and
   (ii) as a pre-treatment prior to reprocessing of an RMD in a washer-disinfector.
   NOTE: The use of an automated cleaning process in a W-D is the preferred means of cleaning as an automated process is more reproducible than a manual cleaning process.

(d) RMD shall have visible soiling removed before being processed using an ultrasonic cleaner. Where an ultrasonic cleaner does not process an RMD through the full cleaning process it is important that after removal of an RMD from the ultrasonic cleaner it is subject to a further manual or mechanical cleaning process.

(e) Loading and unloading of cleaning equipment. Methods used for loading RMDs into cleaning equipment shall ensure that all aspects of an RMD, including internal lumens, are exposed to the cleaning processes and that RMDs are protected from damage. Methods for unloading cleaning equipment shall ensure that risks for cross contamination are minimized.
   NOTE: Reference should be made to the relevant part of ISO 15883 for validation of the mechanical cleaning process.

(f) Drying of cleaned RMD. Methods used shall not compromise the cleanliness of an RMD. Where drying cabinets are not available low linting cloths shall be used or medical grade compressed air. Where medical compressed air is used for drying RMDs appropriate health and safety procedures shall be documented.
   NOTE: Reference should be made to AS 2896.

(g) Cleaning of cleaning equipment and accessories. Cleaning of WD, loading racks, trolleys, ultrasonic cleaners, drying cabinets and other accessories shall be in accordance with manufacturer’s instructions. Brushes and other accessories used for pre-treatment or manual cleaning shall be cleaned and thermally disinfected or sterilized at least daily.

6.3 DISINFECTING PROCESS DEFINITION

6.3.1 General
The purpose of this activity is to define a specification for the process used to kill micro-organisms on a cleaned RMD to achieve low, intermediate or high-level disinfection. Refer to Section 5 for product definition.

6.3.2 Categorizing RMD for disinfection
RMDs requiring exposure to a disinfecting process shall have been categorized as semi-critical or non-critical according to the Spaulding classification.

6.3.3 Non-critical RMD
Where required by HSO policy and/or RMD manufacturer’s instructions for use, non-critical RMD shall be subject to low or intermediate level disinfection using either thermal disinfection or an instrument grade disinfectant in accordance with a documented procedure.

   NOTE: A minimum A9 of 600 on the RMD when using a thermal disinfection process for clean, non-critical items could be suitable. Refer ISO 15883-3 and 15883-6.

The chemical disinfectant manufacturer’s instructions for use shall be followed in relation to exposure time, temperature, pH, water quality for dilution of disinfectant or post disinfection rinsing in order to ensure that the specified level of disinfection is achieved.
6.3.4 Non heat labile semi-critical RMD
A semi-critical RMD that cannot withstand moist heat and/or low temperature sterilization shall undergo thermal or chemical disinfection in accordance with a documented procedure (see Section 5).

Thermal disinfection shall be performed in a washer-disinfector compliant with ISO 15883 and the relevant subsequent part. Table 6.1 identifies the common parameters for thermal disinfection in an ISO 15883 compliant WD.

**TABLE 6.1**
COMMON HOLDING TIMES FOR THERMAL DISINFECTION USING MOIST HEAT TO ACHIEVE $A_{600}$

<table>
<thead>
<tr>
<th>Surface temperature °C</th>
<th>Minimum holding time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>70</td>
<td>100</td>
</tr>
<tr>
<td>75</td>
<td>30</td>
</tr>
<tr>
<td>80</td>
<td>10</td>
</tr>
<tr>
<td>90</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**NOTE:** ISO 15883-1 and subsequent parts relate the above conditions to the achievement of a specific $A_{600}$ lethality level depending on the intended use of the RMD. Refer to Annex B of ISO 15883-1:2006 for guidance on calculating the minimum time and $A_{600}$ for alternative temperatures ≥65°C.

6.3.5 Heat labile semi-critical RMD
Heat labile semi-critical RMDs shall undergo high-level chemical disinfection. When performed in a washer-disinfector this shall be compliant with ISO 15883-4 in accordance with a documented procedure (see Section 5).

In cases of equipment malfunction or breakdown, HSOs shall have a contingency plan.

Where manual immersion of semi-critical RMD in a high-level instrument grade disinfectant is required, the HSO shall have documented procedures for handling, storage and use of the disinfectant.

The chemical disinfectant manufacturer’s instructions for use shall be followed in relation to exposure time, temperature, pH, water quality post disinfection rinsing in order to ensure that the specified level of disinfection is achieved.

**NOTE:** Fume cabinets might be required for use with some disinfectants.

After removal from the disinfectant, RMDs shall be rinsed in a sufficient volume of water of a suitable quality to minimize the risk of injury through exposure to residual disinfectant. The RMD and the disinfectant manufacturer’s instructions shall be followed.

Instruments intended for use in sterile cavities, in known immuno-compromized patients, or for invasive procedures, e.g. ERCP and bronchoscopy shall be rinsed with sterile, or water filtered through a 0.22 μm nominal pore size filter following high level disinfection.

Some types of RMDs because of design are unable to be fully immersed during cleaning and disinfection. Procedures shall be in place to minimize the risk of cross contamination during the reprocessing of these RMDs.
6.4 PACKAGING PROCESS DEFINITION

6.4.1 General

The purpose of this activity is to define a specification for the process used to package an RMD. The selected SBS and protective packaging shall not impede effective sterilization and shall maintain sterility of RMD until the point of use.

Packaged RMDs shall not be sterilized in a steam sterilizer without a drying phase.

A SBS that is intended for single use shall be exposed to the sterilizing process only once.

NOTE: ISO/TS 16775, provides guidance concerning the evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. In addition, it also provides guidance on validation requirements for forming, sealing and assembly processes.

6.4.2 Packaging procedures

HSOs shall develop and implement procedures for the following activities:

(a) Inspection, assembly and testing of RMD prior to packaging. RMD manufacturer’s instructions for testing and/or maintenance and/or lubrication and/or calibration of RMD shall be followed. Instructions for assembly of RMDs into trays or sets, including specifications for containment devices and use of decontamination devices shall be developed.

(b) Selection and use of packaging and packaging materials, including the type of SBS to be used, the method of wrapping (where applicable), the method of sealing or closure, use of tray liners, tip protectors and labelling. The packaging manufacturer’s instructions for use shall be followed.

(i) Packaging materials and sterile barrier systems shall be in accordance with ISO 11607-1 and the corresponding part of the EN 868 series or AS 1079 series. If reusable fabrics are used then they shall comply with AS 3789.8.

(ii) Tray liners, tip protectors and other materials that may be used for the assembly and presentation of packaged RMD shall be intended for that purpose.

(iii) The selected method of packaging shall permit aseptic presentation of the RMD.

(iv) Methods of sealing and closure shall ensure the integrity and maintenance of sterility of the packaging RMD until the point of use. For heat sealed preformed SBS, the sealing process parameters and their tolerances shall be specified and documented. Sealing methods that compromise integrity of the SBS shall not be used.

NOTE: String, non-adhesive tape, staples, pins and elasticized bands are not suitable as sealants as they can compromise the integrity of the SBS.

(v) The method of sealing shall be tamper evident.

(vi) Packaged RMD shall be labelled prior to sterilization. Labelling shall identify the contents and provide information for batch control. The method and materials used for labelling shall not compromise the sterilization process and shall ensure the label remains securely attached until the point of use.

6.5 STERILIZING PROCESS DEFINITION

6.5.1 General

The purpose of this activity is to define a specification for the process used to sterilize an RMD to achieve the required sterility assurance level.
A terminal sterilizing process shall deliver a sterile RMD with a minimum SAL of $10^{-6}$.

Sterilization process definition is provided by the RMD and sterilizer manufacturer. Collaboration may have occurred between the RMD manufacturer and the sterilizer manufacturer to define a suitable sterilization process for the RMD.

The sterilizer and RMD manufacturer shall provide instructions for use to the HSO. The HSO shall review the documentation and confirm they have the capability to follow these instructions.

If an HSO undertake processes outside the sterilizer manufacturer’s supplied process cycles or the RMD manufacturer’s recommendations for suitable process cycles, the HSO shall be responsible for undertaking process definition in accordance with the applicable Standard.

### 6.5.2 Sterilization procedures

With consideration of the RMD and sterilizer manufacturer’s instructions, HSOs shall develop and implement procedures for the following activities:

(a) **The selection of sterilization processes to be applied to the RMD**

The sterilizer manufacturer’s reprocessing instruction shall be used as a basis for selecting an appropriate method of sterilization and a suitable sterilization cycle.

If the HSO intends to apply a method of sterilization outside that recommended by the RMD manufacturer, the effectiveness of these alternative processes shall be established.

(b) **Loading the sterilizer**

The types of RMDs included in the sterilization load shall be in accordance with the sterilizer manufacturer’s specification. Any restrictions or limitations relating to the size, mass, configuration, or loading orientation of RMDs being processed shall be considered (see Clause 4.2).

(c) **Methods for routine monitoring and control of the sterilization process**

The sterilizer manufacturer’s instructions for use and the requirements of this Standard for methods of routine monitoring and control of the sterilization process shall be followed. See also Section 8.

(d) **Unloading the sterilizer**

The area in which sterilized items are unloaded shall be controlled. The environmental conditions in this area shall not adversely affect the quality of the processed RMD. RMDs processed by moist heat shall be allowed to cool prior to handling.

For RMDs processed by ethylene oxide, RMDs shall not be unloaded from the sterilizer chamber until completion of the in-chamber aeration phase. Refer ISO 11135-1, ISO 10993-7, WH&S regulations.

Criteria for load release shall be implemented in accordance with Clauses 9.1 and 9.3.

### 6.5.3 Moist heat sterilization

Table 6.2 illustrates the common parameters for moist heat (saturated steam) sterilizing processes used in HSOs.
Throughout the sterilizing holding time the temperature measured at the reference measurement point of the sterilizer chamber and the saturated steam temperature calculated from the measured chamber pressure shall be within the sterilization temperature band in accordance with the phase boundary line in Figure 6.1.

The minimum steam dryness value shall be 0.95 equivalent to 95% dry saturated steam. See EN 285, Sterilization—Steam Sterilizers—Large Sterilizers.

NOTE: Figure 6.1 illustrates the approximate temperature-pressure relationship for effective moist heat sterilization. Deviations from the phase boundary line represent states of superheated steam or wet steam, or air and steam mixtures that are causes of sterilizing process failure.

### Table 6.2

<table>
<thead>
<tr>
<th>Temperature °C</th>
<th>Holding time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>121</td>
<td>15</td>
</tr>
<tr>
<td>126</td>
<td>10</td>
</tr>
<tr>
<td>132</td>
<td>4</td>
</tr>
<tr>
<td>134</td>
<td>3</td>
</tr>
</tbody>
</table>

NOTE: The correct correlation between temperature and pressure is necessary to ensure the presence of saturated steam. For pressure relationships, see Figure 6.1.

**FIGURE 6.1** TEMPERATURE-PRESSURE RELATIONSHIP TO REMOVE 143 DEGREE LINES FOR MOIST HEAT STERILIZATION
6.5.4 Ethylene oxide sterilization

Process definition shall comply with the requirements of ISO 11135:2007, Clause 8 when ethylene oxide is used to sterilize an RMD.

NOTE: Additional guidance may be found in ISO 11135-1:2007, Paragraph C8 of Annex C.

Table 6.3 illustrates the common range of process conditions for ethylene oxide sterilizing processes used in HSOs.

**TABLE 6.3**

<table>
<thead>
<tr>
<th>EO parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>EO gas</td>
<td>100% EO or EO-inert gas mixture</td>
</tr>
<tr>
<td>EO gas concentration</td>
<td>400–800 mg/L</td>
</tr>
<tr>
<td>Temperature</td>
<td>37–55°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>50–90%</td>
</tr>
<tr>
<td>Gas dwell time</td>
<td>Determined during performance qualification</td>
</tr>
<tr>
<td>Pressure</td>
<td>Dependent on the nature of the EO sterilizing process, the nature of the RMD and its packaging, and gas concentration. This is determined during process definition.</td>
</tr>
</tbody>
</table>

Where a mixture of ethylene oxide and a diluent gas is used as the sterilizing agent, then the gas mixture shall be specified.

A means shall be provided to detect gas leaks if the gas supply is not self-contained within the sterilizer chamber.

A means shall be established to reduce ethylene oxide residual levels so that a reprocessed RMD complies with the requirements of ISO 10993-7.

6.5.5 Dry heat

Process definitions shall comply with the requirements of ISO 20857.

Table 6.4 identifies the common parameters for dry heat sterilizing processes used in HSOs.

**TABLE 6.4**

<table>
<thead>
<tr>
<th>Temperature °C</th>
<th>Holding time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>160</td>
<td>120</td>
</tr>
<tr>
<td>180</td>
<td>60</td>
</tr>
</tbody>
</table>

6.5.6 Low temperature sterilization systems

The manufacturers of low temperature sterilizing process systems, e.g. peracetic acid, hydrogen peroxide and low temperature steam formaldehyde (LSTF) systems, shall—

(a) validate the efficacy of the sterilizing process(es) of the system; and

(b) provide comprehensive instructions for use of the system.

NOTE: Manufacturers of these systems should use ISO 14937 or ISO 25424 (for LTSF) to validate the efficacy of the sterilizing process(es) of these systems.
7.1 GENERAL

7.1.1 General

The purpose of this activity is to demonstrate and document that the cleaning, disinfecting, packaging, or sterilizing processes can be delivered effectively and reproducibly to the loads of RMDs being processed in the HSO.

Validation consists of a number of identified stages; installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). All processes shall be validated. The relationship between these stages is outlined in Figure 7.1.1.

IQ is undertaken to demonstrate that the reprocessing equipment and any ancillary items have been supplied and installed in accordance with their specification.

OQ is carried out either with unloaded equipment or using appropriate test materials to demonstrate the capability of the equipment to deliver the cleaning, disinfection or sterilization process that has been defined by the equipment manufacturer.

PQ is the stage of validation that uses and exposes the products as specified by the HSO (see Sections 5 and 6) to the cleaning, disinfection or sterilization processes and demonstrates that the equipment consistently operates in accordance with predetermined criteria and the process yields product that is clean, disinfected or sterile and meets the specified requirements.

Immediately prior to the conduct of the specified IQ, OQ or PQ, the calibration status of all instrumentation, including any test instruments used for monitoring, controlling, indicating, or recording shall be confirmed. The tests and checks to be performed shall be specified, documented and the results recorded. See also Clause 2.4.4

In exceptional circumstances where sterilizing equipment is unable to have calibration, OQ and PQ conducted on site, for example in the case of some office based practices in remote locations, then the service provider shall comply with the requirements of this Standard.

The service provider shall use RMDs representative of those used by the HSO and loading configurations typical of those used and as specified by the HSO. Upon return of the sterilizer to the HSO, the HSO shall verify the performance of the sterilizer. This shall include but not be limited to the following:

(a) Review of the test report supplied by the service provider.

(b) Conduct of sterilizer performance tests, for example vacuum/leak test, Bowie and Dick-type test.

(c) Process cycles using the reference loads incorporating biological and where applicable, chemical indicators distributed throughout the load prior to using the sterilizer for processing RMD for patient use.
NOTE: See Clause 10.4 for requalification of the different stages of validation.

**FIGURE 7.1 VALIDATION FLOWCHART FOR CLEANING, DISINFECTING AND STERILIZING PROCESSES**

Reference shall be made to the relevant applicable Australian/National and ISO Standards for the requirements for IQ, OQ and PQ for reprocessing equipment. Table 7.1 lists Standards that are required for particular processes and equipment.

**TABLE 7.1**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Reprocessing equipment applicable to processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS 2773-1 or AS 2773-2</td>
<td>For commissioning tests for ultrasonic cleaners. Refer to Section 6</td>
</tr>
<tr>
<td>ISO 15883 and the applicable part</td>
<td>For validation of cleaning and thermal disinfection processes</td>
</tr>
<tr>
<td>ISO 15883-1 and ISO 15883-2</td>
<td>For validation of cleaning and chemical disinfection processes</td>
</tr>
<tr>
<td>AS 2514 and AS 2774</td>
<td>Drying cabinets for medical equipment and respiratory apparatus [respectively]. Refer to Section 6</td>
</tr>
<tr>
<td>ISO 11607-2 and ISO/TS 16775</td>
<td>For validation of packaging and heat sealing processes</td>
</tr>
<tr>
<td>ISO 17665-1</td>
<td>For steam sterilization</td>
</tr>
<tr>
<td>ISO 20857</td>
<td>For dry heat sterilization</td>
</tr>
<tr>
<td>ISO N135</td>
<td>For ethylene oxide sterilization</td>
</tr>
<tr>
<td>ISO 25424</td>
<td>For steam/formaldehyde sterilization</td>
</tr>
<tr>
<td>ISO 14937</td>
<td>For low temperature chemical sterilizing process systems</td>
</tr>
</tbody>
</table>

**7.1.2 Stages of validation**

IQ and OQ shall be undertaken for each individual piece of equipment and PQ shall be performed for each process delivered by each piece of equipment.

A validation protocol shall be developed for each process and include identification of the processing equipment and any associated or ancillary equipment used.
NOTE: In the case where process cycles using the same load configuration only differ by the length of the different phases, the cycle being tested could be the shortest cycle proposed for validation and the longer cycles can be validated by extrapolation. [Adapted from ISO 15883.1:2006 Clause 6.1.3.1.4.]

Validation of the cleaning, disinfecting, packaging and sterilizing processes shall be documented in a validation report.

7.1.3 Sterilization SAL

Validation shall demonstrate attainment of a minimum sterility assurance level of $10^{-6}$ for the terminally sterilized RMD.

7.2 INSTALLATION QUALIFICATION (IQ)

7.2.1 General

IQ is undertaken by the equipment manufacturer or supplier to demonstrate that the reprocessing equipment and any ancillary items have been supplied and installed in accordance with their specification. IQ applies not only to the reprocessing equipment, but also to the services and environment required for this equipment (e.g. water, steam).

IQ shall demonstrate that all cleaning equipment, disinfecting equipment, packaging equipment and sterilizers used in the reprocessing of an RMD, and the environment in which this equipment is installed, complies with the manufacturers’ installation specifications.

7.2.2 Equipment installation qualification

IQ shall be performed upon installation of any reprocessing equipment in accordance with the applicable national or International Standard and manufacturer’s instructions.

Prior to installation of new or relocated reprocessing equipment the HSO in consultation with the equipment manufacturer shall—

(a) specify the location in which the equipment is to be installed;

(b) ensure the environmental conditions in the specified location are in accordance with manufacturer’s recommendations;

(c) ensure the required services, e.g. water, steam, air, are provided in accordance with the manufacturer’s specifications; and

(d) ensure detailed equipment specifications and operational instructions for the equipment have been provided by the manufacturer, see Section 4.

Heat sealing equipment shall be supplied to the reprocessing facility already calibrated for the process variables of temperature, pressure and sealing time. This equipment shall be supplied with a certificate of calibration from the equipment manufacturer.

7.2.3 Services qualification

7.2.3.1 Water quality

Water supplied to the reprocessing facility shall be of a suitable quality for its intended purpose. There shall be consultation and an agreement with the supplier of local water to notify the HSO of changes likely to affect the quality of potable water.

Softened, filtered, demineralized, reverse osmosis or distilled water shall be provided in accordance with the requirements specified by the equipment manufacturer (see Clauses 6.2 and 6.3).
NOTES:
1. Guidance for water quality supplied to the reprocessing facility can be found in AAMI TIR 34, the Australian Drinking Water Guidelines (ADWG) and Drinking-water Standards for New Zealand 2005 (Revised 2008).
2. Manufacturers might require additional treatment of water supplied for various processes, e.g. reverse osmosis water for the final rinse stage in a W-D.

Tests shall be conducted prior to equipment installation to demonstrate the water supplied to equipment is in accordance with the manufacturer's specification and the results recorded.

### TABLE 7.2
WATER QUALITY USED FOR CLEANING RMD

<table>
<thead>
<tr>
<th>Substance</th>
<th>Maximum concentration levels</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cleaning process</td>
<td>Final rinse</td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear, colourless</td>
<td>Clear, colourless</td>
</tr>
<tr>
<td>pH</td>
<td>—</td>
<td>5.5–8.0</td>
</tr>
<tr>
<td>Conductivity at 25°C</td>
<td>—</td>
<td>30 μS/cm</td>
</tr>
<tr>
<td>Total dissolved solids [TDS]</td>
<td>—</td>
<td>0.4 mg/L</td>
</tr>
<tr>
<td>Total hardness [CaCO3]</td>
<td>60 mg/L</td>
<td>50 mg/L</td>
</tr>
<tr>
<td>Chloride [Cl]</td>
<td>120 mg/L</td>
<td>10 mg/L</td>
</tr>
<tr>
<td>Lead [Pb]</td>
<td>—</td>
<td>10 mg/L</td>
</tr>
<tr>
<td>Iron [Fe]</td>
<td>—</td>
<td>2 mg/L</td>
</tr>
<tr>
<td>Phosphate [P₂O₅]</td>
<td>—</td>
<td>0.2 mg/L</td>
</tr>
<tr>
<td>Silicate [SiO₂]</td>
<td>2 mg/L</td>
<td>0.2 mg/L</td>
</tr>
<tr>
<td>Total viable count [cfu/100 mL]</td>
<td>—</td>
<td>100</td>
</tr>
<tr>
<td>Endotoxin [EU/mL]</td>
<td>—</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Adapted from:

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TABLE 7.3
WATER USED FOR STEAM STERILIZATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Feedwater for dedicated steam generator</th>
<th>Steam condensate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colourless without sediment</td>
<td>Clear, colourless without sediment</td>
</tr>
<tr>
<td>pH</td>
<td>5–7.5</td>
<td>5.0–7.0</td>
</tr>
<tr>
<td>Conductivity at 25°C</td>
<td>≤5 μS/cm</td>
<td>≤3 μS/cm</td>
</tr>
<tr>
<td>Cadmium</td>
<td>≤0.005 mg/L</td>
<td>≤0.005 mg/L</td>
</tr>
<tr>
<td>Total hardness [CaCO₃]</td>
<td>0.02 mmol/L</td>
<td>0.02 mmol/L</td>
</tr>
<tr>
<td>Chloride [Cl⁻]</td>
<td>≤0.2 mg/L</td>
<td>≤0.1 mg/L</td>
</tr>
<tr>
<td>Lead [Pb]</td>
<td>≤0.05 mg/L</td>
<td>≤0.05 mg/L</td>
</tr>
<tr>
<td>Iron [Fe]</td>
<td>≤0.2 mg/L</td>
<td>≤0.1 mg/L</td>
</tr>
<tr>
<td>Phosphate [P₂O₅]</td>
<td>≤0.5 mg/L</td>
<td>≤0.1 mg/L</td>
</tr>
<tr>
<td>Silicate [SiO₂]</td>
<td>≤1 mg/L</td>
<td>≤0.1 mg/L</td>
</tr>
<tr>
<td>Endotoxin [EU/mL]</td>
<td>—</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Adapted from:


Terms of use for this guidance can be found at http://www.nationalarchives.gov.uk/doc/open-government-licence/

7.2.3.2 Steam quality

The quality of the water used for the generation of steam for a sterilizing process shall comply with the requirements in Table 7.3.

Tests shall be conducted prior to equipment installation to demonstrate the water supplied to the steam generator is in accordance with Table 7.3 and the results recorded.

NOTE: Compliance should be tested in accordance with standard analytical methods by an accredited laboratory.

Steam quality tests, e.g., steam dryness value, super heat and non-condensable gas tests shall be conducted as part of IQ or OQ and in accordance with EN 285.

NOTE: Steam quality testing does not apply to small steam sterilizers that utilize distilled or RO water for steam generation.

Steam dryness value tests shall be conducted in accordance with the requirements of EN 285. The steam dryness value shall be not less than 0.95.

Testing of the steam supply to determine the steam dryness value is generally performed during IQ. If the requirements for IQ are met, then this test need not be performed regularly; however, it may be a useful test to consider as a tool during investigations to determine the root cause of a nonconforming process.

Steam purity and/or boiler feed water purity tests shall be conducted as part of IQ or OQ and in accordance with the requirements of EN 285 [see also Table 10.3.1(A)].

7.3 OPERATIONAL QUALIFICATION (OQ)

Operational qualification shall be performed by the equipment manufacturer in accordance with the applicable national or International Standards—

(a) immediately after installation or relocation of any reprocessing equipment;

(b) when a service is changed;

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(c) when existing equipment is modified to deliver a new process;
(d) when introducing new medical devices or loading configurations to ensure performance requirements established during original or subsequent OQ continue to be met; and
(e) after repair, prior to equipment being put back into service.

NOTES:
1. The tests conducted during OQ do not constitute PQ.
2. The components of OQ repeated after equipment repair usually consist of manufacturer recommended performance tests.
3. The sterilization and WD Standards require heat distribution (profiling) studies to be conducted during OQ.

7.4 PERFORMANCE QUALIFICATION (PQ)

7.4.1 General
Performance qualification shall be performed by the HSO. PQ may be performed by suitably trained in-house personnel or in conjunction with the equipment manufacturer or a suitably experienced and qualified external contractor.
PQ shall be undertaken in accordance with the applicable national or International Standards.
PQ shall be performed—
(a) immediately after IQ and OQ for newly installed or relocated equipment;
(b) when repairs are made or a service is changed that may adversely impact the quality of the RMD (see Clause 10.5);
(c) when existing equipment is modified to deliver a new process;
(d) using RMDs that are representative of the range of RMDs identified the most difficult to process that are in use in the HSO. Refer to Clause 5.2; and
(e) when introducing new or modified RMD, packaging or loading configurations unless equivalence to a previously qualified reference load, RMD/product family, packaging or loading pattern has been demonstrated.

NOTE: Where a new RMD is introduced and there is doubt as to its equivalence to an existing product family, then a risk-based assessment can be used to establish the need for PQ.

Requalification of the process shall be performed annually. Refer Section 10.

7.4.2 Cleaning processes
In addition to visual inspection an objective means of assessing the performance of the cleaning process for a RMD shall be validated.

NOTE: ISO 15883, Parts 1, 2, 3, 4, 6 and 7 (in draft) and ISO/TS 15883-5 include suitable methods for demonstrating the cleaning efficacy of W-Ds. Some of these methods can be applied to manual cleaning processes (e.g., protein residue testing as described in Annex C of ISO 15883-1:2006).

7.4.3 Washer-disinfectors
PQ of thermal or chemical disinfecting processes using washer-disinfectors shall be performed in accordance with the relevant part of the ISO 15883 series of Standards (see Clause 1.3).
7.4.4 Packaging processes

7.4.4.1 General

PQ of packaging processes shall be conducted in accordance with ISO 11607-2.

NOTES:
1. Additional guidance is provided in ISO/TS 16775, including Annex D, which includes useful checklists to assist in the implementation and documentation of packaging process validation.
2. Packaging process PQ may be conducted as part of sterilization process PQ.

The following packaging processes shall be validated:
(a) Sealing process(es) (e.g. for pouches, reels and bags).
(b) Wrapping process(es) (e.g. for folding and closing of sterilization wraps).
(c) Process(es) for filling and closing of reusable containers.

7.4.4.2 Heat sealing process performance qualification (PQ)

The performance qualification demonstrates that the heat sealing process, including the performance of both the equipment and the operator, will consistently produce acceptable sterile barrier systems under specified operating conditions.

Three batches or sets of sealed sterile barrier systems should be made, these batches should encompass the potential significant sources of variation such as operator, time of day, material (size, source, lot), sterile barrier system contents. Package contents that present the greatest challenge (worst case) should be included.

The batches should then be sterilized in all cycles and sterilization methodologies intended to be used to demonstrate capability. To demonstrate repeatability multiple batches using the same cycle may be used.

The sterile barrier systems should be evaluated after the sterilization cycle and after the expected worst case handling, distribution, and storage until the point of use using acceptance criteria from OQ, results should be documented.

7.4.4.3 Wrapping process performance qualification (PQ)

The performance qualification demonstrates that the process will consistently produce acceptable sterile barrier systems under specified operating conditions.

Three batches or sets of sealed sterile barrier systems should be made, these batches should encompass the potential significant sources of variation such as operator, time of day, material (size, source, lot), sterile barrier system contents. Package contents that present the greatest challenge (worst case) should be included.

The batches should then be sterilized in all cycles and sterilization methodologies intended to be used to demonstrate capability. To demonstrate repeatability multiple batches using the same cycle may be used.

If a reusable sterile barrier system is exposed to multiple and/or different sterilization processes to achieve terminal sterilization the validation should cover all processes in the order performed.

The sterile barrier systems should be evaluated after the sterilization cycle and after the expected worst case handling, distribution and storage until the point of use using acceptance criteria from OQ, results shall be documented.

7.4.4.4 Container performance qualification (PQ)

The manufacturer of the container shall provide validated evidence of the container’s ability to facilitate achievement of sterilization of the contents and maintain sterility of a fully loaded reusable container.
Information should be obtained from the manufacturer of the container concerning their recommendations for sterilization and the subsequent maintenance of sterility of a sterile barrier system.

Three batches or sets of sealed sterile barrier systems should be made, these batches should encompass the potential significant sources of variation such as operator, time of day, material (size, source, lot), sterile barrier system contents. Package contents that present the greatest challenge (worst case) should be included.

The batches should then be sterilized in all cycles and sterilization methodologies intended to be used to demonstrate capability. To demonstrate repeatability multiple batches using the same cycle may be used.

If a reusable sterile barrier system is exposed to multiple and/or different sterilization processes to achieve terminal sterilization the validation should cover all processes in the order performed.

The sterile barrier systems should be evaluated after the sterilization cycle and after the expected worst case handling, distribution and storage until the point of use using acceptance criteria from OQ. In addition to the OQ acceptance criteria contents should be assessed after sterilization to ensure that sufficient drying has occurred in steam sterilization cycle.

7.4.5 Sterilizing processes

PQ shall demonstrate the attainment of the required sterilizing conditions on and throughout an RMD within the specified sterilizer load.

For PQ, an overkill approach is generally used by HSOs to achieve an SAL of $10^{-6}$ for a terminally sterilized RMD.

PQ shall be performed using a load that is representative of loads to be sterilized routinely and which is based on the most challenging load to sterilize. The total mass of the load shall be specified and documented.

An RMD used for PQ shall be packaged in an identical manner to that of the RMD when it is processed routinely. The manner of presenting an RMD to the process, including the orientation of the RMD, shall be specified and documented.

There are two components to PQ, namely physical performance qualification (PPQ) and microbiological performance qualification (MPQ). PQ shall include the assessment of both PPQ and MPQ:

(a) PPQ shall verify attainment of the specified critical physical parameter(s) of the sterilizing process within the load, e.g. exposure time at temperature, sterilizing agent concentration.

(b) MPQ shall demonstrate the microbiological lethality of the process within the load by the placement of biological indicators in the load. MPQ studies shall involve the placement of biological indicators at positions within the load where sterilizing conditions are most difficult to achieve.

Biological indicators used during PQ shall—

(i) comply with the relevant part(s) of ISO 11138 applicable to the chosen method of sterilization;

(ii) be specified by the manufacturer as resistant to the chosen sterilizing agent and shall be more resistant to the chosen sterilizing agent than any bioburden at risk of remaining on the RMD after cleaning and/or disinfection;
(iii) be placed at positions within the packaged RMD where sterilizing conditions are most likely to be difficult to achieve [this may be within a process challenge device (PCD)]; and

(iv) be subject to the BI manufacturer’s validated microbiological method for recovery of spores exposed to the sterilizing process.

PCDs used during PQ shall comply with EN 867-5, or ISO 11140-6 (currently in draft), or ISO 11135, depending on the chosen method of sterilization. PCDs shall be equivalent or more challenging to the process than the position in a packaged RMD where sterilizing conditions are most likely to be difficult to achieve.

Internal chemical indicators if used during PQ shall—

(A) comply with the relevant part(s) of ISO 11140 applicable to the chosen method of sterilization;

(B) be placed at positions within the packaged RMD where sterilizing conditions are most likely to be difficult to achieve (this may be within a PCD);

(C) not adversely affect the RMD; and

(D) not be used as the sole means to establish the sterilizing process.

PQ shall be conducted in accordance with the relevant standards identified in Clause 1.3, i.e.—

1. ISO 14937 for low temperature sterilizing process systems;
2. ISO 17665-1 for steam sterilization;
3. ISO 11135 for ethylene oxide sterilization;
4. ISO 20857 for dry heat sterilization; and
5. ISO 25424 for steam formaldehyde.

PQ studies shall include a series of at least three consecutive successful exposures of the load to the process, within the defined tolerances, to demonstrate reproducibility of the process. Any exposures outside of the defined tolerances shall be reviewed, and corrective action(s) determined and instituted before initiating a new series of exposures.

If a failed exposure can be attributed to factors that are not relevant to the effectiveness of the process being validated, e.g., power failure, loss of services, failure of external monitoring instrumentation, then this failed exposure shall be documented as unrelated to performance of the process and shall not require the performance of three further consecutive successful exposures.

For PQ of a moist heat sterilizing process the penetration time to all parts of an RMD shall be established and added to the sterilization holding time (see Table 6.2 for the most common holding times used for saturated steam sterilizing processes).

During PQ data shall be generated during the process to demonstrate attainment of the defined physical and/or chemical conditions, and microbiological lethality within specified tolerances, throughout the sterilization load. The relationship(s) between the specified conditions occurring at positions in the load that are used to monitor routine sterilizing processes and those conditions occurring throughout the remainder of the load shall be established by measurement of specified conditions at predetermined positions throughout the load.

Where applicable, following exposure to the process, the levels of any process residues shall be demonstrated as being below the specified regulatory limits.
It shall be demonstrated that an RMD meets its specified requirements for safety, quality and performance following application of the defined process at the upper tolerances of the process parameters.

7.5 REVIEW AND APPROVAL OF VALIDATION

7.5.1 General

The purpose of this activity is to undertake and document a review of the validation data as compiled in the validation report in order to confirm the acceptability of the cleaning, disinfection, packaging and sterilizing processes and to approve the overall process specification.

A validation report shall be prepared for each piece of equipment which includes the validation protocol, the information gathered or produced during IQ, OQ and PQ for each specified process.

Data obtained and documented during IQ and OQ shall include but may not be limited to—

(a) confirmation that the calibration of test equipment has been verified and the calibration of each measuring chain fitted to the equipment has been checked and, where necessary, adjusted;

(b) confirmation that the equipment has been tested and reproducibly delivers the defined process;

(c) the process parameters (including their tolerances) used to justify product release; and

(d) for steam sterilizers, the value set for an air detector and/or the interpretation of a biological indicator used alone or in combination with a process challenge device.

Other requirements for inclusion in the validation report are specified in Clause 7.5.2.

The validation report shall be reviewed and approved by the designated responsible person(s). The results of this review shall be documented and approved.

A copy of the validation report shall be retained in the reprocessing facility.

7.5.2 Validation report

In addition to the validation protocol and data obtained during IQ, OQ and PQ, the validation report shall include, where applicable—

(a) the equipment specification and any subsequent changes to it; including any details of modification to the instrumentation or controls;

(b) the location and unique identification for the equipment, e.g. serial number together with name and address of the manufacturer, type of equipment and model reference number;

(c) documentation to demonstrate compliance with the safety specifications;

(d) the pressure vessel certificate(s), if applicable;

(e) a maintenance manual and a planned maintenance schedule for the equipment including operational procedures for all maintenance, checks and tests;

(f) the installation and operating instructions;

(g) copies of any declarations according to medical device regulations, if appropriate;

(h) details of any faults found and how they have been corrected;

(i) the load configuration for each type of load/product family; and, if applicable, packaged product heat penetration studies for each type of sterilizer load/product family;
(j) the parameters used for each cycle and a copy of the specification for each process;
(k) the identity of all personnel together with their professional qualifications (in terms of their competence to do the work) involved in validation
(l) the programme for requalification, periodic testing and routine testing;
(m) training manuals for routine operating personnel; and
(n) for equipment that is in current use, the results of maintenance and confirmation that data from routine performance tests are satisfactory.
SECTION 8  ROUTINE MONITORING AND CONTROL

8.1 GENERAL

The purpose of routine monitoring and control is to demonstrate that the specified and validated cleaning, disinfection, packaging and sterilizing processes for an RMD have been delivered to that RMD.

Data shall be recorded for each cleaning, disinfecting, packaging and sterilizing process to demonstrate that the process specification has been met within the defined tolerances. Refer to Tables 8.1 and 8.2.

Records of routine monitoring and control shall be retained for each operating cycle (see Clause 2.2.5).

8.2 ROUTINE MONITORING AND CONTROL OF CLEANING PROCESSES

8.2.1 General

Routine monitoring and control of the cleaning process shall be performed in accordance with the requirements of Table 8.1.

**TABLE 8.1**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<td>Water quality</td>
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<td>RM</td>
<td>M</td>
<td>B</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Temperature</td>
<td>EC</td>
<td>EC</td>
<td>RM</td>
<td>D</td>
<td>RM</td>
<td>RM</td>
</tr>
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<td>Chemical dosing</td>
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<td>EC</td>
<td>RM</td>
<td>EC</td>
<td>EI</td>
<td>RM</td>
</tr>
<tr>
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<td>EI</td>
<td>EI</td>
<td>B</td>
<td>B</td>
<td>EI</td>
</tr>
</tbody>
</table>

**LEGEND**

- B = not required
- O = optional
- RM = recommended by system manufacturer
- Frequency: EI = each item; EC = each cycle; D = daily; W = weekly; M = Monthly; Q = Quarterly; A = annually

8.2.2 Manual cleaning

The outcome of manual cleaning shall be checked at completion of the process by visual inspection.

8.2.3 Washer disinfectors employing thermal disinfection

The process record shall be checked at the completion of each washer disinfecter cycle to verify that the cycle variables as indicated by the instruments on the WD or shown on the batch process record are within the limits specified by the manufacturer.
The following process variables shall be verified and/or monitored for each stage of the process:

(a) Correct functioning of cleaning and drying equipment (i.e. water pressure, flow, action).
(b) Cleaning agent dosage.
(c) Temperature including the time for which the disinfection temperature was maintained was not less than that specified.
(d) Exposure time.

8.2.4 Ultrasonics

Ultrasonics aluminium foil or pencil load test daily and document reference AS 2773.1 and AS 2773.2.

8.2.5 Cleaning efficacy inspection

Cleaning efficacy shall be undertaken on completion of the cleaning process for RMDs by visual inspection utilizing magnification as appropriate.

NOTES:

1. The most common means of monitoring the efficacy of the cleaning process for an RMD is by visual inspection of the cleaned RMD. However, due to the complex design of many RMDs, visual inspection alone might not be sufficient to monitor cleaning efficacy. Commercially available soil tests or surrogate devices may be used to monitor cleaning process efficacy provided that they have been demonstrated as equivalent to the test soil used during cleaning validation studies (see Section 7).

2. If an RMD is not clean, then the disinfecting and sterilizing processes will be compromised.

8.2.6 Drying cabinets

Dryers temperature shall be checked daily and recorded to ensure operating within specified limits.

8.3 ROUTINE MONITORING AND CONTROL OF MANUAL CHEMICAL DISINFECTION WITH HIGH LEVEL INSTRUMENT GRADE DISINFECTANT

For each use of the instrument grade high level disinfectant the following monitoring activities shall be documented according to manufacturer instructions:

(a) Temperature of the HLD.

NOTE: Some manual HLD systems are not temperature dependent.

(b) Contact time.

(c) Rinse water.

NOTE: There may be special requirements for rinse water quality according to the intended use of the RMD.

The MRC of the instrument grade high level disinfectant shall be monitored prior to each use according to manufacturers’ instructions, or at least daily, and the results documented.

Chemical indicators should be compatible with the high level disinfectant used. MRC indicators may require positive and negative controls to be conducted prior to use to establish that they are able to detect MRC below acceptable limits.

NOTES:

1. Some HLD manufacturers require the MRC to be checked immediately prior to each use, for example HLD that are reused for more than one episode of disinfection and are at risk of dilution.
2. The MRC of some high level instrument grade disinfectants may not need to be checked prior to use, for example HLD that are used for a single episode of disinfection.

8.4 ROUTINE MONITORING AND CONTROL OF WASHER DISINFECTORS EMPLOYING CHEMICAL DISINFECTION FOR THERMOLABILE ENDOSCOPE

The process record, and process indicators, (where they are required by the manufacturer), shall be checked at the completion of each cycle to verify that the process was delivered within defined tolerances or in accordance with the specification.

Routine monitoring and control of the chemical disinfecting process shall be performed in accordance with the requirements of Table 8.1.

Process indicators may be used to verify MRC of the chemical disinfectant if required by the manufacturer.

The following process variables shall be verified and/or monitored:

(a) Correct functioning of disinfecting equipment (e.g. water pressure, flow, action, disinfecting agent solution volume, temperature).

(b) In-use chemical disinfecting agent concentration during disinfection phase if required.

(c) Correct contact/time.

(d) Any additional parameters recommended by the manufacturer of the washer-disinfector and/or disinfecting agent.

(e) Water quality by sampling at the point where the endoscope connects to the AER (W-D). manufacturer recommendations.

NOTE: Additional guidance is in ISO 15883-1 and ISO 15883-4.

8.5 MICROBIOLOGICAL SURVEILLANCE OF FLEXIBLE ENDOSCOPIES WITH CHANNELS

Flexible endoscopes with channels shall undergo microbiological surveillance. Gastrointestinal endoscopes should be tested at least quarterly in accordance with the GENCA guidelines. Flexible endoscopes with channels that are used in and processed by HLD should be tested monthly (e.g. bronchoscopes, cystoscopes and duodenoscopes).

Flexible endoscopes with channels that undergo terminal sterilization should be tested in accordance with HSO policy.

Loaned flexible endoscopes with channels, or returning from repair shall undergo microbiological surveillance within 72 hours of receipt by the HSO.

8.6 ROUTINE MONITORING AND CONTROL OF PACKAGING PROCESSES

Packaging procedures shall be performed in accordance with the specification developed during process definition (see Section 6).

Routine monitoring and control of packaging procedures for sterilization wrap, reusable rigid sterilization containers, PSBS and where applicable, self-adhesive PSBS shall ensure that packaged items produced during routine operation meet the specification. ISO 11607-1, ISO 11607-2 and ISO/TS 16775. This is usually achieved by visually checking each packaged item whilst preparing loads for the sterilizer.
Heat sealers used for sealing PSBS and/or dust covers shall be operated in accordance with the manufacturer's instructions for use. For impulse and rotary heat sealers without a process record, the temperature that the machine has been set for shall be recorded on a daily basis and a visual check shall be made immediately prior to each episode of sealing to ensure that the correct seal temperature has been reached.

For heat sealers where process variables are monitored for each episode of sealing, achievement of correct process variables shall be confirmed at the completion of each episode of sealing (or in accordance with manufacturer's instructions).

On a daily basis one or more samples of heat sealed PSBS shall be checked for seal integrity before and after exposure to a sterilization process. This check involves a subjective visual assessment of seal integrity over the length of the seal. See EN 868-5 for further information.

Rigid reusable sterilization containers shall be subjected to a visual inspection prior to each use. The visual inspection shall ensure that the container and the lid are free from any dents or cracks, that the seal/gasket is intact along its entire length and is not compressed or pinched, the closure mechanism (handles) lock firmly into position and that the filter (if applicable) has been replaced or is within the acceptable number of reuse cycles.

### TABLE 8.2

**REQUIREMENTS FOR ROUTINE MONITORING AND CONTROL OF PACKAGING PROCESSES**

<table>
<thead>
<tr>
<th>Test</th>
<th>Self-adhesive PSBS</th>
<th>Heat sealed PSBS</th>
<th>Single use SBS-wrap</th>
<th>Reusable SBS-wrap</th>
<th>Containers</th>
<th>Sealing tape</th>
<th>Heat sealers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>D</td>
</tr>
<tr>
<td>Seal integrity</td>
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<td>EI</td>
<td>B</td>
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<td>EI</td>
</tr>
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</tr>
<tr>
<td>Seal integrity</td>
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<td>EI</td>
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</tr>
</tbody>
</table>

**LEGEND:**
- B = not required
- O = optional
- RM = recommended by system manufacturer
- Frequency: EI = each item, D = daily

**NOTE:** Additional guidance is in ISO/TS 16775.

### 8.7 ROUTINE MONITORING AND CONTROL OF STERILIZING PROCESSES

#### 8.7.1 General

The process record shall be checked at the completion of each cycle to verify that the process was delivered in accordance with the specification.

Biological indicators (BI) and/or chemical indicators (CI) may be used as an additional method for demonstrating sterilization processes were delivered in accordance with the specification.

Reference shall be made to ISO 14161 for biological indicators and ISO 15882 for chemical indicators for guidance on the selection, use and interpretation of the results of these indicators when used for routine monitoring.

Sterilizing equipment shall be checked to ensure that it is functioning as intended each day, prior to being used for sterilization of RMD.
8.7.2 Low temperature sterilizing systems
Performance tests shall be conducted in accordance with the manufacturer's instruction for use [e.g. peracetic acid, hydrogen peroxide, low temperature steam formaldehyde (LSTF) systems and ethylene oxide].

8.7.3 Dry heat
Performance tests shall be conducted in accordance with the manufacturer's instruction for use.

8.7.4 Moist heat
For moist heat sterilization processes, daily and/or weekly performance tests are required.
A daily air removal and steam penetration test (Bowie and Dick – type test) shall be performed on pre-vacuum steam sterilizers.
Bowie and Dick – type test used on large steam sterilizers shall comply with ISO 11140-3, ISO 11140-4 or ISO 11140-5 as appropriate.
Air removal and steam penetration tests for small steam sterilizers shall comply with EN 867-5.

NOTES:
1. Bowie and Dick – type test should not be used for sterilizers that utilize gravity or positive pressure pulse displacement.
2. Manufacturers of small steam sterilizers should specify the type of air removal and steam penetration test suitable for use on their equipment.

A weekly leak rate/vacuum test and air detector function test shall be performed on steam sterilizers fitted with an air detector. Daily leak rate/vacuum tests shall be performed on steam sterilizers without air detectors.
### Table 8.3
**Requirements for Routine Monitoring and Control of Sterilizing Equipment**

<table>
<thead>
<tr>
<th>Test</th>
<th>Steam sterilizers—Large sterilizers</th>
<th>Small steam sterilizers</th>
<th>Dry heat sterilizers</th>
<th>EO sterilizers</th>
<th>EO aeration cabinets</th>
<th>Low temperature sterilization systems</th>
<th>Low temperature steam and formaldehyde</th>
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<td>W/RM</td>
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<td>CI</td>
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<td></td>
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<td>O/RM</td>
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<td>W or D (if not fitted with an automatic air detector)</td>
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<td>B</td>
<td>O/RM</td>
<td>O/RM</td>
<td>W or D (if not fitted with an automatic air detector)</td>
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<td>Bowie Dick – Type test</td>
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<td>Diagnostic cycle</td>
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</table>

**Legend:**
- B = not required
- O = optional
- RM = recommended by system manufacturer

**Frequency:** EI = each item; EC = each cycle; D = daily; W = weekly; M = Monthly; Q = Quarterly; A = annually

**Notes:**
1. Monitoring of humidity in EO aeration chambers is not necessary to assess the effectiveness of the aeration phase of the sterilization process; however, maintenance of a low level of humidity might be necessary in aeration chambers to reduce the incidence of electrostatic build-up in the sterilized load.
2. Small steam sterilizers with only S type cycles should be monitored according to manufacturer recommendations and EN 13060 and ISO 17665-1.

#### 8.7.5 Biological indicators

Biological indicators used for process development (if applicable), MPQ and routine monitoring and control of sterilizing processes shall comply with ISO 11138 and the relevant applicable part according to the selected method of sterilization.

Biological indicators shall be used as follows:
(a) As part of MPQ.
(b) In every load in a validated ethylene oxide sterilization process.
(c) According to manufacturer’s instructions for use in dry heat and low temperature sterilization systems.
(d) At frequencies determined by the HSO for validated moist heat sterilization processes.

NOTE: The number of biological indicators used is dependent on the size of the sterilization chamber and complexity of the load. Specified requirements for the numbers of biological indicators to be used exist for ethylene oxide sterilization (see ISO 11135 series).

Reference shall be made to ISO 14161 when selecting, using and interpreting the results of biological indicators.

8.7.6 Chemical indicators

Chemical indicators used for process development (if applicable), during PQ and routine monitoring and control of sterilizing processes shall comply with ISO 14140-1 and selected according to sterilization method and/or cycle.

Chemical indicators shall be used as follows:

(a) As part of PQ if internal chemical indicators are to be used routinely.
(b) On the exterior of each packaged RMD.
(c) According to manufacturer’s instructions for low-temperature sterilization systems using a liquid chemical sterilizing agent.
(d) As required by HSO policy for internal indicators.
(e) Where semi-critical RMD are being sterilized unwrapped, in every load.

NOTES:
1 Chemical indicators used inside packaged RMD should be placed at the location determined to be the most difficult to sterilize during validation.
2 Some sterilization may be required to be sterilized prior to re-use of the owner. Where these RMD are sterilized unwrapped, a chemical indicator should be placed in the load to identify processed from unprocessed loads.

Reference shall be made to ISO 15882 when selecting, using and interpreting the results of chemical indicators.

8.7.7 Process challenge devices (PCD)

The suitability of a PCD used to establish the sterilizing process shall be determined. PCDs, if used, shall be equivalent or more challenging to the process than the position within a packaged RMD where sterilizing conditions are most likely to be difficult to achieve.

Reference shall be made to ISO 15882 when selecting, using and interpreting the results of PCDs.

Where PCDs are used to monitor ethylene oxide sterilization processes, the requirements of ISO 11135-1 shall be followed.
PCDs used as an air removal and steam penetration test in small steam sterilizers shall comply with EN 867-5.

NOTES:
1 Development of an International Standard to demonstrate the suitability of a medical device simulator for use during a moist heat sterilizing process is currently under consideration for the ISO 11140 series.
2 Currently there is no Standard for PCDs used for routine monitoring of sterilizing processes in large steam sterilizers.
3 For steam sterilizers with active air removal systems (i.e. pre-vacuum) without an air detector, the use of a PCD may provide a suitable means to verify the absence of residual air that might affect the attainment of sterilizing condition in the load.
SECTION 9 RELEASE OF RMDS FOLLOWING REPROCESSING

9.1 GENERAL

The effectiveness of each individual phase of the overall reprocessing procedures (e.g. cleaning, disinfection, packaging and sterilization) shall be verified prior to a RMD being released to the next phase of reprocessing (see Figures 9.1 and 9.2).

NOTE: The essential prerequisites for effective disinfection and sterilization are that the RMD is clean and is able to withstand the process. If an RMD is not clean, then the disinfecting and sterilizing processes will be compromised.

Prior to release of a RMD from each process, i.e. cleaning, disinfection or sterilization, the process cycle record shall be checked to ensure the process has been delivered in accordance with its specification.

Where used, the results for test soil cleaning indicators, biological indicators, chemical indicators and PCDs shall be checked as part of product release in accordance with HSO policy.

Product release from sterilization processes where biological indicators are used could be delayed until the results of the biological indicators are known.

NOTE: A system should be specified to clearly differentiate between an unprocessed RMD and a processed (disinfected/sterilized) RMD within the reprocessing area.
Return from repair

Acquisition
Purchase
Loan RMD

At all stages:
- Location
- Facilities
- Equipment
- Management
- Policies/Procedures
- Safe work instructions

FIGURE 8.1 REPROCESSING OF A CRITICAL RMD

RMD: Loan/repair as per supplier’s specification
At a minimum, the criteria for release of an RMD from each phase of reprocessing shall comply with the requirements in Table 9.1. Procedures for the reprocessing of an RMD from the cleaning, disinfecting, packing, and sterilizing process shall be specified. These procedures shall define the cleaning, disinfecting, packing, and sterilizing acceptance criteria for designating a cleaning, disinfecting, packing, and sterilizing process as conforming to its specification.
### Table 9.1

**Requirements for Release of an RMD from Reprocessing**

<table>
<thead>
<tr>
<th>Type of process</th>
<th>Release criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning manually</td>
<td>RMD is visually clean and dry.</td>
</tr>
<tr>
<td>Cleaning automated</td>
<td>RMD is visually clean and dry. Cycle records comply with process specification.</td>
</tr>
<tr>
<td>Disinfection thermal</td>
<td>RMD is visually clean and dry. Cycle records comply with process specification.</td>
</tr>
<tr>
<td></td>
<td>NOTE: Thermal disinfection is usually associated with an automated cleaning process.</td>
</tr>
<tr>
<td>Disinfection chemical</td>
<td>Disinfecting agent concentration, exposure time and temperature comply with process specification. RMD has been rinsed in accordance with manufacturer's instructions.</td>
</tr>
<tr>
<td></td>
<td>NOTE: This may be associated with manual or automated endoscope reprocessing.</td>
</tr>
<tr>
<td>Packaging system - PSBS—Sealable pouches and reels</td>
<td>Packaging system is suitable for sterilizing process and of correct size for RMD to be sterilized, is correctly labelled, the PSBS and seal are intact, chemical indicator is present with specified colour change (see ISO 11607).</td>
</tr>
<tr>
<td>Packaging system - SBS—Sterilization wrap, i.e. woven and non-woven</td>
<td>Packaging system utilized is suitable for sterilizing process and of correct size for RMD to be sterilized, is correctly labelled, packaging material and seal are intact, chemical indicator tape is present with specified colour change (see ISO 11607).</td>
</tr>
<tr>
<td>Packaging system - PSBS—Reusable containers</td>
<td>Packaging is suitable for sterilizing process and of correct size for RMD to be sterilized, is tamper evident, sealed, correctly labelled, filter is present (if required), chemical indicator is present with specified colour change (see ISO 11607).</td>
</tr>
<tr>
<td>Sterilization moist heat with drying cycle</td>
<td>Cycle records confirm achievement of process parameters established during PQ and external chemical indicators show specified colour change. Packaged RMD are intact, there is no visible moisture. If used, results for BIs, PCDs, electronic data loggers are present (see ISO 17665-1).</td>
</tr>
<tr>
<td>Sterilization moist heat without drying cycle</td>
<td>Cycle records confirm achievement of process parameters established during PQ and where chemical indicators are used ensure specified colour change is achieved. If used, results for BIs, PCDs, electronic data loggers are present (see ISO 17665-1).</td>
</tr>
<tr>
<td>Sterilization dry heat</td>
<td>Cycle records confirm achievement of process parameters established during PQ and external chemical indicators show specified colour change. If used, results for BIs, electronic data loggers are present (see ISO 20857).</td>
</tr>
<tr>
<td>Sterilization ethylene oxide</td>
<td>Cycle records confirm achievement of process parameters established during PQ and external chemical indicators show specified colour change. No growth detected from exposed BIs/PCDs. Packaged items are intact, there is no visible moisture. Records confirm external aeration (if required) performed in accordance with process specification (see ISO 11135-1).</td>
</tr>
<tr>
<td>Sterilization peracetic acid</td>
<td>Cycle records confirm achievement of process parameters established during PQ and biological and chemical indicators show correct results (see ISO 14937).</td>
</tr>
<tr>
<td>Sterilization hydrogen peroxide system</td>
<td>Cycle records confirm achievement of process parameters established during PQ and biological and chemical indicators show correct results. Packaged items are intact, there is no visible moisture. If used, results for PCDs are correct (see ISO 14937).</td>
</tr>
</tbody>
</table>

(continued)
TABLE 9.1 (continued)

<table>
<thead>
<tr>
<th>Type of process</th>
<th>Release criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization low</td>
<td>Cycle records confirm achievement of process parameters established during PQ and external chemical indicators show specified colour change. No growth detected from exposed Bls. If used, correct result for exposed PCDs. Records confirm external aeration (if required) performed in accordance with process specification (see ISO 25424).</td>
</tr>
<tr>
<td>temperature</td>
<td></td>
</tr>
<tr>
<td>steam/formaldehyde</td>
<td></td>
</tr>
<tr>
<td>Sterilization—Other</td>
<td>Cycle records confirm achievement of process parameters established during PQ and external chemical indicators show specified colour change. No growth detected from exposed Bls/PCDs. Packaged items are intact, there is no visible moisture. Records confirm external aeration (if required) performed in accordance with process specification. Reference may be required to manufacturer’s instructions for use. (See ISO 14937).</td>
</tr>
<tr>
<td>methods</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Traceability systems specified to in Clause 2.4.3.2 shall be part of the release criteria.

9.3 **RMD RELEASE**

An RMD shall not be released from reprocessing until all acceptance criteria for release of the RMD have been met.

If the criteria specified in Table 9.1 are not met, then the RMD shall be designated as nonconforming. A nonconforming RMD shall be quarantined and handled in accordance with the documented procedure for control of nonconforming product (see Clause 2.5).

9.4 **RECORDS OF RMD RELEASE**

The minimum traceable system required for release of RMDs is outlined in Clause 2.4.3.

NOTE: HSOs should be working towards an electronic tracking/process record system.

9.5 **HANDLING, TRANSPORT AND STORAGE OF RELEASED REPROCESSED RMDS**

A reprocessed critical/semi critical RMD shall be handled, transported and stored in a manner which prevents/minimizes the risk of contamination. Maintaining sterility of RMDs and items purchased sterile by the HSO is dependent on maintaining a suitable storage environment, education of staff and the implementation of transport systems which protect package integrity until the point of use.
SECTION 10 MAINTAINING PROCESS EFFECTIVENESS

10.1 GENERAL

The ongoing effectiveness of cleaning, disinfecting, packaging and sterilizing processes shall be periodically assessed to ensure that each process continues to be delivered within its specification. To achieve this, the HSO shall ensure that agreements are in place with suitably trained and/or qualified service providers to undertake planned preventive maintenance, recalibration, reassessment of process effectiveness and annual requalification for all reprocessing equipment.

For all record keeping requirements refer to Clauses 2.2.3 and 2.2.4.

NOTE: Tables 10.1, 10.2 and 10.3 identify the recommended frequencies for calibration, maintenance and testing of reprocessing equipment.

10.2 CALIBRATION

Calibration is the process that is used to ensure that the accuracy and reliability of instrumentation used to control and monitor equipment used to reprocess an RMD. A calibration schedule, based on the equipment history, shall be established and maintained.

Documentation shall be requested by the user from the service provider that includes details of actual and adjusted measurement values. When faults arise, corrective action shall be undertaken. Routine calibration checks and maintenance of all measuring devices, timers, gauges and displays on the equipment should be performed by a trained competent person, using measuring equipment certified by a recognized certification body such as the National Association of Testing Authorities (NATA) in Australia (see AS/NZ ISO 9001) and the report made available. The report should include the certification number of the calibration device used.

NOTE: The quality of the entire validation process depends on the accuracy and reliability of all sterilization parameters measured. It is, therefore, essential that accurate and precise calibration according to equipment-related protocols is performed. (Refer to Section 4.)

10.3 MAINTENANCE OF EQUIPMENT

10.3.1 General

Preventative maintenance of all equipment shall be planned and undertaken in accordance with documented procedures by the equipment manufacturer. This shall be carried out by the manufacturer or a suitably trained and competent person. The procedure for every planned maintenance activity and the frequency at which the activity is to be undertaken shall be specified.

All reprocessing equipment shall undergo an annual electrical safety check. Where necessary, air filters shall be checked and/or changed as required by the manufacturer's instructions for use. Equipment maintenance records shall be retained and readily accessible.

10.3.2 Return to use

Equipment shall not be used to reprocess an RMD until specified maintenance activities have been satisfactorily completed and documented at a minimum in accordance with Table 10.1. The HSO should specify a maximum period that is permitted for any delay in scheduled maintenance.
10.3.3 Maintenance records

The maintenance records shall identify the equipment and shall provide a history of routine periodic maintenance as well as unscheduled maintenance and/or repairs for the equipment. Records shall, as a minimum, include the following information:

(a) The reason for maintenance or repair.
(b) The date of maintenance or repair.
(c) The model and serial number of equipment.
(d) The location of equipment.
(e) A description of the maintenance or repair undertaken.
(f) Details of the parts replaced.
(g) The name of the person or company responsible for performing the maintenance or repair.
(h) The name of the person releasing the equipment back into use.

The preventative maintenance schedule, procedures and records shall be conducted in accordance with the requirements of Section 2 of this Standard.
### Table 10.1

**Recommended Frequency for Recalibration, Preventive maintenance and testing of sterilizing and associated equipment**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Normative reference</th>
<th>Maintenance/recalibration</th>
<th>Air detector function (if fitted)</th>
<th>Air detector performance (if fitted)</th>
<th>Heat distribution</th>
<th>Heat penetration</th>
<th>Steam quality (dryness fraction, superheat and NCG)</th>
<th>Steam quality (purity)</th>
<th>Drying effectiveness</th>
<th>Process residual testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam sterilizers - Large sterilizers</td>
<td>EN 285, ISO 17765</td>
<td>RM/A*</td>
<td>W</td>
<td>A</td>
<td>O</td>
<td>A**</td>
<td>RM</td>
<td>O</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Small steam sterilizers</td>
<td>EN 13060, ISO 17765</td>
<td>RM/A*</td>
<td>RM</td>
<td>RM</td>
<td>O</td>
<td>A**</td>
<td>RM</td>
<td>O</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Dry heat sterilizer</td>
<td>ISO 20837</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>O</td>
<td>A**</td>
<td>RM</td>
<td>O</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>EO aeration cabinet</td>
<td>ISO 25422</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B**</td>
<td>RM</td>
<td>B</td>
<td></td>
<td>B</td>
</tr>
<tr>
<td>Low temperature sterilization</td>
<td>ISO 14937</td>
<td>RM</td>
<td>RM</td>
<td>RM</td>
<td>RM</td>
<td>A**</td>
<td>O</td>
<td>RM</td>
<td></td>
<td>RM</td>
</tr>
<tr>
<td>EO sterilizer</td>
<td>EN 1422</td>
<td>RM/A*</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>A**</td>
<td>RM</td>
<td>O</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Peroxide acid</td>
<td>ISO 14937</td>
<td>RM/A*</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B**</td>
<td>O</td>
<td>B</td>
<td></td>
<td>B</td>
</tr>
<tr>
<td>Steam formaldehyde</td>
<td>EN 14180</td>
<td>RM/A*</td>
<td>W</td>
<td>A</td>
<td>O</td>
<td>A**</td>
<td>RM</td>
<td>O</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Hydrogen peroxide system</td>
<td>ISO 14937</td>
<td>RM/A*</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>RM</td>
<td>RM</td>
<td>A**</td>
<td></td>
<td>B</td>
</tr>
<tr>
<td>BI incubator</td>
<td>ISO 11138-1, ISO 14161</td>
<td>RM/A**</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B**</td>
<td>RM</td>
<td>B</td>
<td></td>
<td>B</td>
</tr>
</tbody>
</table>

**Legend:**
- **B** = not required
- **O** = optional
- **RM** = recommended by system manufacturer
- **Frequency:** W = weekly, M = Monthly, Q = Quarterly, A = Annual
- **+** = the frequency of planned preventative maintenance/recalibration should be based on maintenance/calibration history, with the maximum duration between recalibration being annually. Dependent on ISO 9001 or PQ requirements/outcomes
- **++** = where the sterilizer is fitted with an integral steam generator, and the steam generator water is not being treated chemically, then the quality of the feedwater to the steam generator should be tested and be compliant with the requirements of Table 7.3, (Steam quality for dedicated steam generator). Steam purity delivered to the sterilizer should be compliant with the requirements of Table 7.3, (Steam Condensate)
- **+++** = visual dryness tests are conducted during PQ and requalification. Where dryness tests are required to investigate issues related to drying effectiveness, test specification and guidance are provided in the relevant normative
### TABLE 10.2

**RECOMMENDED FREQUENCY FOR RECALIBRATION, PREVENTATIVE MAINTENANCE AND TESTING OF CLEANING, DISINFECTING AND PACKAGING EQUIPMENT**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Normative reference</th>
<th>Cleaning efficacy</th>
<th>Disinfection efficacy</th>
<th>Load dryness</th>
<th>Leak tests</th>
<th>Thermometric testing</th>
<th>Load</th>
<th>Chamber wall/Profile</th>
<th>Temperature control</th>
<th>Calorifier and tanks</th>
<th>Supply water quality testing</th>
<th>Load carrier alignment and spray system</th>
<th>Maintenance/recalibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washer-disinfector (including batch washer, multi-chamber)</td>
<td>ISO 15883-1, ISO 15883-2</td>
<td>D, Q</td>
<td>A</td>
<td>A</td>
<td>B</td>
<td>A**</td>
<td>A**</td>
<td>A**</td>
<td>M</td>
<td>A</td>
<td>M</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Associated reprocessing equipment e.g. dental hand piece oiling devices</td>
<td></td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>RM</td>
<td>RM, M</td>
<td>RM</td>
<td>RM</td>
<td>RM</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Ultrasonic cleaner</td>
<td>AS 2773.1, AS 2773.2</td>
<td>D</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>RM</td>
<td>M</td>
<td>RM</td>
<td>M</td>
<td>RM/A</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Drying cabinet</td>
<td>AS 2514</td>
<td>B</td>
<td>B</td>
<td>A</td>
<td>B</td>
<td>B</td>
<td>A</td>
<td>A</td>
<td>B</td>
<td>B</td>
<td>RM/A</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Endoscope Storage cabinet</td>
<td>EN 16442</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>B</td>
<td>B</td>
<td>RM/A</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Heat sealer</td>
<td>ISO 11607-2, ISO/DTS 16675.3</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>A</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>RM/A</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Volumetric dispenser (disinfectant, detergent)</td>
<td></td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>RM</td>
<td>RM</td>
<td>B</td>
<td>RM/A</td>
<td>RM</td>
<td>RM/A</td>
</tr>
<tr>
<td>Recirculating fume cabinet</td>
<td>AS/NZS 2243.9</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>RM</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>RM/A</td>
<td></td>
</tr>
<tr>
<td>Ducted fume cabinet</td>
<td>AS/NZS 2243.8</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>BRM</td>
<td>B</td>
<td>B</td>
<td>RM/A</td>
<td></td>
</tr>
<tr>
<td>Water treatment system</td>
<td></td>
<td>B</td>
<td>RM</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>A</td>
<td>M</td>
<td>M</td>
<td>RM/A</td>
<td>RM</td>
<td>RM/A</td>
</tr>
</tbody>
</table>

**LEGEND**

- B = not required
- O = optional
- RM = recommended by system manufacturer
- Frequency: D = Daily, W = Weekly, M = Monthly, Q = Quarterly, A = Annual
- * = The frequency of planned preventative maintenance/recalibration should be based on maintenance/calibration history, with the maximum duration between recalibration being annually and dependent on IQ, OQ and PQ requirements/outcomes
- ** = Testing frequency varies from the relevant normative
- *** = Additional testing specified in Table 8.1
TABLE 10.3
RECOMMENDED FREQUENCY FOR RECALIBRATION, PREVENTATIVE MAINTENANCE AND TESTING OF AUTOMATED ENDOSCOPE REPROCESSORS (AER)

<table>
<thead>
<tr>
<th>Activity/test as specified in ISO 15883-4</th>
<th>Frequency (modified from ISO 15883-4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak tests</td>
<td>M</td>
</tr>
<tr>
<td>Cleaning and disinfection efficacy</td>
<td>M, Q****</td>
</tr>
<tr>
<td>Temperature of disinfection stage</td>
<td>A**</td>
</tr>
<tr>
<td>Disinfection of liquid transport system— Operational and routine</td>
<td>Q</td>
</tr>
<tr>
<td>Self-disinfection test—Operational and routine</td>
<td>RM</td>
</tr>
<tr>
<td>Channels non-obstruction</td>
<td>Q</td>
</tr>
<tr>
<td>Channels not connected test</td>
<td>Q</td>
</tr>
<tr>
<td>Temperature throughout process</td>
<td>A**</td>
</tr>
<tr>
<td>Minimum process temperature test</td>
<td>A**</td>
</tr>
<tr>
<td>Water quality</td>
<td>M**</td>
</tr>
<tr>
<td>Chemical dosing tests</td>
<td>RM</td>
</tr>
</tbody>
</table>

**LEGEND**

B = not required
O = optional
RM = recommended by system manufacturer

**Frequency:** D = Daily, W = Weekly, M = Monthly, Q = Quarterly, A = Annual

* = The frequency of planned preventative maintenance/recalibration should be based on maintenance/calibration history, with the maximum duration between recalibration being annually and dependent on IQ OQ or PQ requirements/outcomes

*** = Testing frequency varies from the relevant normative

**** = Additional testing specified in Table 8.1

Microbiological surveillance is conducted to processed endoscopes monthly/quarterly depending on the type of scope

10.3.4 Identifying faults

Faulty equipment shall be identified and corrective action shall be taken to rectify the fault in a timely manner. Where a fault has the potential to impact on the quality and/or safety of an RMD, or on operator safety, then the equipment shall be removed from use immediately pending repair.

10.3.5 Cleaning of equipment

Equipment shall be cleaned in accordance with HSO's established protocol and in conjunction with the manufacturer's recommendations to minimize the risk of cross-contamination. The methods used and the frequency of cleaning shall be specified and records kept (Refer to Section 2.)

10.4 REQUALIFICATION

10.4.1 General

Performance requalification shall be performed at least annually in accordance with Clause 7.4 and whenever a change is made to a sterilizer load which is not within the limits specified in the performance qualification report.
The responsibility for determining the necessity and extent of repeating parts of performance requalification shall be assigned to a designated person trained in this specialty.

10.4.2 Procedures for requalification

Procedures for requalification shall be specified. Requalification shall be performed in accordance with these procedures. Records of requalification shall be retained.

10.4.3 Review and acceptance of requalification

Requalification data shall be reviewed against defined acceptance criteria to confirm that performance of the process, as originally qualified, has been retained. Records of this review shall be retained together with any corrective action/s taken in the event that defined acceptance criteria are not met.

Data from requalification studies shall be compared to that of the original qualification studies for the process (and any subsequent requalification studies) to confirm that the performance of the process, as originally qualified, has been retained.

NOTE: To facilitate comparison of qualification and requalification data it might be useful for qualification and requalification reports to use a common format.

10.4.4 Process/packaging changes and revalidation

Processes should be revalidated following changes made to the equipment, product, packaging materials or packaging process, which could potentially compromise the original validation and affect the sterility, safety or efficacy of sterile medical devices. However, a documented rationale should be developed to support this conclusion.

NOTE: The following is a list of changes which could affect the status of a validated process:
1. Sterile barrier system material changes.
2. New equipment.
3. Transfer of processes and/or equipment from one facility or location to another.
4. Sterilization process changes.
5. Review of end user complaints or non-conforming product, negative trends in quality or process control indicators.
6. Change in sterile barrier system contents that are outside the worst case originally evaluated.
7. Change of transport route or means (e.g. from within the building only to transport between buildings which may involve significantly changed challenges to the package) revalidation may be required.

The need for revalidation should be evaluated and documented. If the change does not require that all aspects of the original validation be repeated, this revalidation does not have to be as extensive as the initial validation, however a documented rationale should be developed to support.

A documented rationale should be written for the acceptance of changes that are judged to not need revalidation activities (e.g. change of material supplier if supplier provides evidence that the materials are essentially equivalent).

Periodic revalidation activities, verifications or reviews should be considered since multiple minor changes could cumulatively affect the validation status of the process.

Revalidations is also a control that the operation staff still have the required knowledge and competence to carry out the processes in an efficient way and it can be used to retrain personnel and to realign practices.
10.5 ASSESSMENT OF CHANGE

10.5.1 General

Any change to reprocessing equipment or to a process that might impact on the quality of a reprocessed RMD shall be assessed. If the effectiveness of the process(es) might be altered adversely as a result of the change, then a repeat of part, or all, of IQ, OQ or PQ shall be performed (see Section 7). The outcome of this assessment, including the rationale for decisions reached, shall be documented.

10.5.2 Assessment of impact of change

Any change in an RMD, its package, or the presentation of the RMD for reprocessing shall be assessed for the impact of this change on the cleaning, disinfecting, packaging or sterilizing processes. Where necessary, depending on the nature of the change, aspects of process definition and/or PQ shall be performed (see Sections 6 and 7 respectively). The outcome of this assessment, including the rationale for decisions reached, shall be documented.

Examples of these changes can include (but are not restricted to) the following:

(a) A change in the material of construction of an RMD, construction or design of an RMD or assembly of an RMD.

(b) A change in either the packaging system or the packaging system design for an RMD.

(c) A change to packaging labels that might reduce penetration of the sterilizing agent to the contents of the package.
APPENDIX A

GUIDANCE
(Informative)

A1 SCOPE OF APPENDIX

Appendix A provides guidance to assist users to meet the requirements in normative Sections 1 to 10. This Appendix does not repeat the requirements of these normative clauses.

The exclusions in Clause 1.2 also apply to Appendix A.

For ease of reference, the clause numbering in Appendix A corresponds to that of the normative Sections 1 to 10, e.g. guidance in Paragraph A2.2.2 corresponds to Clause 2.2.2. Where there is no guidance, the statement ‘No guidance is offered’ is used to maintain continuity of clause numbering.

A2 GUIDANCE TO SECTION 2: QUALITY MANAGEMENT

A2.1 General

Application of the relevant elements of a quality management system can assist the HSO to comply with the requirements of this Standard, thereby achieving best practice for reprocessing activities.

The following publications provide useful general information about quality management systems:

(b) The Australian Council on Health Care Standards (ACHS) Evaluation and Quality Improvement Program (EQuIP).
(c) AS/NZS ISO 9001.

A2.2 Documentation

A2.2.1 General

No guidance is offered.

A2.2.2 Policies and procedures

The following requirements and recommendations apply to the operation of sterilizing facilities:

(a) Staff should be immunized in accordance with local/state/national immunization schedules. Records of immunization shall be documented in staff personal files. Records should be revised periodically to ensure currency.

NOTE: When such immunization is declined, this should be noted.

(b) Staff with health conditions that pose a potential risk to the reprocessing of RMD should be educated on management of the condition to minimize the risk of contamination.

(c) Staff suffering from dermatitis or skin infections should be examined by a medical practitioner to confirm their suitability for work in reprocessing activities.

(d) Only alcohol based hand rubs (ABHR) and hand creams approved for use in the reprocessing of RMD environment should be used and appropriate training in their use provided.
(e) Residue from hand hygiene products should not be transferred to RMD's or packaging.

(f) Staff should be trained in workplace health and safety including how their actions can impact on the reprocessing of RMD and incident reporting.

(g) Staff should be trained in facility procedures for dealing with an occupational exposure to blood and body substances.

A2.2.3 Document maintenance

No guidance is offered.

A2.2.4 Control of documents and records

Control of documentation is necessary to ensure—

(a) the adequacy of document content prior to issue;

(b) that documents are legible and user friendly;

(c) that the current revision status, including the date of issue, is readily identifiable and that this revision is the only version of the document available as the active document in the workplace;

(d) that documents are reviewed, updated where necessary and reapproved in accordance with HSO requirements;

(e) that the document content is consistent with relevant Department of Health directives and other regulatory standards and guidelines;

(f) that documents from external sources are identified and that their distribution is controlled; and

(g) to prevent the inadvertent use of obsolete documents.

A2.3 Management responsibility

A2.3.1 General

No guidance is offered.

A2.3.2 Resource requirements

Consideration should be given to the quantity and capacity of equipment required to ensure the safe and effective reprocessing of RMDs. This should include the need to build a suitable level of redundancy in the system to allow for periodic maintenance, calibration, recalibration, qualification and requalification activities, as well as for scheduled and non-scheduled down time. The effective planning of reprocessing activities should ensure that allowance is made for future increases in demand for reprocessing activities.

The HSO should ensure that staffing levels are sufficient to maintain the continuous, safe and efficient operation of the reprocessing facility.

A2.3.3 Reprocessing manager

The qualifications and experience of the person in charge of the reprocessing facility should be sufficient to demonstrate thorough understanding of the sterilizing equipment and items being processed in the facility.

The education and training of staff is an integral element of a quality management system. On commencement of employment an assessment of the knowledge and competency level of new staff should be undertaken. This will enable proper planning of initial and ongoing training for staff. There should be a formal induction/orientation and training program for new staff. At a minimum the program should include the following:

(a) Modes of transmission of infection.
(b) Infection control principles, including standard precautions and transmission-based precautions.
(c) Hand hygiene, including the need and importance of removing jewellery, nail polish and artificial nails.
(d) Workplace health and safety issues, including the use of personal protective equipment (PPE), e.g. protective apron or gown, eye protection, closed footwear and gloves.
(e) Reprocessing activities.
(f) Documentation and record keeping.

On completion of training there should be an objective assessment of staff competency to perform reprocessing activities correctly.

All staff should be encouraged to participate in ongoing training and development opportunities. This could include internal and external education. National and state registered courses in reprocessing and sterilization technologies are available. There should be periodic reassessment of the ongoing competency of trained staff. Where necessary, retraining should be undertaken.

Records of training and competency should be maintained.

A2.3.4 Equipment

Policies and procedures should be developed for use in situations where a non-routine reprocessing process might be required to reprocess an RMD, e.g. where a sterile RMD is dropped and there is no suitable replacement RMD available that is sterile. A non-routine reprocessing process that is used to reprocess an RMD should be validated.

Good inventory management practices should ensure that stock rotation is practiced on a ‘first in, first out’ basis wherever practicable. Systems should be instituted that will provide a record as to stock levels and to the disbursement of reprocessed RMDs to users. This can be facilitated through the implementation of an electronic traceability system.

A2.3.5 Contracts

No guidance is offered.

A2.4 Product realization

A2.4.1 General

Reprocessing stages (cleaning, packaging and sterilizing) of existing RMDs should be risk assessed, validated, documented and allocated to a relevant product family.

A2.4.2 Purchasing

When purchasing RMD they should weigh up to 5 kg and not exceed 7 kg. For further information refer to NSW Workcover Authority (2011), Design and Handling of surgical instrument transport cases: A guide on health and safety Standards.

Available at:

Soiled or damaged incoming goods should not be accepted unless an assessment of the suitability of the goods for their intended purpose is undertaken by a competent person. Expired incoming goods should not be accepted. Where goods are not suitable for their intended purpose, they should be returned to the supplier.

Inclusion of installation qualification, operational qualification and staff training should be considered as part of the purchasing agreement with an equipment supplier.
In Australia, sterilizing and disinfecting equipment that is intended by the manufacturer for use in the reprocessing of a medical device is subject to regulation by the Therapeutic Goods Administration (see Clause 4.3.3).

Staff responsible for the reprocessing of an RMD should be involved in the selection process prior to the purchase of the RMD. This is to ensure the effective reprocessing of the RMD using the existing equipment within the reprocessing facility. An RMD that cannot be effectively reprocessed using existing equipment should not be purchased unless suitable reprocessing equipment is specifically purchased and qualified for reprocessing of the RMD. This is also applicable to use of loan and trial RMDs.

A2.4.3 Identification and traceability of product

A2.4.3.1 General

It is recommended that high quality etching, for example, chemical or laser etching, should be used where it is necessary to uniquely identify an RMD for reprocessing. Engraving is not recommended as it can compromise the strength of a reprocessed RMD and can cause pitting.

Colour-coded identification systems, including coloured instrument tape, silicon rings, adhesive labels, can detach from a RMD during surgery, thereby compromising patient safety. In addition, microorganisms can become trapped beneath the adhesive layer of these systems, thereby compromising the ability of the RMD to be reprocessed effectively.

In some clinical settings it might be necessary to utilize an alternative system for the identification of an RMD because of the design of the RMD to be reprocessed, e.g. in dental and gastroenterological procedural units.

A2.4.3.2 Traceability records

No guidance is offered.

A2.4.4 Control of monitoring and measuring equipment

A2.4.4.1 General

Periodic calibration checks of all monitoring and measuring equipment, e.g. timers, gauges, temperature probes, etc. should be performed by a trained and competent person using measuring equipment that is traceable to international or national measurement standards. This can be achieved by using qualified in-house staff or by using qualified external contractors. Calibration equipment should be certified by a suitable certification body, e.g. the National Association of Testing Authorities (NATA) in Australia. A calibration report should be issued for calibration tests performed for each piece of monitoring and measuring equipment. The calibration report should include the certification number of the calibration device used.

A2.4.4.2 Documentation

No guidance is offered.

A2.4.4.3 Non-conformance

No guidance is offered.

A2.5 Measurement, analysis and improvement

A2.5.1 Audits

No guidance is offered.
A2.5.2 Nonconforming RMD

Examples of a nonconforming RMD can include, but are not restricted to an RMD—

(a) that does not meet acceptance criteria after completion of cleaning, disinfecting or sterilizing processes;
(b) that is found to be incorrectly wrapped after completion of a sterilizing process even though process parameters for the sterilizing process were met;
(c) where the sterile barrier system is damaged or opened;
(d) that is wet after completion of a sterilizing process;
(e) that comes into contact with a wet surface after cleaning, disinfection or sterilization;
(f) that is placed or dropped on a dirty surface after reprocessing, for example, a floor or sink area;
(g) that cannot be identified as having been exposed to the appropriate reprocessing processes;
(h) that is non-functional;
(i) that has exceeded its expiry date; or
(j) batch control label.

A2.5.3 Corrective action

A2.5.3.1 General

Examples of factors that can cause an RMD to become nonconforming include, but are not restricted to, the following:

(a) Incorrect cleaning or reprocessing and storage areas.
(b) Exposure of an RMD to moisture and condensation.
(c) Exposure of an RMD to incorrect temperature.
(d) Exposure of an RMD to excessive sunlight or other sources of ultraviolet light.
(e) Exposure of an RMD to vermin and insects.
(f) Use of inappropriate packaging materials.
(g) Inadequate sealing of the packaging system for the RMD.
(h) Use of objects that can damage packaging materials, e.g. sharp objects, ball point pens or elastic bands.
(i) Rough handling of a packaged RMD that can cause damage to packaging materials.
(j) Incorrect handling of a reprocessed RMD during storage and/or transport of the RMD.

A2.5.3.2 Recall procedure

No guidance is offered.

A2.5.4 Preventative action

No guidance is offered.
A3 GUIDANCE FOR SECTION 3 Re-processing agent characterization

A3.1 General

A3.1.1 Introduction
The microbial effectiveness of disinfecting and sterilizing processes for the reprocessing of an RMD within a HSO has been comprehensively documented. This information is available in the published literature and in the technical monographs provided by the suppliers of disinfecting and sterilizing systems. If disinfecting and/or sterilizing processes are employed outside of the range of conditions that are widely recognized and recommended by a supplier of a disinfecting or sterilizing system, then the microbial effectiveness of the alternative disinfecting and/or sterilizing process(es) should be demonstrated.

A3.1.2 Reprocessing agent register
The TGA regulatory process for instrument grade disinfectants and liquid chemical sterilizing agents requires a manufacturer of these products to supply relevant product details for each product to the TGA for review before a product can be included on the ARTG for supply in Australia. These details include, but are not restricted to, the formulation of the product, the spectrum of activity for the product, information and data concerning microbial efficacy, stability and toxicity studies, details of the product container/s and ‘Instructions for Use’. The review process for these products includes assessment of—

(a) the commercial history, regulatory status and regulatory actions;
(b) risk analysis;
(c) product formulation and physical/chemical properties, including stability (this includes shelf life and storage conditions);
(d) microbial efficacy;
(e) toxicity/chemical residues;
(f) material effects of disinfecting and sterilizing agents on medical devices;
(g) product packaging; and
(h) information supplied with the product, e.g. labels, directions for use.

A3.1.3 Reprocessing agent information
No guidance is offered.

A3.2 Cleaning agent
No guidance is offered.

A3.3 Disinfectants
No guidance is offered.

A3.4 Sterilizing agents
No guidance is offered.

A3.5 Microbicidal effectiveness
Dry heat [ISO 2587]
The microbicidal effectiveness of dry heat and its use in sterilization processes has been comprehensively documented and is available in the published literature, for example, Pflug and Holcomb (28). If dry heat is employed outside the range of conditions that are widely recognized, then microbicidal effectiveness should be demonstrated.

Ethylene oxide gas [ISO 11135]

Microbicidal effectiveness data should be developed if it is proposed to use the ethylene oxide outside of the range of compositions that are widely recognized or if a novel diluent is to be used.

NOTE: The inactivation of microorganisms by ethylene oxide has been comprehensively documented in the literature. This literature provides a knowledge of the manner in which the process variables affect microbial inactivation. Reference to these general studies on microbial inactivation is not required by ISO 11135-1.

Other sterilizing agents insert modified text from ISO 14937:2009 derived from the Clause on microbicidal effectiveness.

And this framework would continue for each type of sterilizing agent and disinfectant.

A3.6 Effects on RMD materials

Reprocessing agents should be compatible with the RMD to be processed and with the equipment used to reprocess the RMD.

The assessment of compatibility can be performed by considering the information provided by the manufacturer or supplier of the RMD and by the manufacturer or supplier of the reprocessing agent(s). This information should include the validated reprocessing instructions for the RMD and material compatibility and material incompatibility information for the reprocessing agent(s).

A3.7 Personnel and environmental safety

A3.7.1 Safety information

The SDS should be obtained before the initial use of the reprocessing agent to reprocess an RMD. The reprocessing facility should also obtain the SDS for other chemicals used in the facility, e.g., disinfectants and sanitizers used to clean the reprocessing facility. Staff should be familiar with the content of each SDS to ensure the safe use and handling of reprocessing agents and other chemicals.

A3.7.2 Environmental impact

No guidance is offered.

A3.7.3 Health and safety procedures

The procedures for the handling and storage of reprocessing agents and other chemicals should be documented.

The labelling of containers used for reprocessing agents and other chemicals should comply with local regulatory requirements.

A3.7.4 Health and safety training

Staff suffering from dermatitis or skin infections should be examined by a medical practitioner to confirm their suitability for work in reprocessing activities. Staff with these conditions can pose a potential risk to an RMD that is being reprocessed. In addition, there is an increased risk of infection where skin is not intact.

Hand creams or barrier creams applied to the hands after hand washing should not be used by staff in the reprocessing facility as use of these creams can result in transfer of residue to the surface of the RMD to be reprocessed. This residue can compromise disinfecting and sterilizing processes for the RMD.
Hand creams or barrier creams applied to the hands after hand washing should not be used by staff in the reprocessing facility as use of these creams can result in transfer of residue to the surface of the RMD to be reprocessed. This residue can compromise disinfecting and sterilizing processes for the RMD.

A4 GUIDANCE TO SECTION 4 Process characterization and equipment characterization

A4.1 General

No guidance is offered.

A4.2 Process characterization

The validated reprocessing instructions from the manufacturer of the RMD should include detailed instructions for the following reprocessing steps:

(a) Preparation of the RMD at the point of use.

(b) Preparation of the RMD before cleaning (e.g. disassembly of detachable components, removal of single use components, monitoring of limited life-span components, etc.).

(c) Cleaning, disinfection (if applicable) and drying of the RMD.

(d) Residual moisture can be removed by placing the RMD into a drying cabinet, utilising compressed medical air or with lint-free cloths. HSO policy should indicate that ambient air is not suitable for drying of an RMD as recontamination or damage can occur.

(e) Inspection, maintenance, lubrication if applicable, assembly and testing of the RMD.

(f) Packaging (if applicable) of the RMD.

(g) Sterilization (if applicable) of the RMD.

(h) Storage requirements for the reprocessed RMD.

(i) Limitations on the reuse of the RMD (e.g. the maximum permitted number of reuses, indications for removal of an RMD from use because of wear and tear, damage, etc.).

Full details of the information that should be included in these instructions are identified in ISO 17664.

The HSO should thoroughly review the manufacturer’s instructions for reuse and reprocessing of an RMD prior to the purchase of that RMD to avoid the purchase of an RMD that cannot be reprocessed safely and effectively by the facility. An RMD that cannot be reprocessed safely and effectively by a reprocessing facility using the existing equipment of that facility should not be purchased unless suitable reprocessing equipment is specifically purchased and qualified for reprocessing of that RMD.

If the manufacturer’s instructions for reprocessing and reuse of an RMD are considered to be inadequate, then the RMD should not be purchased and the HSO should submit a complaint report to the relevant regulatory authority, e.g. the TGA in Australia and Medsafe in New Zealand.

Residual moisture can adversely affect the efficacy of disinfecting and sterilizing processes. Residual moisture can also damage an RMD.

A4.3 Equipment characterization

A4.3.1 Equipment specifications

No guidance is offered.
A4.3.2 Controlling and/or monitoring software
No guidance is offered.

A4.3.3 Standards for reprocessing equipment
An ultrasonic cleaner should be provided for cleaning of an RMD where the RMD manufacturer’s instructions for cleaning specify use of this process, or where pre-treatment of an RMD requires use of an ultrasonic cleaner prior to processing of the RMD in a washer-disinfector. An ultrasonic cleaner should be fitted with a lid to prevent the emission of aerosols during use. Lids should be closed whenever the equipment is operated.

A5 GUIDANCE TO SECTION 5 Product definition

A5.1 General
No guidance is offered.

A5.1.1 General
No guidance is offered.

A5.1.2 Classification for reprocessing
The minimum level of reprocessing required for critical, semi-critical and non-critical RMDs is defined in accordance with Spaulding’s classification system. The correct reprocessing of an RMD is necessary to maintain the functionality and integrity of the RMD and to protect patients and staff. The actual method of reprocessing for a specific RMD is dependent on the reprocessing instructions for that particular RMD that are supplied by the manufacturer of the RMD.

A5.1.3 Policies and procedures
A new RMD should be cleaned before its initial use to remove manufacturing residues that might be present, e.g. lubricants and loose matter. For a metal RMD, this cleaning can also enhance the passivation layer (a thin layer of oxide that can assist in minimizing corrosion of the underlying metal surface). Depending on the intended use of an RMD, it is then subject to either a disinfecting or a sterilizing process.

A5.2 Product families
No guidance is offered.

A5.3 Limiting values
No guidance is offered.

A5.4 Pre-disinfection and pre-sterilization cleanliness of RMDs
This can include the following elements:
(a) Effective cleaning and disinfection (if reprocessing is intended) including re-usable packaging systems, when used (e.g. rigid sterilization containers).
(b) Integrity of the packaging before exposure to the sterilization process.
(c) Environmental control in areas that could have an impact on the product bioburden.
See also Clause 5.6.

A5.5 Packaging

A5.5.1 General
No guidance offered
A5.5.2 Compatibility

Trays that are used during the assembly of an RMD and that are sterilized along with that RMD should be suitable for the intended sterilizing process and should permit penetration of the sterilizing agent to all parts of the RMD that are required to be sterile.

RMDs that are assembled into sets should be placed within the tray or cassette in a manner that distributes the mass of the RMDs evenly.

Hollowware should be—
(a) packaged so that all openings face the same direction and the contents are not able to move inside the package;
(b) separated to permit effective contact of the sterilizing agent;
(c) positioned in the package with the opening of the item against the paper component and not the plastic component of a preformed SBS; and
(d) positioned to facilitate effective air removal, sterilization and drying.

A5.5.3 Protective packaging

No guidance offered.

A5.6 Reprocessing environment

A5.6.1 General

Guidance on the requirements for controlled environments that are suitable for the reprocessing of an RMD can be found in the following publications:


(c) HBN 13 Sterile Services Department, 2004, NHS Estates.

(d) HB 260—2003

(e) AS/NZS 1668 series:
   (i) AS/NZS 1668.1:1998
   (ii) AS 1668.2—2002
   (iii) AS 1668.3—2001

A5.6.2 Facility design

No guidance is offered.

A5.6.3 Facility finishes

No guidance is offered.

A5.6.4 Fixtures and finishing

No guidance is offered.

A5.6.5 RMD cleaning sinks

No guidance is offered.
A5.6.6 Water

Water quality is a critical consideration in all stages of the reprocessing of an RMD. Attention should be paid to the quality of water that is used for the pre-cleaning, washing and rinsing of an RMD, and for dilution of cleaning agents. Water of poor quality can adversely affect the cleaning process and damage an RMD. It can be necessary to treat water to ensure that it is of the necessary quality for use in reprocessing activities, including for use in washer-disinfectors and other reprocessing equipment. Water can be treated by a variety of methods.

Water quality should be monitored regularly to ensure that it is maintained and that it does not deteriorate over time. If this monitoring is not performed contamination of water with microorganisms and/or other contaminants might not be detected. This contamination could cause staining or corrosion of an RMD, or an increase in bioburden of an RMD.

Information on the quality of the potable water supply to the reprocessing facility should be available from the local water authority. Testing of water that is treated on-site before use in reprocessing activities can be performed by a NATA accredited laboratory; this testing can cover a wide range of impurities. Test kits can also be used on-site to monitor a narrower range of impurities. The results of water quality monitoring should be reviewed. If test results are not within specified limits then corrective action should be taken to rectify the problem.

The key water quality elements that should be considered are:

(a) hardness;
(b) pH;
(c) total organic carbon;
(d) ionic contaminants (e.g., heavy metals, halides, chlorides, phosphates and silicates) and resistivity;
(e) temperature;
(f) microbial population; and
(g) bacterial endotoxin.

Water with a high mineral content (often referred to as hard water) is not suitable for pre-cleaning, washing and rinsing of an RMD. Hard water is caused by the presence of dissolved salts, e.g. calcium and magnesium salts that deposit as hard mineral layers when the water is heated or evaporated. The mineral layers are often referred to as lime-scale. Water hardness is expressed as milligrams per litre (mg/L) or parts per million (ppm) of calcium carbonate (CaCO₃) equivalents (see Table A6.1).

**TABLE A6.1**

<table>
<thead>
<tr>
<th>WATER HARDNESS RANGE</th>
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<tbody>
<tr>
<td><strong>Description</strong></td>
<td>1 Hardness (as CaCO₃)</td>
</tr>
<tr>
<td>Soft</td>
<td>0–60 mg/L</td>
</tr>
<tr>
<td>Moderately hard</td>
<td>60–120 mg/L</td>
</tr>
<tr>
<td>Hard</td>
<td>120–180 mg/L</td>
</tr>
<tr>
<td>Very hard</td>
<td>&gt;180 mg/L</td>
</tr>
</tbody>
</table>

**NOTE:** Source: AAMI TIR 34:2007.
Water with a high mineral content can reduce the effectiveness of detergents in dispersing soils from a used RMD. Care should be taken in the selection of cleaning detergents and drying agents especially if the water supply is not treated or softened.

NOTE: Some detergent formulations are only intended for use with soft water. If these detergents are used with hard water, then calcium and magnesium salts can precipitate on the surfaces of an RMD and on reprocessing equipment. In some cases there might also be precipitation of some components of the detergent, e.g. surfactants. Detergent precipitation is particularly difficult to remove. Precipitation is enhanced as the temperature of the water increases.

Water with high mineral content can also adversely affect the performance of automated washing systems due to the fouling of heating elements and the deposit of lime-scale in pipe-work. In addition, mineral deposits can cause encrustation on the surface of an RMD that can prevent microorganisms and other contaminants, e.g. tissue and organic material, from being properly removed during the cleaning process. If the cleaning process is compromised, then the subsequent disinfecting and/or sterilizing processes for the RMD will also be compromised. These encrustations can also permanently damage and shorten the serviceable life of an RMD. Rinse water should be regularly monitored for hardness.

Other chemical impurities in the water can cause damage to an RMD. High levels of chloride ions can cause corrosion pitting. This roughens the surface of an RMD and can prevent proper cleaning as microorganisms and other organic material become trapped. High levels of heavy metal ions, e.g. iron, copper and manganese, can cause tarnishing or staining of a stainless steel RMD.

A5.6.7 Workstations
No guidance is offered.

A5.6.8 Lighting
No guidance is offered.

A5.6.9 Storage
No guidance is offered.

A5.6.10 Facility cleaning
No guidance is offered.

A5.6.11 Entry to facility
No guidance is offered.

A5.6.12 Hand hygiene
No guidance is offered.

A5.6.13 Waste disposal
No guidance is offered.

A5.6.14 Ventilation
No guidance is offered.

A6 GUIDANCE TO SECTION 6 Process definition

A6.1 General
No guidance is offered.
A6.2 Cleaning process definition

A6.2.1 General

The cleaning process for an RMD should ensure that all soil is removed prior to the disinfection or sterilization of that RMD. Thorough cleaning is an essential prerequisite for the effective disinfection and sterilization of an RMD. If an RMD is not clean, then the disinfecting and sterilizing processes for that RMD will be compromised as disinfecting agents and sterilizing agents cannot penetrate or become ineffective against most soil, especially organic material. Soil that remains on an RMD can protect microorganisms from disinfecting and sterilizing processes. Inadequate cleaning can also cause an RMD to not function correctly. During the cleaning process care should be taken to ensure that the process does not cause an increase in the bioburden of that RMD. On completion of the cleaning process an RMD should also be free from cleaning agent residue.

There are many different types of RMDs available today. They are supplied in various designs and sizes, are manufactured from various materials, and have varying degrees of complexity. It is important that the cleaning process for each RMD is suitable for that particular RMD. Different cleaning processes can be required for different RMDs. Cleaning processes for the various RMDs or product families reprocessed by the reprocessing facility should therefore be documented clearly.

The HSO is to develop a procedure indicating when automated cleaning processes are not available what cleaning processes are acceptable or whether the item is to wait until an automated cleaning process is available to ensure reprocessing of the RMD is acceptable.

A6.2.2 Transportation and pre-treatment

No guidance offered.

A6.2.2.1 Transportation

Personnel responsible for the collection of a used RMD should be trained in accordance with HSO policies and procedures.

Designated containers should be used for the collection of used RMDs. Selection of these containers should consider the characteristics of the RMDs to be transported. At a minimum these containers should be:

(a) rigid, robust and leak-proof;
(b) of an adequate size to contain the RMD safely, to minimize hazards to staff handling the RMD and to prevent damage to the RMD during transport;
(c) able to be securely sealed or locked to prevent tampering (where applicable);
(d) able to be clearly labelled to identify the contents;
(e) able to be readily cleaned, or cleaned and disinfected and dried; and
(f) able to be safely disposed of when no longer serviceable.

Equipment used for the transportation of a used RMD should be cleaned in accordance with HSO policies and procedures.

A6.2.2.2 Pre-treatment

The initial pre-treatment of a used RMD is performed at the point of use. A delay between the initial pre-treatment and the validated cleaning process for that RMD can result in an increase in the bioburden (through microbial proliferation). It can also cause adherent material to dry on the RMD making removal of this material more difficult.
A6.2.3 Cleaning

Guidance to the Clause 6.2.3 list items is as follows:

(a) No guidance offered.

(b) During the sorting process an inspection should be performed to verify completeness of an RMD and to identify any defects, e.g. confirmation that all parts of multi-component RMD or RMD set are present. Identified defects should be reported in accordance with documented procedures.

(c) The cleaning of used RMD is easier to standardize and control when an automated mechanical process is used. However, an automated mechanical process might not be recommended for cleaning of some RMDs, e.g. certain fragile and/or complex RMDs. Where manual cleaning of an RMD is recommended by the manufacturer of the RMD, it is essential that the cleaning procedure clearly describes how the RMD is to be manually cleaned, rinsed and dried.

Dedicated manual cleaning equipment and accessories should be available. Cleaning equipment and accessories should be—

(i) inspected for cleanliness, damage and suitability for their intended purpose prior to each use;

(ii) properly cleaned and thermally disinfected at the conclusion of each cleaning session; and

(iii) discarded if damaged, worn or contaminated.

The procedure for manual cleaning of an RMD should include the following directions:

(A) To flush/rinse the RMD in cool running water to remove gross contamination.

NOTE: The working channels of flexible endoscopes should be aspirated and flushed through immediately after use. The external surfaces should be wiped with a lint-free, single-use cloth, using detergent and water, in accordance with the manufacturer’s instructions.

(B) To fill a sink with warm water and the specified cleaning agent according to the manufacturer’s instructions.

(C) To disassemble or open (where applicable) the RMD for cleaning prior to immersion of the RMD in the cleaning agent.

(D) To hold the RMD low in the sink to minimize the generation of particle spatter and aerosols during cleaning.

(E) To properly clean all surfaces of the RMD, including lumens and valves.

(F) To rinse the cleaned RMD in warm running water.

(G) To dry the RMD.

(H) To inspect the reprocessed RMD for completeness and to identify any defects.

(d) The RMD manufacturers’ reprocessing instructions should be considered in relation to the suitability of a RMD for ultrasonic cleaning. Ultrasonic cleaning equipment should be used in accordance with the equipment manufacturer’s instructions (see Clauses 4.3). Water and cleaning agent solutions that are used in ultrasonic cleaners should be changed daily, and whenever soil is visible in the tank.

The action of an ultrasonic cleaner is to loosen debris. Where the ultrasonic cleaner does not have a complete cleaning process following the cavitation action, the RMD needs to be exposed to further thorough cleaning.
(e) No guidance offered.

(f) To ensure that a reprocessed RMD is correctly dried it is important that the RMD manufacturer’s reprocessing instructions are carefully followed. Drying of an RMD is considered complete if no residual water is visible on or in the RMD at the end of the drying stage. An RMD should not be left to dry in ambient air.

(g) Where a drying cabinet is used care should be taken to not exceed the temperature tolerances recommended by the manufacturer of the RMD.

Care should be taken with the placement of an RMD in a drying cabinet to ensure the adequate circulation of air within the cabinet to assist in the uniform drying of the RMD. Hot air and compressed air used for drying of an RMD that has been cleaned using either a manual process or an automated mechanical process should be of a quality that does not increase the bioburden of the reprocessed RMD.

NOTE: Alcohol or other flammable liquids should not be used as a drying agent for an RMD, unless specifically recommended by the manufacturer of the RMD.

A6.3 Disinfecting process definition

No guidance is offered.

A6.4 Packaging process definition

A6.4.1 General

No guidance is offered.

A6.4.2 Packaging procedures

Dressing, tubing and textiles should not be combined into a packaging system that contains an RMD.

An RMD that has hinges or ratchets should be assembled in the package in the unlocked state.

A multi-component RMD should be packaged and presented for sterilization as specified in the manufacturer’s instructions.

A container that is intended for use in an emergency should be used in accordance with the manufacturer’s instructions.

Inspection of an RMD prior to its assembly and packaging (including containment devices, such as instrument trays or instrument pins/strings) should include the following checks:

(a) That the surfaces, lumens and grooves of the RMD are visibly free from soil, rust or lint (where applicable, a style or a correct size clean, dry brush should be able to pass through the lumen).

(b) That all cutting edges of the RMD are sharp (where applicable, sharpness should be tested in accordance with the manufacturer’s instructions).

(c) That all surfaces and non-cutting edges of the RMD are smooth (where applicable), well-finished, free of burrs and that there is no visible evidence of pitting or flaking.

(d) That hinges, box joints and crevices are checked for ease of movement and are not damaged or cracked.

(e) That jaws, teeth and tips of the RMD are not hooked or snagged and that they approximate accurately.

(f) That serrations are uniform and not worn.

(g) That ratchets close easily and hold firmly.
(h) That all screws on a jointed RMD are present and are presented for sterilization per manufacturers’ instructions.

(i) That an RMD with valves moves freely and is left in the ‘on’ or open position.

(j) That a multi-component RMD is disassembled for cleaning in accordance with the manufacturer’s instructions.

(k) That post cleaning the RMD is checked for completeness and correct function.

(l) That telescopes and light cables are checked for dents, damage and correct function in accordance with the manufacturer’s instructions.

(m) That an insulated RMD is inspected and/or tested for integrity to confirm that the insulating layer is intact.

(n) Flexible lumen and non-lumen endoscopes are checked for completeness and function, e.g. attachment of accessories such as sterilizing cap according to manufacturer instruction.

Staff performing functional testing of an RMD should be suitably trained to perform the testing in accordance with the instructions from the manufacturer of the RMD and/or testing device.

An RMD that is found on inspection to be faulty or in need of repair should be removed from use immediately in accordance with HSO policies and procedures. Lubrication of an RMD should be performed in accordance with the instructions from the manufacturer of the RMD. The lubricant should be water miscible and should be compatible with the sterilizing agent.

Lubrication of an RMD should be performed in accordance with the instructions from the manufacturer of the RMD. The lubricant should be water miscible and should be compatible with the sterilizing agent.

The SBS has a critical role in patient safety as it prevents the ingress of microorganisms to a sterile RMD and allows aseptic presentation of the RMD at its point of use. Further information concerning the requirements for and guidance on, SBS and protective packaging can be found in ISO 11607-1 and ISO/TS 16775.

There are three main types of SBS—

(i) sealable pouches and reels;

(ii) sterilization wraps; and

(iii) rigid reusable containers.

Protective packaging can be used to protect the SBS and its contents.

The type of sterilization wrap to be used for an RMD is determined by the type of sterilizing process for the RMD and HSO policy.

There are four main types of sterilization wrap—

(A) non-woven synthetic materials;

(B) blended non-woven materials (e.g. combination of cellulose and synthetic fibres);

(C) crepe paper; and

(D) reusable fabrics.

Cotton and cotton polyester wraps have been shown to be much less effective as a microbial barrier than wraps of non-woven materials. 100% polyester fabrics require specialized laundering processes to retain their microbial barrier properties. Tightly woven 100%