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Reprocessing of reusable medical devices and other devices in health and non-health related facilities



AS 5369:2023

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- Australasian College for Infection Prevention and Control
- Australasian Society for Ultrasound in Medicine (ASUM)
- Australian Chamber of Commerce and Industry
- Australian College of Perioperative Nurses
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- Gastroenterological Nurses College of Australia
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Reprocessing of reusable medical devices and other devices in health and non-health related facilities

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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments, to supersede AS/NZS 4187:2014 *Reprocessing of reusable medical devices in health service organizations*, and AS/NZS 4815:2006 *Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*.

The objective of this document is to provide uniform minimum requirements for the cleaning, disinfection and sterilization of reusable medical devices (RMDs) and other devices so that they are safe for use and pose no risk of transmission of infectious agents.

Where reference is made to a Standard by its number only, the reference applies to the current edition of the document. Where reference is made to a Standard by number, year and where relevant an amendment number, the reference applies to that specific document.

Prevention of health care associated infection in patients undergoing dental, allied health, 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 and lessens health care costs. Effective and safe reprocessing of RMDs/other devices in health service organizations (HSOs) is a critical aspect in the prevention of health care associated infection.

The prevention of infection also applies to reprocessing of RMDs/other devices undertaken in non-health related facilities where skin piercing, tattooing and other procedures where the skin is breached occur, or when mucous membranes are contacted.

The structure, content and terminology of this edition of the document is as follows:

- (a) The structure and clause headings of this document mirror that of the International Organization for Standardization, Technical Committee 198 (ISO/TC 198), Sterilization of health care products, suite of Standards.
- (b) This document is intended to be read in conjunction with relevant National and International Standards and guideline documents (see [Clause 1.3](#)).
- (c) This document does not include all the technical requirements already identified in National or International Standards but instead refers to those documents where such requirements can be found. For example, this document refers directly to ISO 17665 (series) for the requirements concerning moist heat sterilization processes.
- (d) This document is not a procedural document. It therefore does not provide details of risk assessment and workplace procedures for all facilities and settings.

The terms “normative” and “informative” have been used in this document to define the application of the Appendix to which they apply. A “normative” Appendix is an integral part of a document, whereas an “informative” Appendix is only for information and guidance.

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Introduction

Reusable medical devices (RMDs) and other devices are used in health and non-health related facilities for diagnosis, treatment and other procedures. They are intended for reprocessing prior to reuse.

When a RMD/other device is used for diagnostic or treatment purposes it can contact the patient/client's skin, mucous membrane or sterile tissue, or it may be used in a non-critical area around a patient/client without direct patient/client contact. As a result, there is potential for the RMD/other device to become contaminated with microorganisms, blood, tissue and other biological material.

Safe and effective reprocessing of RMDs/other devices is essential for protecting patients/clients and staff. Failure to correctly reprocess RMDs/other devices risks the transmission of infectious agents, or an adverse reaction from residual cleaning, disinfection or sterilizing agents.

Reprocessing of RMDs/other devices is based on Spaulding's classification. It is a multistep process that may include cleaning, disinfection, inspection and assembly, testing, packaging and sterilization, transport and storage with appropriate handling to render them safe for reuse. Examples of steps in this process are as follows:

- (a) Manual or automated cleaning removes soil from RMDs/other devices. Thorough cleaning is conducted prior to disinfection and sterilization RMDs/other devices because residual inorganic and organic soil on the surfaces of RMDs/other devices can interfere with the effectiveness of these processes.
- (b) Disinfection of RMDs/other devices kills many microorganisms, including human pathogens. Unlike sterilization, disinfection is not effective against high numbers of bacterial endospores. Many factors affect the efficacy of a disinfection process (presence of soil, nature and level of microbial contamination, RMD/other device 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 endospores. High-level instrument grade disinfectants kill all microorganisms with the exception of high numbers of bacterial endospores. Some disinfectants used as high-level instrument grade disinfectants are chemical sterilizing agents that kill high numbers of bacterial endospores with prolonged exposure under controlled and defined conditions.
- (c) Sterilization destroys microorganisms on the internal and external surfaces of RMDs/other devices, rendering them free from viable microorganisms. Moist heat sterilization, low temperature sterilization and dry heat sterilization are the principal processes that may be used by facilities to sterilize RMDs/other devices. Moist heat sterilization is the preferred process for sterilization of RMDs/other devices 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 sterilization process, a suitable, alternative sterilization process may be used sterilization process.
- (d) Handling, storage and transport of reprocessed critical/semi-critical RMDs/other devices, undertaken in a manner that prevents or minimizes the risk of contamination and interference with package integrity until the point of use.

This document does not require all RMDs/other devices to be sterilized. The Spaulding Classification Scheme provides a system to determine the level of reprocessing appropriate for an RMD/other device based on its intended use as follows:

- (i) Critical RMDs/other devices: cleaning followed by sterilization.
- (ii) Semi-critical RMDs/other devices: cleaning followed by high-level disinfection at a minimum. Sterilization of these items is strongly recommended.

- (iii) Non-critical RMDs/other devices: cleaning, which may be followed by low- or intermediate-level disinfection.

Appropriate validation and control of cleaning, disinfection, packaging and sterilization processes reduces the risk of transmission of infectious agents associated with the use of RMDs/other devices. A facility may strive towards development of state-of-the-art reprocessing 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. If pursuing such an objective, the facility should ensure that its reprocessing staff are educated and trained, that they adhere to defined work practices and have demonstrated current 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/other devices of varying design and complexity. These advances can pose significant challenges to the effective reprocessing of RMDs/other devices. The design of an RMD/other device should enable it to be effectively cleaned, disinfected and sterilized. In this regard the design requirements for an RMD/other device no longer only focus on clinical need and device functionality, but also on reuse considerations. Prior to purchasing or otherwise acquiring an RMD/other device, all facilities should consider carefully the reprocessing instructions provided with the device and evaluate their in-house capability to reprocess the device effectively and safely.

This document reflects the conscientious efforts of health care professionals and non-health professionals representing national and regional health authorities, professional associations and industry associations in Australia, to develop minimum requirements for the effective and safe reprocessing of RMDs/other devices in all facilities.

NOTE State, territory, and federal regulatory bodies and professional bodies may require conformity with this document.

Australian Standard®

Reprocessing of reusable medical devices and other devices in health and non-health related facilities

1 Scope and general

1.1 Scope

This document specifies requirements and practices for the effective and safe reprocessing, storage, handling and transportation of RMDs/other devices used in human health care and other treatments.

This document is applicable wherever RMDs/other devices are reprocessed in facilities, including for example, the reprocessing of RMDs/other devices used in post-mortem examinations.

The application of the principles of this document recognizes and acknowledges that there are similarities and differences between different types of facilities (e.g. hospitals, medical imaging practices, office-based practices including medical clinics, dental practices, podiatry practices, aesthetics and body modification practices).

The similarities are the common need for quality systems, staff training and competency, and conformance to reprocessing procedures. The main differences relate to the physical and organizational conditions in different types of facilities (e.g. reprocessing equipment and ability to physically segregate the reprocessing environment).

The principles of this document also apply to processing of single-use RMDs/other devices supplied to facilities in a non-sterile state and which require sterilization in accordance with the device's processing instructions prior to single use.

The principles of infection prevention and control preclude the interchange of RMDs/other devices between live patient/client health care (including harvesting of organs after brain death) and RMDs/other devices in any of the following activities:

- (a) autopsy, post-mortem examinations, anatomy dissections of deceased persons, mortuary care and embalming;
- (b) veterinary procedures; and
- (c) preclinical training using animal or removed human tissue (e.g. extracted teeth).

This document therefore does not contain requirements for RMDs/other devices used in any of these activities.

The principles of this document may be applied to the reprocessing of RMDs/other devices used in veterinary practice.

1.2 Exclusions

This document does not include requirements for the following:

- (a) Medical devices that are intended for single use only.

NOTE 1 Reprocessing of these medical devices is a manufacturing activity that is regulated by the Therapeutic Goods Administration (TGA). The Therapeutic Goods Administration administers the Australian Therapeutic Goods Register (ARTG).
- (b) The reprocessing of RMDs potentially contaminated with Transmissible Spongiform Encephalopathies (TSEs) [e.g. Creutzfeldt Jakob Disease (CJD)].

NOTE 2 For information on CJD, refer to *The Creutzfeldt Jakob disease*, Jan 2013 (<https://www1.health.gov.au/internet/main/publishing.nsf/Content/icg-guidelines-index.htm>) or the NHMRC/ACSQHC, Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019).

- (c) The sterilization of bandages, dressings and other consumable products in facilities. Sterilization of these single-use medical devices requires the estimation of the pre-sterilization bioburden to ensure that performance qualification of the sterilization process delivers the product with the necessary sterility assurance level (SAL).
- (d) Items not intended to be used as medical devices (e.g. sterilizing empty plastic water bottles, rubber bands, cardboard cut from store-packs, dessert spoons and paper clips).
- (e) The manufacture of chemical indicators (CI) or biological indicators (BI).

NOTE 3 Requirements for the manufacture of these indicators are specified in relevant International Standards.

- (f) The manufacture of reprocessing equipment.

NOTE 4 Requirements for the manufacture of this equipment are specified in relevant International and National Standards.

- (g) Third parties as part of a tender process, who deem conformance of measurement devices or other monitoring tools to this document.

1.3 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document:

NOTE 1 Documents for informative purposes are listed in the Bibliography.

AS 1668.2, *The use of ventilation and airconditioning in buildings, Part 2: Mechanical ventilation in buildings*

AS 2773, *Ultrasonic cleaners for health service organisations*

AS 3789.8, *Textiles for healthcare facilities and institutions, Part 8: Recyclable barrier fabric*

AS 5330, *Drying cabinets for reusable medical devices*

AS/NZS 2243.8, *Safety in laboratories, Part 8: Fume cupboards*

AS/NZS 2243.9, *Safety in laboratories, Part 9: Recirculating fume cabinets*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11138 (series), *Sterilization of health care products — Biological indicators*

ISO 11140 (series), *Sterilization of health care products — Chemical indicators*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15882, *Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results*

ISO 15883-1, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 15883-2, *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc*

ISO 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

ISO 15883-5, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

ISO 15883-6, *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*

ISO 15883-7, *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 17665, *Sterilization of health care products — Moist heat*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO/TS 22421, *Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities*

ISO 22441, *Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

EN 868 (series), *Packaging materials and systems for medical devices which are to be sterilized*

EN 285, *Sterilization — Steam sterilizers — Large sterilizers*

EN 1422, *Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods*

EN 13060, *Small steam sterilizers*

EN 14180, *Sterilizers for medical purposes — Low temperature steam formaldehyde sterilizers — Requirements and testing*

EN 16442, *Controlled environment storage cabinet for processed thermolabile endoscopes*

DEVEREAUX B.M., JONES D., WARDLE E. Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021 (GENCA Guidelines for Infection Prevention and Control in Endoscopy, available at <https://www.genca.org/standards-positions/guidelines/>)

1.4 Abbreviations

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

ACSQHC	Australian Commission on Safety and Quality in Health Care
ADWG	Australian Drinking Water Guidelines (NHMRC)
AFER	Automated flexible endoscope reprocessor (aka AER, or WD for thermo labile endoscopes)
ARTG	Australian Register of Therapeutic Goods
BI	Biological indicator
CDC	Centers for Disease Control and Prevention
CI	Chemical indicator
CJD	Classical Creutzfeldt Jacob Disease
EO	Ethylene oxide
GESA/GENCA	Gastroenterological Society of Australia/Gastroenterological Nurses College of Australia
GMDNS	Global Medical Device Nomenclature System
HLD	High-level disinfection
IFU	Instructions for use
IQ	Installation qualification
MEC	Minimum effective concentration
MPQ	Microbiological performance qualification
MRC	Minimum recommended concentration
NHMRC	National Health and Medical Research Council
OQ	Operational qualification
PCD	Process challenge device
PPE	Personal protective equipment (e.g. gloves, visors, aprons)
PPQ	Physical performance qualification
PQ	Performance qualification
PSBS	Preformed sterile barrier system
RMD	Reusable medical device
SAL	Sterility assurance level
SBS	Sterile barrier system
SDS	Safety data sheet (see Note)
TGA	Therapeutic Goods Administration

TGO Therapeutic Goods Order

WD Washer-disinfectant

NOTE An SDS was previously known as a Material Safety Data Sheet (MSDS).

1.5 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

1.5.1

A₀

measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a z value of 10 K

[SOURCE: ISO 11139:2018, 3.1]

1.5.2

aeration

part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached

[SOURCE: ISO 11139:2018, 3.7]

1.5.3

Australian Register of Therapeutic Goods

ARTG

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

Note 1 to entry: The ARTG is a record of the contents and classification details of therapeutic goods. It is not intended to provide guidance, advice or recommendations regarding those goods.

1.5.4

batch

defined quantity of a product intended or purported to be uniform in character and quality produced during a specified cycle of manufacture

[SOURCE: ISO 11139:2018, 3.21]

1.5.5

bioburden

population of viable microorganisms on or in a product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]

1.5.6

biofilm

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

[SOURCE: Glossary, Guideline for Disinfection and Sterilization in Healthcare Facilities, CDC 2008]

1.5.7

biological indicator

BI

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

[SOURCE: ISO 11139:2018, 3.29]

**1.5.8
calibration**

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO 11139:2018, 3.31]

**1.5.9
chemical indicator
CI**

test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

[SOURCE: ISO 11139:2018, 3.43]

**1.5.10
cleaning**

removal of contaminants to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

**1.5.11
cleaning agent**

physical or chemical entity, or combination of entities, having activity to render an item clean

[SOURCE: ISO 11139:2018, 3.47]

**1.5.12
client**

recipient of a service or treatment in a non-health related facility

**1.5.13
competent person**

person who has acquired, through education, training, qualification or experience or a combination of these, the knowledge and skill enabling that person to perform the task required

**1.5.14
condensate**

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

Note 1 to entry: For example, water is formed when steam condenses.

**1.5.15
containment devices**

device used inside the Sterile Barrier System (SBS) to facilitate organization, drying and aseptic presentation of the reusable medical device (RMD)

Note 1 to entry: For example, instrument stringer, instrument organizer tray, tray liners or cassettes.

**1.5.16
contamination**

presence of microorganisms or foreign matter

**1.5.17
control measure**

action or activity that is essential to prevent a significant safety hazard or reduce it to an acceptable level

Note 1 to entry: Control measure(s) is (are) identified by hazard analysis.

[SOURCE: ISO 22000:2018, 3.8; modified]

1.5.18
control point
CP

step at which control may be applied

1.5.19
corrective action

action to eliminate the cause of a nonconformity and to prevent recurrence

[SOURCE: ISO 11139:2018, 3.65; Note 1 to entry modified]

Note 1 to entry: A single instance of nonconformity can have multiple causes.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

1.5.20
critical control point
CCP

step at which control may be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level

[SOURCE: Food and Agriculture Organization (FAO) of the United Nations website available at <https://www.fao.org/3/y1579e/y1579e03.htm>, modified]

1.5.21
critical limit

criterion which separates acceptability from unacceptability

[SOURCE: Food and Agriculture Organization (FAO) of the United Nations website available at <https://www.fao.org/3/y1579e/y1579e03.htm>, modified]

Note 1 to entry: This criterion may include measurable value.

Note 2 to entry: Critical limits are established to determine whether a CCP ([1.5.20](#)) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products.

1.5.22
critical medical device

item intended to be introduced directly into or have contact with the vascular system or normally sterile areas of the body

Note 1 to entry: A critical medical device contaminated with microorganisms confers a high risk of transmission of infectious agents.

1.5.23
disinfectant

chemical or combination of chemicals used for disinfection

[SOURCE: ISO 11139:2018, 3.82]

Note 1 to entry: TGA Regulations define a disinfectant as a substance —

- (a) that is recommended by its manufacturer for application to an inanimate object to kill microorganisms; and
- (b) that is not represented by the manufacturer to be suitable for internal use.

Note 2 to entry: See also the definitions for high-level disinfectant ([1.5.25](#)), hospital-grade disinfectant ([1.5.28](#)), instrument-grade disinfectant ([1.5.34](#)), intermediate-level disinfectant ([1.5.35](#)) and low-level disinfectant ([1.5.39](#)).

**1.5.24
disinfection**

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

**1.5.25
drying phase**

part of an operating cycle that is dedicated to removing moisture from the load

[SOURCE: ISO 11139:2018, 3.93]

**1.5.26
equilibration time**

period between the attainment of defined sterilization process parameters at the reference measurement point and the attainment of the specified sterilization process parameters at all points within the load

Note 1 to entry: For the purposes of this document the process parameter to which this definition refers is temperature.

Note 2 to entry: Equilibration time is also known as thermal penetration time.

[SOURCE: ISO 11139; notes to entry added]

**1.5.27
exposure phase**

cycle stage between the introduction of the disinfection or sterilizing agent into the chamber and when the agent is removed

[SOURCE: ISO 11139:2018, 3.111]

**1.5.28
fault**

situation in which one or more of the process or cycle parameters is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

**1.5.29
health service organization
HSO**

separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body

[SOURCE: NSQHS Standards 2021, modified]

Note 1 to entry: A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. It may be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms.

**1.5.30
high-level disinfectant**

disinfectant that kills all microbial pathogens, except large numbers of bacterial endospores

[SOURCE: Therapeutic Goods Regulations 1990, Part 1, [Section 2](#) Interpretation; definition modified]

1.5.31**holding time**

period during which process parameters are maintained, within their specified tolerances

[SOURCE: ISO 11139:2018, 3.133]

1.5.32**hollowware**

items such as bowls, flasks, jugs and containers

1.5.33**hospital-grade disinfectant**

disinfectant that is represented to be suitable for therapeutic use —

- (a) in premises used for—
 - (i) the investigation or treatment of a disease, ailment or injury; or
 - (ii) procedures that are carried out involving the penetration of the human skin; or
- (b) in connection with—
 - (i) the business of beauty therapy or hairdressing; or
 - (ii) the practice of podiatry;

but does not include—

- (c) an antibacterial clothes preparation; or
- (d) a sanitary fluid; or
- (e) a sanitary powder; or
- (f) a sanitiser.

[SOURCE: Therapeutic Goods Regulations 1990, Part 1, [Section 2](#) Interpretation]

1.5.34**immediate use sterilization**

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

1.5.35**implantable medical device**

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.

[SOURCE: TGA Acronyms and Glossary]

Note 1 to entry: This also applies to medical devices implanted by endoscopic means.

1.5.36
infectious agents
pathogen
germ

biological agent that causes disease or illness to its host

[SOURCE: NHMRC, 2019, modified]

Note 1 to entry: Most infectious agents are either microorganisms (such as bacteria, viruses, fungi and protozoa), parasites or prions.

1.5.37
installation qualification
IQ

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

1.5.38
instructions for use
IFU

directions provided to the user for the use of an RMD/other device and/or accessories, and equipment

Note 1 to entry: For example, a user instruction manual for reprocessing an RMD and its packaging, or operation of a washer-disinfector (WD).

1.5.39
instrument grade disinfectant

disinfectant that is used to reprocess RMDs

Note 1 to entry: Instrument grade disinfectants are classified and regulated as medical devices.

Note 2 to entry: The following pairs of terms have the same meaning in this document —

Note 3 to entry: (a) “high-level disinfectant” and “high-level instrument grade disinfectant”;

Note 4 to entry: (b) “intermediate-level disinfectant” and “intermediate-level instrument grade disinfectant”; and

Note 5 to entry: (c) “low-level disinfectant” and “low-level instrument grade disinfectant”.

1.5.40
intermediate-level disinfectant

disinfectant that kills all microbial pathogens except bacterial endospores which is bactericidal, tuberculocidal, fungicidal (against asexual spores but not necessarily dried chlamydospores or sexual spores), and virucidal

1.5.41
labile

RMD that is damaged when exposed to conditions outside of the device's processing specifications

Note 1 to entry: Example of exposed conditions is heat or moisture.

1.5.42
liquid chemical sterilizing agent

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

[SOURCE: ISO 14160, 3.10]

1.5.43**loan or trial reusable medical device**

RMD that is not owned by the facility but that is supplied to the facility by a commercial supplier or other facility, or individual clinician

1.5.44**low-level disinfectant**

agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores

[SOURCE: Glossary, Guideline for Disinfection and Sterilization in Healthcare Facilities, CDC 2008]

1.5.45**lumen device**

item that consists of tube(s) or pipe(s)

[SOURCE: ISO 11139:2018, 3.158]

1.5.46**may**

indicates the existence of an option

1.5.47**medical device**

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical 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; or
- (g) providing information by means of *in vitro* examination of specimens derived from the human body;

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

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include—

- (i) items specifically intended for cleaning or sterilization of medical devices;
- (ii) pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;
- (iii) disinfection substances;
- (iv) aids for persons with disabilities;
- (v) devices incorporating animal and/or human tissues; and/or
- (vi) devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 11139:2018, 3.166]

1.5.48**microbicidal**

destructive to microorganisms

1.5.49**minimum recommended concentration****MRC**

lowest concentration of a chemical or product specified for use in a process

[SOURCE: ISO 11139:2018, 3.178]

Note 1 to entry: The MRC is not necessarily equivalent to the minimum effective concentration (MEC) as determined by dose response testing. MRC testing may often be referred to as an MEC test.

1.5.50**monitoring**

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 1 to entry: This may include measurement of process variables and comparison of the values obtained with the values specified for the process.

1.5.51**nonconforming product**

non-fulfilment of a requirement (not meeting specification)

[SOURCE: AS/NZS ISO 9000, modified]

1.5.52**non-critical medical device**

medical device that comes into contact with intact skin but not mucous membranes

[SOURCE: NHMRC 2019, modified]

Note 1 to entry: Some non-critical medical devices might not come into direct contact with a patient, e.g. a receiver or bowl. However, as the item is used within the patient environment there is potential for the item to become contaminated.

1.5.53**non-health related facilities**

facilities or clinics that provide skin penetration procedures to clients for non-medical purposes

Note 1 to entry: A skin penetration procedure is any treatment which involves the cutting, shaving, piercing, puncturing or tearing of the skin and mucous membrane or reduces the barrier function of the skin. Examples include physical, chemical or electromagnetic treatments.

Note 2 to entry: Reprocessing of devices utilized in these facilities/clinics is required to minimize the risk/transmission of infection.

Note 3 to entry: Such facilities or clinics include those providing aesthetic services such as tattoo application and removal, skin and mucous membrane piercings, nail treatments, skin microdermabrasion, etc., but do not include dermatology clinics, which are categorised as an HSO.

1.5.54**non-invasive medical device**

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

[SOURCE: ISO 11139:2018, 3.184, modified]

1.5.55**office based practice****office based health care facility**

provision of health care services in sites not involved in complex patient procedures and processes

Note 1 to entry: Such sites include private consulting rooms, dentistry and health clinics.

1.5.56**operational qualification****OQ**

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

[SOURCE: ISO11139:2018, 3.220.3]

1.5.57**other device(s)**

devices that are not considered a medical device but are designated a reusable device requiring reprocessing according to Spaulding's classification between uses

Note 1 to entry: Other devices differ from medical devices ([1.5.47](#)) and RMDs ([1.5.77](#)) in not being regulated by the TGA.

1.5.58**overkill approach**

method of defining a sterilization process that achieves a maximal sterility assurance level (SAL) for product substantially less than 10^{-6}

[SOURCE: ISO 11139:2018, 3.190]

1.5.59**packaging system**

combination of the sterile barrier system and protective packaging

[SOURCE: ISO11139:2018, 3.192]

1.5.60**patient**

person receiving a service or treatment, or undergoing a procedure in a health related facility

1.5.61**performance qualification****PQ**

process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

[SOURCE: ISO 11139:2018, 3.220.4]

1.5.62**preformed sterile barrier system****PSBS**

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

[SOURCE: ISO 11139:2018, 3.201, modified]

Note 1 to entry: Examples include —

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

1.5.63**pre-treatment**

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

1.5.64**preventive action**

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

[SOURCE: ISO 11139:2018, 3.203]

Note 1 to entry: Nonconformity can have multiple causes.

Note 2 to entry: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

1.5.65**process challenge device****PCD**

item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process

[SOURCE: ISO 11139:2018, 3.205]

1.5.66**process parameter**

specified value for a process variable

[SOURCE: ISO 11139:2018, 3.211]

Note 1 to entry: The specification for a sterilization process includes the process parameters and their tolerances.

1.5.67**process variable**

chemical or physical attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: ISO 11139:2018, 3.213]

1.5.68**processing**

<preparation of medical devices> activity to prepare a new or used health care product for its intended use

[SOURCE: ISO 11139:2018, 3.214]

Note 1 to entry: This may include cleaning, disinfection, sterilization and related procedures.

1.5.69**processing category**

collection of different product or product families that may be processed together

[SOURCE: ISO 11139:2018, 3.215]

1.5.70**product**

tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), health care product(s).

[SOURCE: ISO 11139:2018, 3.217]

Note 1 to entry: For the purposes of this document, the term “product” is synonymous with RMD/other device.

1.5.71

product family

group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes

[SOURCE: ISO 11139:2018, 3.218]

Note 1 to entry: Similar attributes may include material, construction, shapes, lumens, SBS or packaging system, which can present a similar challenge to the cleaning, disinfection and/or sterilization processes.

1.5.72

protective packaging

configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

1.5.73

relevant authority

agency authorized by legislation or regulation to issue determinations, orders, or other instructions in respect of any subject covered by this document

1.5.74

reprocessing

all activities required to ensure that a used RMD/other device is safe for its intended purpose

Note 1 to entry: This is a multistep process that includes cleaning, inspection/examination and assembly, functional testing (if applicable), disinfection (if applicable), packaging and labelling, and sterilization (if applicable).

1.5.75

requalification

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

[SOURCE: ISO 11139:2018, 3.220.5]

1.5.76

reusable container

rigid SBS designed to be used repeatedly

[SOURCE: ISO 11139:2018, 3.235]

1.5.77

reusable medical device

RMD

medical device designated or intended by the manufacturer as suitable for processing and reuse

[SOURCE: ISO 11139:2018, 3.236; definition modified]

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single use only.

Note 2 to entry: 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.

Note 3 to entry: For the purposes of this document, the term RMD includes both loan RMDs and trial RMDs.

1.5.78**reverse osmosis****RO**

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 1 to entry: 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.

1.5.79**safety data sheet****SDS**

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

1.5.80**saturated steam**

water vapour in a state of equilibrium between its liquid and gas phases

[SOURCE: ISO 11139:2018, 3.241]

1.5.81**semi-critical medical device**

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

[SOURCE: NHMRC 2019, modified]

1.5.82**shall**

indicates that a statement is mandatory

1.5.83**should**

indicates a recommendation

1.8.84**soil**

natural or artificial contamination on a device or surface following its use or simulated use

[SOURCE: ISO 11139:2018, 3.257]

Note 1 to entry: Soil can protect, harbour or assist the growth of microorganisms and includes organic matter, inorganic matter, blood tissue and other biological material.

1.5.85**Spaulding Classification Scheme**

system used to classify reusable medical devices and other devices as critical, semi-critical, or non-critical on the basis of risk to patient/client safety from device contamination, and to determine the level of microbicidal action required for reprocessing

Note 1 to entry: See [Clause 5.1.2](#) for further information on Spaulding Classification.

1.5.86**specify**

stipulate in detail within an approved document

[SOURCE: ISO 11139:2018, 3.259]

1.5.87**standard precautions**

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

[SOURCE: NHMRC 2019, modified]

Note 1 to entry: These are recommended for the treatment and care of all patients/clients.

Note 2 to entry: Standard precautions include reprocessing.

1.5.88**steam penetration resistance**

challenge to a moist heat sterilization process from a medical device, including any sterile barrier system, that can delay attainment of the process parameters

[SOURCE: ISO 11139:2018, 3.267]

1.5.89**sterile**

free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

1.5.90**sterile barrier system****SBS**

minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

[SOURCE: ISO 11139:2018, 2.272]

1.5.91**sterility**

state of being free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.274]

Note 1 to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

1.5.92**sterility assurance level****SAL**

probability of a single viable microorganism occurring on an item after sterilization

[SOURCE: ISO 11139:2018, 3.275]

Note 1 to entry: It is expressed as the negative exponent to the base 10.

1.5.93**sterilization**

validated process used to render a product free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.277]

Note 1 to entry: 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.

1.5.94**sterilization process**

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

[SOURCE: ISO 11139:2018, 3.284]

Note 1 to entry: 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.

1.5.95**sterilizing agent**

physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under specified conditions

[SOURCE: ISO 11139:2018, 3.288]

1.5.96**terminal sterilization**

process whereby a product is sterilized within its SBS

[SOURCE: ISO 11139:2018, 3.295]

1.5.97**traceability**

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

[SOURCE: AS/NZS ISO 9000, modified]

Note 1 to entry: When considering product, traceability may relate to —

- (a) the origin of materials and parts;
- (b) the processing history; and
- (c) the distribution and location of the product after delivery.

Note 2 to entry: Some professional groups refer to “traceability” as “tracking” or “batch control identification”.

1.5.98**transmission-based precautions**

extra work practices in situations where standard precautions alone can be insufficient to prevent infection

[SOURCE: NHMRC 2019, modified]

Note 1 to entry: Transmission-based precautions are used in addition to standard precautions.

Note 2 to entry: Such precautions are taken with patients/clients known or suspected to be infected or colonized with infectious agents..

1.5.99**validation**

confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: ISO 11139:2018, 3.313]

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation may be real or simulated.

**1.5.100
verification**

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: ISO 11139:2018, 3.314]

Note 1 to entry: The objective evidence needed for a verification may be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “verified” is used to designate the corresponding status.

**1.5.101
washer-disinfector
WD**

equipment designed to clean and disinfect product

[SOURCE: ISO 11139:2018, 3.319]

Note 1 to entry: Product may include medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

2 Quality assurance**2.1 General****2.1.1 Overview**

This section specifies elements of a system that underpin and maintain quality using a risk-based approach, and that are necessary to ensure the repeatable and reproducible, safe and effective reprocessing of RMDs/other devices. Workplace procedures shall be based on the requirements of this document.

REGIONAL OR NATIONAL DEVIATION

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2.1.2 Critical elements in product realization

The development, validation, routine control and monitoring of cleaning, disinfection and sterilization processes are critical elements in product realization (see [Clause 2.5](#)) when reprocessing medical devices or other devices (e.g. products). To ensure the consistent implementation of the requirements specified in this document, the necessary processes need to be established, implemented and maintained. Processes of particular importance in relation to the development, validation, routine control and monitoring of reprocessing RMDs/other devices, to provide an assurance of the quality of the reprocessed item, include —

- (a) control of documentation, including records;
- (b) assignment of management responsibility;
- (c) provision of adequate resources, including competent human resources and infrastructure;
- (d) control of services or product provided by external parties;
- (e) identification and traceability of reprocessed items throughout the process; and
- (f) control of nonconforming product.

NOTE 1 The relevant authority may require facilities to implement an organization-wide quality management system.

NOTE 2 ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes.

NOTE 3 AS/NZS ISO 9001 provides a model for generic quality management system requirements suited to other devices.

2.1.3 Calibration and preventive maintenance

A process shall be specified for the calibration and preventive maintenance of all reprocessing equipment, including instrumentation for test purposes, used in meeting the requirements of this document.

2.2 Risk-based approach

A risk-based approach shall be established for a quality assurance program. Such an approach involves —

- (a) a systematic review of the hazards and threats that could occur during the reprocessing of RMDs/other devices; and
- (b) the application of risk assessment criteria to determine the level of risk that those hazard(s) or threat(s) pose.

NOTE 1 See [Appendix B](#) for guidance on the risk-based approach.

NOTE 2 Refer to ISO 14971 for further information on risk management in relation to medical devices.

2.3 Documentation

2.3.1 General

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

2.3.2 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/other devices and reprocessing equipment including IFU and critical consumables (see [Clause 2.5.2](#)).
- (c) Qualification of equipment including RMDs/other devices and reprocessing equipment.
- (d) Validation and requalification of cleaning, disinfection and sterilization processes, including the rationale for assigning a particular RMD/other device to a specific product family and processing category (see [Clause 5.1.3](#) and [Clause A.5.1.2](#)).
- (e) Routine monitoring and control of cleaning, disinfection and sterilization processes.
- (f) The initial treatment of used RMDs/other devices prior to their return to the designated reprocessing area or facility.
- (g) The collection of used RMDs/other devices from point of use or designated holding area.

- (h) Handling of specialized RMDs/other devices, including instruments on loan and instruments on trial [see [Clause 2.5.2\(g\)](#)].
- (i) Cleaning of RMDs/other devices prior to disinfection and/or sterilization.
- (j) Inspection, assembly and testing (where applicable) of RMDs/other devices prior to disinfection.
- (k) Inspection, assembly and testing (where applicable) and packaging of RMDs/other devices prior to sterilization.
- (l) Loading and unloading of equipment used to reprocess RMDs/other devices.

NOTE 1 Examples include washer-disinfector (WD), automated endoscope reprocessor (AFER) and sterilizer.

- (m) Traceability of reprocessed semi-critical (if applicable) and critical RMDs/other devices.
 - (n) Disinfection of cleaned RMDs/other devices.
 - (o) Sterilization of cleaned RMDs/other devices.
 - (p) Validation and routine control of cleaning, disinfection processes and sterilization processes.
 - (q) Release of RMDs/other devices after reprocessing.
 - (r) Handling, transport and storage of reprocessed RMDs/other devices.
 - (s) Cleaning of reprocessing equipment and the reprocessing facility.
 - (t) Periodic preventive maintenance of reprocessing equipment.
- NOTE 2 For example, this may include the calibration of monitoring instrumentation.
- (u) Action to be taken in the event of a biological or chemical spill or exposure.
 - (v) Control of nonconforming RMDs/other devices.
 - (w) Recall of RMDs/other devices.
 - (x) Review of deviation reports and other indicators of quality or procedural problems.
 - (y) Handling of product complaints.
 - (z) Corrective action and preventive action.
 - (aa) Staff training and assessment of competency.
 - (bb) Business continuity planning including contingency planning in the case of an emergency.

2.3.3 Records

Records at a minimum shall include:

- (a) Purchasing records of RMDs/other devices and reprocessing equipment.
- (b) Monitoring of reprocessing equipment.
- (c) Cleaning process records.
- (d) Sterilization process records.
- (e) High-level disinfection process records.
- (f) Microbiological surveillance testing (where applicable).

- (g) Cleaning of reprocessing equipment.
- (h) Cleaning of the reprocessing facility.
- (i) Staff training and competency to undertake reprocessing activities.
- (j) Staff rosters and allocations.
- (k) Maintenance records for RMDs/other devices (where applicable) and reprocessing equipment.
- (l) IQ, OQ and PQ for reprocessing equipment (where applicable).
- (m) Process deviation reports and where applicable, records of corrective action or preventive action.
- (n) Recall records (where applicable).

2.3.4 Control of documents and records

Documents required by this document shall be reviewed at defined intervals according to the facility's policy.

Regulatory authorities may have additional requirements regarding the intervals at which documents should be reviewed.

Documents shall be approved by competent persons.

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

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

2.4 Management responsibility

2.4.1 General

The facility's executive management shall ensure organizational structure supports the implementation of the requirements of this document.

NOTE The facility's executive management may include members of senior management or a business owner.

Responsibilities and authorities shall be defined, documented and communicated within the facility and with any external stakeholders.

Relationships shall be established between all competent persons who manage, perform and verify work affecting reprocessing.

Irrespective of where reprocessing of non-critical, non-invasive RMDs/other devices occurs, appropriate resources shall be provided to ensure that the principles of this document are followed.

Appropriate systems shall be in place (e.g. a business continuity plan) to ensure that the requirements of this document are met at all times, regardless of emergency or other suboptimal operating conditions (e.g. water restrictions). Back up procedures shall be in place and include documented processes describing how to activate these procedures.

2.4.2 Resource requirements

The resources shall be determined and provided to —

- (a) implement the requirements of this document, and the applicable requirements of the normatively referenced documents;

- (b) implement the quality assurance program and to maintain its effectiveness through review;
- (c) meet customer requirements in a timely manner;
- (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 reprocessing of RMDs/other devices;
- (f) procure reprocessing equipment appropriate to purpose;
- (g) maintain buildings, workspaces, associated utilities and process equipment;
- (h) provide supporting services; and
- (i) endorse staff training and ongoing education.

NOTE The relevant authority may specify requirements which apply to items in the above list.

2.4.3 Reprocessing facility

The competent person directly accountable for the reprocessing of RMDs/other devices within the facility shall —

- (a) have relevant qualifications and experience in reprocessing RMDs/other devices;
- (b) have the authority to implement the requirements of this document and the applicable requirements of the normative reference documents associated with this document wherever reprocessing activities occur throughout the entire organization;
- (c) implement policies and procedures to ensure the safety and quality of reprocessed RMDs/other devices;
- (d) be directly involved in the supervision of the day-to-day activities within the reprocessing facility; and

NOTE Reprocessing of critical and semi-critical RMDs/other devices may also occur in separate endoscopy units, day surgery facilities, outpatient clinics, radiology units, etc..

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

2.4.4 Equipment

The total time required to reprocess RMDs/other devices correctly shall be taken into account as part of operational planning to ensure that sufficient quantities of RMDs/other devices and reprocessing resources are available to meet the demand.

Sufficient appropriate reprocessing equipment shall be available to meet the needs of the reprocessing facility, taking into consideration the volume and type of RMDs/other devices requiring reprocessing.

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

2.4.5 Contracts

If any activities covered by this document are outsourced, an agreement should be in place that identifies the responsibilities of each party, including conforming to the requirements of this document.

NOTE Activities may include outsourcing of reprocessing, equipment maintenance and testing, staffing and training.

2.5 Product realization

2.5.1 General

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

2.5.2 Purchasing

Procedures for purchasing reprocessing equipment, RMDs/other devices and accessories for these devices shall be established by the facility.

Procedures for purchasing the selected product shall include:

- (a) Criteria for product selection and evaluation that are risk-based and which address workplace health and safety requirements.
- (b) Involvement of a competent person from the reprocessing facility in the selection process prior to the loan, trial or purchase of an RMD/other device.
- (c) Evaluation to ensure compatibility with the reprocessing systems available for use in the reprocessing facility.
- (d) The requirement for reprocessing equipment to conform to the equipment to be reprocessed.

NOTE 1 The relevant authority may have additional requirements regarding purchasing of reprocessing equipment.
- (e) The TGA requirement for RMDs and accessories to RMDs and reprocessing equipment to be entered on the ARTG.
- (f) Provision of operational IFU for reprocessing equipment and accessories to medical or other devices.
- (g) Provision of documented and validated reprocessing instructions in accordance with ISO 17664-1 or ISO 17664-2 for RMDs (including trial and loan RMDs/other devices).
- (h) Acceptance criteria when taking delivery.

NOTE 2 Inclusion of IQ, OQ and PQ and staff training may be considered as part of the purchasing agreement.

NOTE 3 Accessories to medical or other devices may include cleaning agents, cleaning utensils, packaging materials and SBSs.

NOTE 4 Acceptance criteria may include checking of packaging for evidence of tampering or damage, product expiry dates, compliance with purchasing specifications, etc.

2.5.3 Identification and traceability of product

2.5.3.1 General

Procedures shall be specified and documented for the identification and tracking/traceability of critical RMDs/ other devices, including trial and loan RMDs/other devices, during reprocessing and subsequent use on patients/clients undergoing surgical or skin/mucous membrane penetration procedures. At a minimum the tracking system used shall be sufficient to enable the identification of the individual cycle from a specified sterilizer in which the critical RMDs were sterilized with documentation of parametric release.

Procedures shall also be specified and documented for the identification and tracking/traceability of semi-critical RMDs/other devices undergoing high level disinfection. At a minimum the tracking system used shall be sufficient to enable the identification of the individual cycle of a high-level disinfection system in which the semi-critical RMDs/other devices were disinfected.

NOTE 1 The relevant authority may specify requirements for traceability of RMDs/other devices to individual patient/client uses.

NOTE 2 Based on a risk assessment, consideration should be given to implementing a means of traceability for semi-critical RMDs/other devices that are released for use after high-level disinfection, in particular, for complex RMDs/other devices that are stored after processing for later use.

NOTE 3 In the event of recall action, procedures should be sufficient to ensure traceability of an implantable RMD/other device that is subject to numerous reprocessing cycles, e.g. screws and plates used in orthopaedic or plastic surgery, and dental implant burs.

2.5.3.2 Traceability records

Traceability systems shall, at a minimum, identify the following for each RMD/other device:

- (a) High-level disinfection — Disinfection process records [see [Clause 2.3.3](#), Item(e)]:
 - (i) Type of RMD/other device, e.g. trans-rectal ultrasound probe, colonoscope, vaginal probe, endoscope.
 - (ii) Unique identification number of the RMD/other device e.g. the serial number.
 - (iii) Date of cleaning of the RMD/other device and identification of the competent person responsible.
 - (iv) Identification of the competent person accountable for connecting the RMD/other device to the reprocessing equipment/system or method.
 - (v) Identification of the automated equipment used to process the RMD/other device, e.g. equipment identification number or code (if there is more than one unit in the reprocessing facility).
 - (vi) Disinfection process cycle number and date of disinfection.
 - (vii) Other records, including the following:
 - (A) Disinfectant type/brand, batch number, manufacturer's expiry date, date of decanting/opening and in-use expiry date/date for disposal.
 - (B) Test strips brand/type of test strip, batch number, manufacturer's expiry date, date of decanting/opening of test strips and in-use expiry date/date for disposal, results of any positive/negative controls performed upon opening, results of test strips used for daily MRC or MRC check for each use/cycle, identification of competent person conducting positive and

negative controls and identification of competent person conducting MRC check.

- (C) Cycle process record/printout, self-disinfection cycles (where required), water filter pressures and date of chemical and filter changes.
- (D) Manual immersion into disinfectant, temperature of disinfectant, time of immersion into disinfectant, time removed from disinfectant, final rinse according to chemical disinfectant and RMD/other device's IFU.
- (viii) Documented evidence of attainment of process parameters, e.g. process record/printout (where applicable).
- (ix) Identification of the competent person accountable for release of the RMD/other device.
- (b) Sterilization — Sterilization process records [see [Clause 2.3.3](#), Item(d)]:
 - (i) Date of sterilization and sterilization 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/other device (e.g. device name or name of a set of devices) and the number of these items within the load.
 - (iv) Identification of the competent person accountable for loading the RMD/other device into the sterilizer.
 - (v) Other records, including the following:
 - (A) Results of any performance tests required to determine functional performance of the equipment prior to use, e.g. leak rate test, Bowie and Dick — type test.
 - (B) Results of chemical and biological monitoring undertaken for individual cycles or on a periodic basis (see [Section 8](#)).
 - (C) Sterilizing agent (where applicable), batch number and expiry date.
 - (vi) Documented evidence of attainment of process parameters, e.g. process record/printout (where applicable).
 - (vii) Identification of the competent person accountable for release of the RMD/other device (sterilization load).

NOTE 1 Process records may be paper-based or electronic. Where electronic records are kept, procedures should be in place to determine attainment of process parameters at the conclusion of every cycle. If paper-based records are kept, they should be prepared and maintained so that they remain legible for the specified time period.

NOTE 2 Additional information may be linked to an RMD/other device where an electronic traceability system is in place. These systems can assist in other management activities, including asset management.

2.5.4 Control of monitoring and measuring equipment

2.5.4.1 General

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

NOTE 1: Laboratories and individuals that perform the tests outlined in this document should meet the requirements of AS ISO/IEC 17025.

NOTE 2 See [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.

2.5.4.2 Documentation

A calibration report shall be obtained from the competent person implementing the calibration. The report shall include calibration tests performed for each piece of monitoring and measuring equipment. Records of calibration and any adjustments shall be kept and be readily accessible

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

2.5.4.3 Nonconformance

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

2.6 Measurement, analysis and improvement

2.6.1 Audits

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

2.6.2 Nonconforming RMD/other device

Nonconforming RMDs/other devices shall include those items that do not meet acceptance criteria after completion of cleaning, disinfection or sterilization processes, and packaging, as applicable.

NOTE See [Clause A.2.6.2](#), for examples of nonconforming RMDs/other devices.

An investigation shall be performed for a nonconforming RMD/other device in accordance with facility risk assessment policy.

2.6.3 Corrective action

2.6.3.1 General

Where a nonconforming device is detected after delivery or use, action shall be taken appropriate to the type and possible effects of the nonconformity.

Corrective action taken in relation to a nonconforming RMD/other device 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 determine its effectiveness in resolving the nonconformity; and
- (e) where applicable, implementation of additional corrective action to further resolve the nonconformity.

NOTE Corrective action may also include recall of a nonconforming device.

2.6.3.2 Recall procedure

A released RMD/other device shall be recalled in a timely manner where there is evidence of failure during the cleaning, disinfection, packaging or sterilization processes, or during transport and storage of a reprocessed device.

Recall procedures shall —

- (a) identify examples of situations where recall of a distributed RMD/other device is warranted;
- (b) emphasize that recall activities should be performed in a timely manner;
- (c) identify the person(s) accountable for coordinating recall activities;
- (d) identify the persons to be notified in the event of recall within or outside of the facility;
- (e) identify the person(s) accountable for retrieving distributed RMDs/other devices, including devices that have been distributed off-site;
- (f) identify the person(s) accountable for reporting on recall activities;
- (g) identify the critical information to be included in a recall notice, e.g. the departments for which the recall notice is intended, the RMD/other device and quantity to be recalled, the reason for recall and the action to be taken by persons receiving the recall notice (i.e. return of the device or holding/quarantining of the device pending further instructions); and
- (h) include the need to reconcile quantities of recalled RMDs/other devices with the device distribution records.

2.6.3.3 Recall report

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

- (a) Identification of the circumstances that initiated the need for recall of the RMD/other device.
- (b) Identification of the recalled RMD/other device and reconciliation of quantities of the recalled device with the device distribution records.
- (c) Where applicable, identification of patients/clients 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/other device, 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.

2.6.4 Preventive action

Potential causes of a nonconforming RMD/other device should be identified to prevent their occurrence. At a minimum, preventive action should include —

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

3 Reprocessing agent characterization

3.1 General

3.1.1 Introduction

Reprocessing agent characterization shall:

- (a) define the reprocessing (cleaning, disinfection and sterilization) agent(s), necessary to demonstrate microbicidal effectiveness;
- (b) identify the factors that influence microbicidal effectiveness;
- (c) assess the effects that exposure to the reprocessing agent(s) has on RMDs/other devices; and
- (d) identify requirements for the safety of personnel and for the protection of the environment.

Examples of reprocessing agents include —

- (i) cleaning agents;
- (ii) chemical disinfection agents;
- (iii) physical disinfection processes;
- (iv) physical and chemical sterilizing agent(s); and
- (v) any other agents involved in reprocessing, such as utilities.

NOTE Examples of utilities include water, gas, steam and compressed air.

In characterizing reprocessing agents sterilizing agent the following shall be determined —

- (A) the effects that exposure to reprocessing agents has on RMDs/other devices;
- (B) requirements for safety of personnel and the environment; and
- (C) 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, high-level disinfection systems and liquid chemical sterilizing agents that are supplied in Australia and which are intended for use on RMDs are required by the TGA to be included in the ARTG. The TGA may specify its own requirements which a product must satisfy in order to be included on the ARTG.

NOTE 1 Cleaning agents, chemical disinfectants, high-level disinfection systems and liquid chemical sterilizing agents that are intended for use on medical devices are regulated by the TGA as accessories to medical devices.

NOTE 2 Cleaning agents are classified as Class I medical devices. Disinfectants, high-level disinfection systems and liquid chemical sterilizing agents are classified as Class IIB medical devices.

3.1.3 Reprocessing agent information

At the time of acquisition, the following information shall be obtained for each cleaning agent(s), disinfectant and sterilizing agent (where applicable):

- (a) Safety data sheet.
- (b) Regulatory status.
- (c) Active ingredient(s) and physical/chemical properties, including stability (shelf life).
- (d) Microbial efficacy.
- (e) Toxicity/residues.
- (f) Material effects of the agent on RMDs/other devices, including known device material compatibilities and known device material non-compatibilities.
- (g) Container/packaging.
- (h) Labelling (including shelf life and storage requirements).
- (i) Directions for use and, where intended for the product, reuse.

3.2 Cleaning agents

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

A documented specification shall be obtained for each cleaning agent, at the time of acquisition, that provides the requisite information as detailed in [Clause 3.1.3](#).

NOTE 1 Different cleaning agents may be used for manual cleaning, as opposed to cleaning in a WD or ultrasonic cleaner.

A cleaning agent shall not be used where the instructions for reprocessing an RMD/other device recommend against its use. The cleaning process should have been validated for the device without the use of a cleaning agent.

NOTE 2 ISO 17664 (series) specifies requirements for IFUs.

Cleaning agents shall be —

- (a) intended for use on medical devices;
- (b) used only if they are on the ARTG;
- (c) compatible with the RMDs/other devices being processed and the selected method of cleaning;

- (d) diluted and used in accordance with their IFU;
- (e) compatible with the available water quality;
- (f) preferably biodegradable;
- (g) non-toxic at the in-use dilution;
- (h) non-abrasive;
- (i) low foaming;
- (j) free rinsing; and
- (k) preferably in liquid form.

3.3 Disinfection agents and systems

3.3.1 Disinfection agents

A chemical disinfectant used to reprocess an RMD/other device shall be labelled as an “instrument grade disinfectant”.

The following criteria shall be met in selection of such a disinfection agent:

- (a) A high-level instrument grade disinfectant shall be the minimum grade disinfectant used for disinfection of a semi-critical RMD/other device (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/other device where required (see [Section 5](#) and the Spaulding Classification Scheme).

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

3.3.2 Disinfection systems

A disinfection system shall only be used if it has been entered on the ARTG and validated for use with the intended RMD/other device.

3.4 Sterilizing agents

The specification shall be obtained for each sterilizing agent at the time of acquisition. At a minimum it shall include the following:

- (a) The identity of the sterilizing agent.
- (b) The active ingredient(s).
- (c) The shelf life.
- (d) The storage conditions necessary to maintain the sterilizing agent within specification for the duration of the stated shelf life.
- (e) The requirements to be met for reuse of the sterilizing agent if this is permitted.

These requirements apply to 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 disinfection and sterilizing agents used for reprocessing of RMDs/other devices in facilities has been comprehensively documented. This information is available in the published literature and in the technical monographs provided with disinfectants and sterilizing agents and the equipment in which these agents are used.

Where cleaning agents make claims of microbicidal effectiveness, evidence of this claim shall be provided with the product.

Where disinfection and sterilizing agents are used in disinfection or sterilization processes outside of the range of conditions specified by a disinfection or sterilization system, then the facility should compare this process with the current practice to ascertain the microbicidal effectiveness of the new process.

Reference shall be made to the following:

- (a) For disinfectants and chemical sterilizing agents.

NOTE 1: TGO 104 provides information on microbial efficacy requirements for disinfectants.

- (b) For moist heat sterilization — ISO 17665 (series).

- (c) For dry heat sterilization — ISO 20857.

- (d) For ethylene oxide gas sterilization — ISO 11135.

NOTE 2 For flexible chamber EO sterilization processes, refer to ISO 14937.

- (e) For low temperature steam formaldehyde — ISO 25424.

- (f) For sterilization processes where no other standard applies refer to ISO 14937.

- (g) For WDs — ISO 15883 (relevant Part).

For disinfection process technology where no standard applies, reference should be made to the regulatory status and peer-reviewed publications.

3.6 Effects on RMD/other device

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

Assessment of compatibility and the effects on materials shall occur through review of information provided with the RMD/other device (see also [Clause 5.3](#)). The outcome of this assessment shall be documented. A facility may perform this assessment by considering information provided with the RMD/other device and the reprocessing agent.

Where an RMD/other device using a cleaning agent, disinfectant or sterilizing agent or a cleaning, disinfection or sterilization process that is not consistent with the validated reprocessing instructions provided is chosen, then the possible effects of repeated exposure of the device to the proposed agent(s) and process should be taken into account. The outcome of any discussions of this matter with stakeholders should be documented.

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.

NOTE 1 A current SDS may be obtained from the product manufacturer or supplier. Checks to ensure the most up-to-date SDS is available should occur at least annually.

NOTE 2 An SDS was previously known as a Material Safety Data Sheet (MSDS).

Sufficient information about the safe use, handling and storage of the hazardous chemical shall be readily accessible to —

- (a) workplace staff; and
- (b) emergency services personnel.

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 and control measures implemented. This assessment, including details of control measures in place, shall be documented.

NOTE The relevant authority may have additional requirements regarding environmental impact assessments and controls.

3.7.3 Health and safety procedures

Procedures shall be developed for the storage, handling, decanting and disposal of chemicals, and the use of appropriate PPE in accordance with IFU and the SDS.

NOTE 1 The relevant authority may have additional requirements regarding the storage, handling, decanting and disposal of chemicals, as well as for the labelling of chemical containers, including containers holding decanted chemicals.

The spill kit for the reprocessing facility shall be reviewed alongside each SDS to ensure the kit contains required spill mitigation methods. Emergency procedures for correct use of the spill kit shall be documented and readily accessible.

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.

4 Process characterization and equipment characterization

4.1 General

The processes and the equipment used to deliver safe, effective and reproducible cleaning, disinfection and sterilization processes shall be defined.

RMDs/other devices shall only be reprocessed with equipment intended for such use.

The following actions shall be taken:

- (a) Obtain process and equipment specifications.

- (b) Review the process and equipment specification and establish that the services and infrastructure necessary to safely operate the equipment exist (see also [Clauses 4.2](#) and [4.3](#)).
- (c) Select RMDs/other devices compatible with the processes delivered by the reprocessing equipment.

NOTE The equipment's process specifications and the RMD/other device's reprocessing instructions may be used jointly to determine compatibility of the device with the available processes and equipment.

4.2 Process characterization

Detailed equipment capability shall be obtained for the processes delivered by the cleaning, disinfection and sterilizing equipment.

The information provided shall include:

- (a) A detailed description of the process cycle.
- (b) The process parameters, together with their tolerances.
- (c) The means by which the process variables are monitored and controlled.
- (d) Measures to ensure that a failure to achieve specified process parameters do not result in an ineffective cleaning, disinfection or sterilization process being recorded as effective.

NOTE 1 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 could 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 or categories that are able to be safely and effectively processed.
- (g) Any restrictions or limitations relating to the size, mass, configuration, or loading orientation of RMDs/other devices being processed.
- (h) Post process cycle treatment (if applicable).

NOTE 2 Reference should be made to the applicable ISO/TC 198 Sterilization of Healthcare Products Standard for each specified process for further information. See [Clause 1.3](#).

4.3 Equipment characterization

4.3.1 Equipment specifications

Detailed specifications shall be obtained for the equipment used to deliver cleaning, disinfection and sterilization processes.

Information provided shall include:

- (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, disinfection and sterilization processes, including the locations of sensors.