AS 5369:2023
the changes, impacts & risks

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Disclosures

- Member of the HE-023 Processing of Medical and Surgical Instruments Committee

  (representing Federation of Sterilizing Research Advisory Councils [FSRACA])

Content

- Comparison between standards –

  AS/NZS 4815:2006, AS/NZS 4187:2014 & AS 5369:2023

- Key changes from AS/NZS 4187:2014 to AS 5369:2023

- Transitioning to AS 5369:2023

AS/NZS 4815:2006

Australian/New Zealand Standard™

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

Originated as AS/NZS 4815:2001
Second edition 2006.

SUPERSEDED

Jointly published by Standards Australia, GPO Box 476, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 7369 9

AS/NZS 4187:2014

Australian/New Zealand Standard™

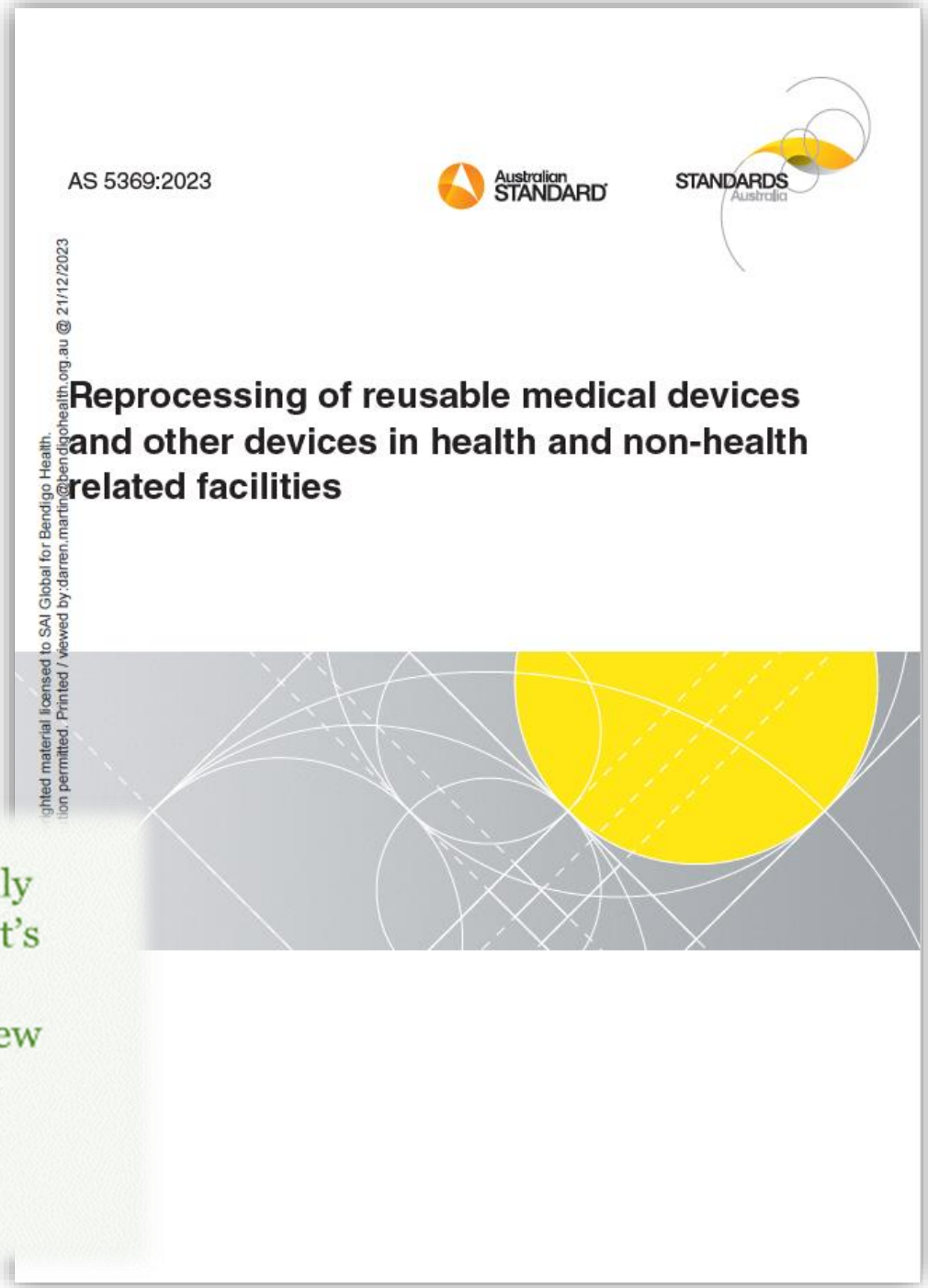
Reprocessing of reusable medical devices in health service organizations

SUPERSEDED

STANDARDS Australia

STANDARDS NEW ZEALAND
PAEREWA AOTEAROA

A New Era



"And suddenly you know... It's time to start something new and trust the magic of beginnings."


CORRECTED
COMPARISON
- BETWEEN -
STANDARDS
– AS/NZS 4815 – AS/NZS 4187 –
– AS 5369 –
BETWEEN
STANDARDS
CORRECTED
STANDARDS

Comparison between Standards

Scope

AS 5369:2023

Section 1.1 Scope

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)

Section 1.5 Terms and definitions

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

Comparison between Standards

AS 5369:2023 - Preface

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.

Comparison between Standards

Aspect	AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Documentation	Specific for small facilities	Detailed, designed to cover all aspects of reprocessing	**Detailed. *Some* updates covering control of documents and management responsibility**
Cleaning	Detailed but basic cleaning *Section 2 Cleaning and Handling of Used Items*	Emphasis on automated cleaning *6.2 Cleaning process definition* *6.2.3 Cleaning* *Referenced throughout document*	**6.2.3 NOTE 1 An automated cleaning process in a WD should be used because an automated process is easier to replicate than a manual cleaning process**
Traceability	Limited, reference to sterilisers	Detailed for semi-critical and critical RMDs, HLD and sterilisation	**Detailed for semi-critical and critical RMDs; HLD and sterilisation**
Performance Qualification	Basic validation for sterilisers	Extensive validation processes for all reprocessing equipment/ processes	**Extensive validation processes for all reprocessing equipment/ processes**

Comparison between Standards

Aspect	AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Reprocessing layout	Simple layout for small facilities, physical segregation not necessary	Dedicated reprocessing areas with physical segregation between dirty and clean	**5.6.2 Reprocessing facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities**
Risk management	Specific for small facilities	Comprehensive procedures required	**Comprehensive procedures required.** **Appendix B Guidance on risk-based approach**
Guidance	Simple and specific guidance for small facilities	Limited *(less guidance than 2003 edition)*	**Increase in guidance for some aspects *e.g. Product Families***
Application	Not in line with current practices *(last edition 2006)* *Sequential order e.g. cleaning, packing, sterilising*	In line with international standards. *Contents spread throughout the document*	**In line with international standards, updated to align with current practices and technology**

Comparison between Standards

Normative references

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Appendix A Referenced documents	1.3 Normative references	**Updated with new standard added:** 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 [current 1st edition, 2022]*

Normative references are documents that contain information that must be understood and used to implement the standard

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/)


WHAT
ARE THE
CHANGES?

Section 3
Reprocessing Agent Characterization

Section	AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
3.3.2 Disinfection systems	Not specified *- Section 10 Disinfection*	Minimum requirements for HLD and sterilising process records *- 6.3 Disinfection process definition*	**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**
3.7.3 Health and safety procedures	Limited *- Section 8 Quality Management*	Procedures shall be developed *- 3.7.3 Health and safety procedures*	**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**

Section 5 Product Definition

5.2 / A.5.2 Product families

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Not specified	Classify RMDs into a product family and methods of reprocessing - no guidance	**Additional guidance in Appendix A including a flowchart**

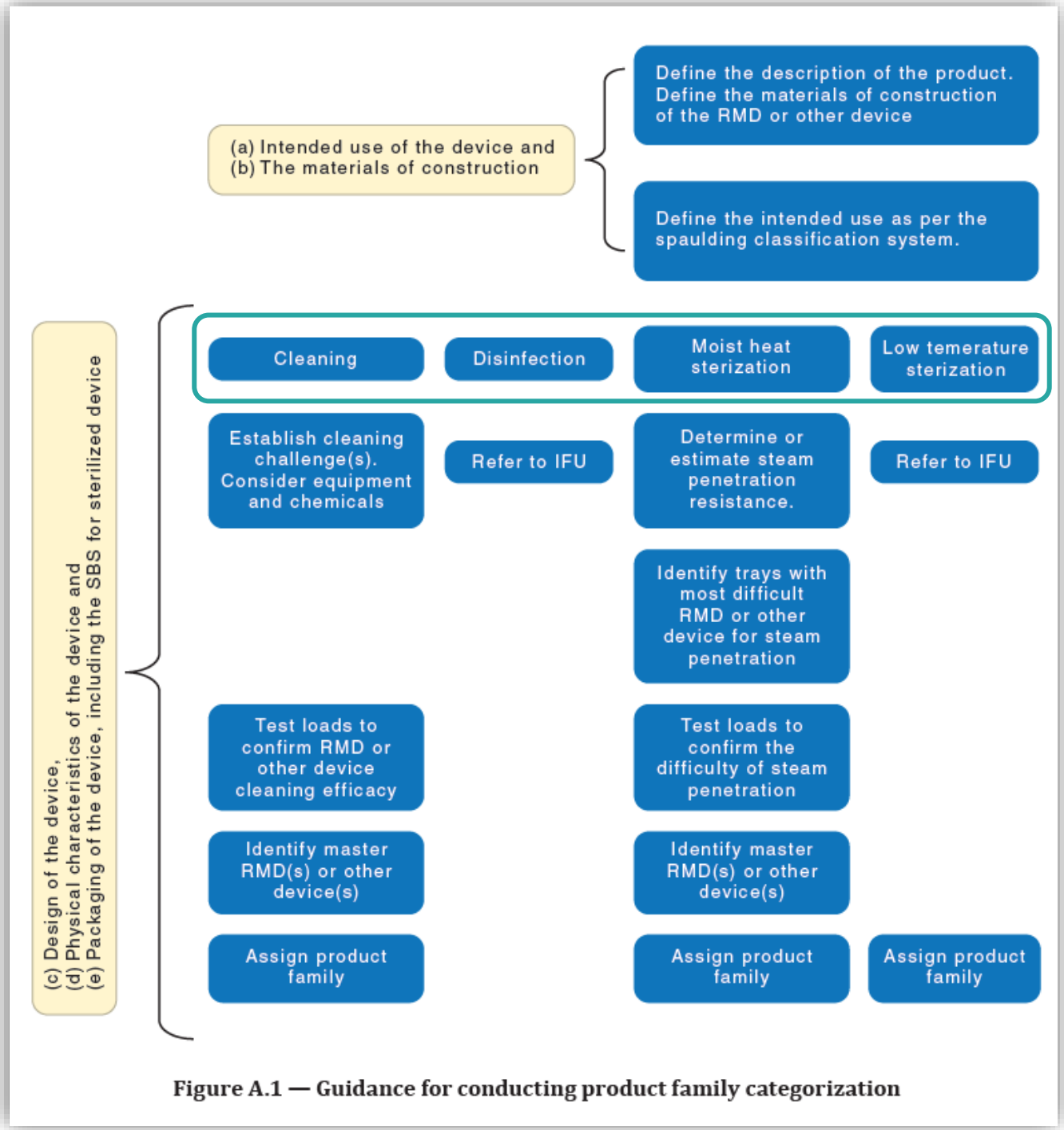


Figure A.1 — Guidance for conducting product family categorization

Figure A.1

showing all reprocessing stages for product families

Section 5 Product Definition

- **5.2 Product families**

  NOTE 3 ISO 17665 (series) and ISO 17664 (series) provide useful information to assist in assigning an RMD to a product family.

- **A.5.2 Product families**

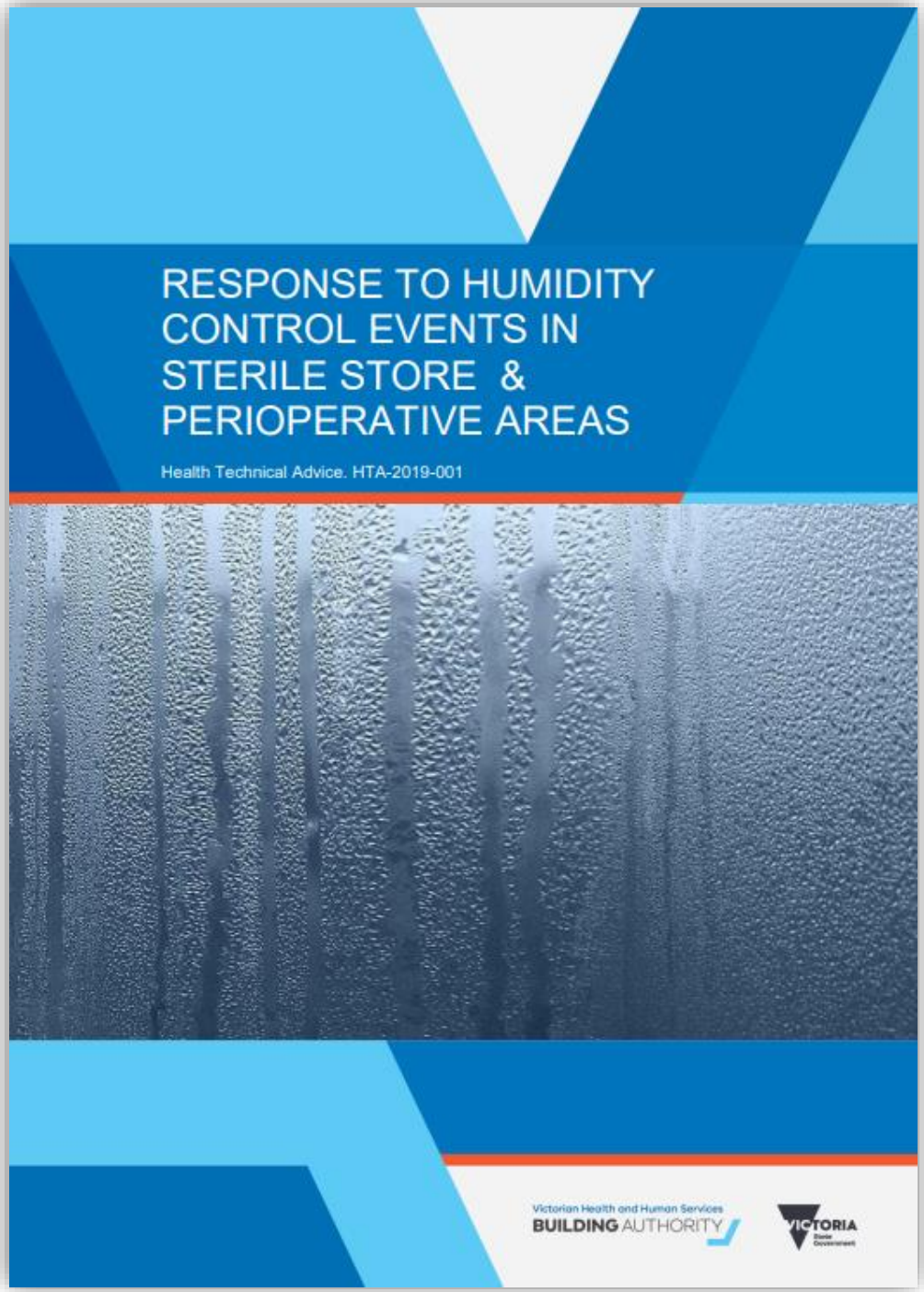
  NOTE 1 RMDs/other devices that present a challenge to steam penetration can be simple to wash or disinfect, and vice versa, therefore consideration should be given to determining separate product families for WD and disinfection processes.

  Guidance only refers to steam penetration resistance

Section 5 Product Definition

A.5.6.9 Storage

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Section 9 Storage and Handling of Processed Items - *Storage areas* - *Dust covers* - *Transportation* - *Commercially prepared items* - *Shelf life*	Section 5.6.9 Storage Table 5.1 General criteria for reprocessing & storage of RMDs in HSOs Section 9.5 Handling, transport and storage of released reprocessed RMDs - no guidance	**A.5.6.9** **Reference to the Victorian Health and Human Services technical advice document HTA-2019-001 *Response to humidity control events in sterile store and perioperative areas***



Why is humidity important in healthcare?

We are unable to see water molecules. We are only able to see water when it is in its liquid or solid form. The water vapour in the air around us is continually switching states between liquid and vapour long before it reaches a saturation point. The higher the humidity the greater the frequency of water forming and immediately evaporating again. At point of saturation (100% RH) the water condenses and does not re-evaporate, the liquid and vapour states reach equilibrium, and we are able to see it as condensation. At lower humidity water is always condensing and evaporating, we are just unable to see it.

Figure 1 shows that at a RH of >60%, there is enough water condensing in the air and on surfaces to support growth at a microbial level under certain temperature conditions. The more humid the air becomes the wider the temperature band that can support biological growth. It is therefore important to recognise this and control the amount of water vapour in the air to ensure that surfaces and equipment that are required to be sterile are not exposed to elevated humidity conditions.

Experts have determined that prolonged exposure to saturation levels greater than 70%, would provide enough moisture to support microbial growth, and therefore a limit of 70% RH has been set in AS 4187[2] for storage of sterile stock.

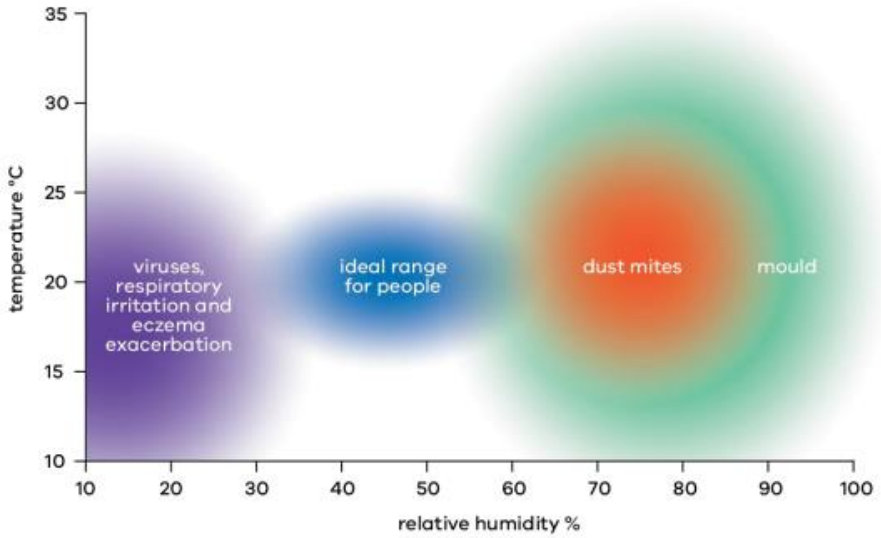


Figure 1 Humidity and its effects on our environment

It should also be noted that, in a healthcare scenario low humidity can also be a problem, water vapour is able to evaporate (escape) very easily and is not recaptured. This can lead to drying of moist tissue, discomfort, degradation of materials, AS 4187 recognises the lower limit as 35%.

Section 6 Process Definition

6.5 / A.6.5.1 Sterilization process definition

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Extended sterilisation cycles not specified	Extended sterilisation cycles not specified	**Where the IFU for an RMD/other device recommends the use of an extended sterilization cycle for a particular device, this recommendation shall be followed to ensure effective sterilization of that device, thereby rendering it safe for patient/client use**

Section 6 Process Definition

- **6.5.1 General**

An RMD/other device that does not require the use of an extended sterilization cycle to achieve an SAL of 10−6 shall not be subject to an extended sterilization cycle unless permitted by the IFU

Section 6 Process Definition

- **6.5.1 General**

NOTE 1 An extended sterilization cycle is a moist heat sterilization cycle specified in the IFU for a specific RMD or other device, where a process parameter/s deviates from the conventional process parameters for a moist heat sterilization cycle (see Table 6.2). An extended sterilization cycle could include a longer exposure time, a higher temperature, a longer drying time, or a combination of these.

Table 6.2 — Common holding times for saturated steam

Temperature °C	Holding time min
121	15
126	10
132	4
134	3

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

Section 6 Process Definition

A.6.2.2.2 Pre-treatment

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Initial treatment of used items *Gross residual soil to be removed as soon as practicable*	HSO shall develop and implement procedures for pre-treatment *Initial pre-treatment of a used RMD to be performed at point of use*	**Single-use attachments and accessories to RMD/other devices should be removed at the point of use** **Single-use sharps such as scalpel blades should be safely discarded as part of the pre-treatment process *(point of use)***

Section 7 Validation

7.2.3.1 Water Quality

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
No stringent water requirements Section 2.1 Water quality for cleaning: “Water suitable for drinking <u>should</u> be suitable for cleaning”	7.2.3.1 Water Quality Amendment No. 2 / 2019	**No change !** *(from 4187)*

Section 7 Validation

7.4.4 Controlled-environment storage cabinets for thermolabile endoscopes

AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Not specified	EN16442 in draft	**Performance qualification (PQ) of controlled-environment storage cabinets for processed thermolabile endoscopes shall be conducted in accordance with EN16442.**

Section 8
Routine Monitoring and Control

Section	AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
8.7.4 Moist heat	Table 7.1 (a) Moist heat 7.7.3.2 Air removal and steam penetration test	8.7.4 Moist heat	**8.7.4** **A hollow load test may take various forms, such as a helix design, fibrous layers or closed ended tubes**
8.7.5 Biological indicators	7.7.6 Biological/enzymatic indicators	8.7.5 Reference shall be made to ISO 14161 when selecting, using and interpreting the results of biological indicators	**8.7.5** **Reference shall be made to ISO 11138-7 when selecting, using and interpreting the results of BIs** *ISO 14161 withdrawn*

Section 9
Release of RMDs/Other Devices following Reprocessing

Section	AS/NZS 4815:2006	AS/NZS 4187:2014	AS 5369:2023
Table 9.1	10. Disinfection *Only thermal & chemical disinfection is referenced*	Table 9.1 Criteria for release of an RMD from reprocessing *Only thermal & chemical disinfection is referenced*	**Table 9.1** **Other high-level disinfection systems (not thermal or chemical)** RMDs/other devices that are compatible with the disinfection system are clean and any specific system controls and indicators confirm effectiveness of the process and expected performance of the equipment
9.5 Handling, transport and storage of released reprocessed RMDs	9.4 Transportation of sterile items	9.5 / A9.5 Handling, transport and storage of released reprocessed RMDs	**Where RMDs/other devices are transported between sites, the procedure shall be subject to a risk assessment and the conditions for non-conformance of RMDs/other devices due to transport documented**

Appendix B *(informative)*
Guidance on a Risk-based Approach

Section	**AS 5369:2023**
B.1 General	**Guidance on how to apply a risk-based approach to reprocessing RMDs/other devices**
B.2 Risk-based program	- **Assemble a team;** IPC, CSSD Manager, Mgt, Theatre, HR, and others - **Develop a process flow;** RMD pathways - **Risk analysis;** identify risks using four categories: *Physical, Chemical, Biological or Quality*
B.3 Risk evaluation	**Using a risk matrix to evaluate risk** *based on likelihood of occurrence, frequency of occurrence and impact to patient/client*
B.4 Risk control	**Risk score ranking and corrective actions and precautions**
B.5 Risk evaluation	**Risk evaluation and hazard control** monitoring procedures, corrective actions and records
B.5 Review	**Determine frequency for review**

Table B.1 — Examples of categories of hazards

Category of hazard	Examples
Physical	Debris in/on RMD, instruments requiring extended cycles,, instruments compromising SBSs, loading orientation/weight in the sterilizer outside accepted criteria not tested, debris in/on lumens, complexity of device being reprocessed, boiler water not feeding at the correct temperature.
Chemical	Improperly rinsed eye sets, incorrect dosing at cleaning station, hand moisturizer on technician hands, saline wipe of dirty instruments, skin prep residue on Rampley sponge holders (e.g. CHG, IPA, PVP), debris on/ in RMD (e.g. cement).
Biological	Staff Illness, residual hand cream not removed during handwashing, biofilm development on/in RMD's, ultrasonic bath water, early release of implants, prion contaminated devices, staff illness.
Quality (environmental and personnel)	Improper point of use care, quarantine of devices after processing to wait for release criteria monitoring results, insufficient eye sets for the day's surgery, instrument sets over 7 kgs, IFUs unavailable.

Table B.3 — Examples of threats or hazards in relation to Figure B.2 process flow

Step	Pre-process	Cleaning	Inspection/ function testing	Packaging	Loading	Sterilization	Storage	Use
Threat or hazard	Incorrectly classified devices (Spaulding's classification)	IFU not followed (Q)	Equipment damaged (P)	Incorrect pack size or wrap size for device (P/Q)	Incorrect loading orientation/ weight (outside of validation criteria) (P/M)	Poor steam quality (P)	Relative Humidity (RH) too high/too low (Q)	Not enough tray sets for procedures (Q)
	Staff training incomplete (Q)	Chemical dosing incorrect (C)	Debris on instrumentation (P/Q)	Incompatible material for sterilization process (P)	Staff hygiene (Q/B)	Incorrect sterilization cycle (Q/M)	Temperature of storage area too high/too low (Q)	Transfer of used to processing RMDs not timely (Q/M)
	Staff hygiene (Q/B)	Delayed reprocessing	Mechanical malfunction	Staff hygiene (Q/B)		Instruments Requiring extended sterilization cycles (P)	Shelf life (P/M)	Staff hygiene (Q/B)
		Undetected debris in lumens (P)	Staff hygiene (Q/B)			Staff hygiene (Q/B)	Staff hygiene (Q/B)	
		Staff hygiene (Q/B)						

NOTE This table includes examples of only some of the threats or hazards that can occur at each step of the process flow indicated in Figure B.2. The identification of these threats or hazards should be completed with the team assembled in Clause B.2.1.

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		Undetected debris in lumens (P)	Staff hygiene (Q/B)			Staff hygiene (Q/B)	Staff hygiene (Q/B)	
		Staff hygiene (Q/B)						

NOTE This table includes examples of only some of the threats or hazards that can occur at each step of the process flow indicated in Figure B.2. The identification of these threats or hazards should be completed with the team assembled in Clause B.2.1.

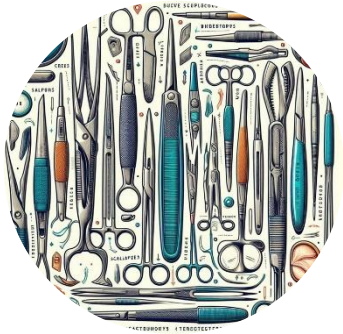
Reprocessing reusable equipment and devices

Reprocessing of reusable equipment and devices meets current best practice and is consistent with current national standards.

Item	Action	
Reprocessing of reusable equipment and devices	3.17	When reusable equipment and devices are used, the health service organisation has: a. Processes for reprocessing that are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines b. A traceability process for critical and semi-critical equipment, instruments and devices that is capable of identifying • the patient • the procedure • the reusable equipment, instruments and devices that were used for the procedure c. Processes to plan and manage reprocessing requirements, and additional controls for novel and emerging infections


Transitioning to AS 5369:2023

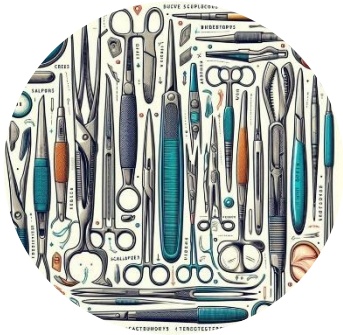
Transitioning to AS 5369:2023



Transitioning from AS/NZS 4815:2006 to AS 5369:2023

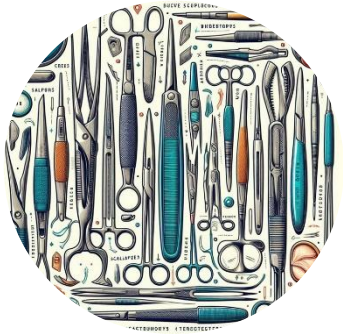
Transitioning from AS/NZS 4187:2014 to AS 5369:2023

Transitioning to AS 5369:2023



Aspect	**Actions**
Fundamentals	Understanding the key changes ▪ Documentation ▪ Validation ▪ Traceability ▪ Product Families ▪ Risk-based approach
Gap analysis	Assess the differences between standards, assess current compliance to AS 5369:2023 *(conduct an audit)*, develop action and implementation plan
Policies & Procedures	Create/review/update policies and procedures ▪ Section 2.3.2 and throughout document
Staff Education	Educate staff on changes, develop staff competencies for AS 5369:2023
Reprocessing Layout	Review dirty/clean processes, assess separation of areas ▪ Consider minor modifications to improve workflows *(physical and/or procedural barriers)*

Transitioning to AS 5369:2023



Aspect	**Actions**
Product Families	Develop product families for all reprocessing stages
Upgrade Equipment	Ensure reprocessing equipment is compliant (when replaced)
Improve Processes	Review processes to ensure compliance
Traceability	Review traceability systems covering semi-critical & critical RMDs
Performance Qualification	Validation of all reprocessing equipment/processes e.g. cleaning, disinfection, packing, sterilising
Risk Assessments	Assess compliance. Identify and evaluate risks

Potential Impacts

- Financial
  - Update equipment, validation, water quality
- Knowledge of standards
  - Normative references
- Design and size of reprocessing area
  - Review layout, improve workflows, modifications
- Compliance challenges
  - Update P&P, validation, processes, staff education
- Centralised &/or off-site reprocessing
  - Reprocessing; potential for multiple sites merging &/or send off-site for reprocessing

Last words

Compliance with AS 5369 is crucial for maintaining high standards of patient safety in healthcare settings.

It ensures that reusable medical devices are properly decontaminated and sterilised, reducing the risk of infection and other complications

ChatGPT

Good luck!

References

- Australian Commission on Safety and Quality in Health; Advisory AS24/01: National Safety and Quality Health Service Standards requirements for reprocessing of reusable medical devices in health service organisations (12 November 2024)
- Australian Commission on Safety and Quality in Health; Transitioning from AS/NZS 4815:2006 to AS 5369:2023 Identifying changes and implementation strategies for healthcare services (August 2024)
- Australian Commission on Safety and Quality in Health; Transitioning from AS/NZS 4187:2014 to AS 5369:2023 Identifying changes and implementation strategies for health service organisations (August 2024)
- Australian Standard 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities
- Australian Standard / New Zealand Standard 4187:2014 Reprocessing of reusable medical devices in health service organizations (Superseded)
- Australian Standard / New Zealand Standard 4815:2006 Office-based health care facilities – reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment
- National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, V11.24 (2024) https://www.nhmrc.gov.au/health-advice/public-health/preventing-infection
- Victorian Health and Human Services Building Authority; Response to humidity control events in sterile store and perioperative areas. Health Technical Advice. HTA-2019-001