Review of HPU 190 ‘Sterilizing Services and Endoscope Reprocessing Units’ Against AS 5369 – Proposed Changes, Revision 1, April 2025

Background

This paper has been developed to inform updates to the AusHFG HPU 190 Sterilizing Services and Endoscope Reprocessing Units and is based on a document issued by the Australian Commission on Safety and Quality in Health Care (ACSQHC) in August 2024, ‘*Transition from AS/NZS 4187:2014 to AS 5369: 2023: Identifying Changes and Implementation Strategies for Health Service Organisations*’.

The ACSQHC document includes a summary table of major changes associated with transition to the new standard which has been modified in this paper to also outline proposed implications for the planning and design of sterilising services that require considerations as part of the review of AusHFG HPU 190.

Key changes

The ACSQHC document outlines the following key changes associated with the transition from AS/NZS 4187:2014 to AS 5369:2023. Changes that directly impact facility design are highlighted in bold text.

- An expanded scope to include office-based and non-health related facilities that use RMDs and other devices for diagnosis, treatment, and other procedures
- No recommendation on the timeframe for health service organisations to implement the requirements of AS 5369:2023, while AS/NZS 4187:2014 recommended a two-year timeframe
- An emphasis on a risk-based approach
- A recommendation for annual training of staff in infection prevention and control and occupational exposure procedures
- An emphasis on management responsibilities, and the establishment of systems such as business continuity planning to ensure compliance with the standard under all conditions
- Requirements about evidence of accreditation and quality management activities in contracts with third parties for reprocessing services
- The involvement of competent persons to oversee document and record controls and product selection processes
- Guidance for grouping devices into product families, which determine the methods for reprocessing
- **An emphasis on Therapeutic Goods Administration (TGA) requirements for RMDs, RMDs accessories, reprocessing equipment, and reprocessing agents**
- **Additional guidelines for maintaining traceable and legible records**
- **Facility design that supports dedicated reprocessing areas and adherence to unidirectional workflows to mitigate cross-contamination risks**
- **Stipulations for cleaning sinks, hand hygiene facilities and ventilation systems**
- **Enhanced risk assessment and performance qualifications for handling, storage, and transport of RMDs and other devices to prevent contamination and ensure safety throughout the reprocessing cycle.**

Table 1. Major changes in AS 5369:2023 and implementation strategies for health service organisations

Heading	AS/NZS 4187:2014	AS 5369:2023	Implications for implementation of AS 5369:2023 in health service organisations	AusHFG HPU 190 Implications
Scope	Specifies the requirements and practices necessary for the effective and safe reprocessing, storage, handling, and transportation of RMDs in health service organisations.	Specifies reprocessing requirements for all healthcare facilities, including office-based facilities (such as medical clinics, dental practices, and podiatry practices) that use RMDs and other devices for diagnosis, treatment, and other procedures (previously covered under AS/NZS 4815:2006). Lists some products that may be considered to be medical devices in some jurisdictions, such as items specifically intended for cleaning or sterilisation of medical devices; pouches, reel goods, sterilisation wrap, and reusable containers for packaging of medical devices for sterilisation; disinfection substances; aids for persons with disabilities; devices incorporating animal and/or human tissues; and/or devices for in vitro fertilization or assisted reproduction technologies.	Health service organisations should adopt a risk-based approach and develop a risk assessment process and management system for reprocessing RMDs and other devices. Health service organisations should follow the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (the Guidelines) and their jurisdiction requirements about which products should be included as reusable medical devices and ensure their local procedures and processes on reprocessing, storage, handling, and transportation are in line with the new standard AS 5369:2023. Health service organisations can refer to Section 3.1.4 *Reprocessing of reusable medical devices* of the Guidelines and Appendix B *Guidance on a risk-based approach* of AS 5369:2023.	Nil
Education and training	Provides occupational health, workplace health and safety and training	Recommends that staff should be trained annually in local procedures for occupational exposure to blood and body substances.	Health service organisations should review the training needs of its workforce involved in reprocessing, storage, handling, and transportation of RMDs and other devices, focusing on infection prevention and control	Nil

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	recommendations that apply to the operation of sterilising facilities.	Recommends that staff should be trained annually on infection prevention and control methods, such as personal protective equipment (PPE), hand hygiene and waste disposal.	procedures and protocols, use of PPE, hand hygiene, waste management and occupational exposure prevention and management. Set a schedule for training workforce where knowledge and skills deficits are identified. Health service organisations should refer to the Clinical Governance Standard and the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions that relate to staff training. Health service organisations can refer to Section 4.3 *Education and training* of the Guidelines on education strategies.	
	Lists a minimum formal induction/orientation and training program for new staff should include modes of transmission of infection, infection prevention and control principles, hand hygiene, workplace health and safety issues, reprocessing activities, documentation, and record keeping.	Recommends incorporating an overview of quality management systems in relation to patient safety programs into the minimum formal induction/orientation and training program.	Health service organisations consider updating their formal orientation and training program to incorporate an overview of their quality management system. Health service organisations should refer to the Clinical Governance Standard and the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions that relate to staff training. Health service organisations can refer to Section 4.3 *Education and training* of the Guidelines on education strategies and ISO 9001:2015 *Quality management systems requirements* for the requirements on how to establish, implement, maintain and continually improve a quality management system.	Nil

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Documentation	Documents required by the standard shall be approved by designated personnel.	Documents required by the new standard shall be approved by competent persons. Documents and records should include purchasing records, monitoring of reprocessing equipment records, cleaning process records, cleaning of the reprocessing facility, sterilisation and high-level disinfection process records, staff training and competency records, maintenance records for RMDs and other devices and reprocessing equipment, microbiological surveillance testing, Installation Qualification, Operational Qualification and Performance Qualification for reprocessing records, process deviation reports and recall records.	Health service organisations should determine approval processes for these documents consistent with their local governance arrangements, including governance of reprocessing services. Health service organisations should refer to the Clinical Governance Standard of the NSQHS Standards for relevant actions that related to clinical performance and effectiveness.	Nil
Management responsibilities	Requires health service organisations' executive management to ensure an organisational structure supports the requirements of the standard.	Details the management responsibilities to have appropriate systems, such as a business continuity plan, to ensure the requirements of the new standard are met at all times, regardless of emergency or other suboptimal operating conditions.	Health service organisations should have business continuity processes in place to ensure that reprocessing of RMDs and other devices can continue safely regardless of emergency or other suboptimal operating conditions. Management should be involved in regular reviews of their organisational structure and business continuity or disaster plan to ensure strategic alignment and resource availability for compliance. Health service organisations should refer to the Clinical Governance Standard and the	Nil

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			Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions related to management and clinical governance. Health service organisations can refer to Section 4.1 *Management and clinical governance* of the Guidelines on their roles and responsibilities.	
Contracts	For reprocessing services that have been outsourced to a third party, health service organisations shall ensure that an agreement is in place that identifies the responsibilities of each party, including the requirement to comply with the standard.	In addition to the agreement, AS 5369:2023 stipulates that the contract should include evidence of accreditation, internal or external audit or other quality activities that demonstrate a satisfactory level of risk management and conformance to the new standard.	When a third-party provider is involved, health service organisations should ensure all contracts for reprocessing services include: • Responsibilities of each party • Evidence of third party's compliance with relevant standards • Provision for audits of records and quality checks, based on a risk assessment. Health service organisations should regularly review third party contracts to ensure compliance with the new standard. Health service organisations should ensure that all requirements by the new standard on contract agreement are documented in relevant policies, procedures, or protocols. Staff who are involved in developing contract agreement and approval processes should be informed of any changes. Health service organisations should refer to the Clinical Governance Standard and the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions related to outsourced services.	Nil

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Purchasing	Requires reprocessing facility manager involvement in the selection process before purchasing an RMD.	Requires the involvement of a competent person in the procedures for purchasing of the selected products for reprocessing, RMDs or other devices and accessories.	Health service organisations should ensure the involvement of personnel with reprocessing expertise in the selection process of products for reprocessing and RMDs/other devices. Health service organisations should refer to the Clinical Governance Standard of the NSQHS Standards for relevant actions related to clinical performance and effectiveness.	Nil
	Does not specify the TGA requirements for RMDs and accessories to RMD and reprocessing equipment.	Includes the TGA requirements for RMDs/other devices and accessories to RMDs and reprocessing equipment to be entered on the Australian Register of Therapeutic Goods (ARTG).	Health service organisation should review the TGA requirements when purchasing new reprocessing equipment, RMDs and other devices, and accessories for these devices. Health service organisation should conduct a risk assessment in relation to existing reprocessing equipment, RMDs and other devices and accessories for these devices, and consider risk mitigation strategies for high risk equipment, RMDs, and other devices, and accessories for these devices. Health service organisations should review and update their policies, procedures, or protocols on the processes for purchasing reprocessing equipment, RMDs and other devices, and accessories for these devices to incorporate reference to the TGA requirements. Staff who are involved in those processes should be informed of any changes. Health service organisations can refer to Section 3.1.4 *Reprocessing of reusable medical devices* of the Guidelines on TGA requirement.	**HPU Section 3.10.2 Equipment Standards** currently notes: Equipment used within the SSU / ERU must comply with the applicable European Norms, ISO or Australian Standards as specified in AS 5369:2023. Proposed additional text to include: When purchasing new reprocessing equipment, RMDs, other devices and related accessories, the TGA requirements must be reviewed and items included on the Australian Register of Therapeutic Goods (ARTG). For further information refer to: • AS5369:2023, Clause 2.5.2 • ACSQHC, Australian Guidelines for the Prevention and Control of Infection in Healthcare, Section 3.1.4

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Traceability records	Lists minimum requirements of traceability systems for high level chemical disinfection process records and sterilising process records.	In addition to the minimum requirements, AS 5369:2023 specifies requirements for traceability labels and paper-based records: • Where labels are present on a reusable or single-use medical or other device, the user should affix these to the individual's notes/records • If paper-based records are kept, they should be prepared and maintained to remain legible for the specified time period.	Health service organisations should review and update their policies, procedures, or protocols on the traceability processes for critical and semi-critical equipment, instruments, and devices taking the new standard into consideration. Changes to policies, procedures or protocols should be informed by a risk assessment. Staff who are involved in those processes should be informed of any changes. Health service organisations should refer to Action 3.17 the Preventing and Controlling Infections Standard of the NSQHS Standards for requirements on the traceability process for critical and semi-critical equipment, instruments and devices.	**HPU Section 2.2.14 Traceability of Reusable Medical Devices** Proposed update: ~~The Australian National Safety and Quality Health Service (NSQHS) Advisory A18/07 (Version 8)~~ AS5369:2023 and Action 3.17 of the ACSQHC's Preventing and Controlling Infections Standard require health services to have a traceability process in place for critical and semi-critical RMDs that is capable of identifying the patient, the procedure and the reusable equipment, RMDs and devices that were used for the procedure. Whilst traceability systems can be manual or electronic, health services should be working towards implementation of electronic traceability systems as recommended in ~~AS/NZS4187:2014~~ AS 5369:2023.
Control of monitoring and measuring equipment	Requires periodic calibration checks of all monitoring and measuring equipment by qualified in-house staff or external contractors. Calibration equipment should	Requires periodic calibration checks of all monitoring and measuring equipment by a competent person. Monitoring and measuring equipment should be calibrated by a competent person. A certification body, e.g. the NATA, may be used to certify the	Health service organisations should ensure the person, who is involved in monitoring and measuring equipment has acquired the knowledge and skills to perform the tasks through education, training, qualification, experience, or a combination of these. Health service organisations should review and update their policies, procedures, or protocols on the monitoring and measuring	Nil further. **HPU Section 2.2.4 Staffing** currently notes: Staffing profiles will include consideration of requirements relating to validation, monitoring and testing of equipment. This includes data analysis for monitoring of quality standards.

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	be certified by a suitable certification body, such as the National Association of Testing Authorities (NATA) in Australia.	calibration of the monitoring and measuring equipment.	equipment processes to ensure compliance with the new standard. Staff who are involved in those processes should be informed of the change. Health service organisations can refer to Section 4.3 *Education and training* of the Guidelines on education strategies.	
Reprocessing agent register	Requires cleaning agents, instrument grade chemical disinfectants and liquid chemical sterilising agents that are supplied in Australia and which are intended for use on RMDs be included in the ARTG.	Also requires high-level disinfection systems that are supplied in Australia, and which are intended for use on RMDs to be included in the ARTG.	Health service organisations should ensure that high-level disinfection systems (such as an instrument chemical-disinfection system) used for RMDs are included in the ARTG. Health service organisations should review and update their policies, procedures, or protocols on the TGA requirement for high-level disinfection systems to ensure compliance with the new standard. Staff who are involved in those processes should be informed of the change. Health service organisations can refer to Section 3.1.4 *Reprocessing of reusable medical devices* of the Guidelines on TGA requirement.	**HPU Section 2.1.6 Point of Care Reprocessing** Additional dot point to note the following: • High level disinfection systems used for RMDs should be provided with reference to TGA requirements and included on the Australian Register of Therapeutic Goods (ARTG).
Standards for reprocessing equipment	Lists the applicable standards for washer-disinfectors, ultrasonic cleaners, drying cabinets, heat sealers, steam sterilisers, dry heat sterilisers, ethylene oxide sterilisers,	Includes the addition of low-temperature hydrogen peroxide sterilisers and their applicable international standards to the list of reprocessing equipment.	When low-temperature hydrogen peroxide steriliser is used, health service organisations should follow manufacturers' guidelines and consider relevant standards in development of local procedures or protocols, informed by a risk assessment. Staff who are involved in using this equipment should be informed of and comply with the health service	**HPU Section 3.10.2 Equipment Standards** Proposed update to reference new standard: Equipment used within the SSU / ERU shall comply with the applicable European Norms, ISO or Australian Standards as specified in

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	steam/formaldehyde sterilisers, aeration cabinets, controlled environment storage cabinet for processed thermolabile endoscopes, and biological indicator incubators.		organisation's requirements relevant to applicable standards. When health service organisations are reviewing and planning to upgrade obsolete reprocessing equipment, they should compliance with these standards. Health service organisations should have processes to meet Action 3.17a of the Preventing and Controlling Infections Standard which requires reprocessing are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines.	~~AS/NZS4187:2014~~ AS 5369:2023 Clause 4.3.3.
Product families	Requires health service organisations to consider and document the classification and method of reprocessing an RMD.	Provides additional guidance and a flowchart to assist with assigning RMDs and other devices to product families based on the intended use of the device, the materials of construction, design of, physical characteristics and packaging of the device.	Health service organisation should consider the product family categorisation methods as specified in Appendix A.5.2 *Product families* of AS 5369:2023 for local procedures or protocols.	Nil
Reprocessing environment and facility design	Includes requirements for environmental control in areas that can impact the bioburden of an RMD, e.g. control of temperature, humidity, traffic flow, and	Provides additional information on the requirements on reprocessing environment and facility design: • Where reprocessing of RMDs occurs at the point of use, a dedicated area or room for reprocessing of RMDs shall be provided that is separate to the patient/clinical treatment area or room. If	Health service organisations should conduct a gap analysis using a risk-based approach for their reprocessing environment to determine what changes would be necessary to align with the new requirements. Health service organisation should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation	Recommend change terminology throughout HPU from 'Point of Care' Reprocessing to 'Point of Use' Reprocessing to align with AS5369 terminology. **HPU Section 2.1.6 Point of Care Use Reprocessing** Proposed additional points to be included:

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	reprocessing, ventilation and air flow. Includes requirements on facility design that facilitates a unidirectional workflow from dirty to clean and minimises the risk from cross contamination of a cleaned, disinfected, and sterilised RMD.	patient care and reprocessing occur in the same room, they should not take place simultaneously. If these activities are undertaken simultaneously, a risk assessment shall be undertaken to ensure this is safe • The point of use reprocessing area/room shall meet the requirements for environmental control, effective segregation of clean and dirty activities, unidirectional workflows and facility fixtures and finishes. All other requirements of this document apply to point of use reprocessing • A process map or flow diagram shall be developed and followed to ensure the risks for cross contamination, including airflows, are effectively managed in accordance with the risk assessment • Where reprocessing equipment lacks pass-through capability, effective segregation of clean and dirty activities shall be achieved through adherence to unidirectional workflows from dirty to clean activities. Segregation of the cleaning	service to working toward meeting the requirements of the new standard. When a health service organisation commences occupation of a new build, the new facility must be compliant with the new standard and the Australasian Health Facility Guidelines (AusHFG). Health service organisations should review and update their policies, procedures, or protocols on the reprocessing environment and facility design to ensure compliance with the new standard. Staff who are involved in those processes should be informed of the change. Health service organisations should refer to the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions related to environmental control and facility design.	• Where reprocessing of RMDs occurs at the point of use in new or refurbished facilities, a dedicated area or room for reprocessing of RMDs shall be provided that is separate to the patient/clinical treatment area or room. • The point of use reprocessing area/room shall meet the requirements for environmental control, effective segregation of clean and dirty activities, unidirectional workflows and facility fixtures and finishes. This should be informed by a process map or flow diagram to minimise the risk of cross contamination.

Heading	AS/NZS 4187:2014	AS 5369:2023	Implications for implementation of AS 5369:2023 in health service organisations	AusHFG HPU 190 Implications
		areas from the other reprocessing areas is integral in the redevelopment of a reprocessing facility to meet the requirements of this document.		
RMD/other device cleaning sinks	Includes requirements on sink workstations that can provide sufficient bench space to facilitate a unidirectional workflow and minimise the risk of cross contamination.	Provides additional information on the requirements on RMDs and other devices cleaning sinks: • Facilities to enable water or air flushing of a lumened RMD/other device shall be provided, including water flushing of a lumened RMD/other device, on the dirty side of the sink; and air flushing, on the clean side of the sink.	Health service organisations should review and update their policies, procedures, or protocols on the sink workstations by conducting gap analysis with a risk-based approach to ensure they are working toward meeting the new standard. Staff who are involved in those processes should be informed of any changes. Health service organisations should refer to the AusHFG for cleaning sink requirements.	Nil further. **HPU Section 2.2.8 Cleaning Sinks** currently notes: Sinks for general RMD cleaning should be configured so that a water gun is available on the dirty side of the sink to enable water flushing of cannulated RMDs. Air guns, connected to Medical Air should be located on the clean side of the sink and are used to blow excess water out of the cannulated RMD and check for cleanliness. These will not be required if cannulated RMDs will never be reprocessed in the unit.
Hand hygiene	Includes requirements on sufficient hand hygiene facilities available and accessible in all work areas.	Provides additional information on the requirements on hand hygiene basins: • Hand hygiene basins should not be located in clean work areas because such basins can be a source of contamination	Health service organisations should conduct a gap analysis using a risk-based approach on their hand hygiene facilities to determine what changes are necessary to align with the new requirements on hand hygiene basins. If hand hygiene basin is located in clean work areas, health service organisations should consider strategies for mitigating contamination risks from the basin, and	**HPU Section 3.5 Infection Prevention and Control** Proposed clarification to the following existing information noted in red text: Hand hygiene basins should not be located in the Inspection, Assembly and Packaging (IAP) Room or in the sterile store room as the sinks pose a hazard for contamination of RMDs.

Heading	AS/NZS 4187:2014	AS 5369:2023	Implications for implementation of AS 5369:2023 in health service organisations	AusHFG HPU 190 Implications
		• Hand hygiene basins should be located in an anteroom or corridor accessible from the clean work areas and should be used prior to entry to the clean work areas and if hands become visibly soiled.	opportunities for using alternative hand hygiene facilities. For example, placing alcohol-based hand rubs in the clean work areas. Health service organisation should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to ensure that the health service organisation can meet these requirements of the new standard. Health service organisations should refer to the AusHFG, Part D for hand hygiene requirements. Health service organisations should refer to the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions related to hand hygiene.	Alcohol based hand-rubs (ABHR) are more suitable for use in these areas. However a clinical hand basin (Type B) should be accessible to the clean areas and may be located in at the entry point into the clean areas for use prior to entry and if hands become visibly soiled. A clinical hand basin (Type B) will be required in the Cleaning (Decontamination) Room.
Ventilation	Requires health service organisations to ensure ventilation systems for reprocessing areas conform to AS 1668.2.	Emphasises on a risk-based approach in determining the design and operation of ventilation systems. Includes additional information on ventilation systems for dirty, clean, and specified purpose areas (e.g. sterile storeroom).	Health service organisations should conduct a gap analysis using a risk-based approach on their ventilation requirements. For operating theatres and adjoining stores, health service organisations should work towards complying with AS1668.2 *The use of ventilation and airconditioning in buildings, Part 2: Mechanical ventilation in buildings*. For other reprocessing and storage areas, health service organisations should conduct a gap analysis using a risk-based approach and consider the guidance in the Appendix A.5.6.15 *Ventilation* of AS 5369:2023 when determining changes to their ventilation system.	**HPU Section 3.11.1 Air-Handling** Update references: • Standards Australia ~~2012~~2024, AS 1668.2: The use of air conditioning and ventilation in buildings • Include: ACSQHC, 2022, Optimising ventilation for infection prevention and control in healthcare settings • Include: AS5369 Sections 5.6.15 Ventilation and Appendix A including Figure A.5.6.15 Ventilation design and operation • Include: Devereaux BM, Jones D, Wardle E, on behalf of the Infection

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			Health service organisations should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to ensure that the health service organisation can meet the requirements of the new standard. Health service organisations should refer to the AusHFG for guidance on ventilation system and the guidance on *Optimising ventilation for infection prevention and control in healthcare settings*.	Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021. • Include: Jurisdictional engineering services guidelines for healthcare facilities • Include: NSW Health Clinical Excellence Commission, 2024, Risk assessment and escalation of temperature or humidity variation in perioperative and sterile stock environments. Update the following text to align with AS 5369: The system shall be designed to address heat gain and vapours discharged from washer-disinfectors and to achieve a minimum of ~~10~~ 12 air changes per hour. ~~In the IAP and sterile store rooms, ventilation rates will be maintained when the area is unoccupied to ensure dilution rates are maintained~~. In line with AS 5369:2023, ventilation systems for IAP and sterile store rooms shall be continuously operational.

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				HPU Section 3.6.1 Temperature and Humidity Proposed update to align with AS5369 Section 5.6.15: ~~Many jurisdictions require automatic monitoring of temperature and humidity in sterile storage rooms.~~ Ventilation of storage areas for reprocessed RMDs shall control temperature and relative humidity with appropriate processes in place to alert and respond to variations.
Pre-treatment	Requires the initial pre-treatment of a used RMD to be performed at the point of use.	Adds information on single-use attachments and accessories to RMD/other devices: • Before transport to the reprocessing area, single-use attachments and accessories should be removed at the point of use as part of the pre-treatment process • Single-use sharps, such as scalpel blades should be safely discarded.	Health service organisations should review and update their policies, procedures, or protocols on the pre-treatment processes of a used RMD/other device to ensure compliance with the new standard. Staff who are involved in those processes should be informed of any changes. Health service organisations should include updated processes as part of induction training for new staff and keeping the relevant training records. Health service organisations should refer to the Clinical Governance Standard and the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions that relate to staff training. Health service organisations can refer to Section 4.3 *Education and training* of the Guidelines for education strategies.	Nil

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Non-heat-labile semi-critical RMD/other device	Requires a semi-critical RMD that cannot withstand moist heat or low temperature sterilisation to undergo thermal or chemical disinfection in accordance with a documented procedure.	Requires a semi-critical RMD that cannot withstand moist heat sterilisation to undergo low temperature sterilisation, thermal disinfection, or high-level disinfection process in accordance with a documented procedure.	Health service organisations should review and update their policies, procedures, or protocols to ensure any semi-critical RMD/other device that cannot withstand moist heat sterilisation undergo disinfection processes according to the new standard. Staff who are involved in those processes should be informed of the change.	Nil
Sterilisation process definition	No information on extended sterilisation cycle.	Provides additional guidance on the extended sterilisation cycle that has been validated for some RMDs and other devices for reprocessing before their supply.	Health service organisations should keep a register to identify and record any RMDs and other devices that require extended sterilisation cycle, and circumstances to use extended sterilisation cycle. Health service organisations should review and update their policies, procedures, or protocols on the extended sterilisation cycle for RMD/other devices to ensure compliance with the new standard. Staff who are involved in those processes should be informed of any changes. Health service organisations should include updated processes in induction training for relevant new staff and keeping the relevant training records. Health service organisations should refer to the Clinical Governance Standard and the Preventing and Controlling Infections Standard of the NSQHS Standards for relevant actions that relate to staff training.	Nil

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			Health service organisations can refer to Section 4.3 *Education and training* of the Guidelines on education strategies.	
Water quality	Sets the water quality requirements for pre-cleaning, cleaning, and rinse before the final rinse, and final rinse water used for reprocessing RMDs/other devices.	No change.	Health service organisations should consider the requirements of 7.2.3.1 *Water quality* of AS 5369:2023 and use a risk-based approach when conducing a gap analysis on their water quality for processing RMDs/other devices to determine what changes may be necessary. Health service organisations should assess their local water conditions, reprocessing methods, types of RMDs/other devices being processed, and equipment replacement needs when deciding on the most suitable water treatment options. Health service organisations should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to ensure that the health service organisations can meet the requirements of the new standard.	Minor updates only proposed to reference the new standard only. **HPU Section 2.2.8 Cleaning of RMDs** Water quality for cleaning and rinsing of RMDs must be in accordance with requirements in ~~AS/NZS4187:2014~~ AS 5369:2023. Water treatment systems to improve the quality of water used for all stages of cleaning RMDs may be necessary in some geographical areas. **HPU Section 3.11.8 Water Quality for Manual Cleaning and Supply to WDs and AFERs** The quality of water required for each process stage must be provided in accordance with ~~AS/NZS4187:2014~~ AS 5369:2023. In some geographical areas water treatment systems may be required to improve the quality of water used for all process stages in cleaning, disinfection and sterilisation of RMDs. This will be influenced by the quality of the incoming water supply and in some cases, seasonal variations. The hot and cold tap water supplied to cleaning sinks should have a hardness level of <150mg/L and chlorides <120mg/L. If these levels cannot be achieved from

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				the mains water supply, a water treatment system will need to be installed. These levels noted align with AS 5369.
Handling, transport, and storage of released reprocessed RMDs/other devices	Requires a reprocessed critical/semi-critical RMD to be handled, transported, and stored in a manner that prevents and minimises the risk of contamination.	Requires health service organisations to conduct a risk assessment and document the conditions for non-conformance of RMDs and other devices due to transport when RMDs and other devices are transported between sites.	Health service organisations should review and update their policies, procedures, or protocols on handling, transporting, and storing reprocessed critical/semi-critical RMDs and other devices to align with the recommendations as specified in Appendix A.9.5 *Handling, transport and storage of released reprocessed RMDs/other devices* of AS 5369:2023. Staff who are involved in those processes should be informed of the change. Health service organisations consider adding those processes as part of induction training for relevant new staff and keeping the relevant training records. Health service organisations can refer to Section 3.1.4 *Reprocessing of reusable medical devices* and Section 4.3 *Education and training* of the Guidelines on storage and maintenance and education strategies. Health service organisations should refer to the AusHFG for guidance on stock storage.	**HPU Section 2.2.7 Transport of Used / Soiled RMDs** The following additional text is proposed: Where RMDs/other devices are transported between sites the procedure shall be subject to a risk assessment in line with AS5369:2023Section 9.5 and Appendix B.

Additional Item for Discussion at HPU 190 Expert Reference Group meeting

Pass Through Equipment

AS5369 (Clause 5.6.2) notes that '<u>pass through reprocessing equipment should be included in new or refurbished facility design</u>'. This is recommended in the currently published HPU 190 for WDs and Automated Flexible Endoscope Reprocessors (AFERs) but for sterilisers it is noted that it is still accepted practice in some facilities to have single door opening machines. ERG to discuss whether this is still acceptable advice.

Relevant HPU extracts in currently published version below:

- **HPU Section 2.4.5 Inspection, Assembly and Packaging Room (IAP) (Clean Room): '**Sterilizers will preferably be of a pass-through type, however it is still accepted practice in small facilities to have single door opening machines.'
- **HPU Section 2.2.8 Cleaning of RMDs:** To facilitate unidirectional workflows and effectively separate soiled and clean activities, it is recommended that pass-through WDs and AFERs are installed in SSU and ERU.

April 2025 – Proposed update following ERG meeting:

- **HPU Section 2.4.5 Inspection, Assembly and Packaging Room (IAP) (Clean Room):** Pass-through sterilizers are best practice and should be provided, however they may not be practical in all circumstances, and it is still accepted practice in small facilities to have single door opening machines. Where pass-through sterilizers are not provided, the design shall ensure effective segregation of cleaning and dirty activities and unidirectional workflows from dirty to clean activities.
- **HPU Section 2.2.8 Cleaning of RMDs:** To facilitate unidirectional workflows and effectively separate soiled and clean activities, pass-through WDs and AFERs should be installed in SSU and ERU.