AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

National Safety and Quality Primary and Community Healthcare Standards

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

Identifying changes and implementation strategies for healthcare services

August 2024

Contents

About this document

This document is to assist healthcare services to implement the updated and new requirements introduced in AS 5369:2023 *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*.

Healthcare services involved in complex cleaning, disinfecting and sterilising processes (such as anaesthetic equipment processing, endoscopy equipment processing and processes involving low temperature sterilising systems) should refer to *Transitioning from AS/NZS 4187:2014 to AS 5369:2023* for mapping of the changes and implementation strategies.

Overview

Action 3.13a of the Preventing and Controlling Infection Criterion of the National Safety and Quality Primary and Community Healthcare Standards (Primary and Community Healthcare Standards) requires healthcare services, where reusable equipment, instruments and devices are used, to have processes for reprocessing that are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines.

In December 2023, AS 5369:2023 superseded AS/NZS 4815:2006 *Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* and AS/NZS 4187:2014 *Reprocessing of reusable medical devices in healthcare services*.

AS 5369:2023 specifies the requirements for the effective and safe reprocessing, storage, handling, and transportation of reusable medical devices (RMDs) and other devices used in human health care and other treatments. Implementation of AS 5369:2023 is required in all healthcare settings as well as other non-healthcare settings where RMDs and other devices are in use.

Key changes

The transition from AS/NZS 4815:2006 to AS 5369:2023 involves the following key changes, several of which are significantly different to AS/NZS 4815:2006 and have resource implications for primary and community healthcare services:

- An expanded scope to include health and non-health related facilities that use RMDs and other devices for diagnosis, treatment, and other procedures
- No recommendation on the timeframe for healthcare services to implement the requirements of AS 5369:2023
- 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 a competent person to oversee document and record controls and product selection processes
- An emphasis on Therapeutic Goods Administration (TGA) requirements for RMDs, RMD accessories, reprocessing equipment, and reprocessing agents
- Additional guidelines for maintaining traceable and legible records
- An emphasis on appropriate and preventive actions for nonconforming RMDs/other devices

- Guidance for grouping devices into product families, which determine the methods for reprocessing
- 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
- Stricter requirements on water quality for pre-cleaning, cleaning and rinses before the final rinse, and the final rinse water for sterilisers, sterilisation, and washer-disinfectors
- Detailed processes and requirements for all stages of validation (Installation Qualification, Operational Qualification and Performance Qualification)
- Detailed requirements for calibration, maintenance, and testing frequencies for various sterilising and associated types of equipment.

Table 1 maps AS 4815:2006 to the detailed updates and new requirements of AS 5369:2023 and includes suggestions for implementation strategies for healthcare services. In general, a staged implementation process, informed by risk assessment, is recommended.

Implementation considerations

Where critical and semi-critical RMDs and other devices are used, healthcare services should conduct a gap analysis using a risk-based approach to determine changes that are necessary to align with the new requirements in AS 5369:2023.

Healthcare services should update or develop an asset management plan, including timelines for future redevelopment or upgrade to their reprocessing service to meet the requirements of AS 5369:2023.

Table 1. Major changes in AS 5369:2023 and implementation strategies for primary care and community healthcare services

Heading	AS/NZS 4815:2006	AS 5369:2023	Implications for implementation of AS 5369:2023 in healthcare services
Scope	Specifies the requirements, procedures and process development which can be validated for the cleaning, disinfection and sterilisation of reusable medical and surgical instruments and equipment, and maintenance of associated environments in office-based health care facilities not involved in complex patient procedures and processes.	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. Categorises RMDs/other devices into critical, semi-critical and non-critical according to their intended use and subsequent level of reprocessing required to render them safe for reuse using the Spaulding Classification Scheme.	Healthcare services should adopt a risk-based approach and develop a risk assessment process and management system for reprocessing RMDs and other devices relevant to the setting in which they deliver services. Healthcare services should follow the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (the Guidelines) and guidance from their respective regulatory authority and professional association about which equipment, instruments, and devices should be included as critical, semi-critical and non-critical RMDs/other devices. Healthcare services should ensure local procedures and processes on reprocessing, storage, handling, and transportation are informed by the new standard AS 5369:2023, where practicable. Healthcare services 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.
Education and training	Includes occupational health and safety issues, infection control principles and quality management	Recommends that staff should be trained annually in local procedures for	Healthcare services should follow their current policy with regard to training their reprocessing workforce on these topics at orientation, and at regular intervals. The schedule for training the

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	training recommendations that apply to the operation of sterilising facilities.	occupational exposure to blood and body substances. Recommends that staff should be trained annually on infection prevention and control methods, such as personal protective equipment (PPE), hand hygiene and waste disposal. Recommends incorporating an overview of quality management systems in relation to patient safety programs into the minimum formal induction/orientation and training program.	workforce should incorporate consideration of knowledge and skills deficits. Healthcare services should consider updating orientation and training programs to incorporate an overview of their quality management system. Healthcare services should refer to the Clinical Governance Standard and the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards for relevant actions that relate to staff training. Healthcare services 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.
Documentation	Requires healthcare facilities to have documented policies and procedures for all reprocessing activities.	Requires all policies and procedures for reprocessing activities to be documented and dated. Details the minimum procedures for reprocessing activities that should be included in local policies and procedures. Details the minimum documents and records that should be maintained, including purchasing records, monitoring of reprocessing equipment records, cleaning process records, cleaning of the	Healthcare services should ensure that local policies and procedures for reprocessing activities are documented and dated. Healthcare services should consider the minimum procedures requirements in developing their own policies, informed by a risk assessment and the range of services they provide. Healthcare services should determine approval processes for these documents consistent with

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		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. Documents and records required by the new standard shall be approved by competent persons.	their local governance arrangements, including governance of reprocessing services. Healthcare services should refer to the Clinical Governance Standard of the Primary and Community Healthcare Standards for relevant actions that related to clinical performance and effectiveness.
Management responsibilities	Details the responsibilities of the person in charge of providing reprocessing activities.	Details the management responsibilities to have an organisational structure to support the requirements of the new standard, and 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.	Healthcare services should have structures and business continuity processes in place to support the implementation of AS 5369:2023 appropriate to the range of services they deliver and their local governance and risk management processes. Healthcare services should refer to the Clinical Governance Standard and the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards for relevant actions related to management and clinical governance. Healthcare services can refer to Section 4.1 *Management and clinical governance* of the Guidelines on their roles and responsibilities.

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Contracts	Does not specify the requirements on contractual agreement for reprocessing outsourced to a third party.	For reprocessing services that have been outsourced to a third party, healthcare services shall ensure that an agreement is in place that identifies the responsibilities of each party and 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.	Healthcare services should ensure that all third party 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. Healthcare services should refer to the Clinical Governance Standard and the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards for relevant actions related to outsourced services.
Purchasing	Does not specify the involvement of a competent person in the procedures for the purchasing.	The procedures for purchasing of the selected products for reprocessing, RMDs or other devices and accessories shall include the involvement of a competent person.	Healthcare services should ensure the involvement of personnel with reprocessing expertise in the selection process of products for reprocessing and RMDs/other devices. Healthcare services should refer to the Clinical Governance Standard of the Primary and Community Healthcare Standards for relevant actions related to clinical performance and effectiveness.
	Includes information on TGA requirements for steriliser, sterilising equipment, and disinfectants for	Includes the TGA requirements for RMDs/other devices and accessories to RMDs and reprocessing equipment to be	Healthcare services should review the TGA requirements when purchasing new reprocessing equipment, RMDs and other devices, and accessories for these devices.

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	reprocessing reusable instruments.	listed on the Australian Register of Therapeutic Goods (ARTG).	Healthcare services 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. Healthcare services 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. Healthcare services can refer to Section 3.1.4 *Reprocessing of reusable medical devices* of the Guidelines on TGA requirement.
Identification and traceability of product	Requires procedures to link steriliser cycle batch information of a critical item to the patient. Lists requirements of maintaining sterilising process records.	Requires documented procedures for identifying and tracking critical RMDs/other devices during reprocessing and subsequent use on patients/clients. Requires documented procedures for identifying and tracking semi-critical RMDs/other devices undergoing high level disinfection. Lists minimum requirements of traceability systems for high level disinfection process records and sterilising process records. Adds specific	Healthcare services 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. Healthcare services should refer to Action 3.13 of Preventing and Controlling Infection criterion of the Primary and Community Healthcare

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		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.	Standards for requirements on the traceability process for critical and semi-critical equipment, instruments and devices.
Nonconforming RMD/other device	Defines which conditions of stock are considered nonconforming and identifies the factors causing nonconformance.	Requires local policies and procedures to include appropriate actions and preventive actions for nonconforming RMDs/other devices.	Healthcare services should review and update their policies, procedures, or protocols for handling, transporting, and storing reprocessed RMDs/other devices, as well as managing nonconforming devices, using a risk-based approach informed by the new standard. Staff who are involved in those processes should be informed of any changes. Healthcare services can refer to Section 3.1.4 *Reprocessing of reusable medical devices* of the Guidelines on storage and maintenance. Healthcare services should refer to the Australasian Health Facility Guidelines (AusHFG) for guidance on stock storage.
Recall procedure and report	Mandates the development of policies and procedures for recalling supplies from	Requires that any RMD/other device released from a facility must be promptly recalled if there is evidence of failure during any stage of the cleaning,	Healthcare services should review and update their policies, procedures, or protocols using a risk-based approach to determine whether any changes are necessary for recall procedures

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	issued or stored loads when evidence of sterilisation process failure exists. Records of these recalls must be maintained.	disinfection, packaging, sterilisation processes, or during transport or storage of a reprocessed RMD/other device. Specifies the recall procedures and the minimum information that needs to be included in the recall report.	and reporting processes. Staff who are involved in those processes should be informed of any changes.
Reprocessing agent register	Requires chemical disinfectants that are supplied in Australia and intended for use on RMDs to be included in the ARTG. Requires Product Data Bulletins and Material Safety Data sheets for all cleaning agents shall be obtained.	Requires reprocessing agents, including cleaning agents, instrument grade chemical disinfectants, high-level disinfection systems and liquid chemical sterilising agents, that are supplied in Australia and intended for use on RMDs to be included in the ARTG. Requires documented specification to be obtained for each cleaning agent, disinfectant, and sterilising agent (where applicable) at the time of acquisition.	Healthcare services should review their existing reprocessing agents intended for use on RMDs and ensure that they are included in the ARTG. Healthcare services should ensure that documented specifications required by AS 5369:2023 are obtained from manufacturers. Healthcare services should review and update their procurement policies, procedures, or protocols for reprocessing agents intended for use on RMDs to ensure they are included on the ARTG. Staff who are involved in those processes should be informed of the change. Healthcare services can refer to Section 3.1.4 *Reprocessing of reusable medical devices* of the Guidelines on TGA requirement.
Personnel and environmental safety	Does not specify requirements on personnel and environmental safety.	Requires that a safety data sheet (SDS) or other relevant safety information about the safe use, handling and storage of the hazardous chemical shall be accessible to workplace staff and emergency service workers.	Healthcare services should ensure that SDSs or other relevant safety information for each hazardous chemical is available and accessible to relevant staff and emergency service workers. For example, placing the SDS or other relevant safety information in a central,

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		Requires a documented environmental impact assessment, including details of control measures in place, to be undertaken for any substance that could be released during or after use of a cleaning, disinfectant, or sterilising agent. Requires healthcare services to develop procedures for the storage, handling, decanting and disposal of chemicals, including the use of appropriate PPE and spill kit.	easily accessible location or where the chemical is stored and used; providing digital access to the SDS or other relevant information. Healthcare services should regularly inspect the locations for accessibility and compliance and perform audits to ensure that all hazardous chemicals have a current SDS or other relevant information available. Healthcare services should conduct an environmental impact assessment for all substances that could be released during or after reprocessing activities, including control measures, to ensure compliance with national and local regulatory requirements. Healthcare services should review and update their policies, procedures, or protocols on personnel and environmental safety requirements by conducting gap analysis with a risk-based approach to ensure compliance with the new standard. Staff who are involved in those processes should be informed of any changes. Healthcare services should review and address the training needs of the workforce involved in handling, using, and storing of cleaning agents, disinfectants, and chemical sterilising agents, and procedures for spills and exposure management.

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Standards for reprocessing equipment	Does not specify the applicable 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, steam/formaldehyde sterilisers, aeration cabinets, controlled environment storage cabinet for processed thermolabile endoscopes, and biological indicator incubators.	When reprocessing equipment is used, healthcare services 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 healthcare services' requirements relevant to applicable standards. When healthcare services are reviewing and planning to update obsolete reprocessing equipment, they should compliance with these standards. Healthcare services should have processes to meet Action 3.13 of the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards, which requires reprocessing are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines.
Product families	Does not include information on product families.	Provides 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.	Healthcare services 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.

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Reprocessing environment and facility design	Requires healthcare facilities to incorporate the principles of environmental control (such as ventilation, temperature, humidity, and the general cleanliness of the area) to minimise particulate contamination and bioburden. Includes facility design requirements that facilitates a unidirectional workflow from dirty to clean and minimises the risk from cross contamination of a cleaned, disinfected, and sterilised RMD.	Includes detailed requirements for environmental control 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 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	Healthcare services 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. Healthcare services should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to working toward meeting the requirements of the new standard. When a healthcare service commences occupation of a new build, the new facility must be compliant with the new standard and the AusHFG. Healthcare services 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. Healthcare services should refer to the Clinical Governance Standard and the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards for relevant actions related to environmental control and facility design.

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		activities shall be achieved through adherence to unidirectional workflows from dirty to clean activities. Segregation of the cleaning 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	Recommends two dedicated cleaning sinks large and deep enough for practical use.	Adds information on the requirements on cleaning sinks: • Provides sufficient bench space to facilitate a unidirectional workflow to minimise the risk of cross-contamination • Provides dedicated dirty and clean sinks for pre-treatment, manual cleaning, and rinsing of RMDs/other devices • 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.	Healthcare services should conduct a gap analysis using a risk-based approach on their reprocessing environment to determine what changes would be necessary to align with the new requirements. Healthcare services should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to ensure that they are working toward meeting the cleaning sinks requirements of the new standard. Where requirements of the standard cannot be met in a facility for the foreseeable future or planning period, a risk assessment and risk mitigation strategies should be implemented. Healthcare services should review and update their policies, procedures, or protocols on the sink workstations to ensure compliance with the new standard. Staff who are involved in those processes should be informed of any changes.

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			Healthcare services should refer to the AusHFG for cleaning sink requirements. Whenever a healthcare service commences occupation of a new build, the new facility must be compliant with the new standard and the AusHFG.
Hand hygiene	Requires separate handwashing facilities.	Provides information on the requirements on hand hygiene basins: • Hand hygiene facilities shall be available and accessible in all work areas • Hand hygiene basins should not be located in clean work areas because such basins can be a source of contamination. 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.	Healthcare services 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, healthcare services should consider strategies for mitigating contamination risks from the basin, and opportunities for use of alternative hand hygiene facilities, where feasible. For example, placing alcohol-based hand rubs in the clean work areas. Healthcare services should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to ensure that the healthcare service can meet these requirements of the new standard, where feasible. Healthcare services should refer to the AusHFG, Part D for hand hygiene requirements. Healthcare services should refer to the Preventing and Controlling Infection criterion of the Primary and Community Healthcare

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			Standards for relevant actions that relate to hand hygiene.
Ventilation	Requires efficient ventilation in reprocessing area and storage areas for sterile items. Additionally, it requires healthcare facilities to maintain specified temperature and humidity levels through ventilation systems wherever a steriliser is installed.	Emphasises on a risk-based approach in determining the design and operation of ventilation systems. Requires healthcare services to ensure ventilation systems of reprocessing and storage areas conform to AS 1668.2 *The use of ventilation and airconditioning in buildings, Part 2: Mechanical ventilation in buildings*. Emphasis 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).	Healthcare services should conduct a gap analysis using a risk-based approach on their ventilation requirements. For operating theatres and adjoining stores, healthcare service should work towards complying with AS1668.2. For other reprocessing and storage areas, healthcare services 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. Healthcare services should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation service to ensure that the healthcare service can meet the requirements of the new standard, where feasible. Healthcare services should refer to the AusHFG for guidance on ventilation system and the guidance on *Optimising ventilation for infection prevention and control in healthcare settings*.

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Transportation and pre-treatment	Requires documented procedures for initial treatment and collection of used items.	Requires initial pre-treatment of a used RMD/other device 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.	Healthcare services should review and update their policies, procedures, or protocols on the transportation and pre-treatment processes of a used RMD/other device by conducting gap analysis with a risk-based approach to ensure compliance with the new standard, where feasible. Staff who are involved in those processes should be informed of any changes. Healthcare services should include updated processes as part of induction training for new staff and keeping the relevant training records. Healthcare services should refer to the Clinical Governance Standard and the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards for relevant actions that relate to staff training. Healthcare services can refer to Section 4.3 *Education and training* of the Guidelines for education strategies.
Types of packaging and wrapping materials	Includes the following materials as sterilisation wrapping materials: • Paper materials intended for specific use • Woven and non-woven materials intended for specific use	Includes the following materials as sterilisation wrapping materials: • Crepe paper • Non-woven synthetic materials • Blended non-woven materials, consisting of cellulose and synthetic fibres • Reusable fabrics.	Healthcare services should audit their current sterilisation wrapping materials to confirm that only approved materials are used for sterilisation wrap. Healthcare services should review and update their procurement policies, procedures, or protocols on sterilisation wrapping materials selection to ensure compliance with the new standard. Staff who are involved in those processes should be informed of any changes.

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	• Flexible packaging materials consist of paper or non-woven materials combined with a clear laminate to form pouches or continuous reels.		
Sterilisation process definition	Requires compliance with manufacturers' written instructions for operating the sterilisers. No information on extended sterilisation cycle.	Requires a defined specification for the process used to sterilise an RMD/other device to achieve the required sterility assurance level. Provides additional guidance on the extended sterilisation cycle that has been validated for some RMDs and other devices for reprocessing before its supply.	Healthcare services should ensure that all RMDs/other devices have sterilising process specifications and sterilisation instructions supplied by manufacturers. Healthcare services should review the specifications and instructions to ensure they have the capability to sterilise the RMDs/other devices in accordance with the manufacturers' instructions for use. The process specifications and instructions should be easily accessible to their workforce. Healthcare services 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. Healthcare services should review and update their policies, procedures, or protocols on extended sterilisation cycle for RMDs/other devices to ensure compliance with the new standard. Staff who are involved in those processes should be informed of any changes.

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			Healthcare services should include updated processes in induction training for relevant new staff and keeping the relevant training records. Healthcare services should refer to the Clinical Governance Standard and the Preventing and Controlling Infection criterion of the Primary and Community Healthcare Standards for relevant actions that relate to staff training. Healthcare services can refer to Section 4.3 *Education and training* of the Guidelines on education strategies.
Validation processes	Requires healthcare facilities to have a validation programme to evaluate the reliability of a sterilisation process.	Lists detailed processes and requirements for each stage of validation: • Installation Qualification (IQ): verifies and documents that the equipment or systems are received as designed and specified, that they are properly installed in the selected equipment, and that this installation adheres to the manufacturer's approved specification and recommendations • Operational Qualification (OQ): verifies and documents that the installed equipment or system operates according to its intended operational range specified by the manufacturer requirements • Performance Qualification (PQ): verifies and documents that installed equipment or system performs	Healthcare services should review and update their policies, procedures, or protocols on the validation processes, including the sequencing and timing of testing by conducting gap analysis with a risk-based approach to align with the new standard. Staff who are involved in those processes should be informed of any changes. Healthcare services should maintain records of their equipment or systems specifications (such as model numbers, serial numbers, and software versions), calibration documentation and operational instructions. Healthcare services should ensure the installation site provides supporting utilities (such as power, water, stream, and air supply) and environmental conditions (such as

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		effectively and consistently in accordance with predetermined criteria and specifications under real-world, operational conditions. Requires a competent person to analyse and approve the validation reports.	temperature, humidity, and ventilation) for proper equipment or systems operation. Healthcare services should ensure that OQ is performed after installation, significant maintenance, or modification, or when introducing new RMDs/other devices or loading configurations. Healthcare services should ensure that PQ is performed after IQ and OQ, significant maintenance or modification, or when introducing new RMDs/other devices or loading configurations. Healthcare services should ensure that a person with appropriate expertise is involved in the validation process.
Water quality	Permits the use of drinking quality water for cleaning used RMDs but specifies that water with high mineral content should not be used for rinsing instruments. Requires health care facilities to obtain information on the quality of water from their local water authority.	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. Specifies the minimum water quality requirements for pre-cleaning, cleaning, and rinses before the final rinse, including water hardness and chloride level. Specifies the final rinse water quality requirements, including pH, conductivity, total hardness, chloride, iron, phosphates, silicates, total viable count, and bacterial endotoxins level.	Healthcare services 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. Healthcare services 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, such as using softened, filtered, demineralised or reverse osmosis water for final rinse water.

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		Recommends that healthcare services should seek information on the quality of the potable water supply to their reprocessing facility from their local water authority and test water that is treated on-site before use in reprocessing activities.	Healthcare services should update or develop an asset management plan for future redevelopment or upgrade to their sterilisation area that consider the requirements of the new standard when redeveloping or upgrading the healthcare service. Healthcare services considers the need for a water quality management plan, developed using a risk-based approach, including for the monitoring of water quality, frequency and tests conducted. Healthcare services should review and update their policies, procedures, or protocols on the processes for managing water quality. Staff who are involved in these processes should be informed of any changes.
Routine monitoring and control	Lists the requirements for performance testing, calibration, and maintenance of moist heat (stream) sterilisers and dry heat sterilisers. Lists the requirements and frequencies for calibration, monitoring and maintenance of associated equipment, including drying cabinets, washer-disinfectors, incubator for self-contained biological	Lists recommended frequencies for recalibration, maintenance and testing of sterilising equipment, including large/small steam sterilisers and dry heat sterilisers. Lists recommended frequencies for calibration, maintenance and testing of associated equipment, including washer-disinfector, associated reprocessing equipment (such as dental hand pieces oiling devices), ultrasonic cleaner, drying cabinet, endoscopy storage cabinet, heat sealer, volumetric dispenser, recirculating fume cabinet and ducted fume cabinet.	Healthcare services should conduct a gap analysis using a risk-based approach on their procedures on the performance testing, calibration, and maintenance of sterilising and associated equipment to determine what changes may be necessary to align with the new requirements as specified in AS 5369:2023. Healthcare services should follow manufacturers' instructions and consider AS 5369:2023, using a risk-based approach when determining frequencies for calibration, maintenance, and testing of sterilising and associated equipment.

Heading	AS/NZS 4815:2006	AS 5369:2023	Implications for implementation of AS 5369:2023 in healthcare services
	indicators, ultrasonic cleaner, and heat sealer.		
RMD/other device release criteria	Provides general criteria for release of processed items and does not specify the release criteria for each phase of reprocessing. Requires healthcare facilities to maintain records for released RMDs, including identification of the items, identification of the process or cycle, the time of the release and the name of the person authorising the release.	Adds detailed criteria for release of an RMD/other device from each phase of reprocessing, including manually/automated cleaning, thermal/chemical and other high-level disinfection, packing system, and sterilisation.	Healthcare services should review their policies, procedures, or protocols on the release criteria from each phase of reprocessing, informed by a risk assessment, to align with the requirements as specified in Table 9.1 *Criteria for release of an RMD/other device from reprocessing* of AS 5369:2023. Staff who are involved in those processes should be informed of any changes. Healthcare services should have a system for traceability of released RMDs/other devices.

More information

For more information on the Primary and Community Healthcare Standards, please visit: https://www.safetyandquality.gov.au/standards/primary-and-community-healthcare

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