Advisory AS24/01: National Safety and Quality Health Service Standards requirements for reprocessing of reusable medical devices in health service organisations

12 November 2024

To describe the minimum compliance requirements within Action 3.17 for health service organisations that reprocess reusable medical devices (RMDs).

Advisory details

Item	Details
Advisory number	AS24/01
Version number	1.0
TRIM number	D24-53934
Publication date	11 November 2024
Replaces	Replaces advisory AS18/07 which is rescinded
Compliance with this advisory	It is mandatory for approved accrediting agencies to implement this Advisory
Information in this advisory applies to	• All approved accrediting agencies • All health service organisations
Key relationship	NSQHS Standards Preventing and Controlling Infections Standard Actions 3.17 Australian Guidelines for the Prevention and Control of Infection in Healthcare
Attachment	N/A

Item	Details
Notes	This advisory replaces advisory AS18/07 and provides advice regarding the recently released AS 5369:2023, which supersedes both AS/NZS 4187:2014 and AS/NZS 4815:2006. As deadlines for compliance have been removed from this Advisory, applications from health service organisations for extension are no longer required. • ***Comply*** means meeting the requirements in a standard. • ***Align*** means considering the requirements of the standards and the organisation's risks to determine how and to what extent the standard is implemented when full compliance is not feasible. • Clarification of an 'exemption' to the requirements of rating an action met with recommendations, across assessment cycles
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To be reviewed	December 2026

Purpose

To describe the minimum compliance requirements within Action 3.17 for health service organisations that reprocess reusable medical devices (RMDs).

Issue

Action 3.17 of the 2021 National Safety and Quality Health Service (NSQHS) Standards states: 'when reusable equipment and devices are used, the health service organisation has:

1. Processes for reprocessing that are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines
2. 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
3. Processes to plan and manage reprocessing requirements, and additional controls for novel and emerging infections.'

In December 2023, Standards Australia released *AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities* which supersedes both *AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations*, and *AS/NZS 4815:2006 Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*. AS 5369:2023 does not include timeframes for compliance.

AS 5369:2023 is the national standard commonly used by health service organisations to inform implementation of Action 3.17.

To support transition arrangements, the Commission has developed a resource to assist in conducting a gap analysis to identify key changes and requirements between AS/NZS 4187:2014 and AS 5369:2023.

Requirements

Perform a gap analysis by 30 June 2025

Health service organisations using critical and semi-critical RMDs and other devices that require reprocessing are to update their gap analysis for AS4187 against AS 5369:2023 to determine compliance with the national or international standards for reprocessing of reusable medical devices. AS 5369:2023 should be used as the guide to undertake this analysis.

> At assessment, assessors are to ensure a gap analysis is completed by 30 June 2025 and implementation on an action plan commenced from that time.

Implement risk mitigation

Where risks are identified, risk mitigation strategies must be implemented and routinely monitored and reported to the relevant clinical governance body or individual.

This includes risks related to:

- Segregation of clean and dirty activities
- Storage of reprocessed medical devices
- Cleaning, disinfecting and sterilising equipment.

> At assessment, assessors are to confirm a risk assessment has been conducted, and that there is routine monitoring and reporting on actions taken to mitigate identified risks. Strategies being implemented are to move the organisation towards full compliance with the national or international standards for reprocessing of reusable medical devices.

Compliance with national or international standards for reprocessing of reusable medical devices

Health service organisations are expected to work towards compliance with national or international standards for reprocessing of reusable medical devices. While implementing the requirements of national or international standards, risks are to be identified and mitigation processes put in place.

Health service organisations must develop a plan for compliance that includes timeframes to align with national or international standards, manufacturers' guidelines, the current edition of the Australian Guidelines for the Prevention and Control of Infection in Healthcare and relevant state and territory requirements for reprocessing of reusable medical devices.

Whenever a new health service facility commences operations, the health service organisation must align its processes for reprocessing of medical and other devices with national or international standards for reprocessing of reusable medical devices,

manufacturers' guidelines, the current edition of the Australian Guidelines for the Prevention and Control of Infection in Healthcare and relevant state and territory requirements.

> At assessment, assessors are to review evidence the organisation is implementing its plan to comply with national or international standards for reprocessing of reusable medical devices, manufacturers' guidelines, the current edition of the **Australian Guidelines for the Prevention and Control of Infection in Healthcare** and relevant state and territory requirements. This includes ongoing monitoring and compliance with the specified timeframes.

Replacement of equipment

The risk of infection and manufacturers' guidelines and instructions should inform the timeline for declaring equipment, devices and water filtration equipment inoperable or obsolete. The economically useful life of reprocessing equipment and devices and water filtration systems is to be detailed in the organisation's asset register. Decommissioning and replacement of equipment is a matter for health service organisations to consider as part of their capital and risk governance.

Health service organisations replacing inoperable or obsolete reprocessing or water filtration equipment are to replace equipment with equipment that meets the relevant national or international standards.

Where reprocessing equipment is replaced with previously used equipment, the replacement equipment should operate as originally intended and conform with national or international standards for reprocessing of reusable medical devices, the current edition of the Australian Guidelines for the Prevention and Control of Infection in Healthcare and relevant state and territory requirements.

> At assessment, assessors are to review evidence that replaced reprocessing equipment complies with the national or international standard.

Water Treatment

Health service organisations are to conduct a risk assessment and monitor water quality, in line with equipment manufacturers' and service providers' recommendations, to determine whether water as supplied is of a suitable quality.

Health service organisations should:

- Monitor water quality taking into consideration the requirements in AS 5369:2023 and manufacturers' recommendations
- When determining the most suitable water treatment options, health service organisations should conduct a risk assessment in consultation with requirements in AS 5369:2023 and manufacturers' recommendations
- Monitor the water treatment equipment and processes to align with the requirements in AS 5369:2023 and manufacturers' recommendations.

At assessment, assessors are to rate Action 3.17:

- **'not met'** if a gap analysis is not complete by July 2025, if the action plan is not being implemented in line with the timeframes specified in the action plan, and/or ongoing monitoring specified in this Advisory is not evident.
- **'met with recommendations'*** when there is evidence that systems and processes for reprocessing of reusable medical and other devices are not aligned with the requirements of AS 5369:2023, however:
    - a gap analysis has been undertaken by 30 June 2025
    - an action plan is being implemented and monitored
    - risks are routinely monitored and mitigation strategies are in place
    - compliance aligns with the requirements of this Advisory.
- **'met'** when the health service organisation has systems and processes for reprocessing of reusable medical and other devices that are aligned with the requirements of AS 5369:2023.

***Where timelines for implementation exceed 3 years, health service organisations may apply to the Commission for an exemption to the rules of the AHSSQA Scheme, relating to the rating scale for assessment. See Fact Sheet 4: Rating scale for assessment

An exemption supports Action 3.17 to be rated 'met with recommendations' across assessment cycles. Where the requirements of the advisory have been met, the rating of MWR will not count towards a remediation period, nor mandatory reassessment.

The link to applications for an exemption is here.

Topics

NSQHS Standards (second edition)