AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

ADVISORY

TITLE	**Reprocessing of reusable medical devices in health service organisations**
Advisory number	AS18/07
Version number	8.0
TRIM number	D21-13942
Publication date	26 July 2021
Replaces	AS18/07 version 7.0 published March 2021
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
Attachment	n/a
Notes	Following release of the amended 2021 NSQHS Standards - Preventing and Controlling Infections Standards, changes to this advisory are related to: • Updated number formatting of the actions throughout the NSQHS Standards • Update of the name and numbering of Preventing and Controlling Infections Standards actions
Responsible officer	Margaret Banks Director, National Standards Phone: 1800 304 056 Email: AdviceCentre@safetyandquality.gov.au
To be reviewed	December 2022

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

ADVISORY

AS18/07: Reprocessing of reusable medical devices in health service organisations

PURPOSE:

To describe the minimum requirements for health service organisations' compliance with Action 3.17 (formerly Action 3.14 in the 2017 NSQHS Standards) to relevant national or international standards for reprocessing of reusable medical devices in health service organisations.

ISSUE:

Action 3.17 of the 2021 amended National Safety and Quality Health Service (NSQHS) Standards states:

Where reusable equipment, instruments and devices are used, the health service organisation has:

a. Processes for reprocessing that are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines
b. A traceability process for critical and semi-critical equipment, instruments and devices that is capable of identifying
    - the patient
    - the procedure
    - the reusable equipment, instruments and devices that were used for the procedure.

The Australian Standard AS/NZS 4187 is the national standard most commonly used by hospitals and day procedure services to meet the requirements in Action 3.17. Standards Australia released *AS/NZS 4187:2014: Reprocessing of reusable medical devices in health service organisations* in 2014 and it became operational in December 2016.

Standards Australia's *AS/NZS 4815:2006 - Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* is commonly used in office-based practice. This standard is still operational and is not covered by this Advisory.

In response to concerns raised by health service organisations and state and territory health departments the Commission has reviewed the implementation of *AS/NZS 4187:2014* and revised the compliance timeframe requirements. This revised Advisory specifies the minimum requirements needed to comply with Action 3.17 in the NSQHS Standards.

REQUIREMENTS:

To comply with the requirements of Action 3.17 health service organisations should:

a. By June 2021, complete a gap analysis to determine its current level of compliance with the relevant national or international standards for reprocessing reusable medical devices in use by the health service organisation

b. By December 2021, develop and document a plan to address identified gaps in compliance with the national or international standards in use by the organisation, specifying timeframes, milestones and deliverables to support implementation

Compliance gaps may be addressed in a standalone plan or may be addressed as part of the organisation's capital works and/or asset management and procurement planning cycles and may form part of a jurisdictional or private sector health services group capital works or asset management plan.

The plan should include:

- A strategy to identify and manage any current and emerging risks associated with the compliance gap(s)
- The timeframes and actions required to address the compliance gap(s)
- Executive endorsement

c. Demonstrate progress toward implementing the plan, noting the following:

1. Segregation of clean and dirty activities

By 31 December 2022, the Commission expects organisations to comply with relevant national or international standards for effective segregation of clean and dirty activities.

Prior to 31 December 2022 to be assessed as meeting Action 3.17, organisations still working towards full compliance of national or international standards for the effective segregation of clean and dirty activities should:

- Implement strategies to ensure unidirectional work and airflow to reduce the risk of cross contamination
- Identify and manage the risks associated with the gaps between current status and compliance with relevant national or international standards
- Document a process map or flow diagram to indicate how risks of cross contamination are being identified and managed.

From 1 January 2023, Action 3.17 is to be rated met with recommendations in organisations that are still working towards full compliance for effective segregation of clean and dirty activities

From 1 January 2023, Action 3.17 is to be rated met in organisations that are fully compliant with the national or international standard in use by the organisation effective segregation of clean and dirty activities.

Segregation of clean and dirty activities does not automatically require separate clean and dirty rooms.

Whenever an organisation commences occupation of a new build, it must be compliant with relevant national or international standards for the segregation of clean and dirty activities.

Exceptions to these requirements can be sought from the Commission on a case-by-case basis for health service organisations moving into new facilities, redeveloping facilities or with planned and funded redevelopments.

2. Design of storage areas for sterile stock

By 31 December 2022, the Commission expects organisations to comply with requirements in relevant national or international standards for storage of sterile stock in compliant shelving.

Organisations must mitigate the risk of contamination of sterile stock in storage. This includes assessing and managing the risk of:

- Humidity and temperature on stored sterile stock
- The co-location of sterile and non-sterile stock in a storage area.

Prior to 31 December 2022 to be assessed as meeting Action 3.17, organisations still working towards full compliance of national or international standards for sterile stock should develop an implementation plan that:

- Identifies and manages the risks associated with the gaps between current status and compliance with national or international standards in use by the organisation
- Is endorsed by the organisation executive
- Details the strategies to achieve full compliance
- Includes realistic timeframes, costings and options for funding that are approved by the executive
- Includes regular review of the risks, implementation of mitigation strategies and progress with the implementation plan.
- Ensures review processes are documented.

From 1 January 2023, Action 3.17 is to be rated met with recommendations in organisations that:

- Are still working towards full compliance for sterile stock storage
- Have completed an executive-endorse implementation plan
- Can provide evidence of ongoing progress implementing the executive-endorsed plan.

From 1 January 2023, Action 3.17 is to be rated met in organisations that are fully compliant with the relevant national or international standards for sterile stock storage.

Exceptions to these requirements can be sought from the Commission. Submissions will be considered on a case-by-case basis for organisations moving into new facilities, redeveloping facilities or facilities with planned redevelopment.

3. Replacement of AS/NZS 4187:2014 non-compliant cleaning, disinfecting and sterilising equipment

By 31 December 2022, the Commission expects organisations to comply with relevant national or international standards for cleaning, disinfecting and sterilising equipment.

All compliant equipment should be operated and maintained in accordance with the manufacturer's requirements and the relevant national or international standard, including for water quality and water quality monitoring.

Organisations must develop and use operational procedures for this equipment that are compliant with the national or international standards in use by the organisation.

Prior to by 31 December 2022 to be assessed as meeting Action 3.17, organisations still working towards full compliance of national or international standards for cleaning, disinfecting and sterilising equipment should develop an implementation plan that:

- Identifies and manages the risks associated with the gaps between current status and compliance with relevant national or international standards
- Is endorsed by the organisation executive
- Details the strategies to achieve full compliance
- Includes realistic timeframes, costings and options for funding that are approved by the executive
- Includes regular review of the risks, implementation of mitigation strategies and progress with the implementation plan.
- Ensures review processes are documented.

From 1 January 2023, Action 3.17 is to be rated met with recommendations in organisations that:

- Are still working towards full compliance for cleaning, disinfecting and sterilising equipment
- Have completed an executive-endorse implementation plan
- Can provide evidence of ongoing progress implementing the executive-endorsed plan

From 1 January 2023, Action 3.17 is to be rated met in organisations that are fully compliant with the relevant national or international standards for cleaning, disinfecting and sterilising equipment.

Whenever an organisation replaces cleaning, disinfecting and/or sterilising equipment, it must install equipment that is compliant with the relevant national or international standards for reprocessing reusable medical devices.

Equipment and design of all new builds, refurbishments and redevelopments of sterilising services units must comply with relevant national or international standards.

Exceptions to these requirements can be sought from the Commission. Submissions will be considered on a case-by-case basis.

4. Monitoring requirements for water quality

By 31 December 2022, the Commission expects organisations to comply with requirements in relevant national or international standard for monitoring water quality.

By 31 December 2022 to be assessed as meeting Action 3.17, organisations still working towards full compliance of national or international standards for monitoring water quality must develop an implementation plan that:

- Identifies and manages the risks associated with the gaps between current status and compliance with national or international standards in use by the organisation
- Is endorsed by the organisation executive
- Details the strategies to achieve full compliance
- Includes realistic timeframes, costings and options for funding that are approved by the executive
- Includes regular review of the risks, implementation of mitigation strategies and progress with the implementation plan.
- Ensures review processes are documented.

From 1 January 2023, Action 3.17 is to be rated met with recommendations in organisations that:

- Are still working towards full compliance for monitoring water quality
- Have completed an executive-endorse implementation plan
- Can provide evidence of ongoing progress implementing the executive-endorsed plan

From 1 January 2023, Action 3.17 is to be rated met in organisations that are fully compliant with the relevant national or international standards for monitoring water quality.

When an organisation replaces equipment that is used in the cleaning, disinfecting or sterilisation process, water quality requirements should be included in the planning and risk assessment undertaken.

Exceptions to this requirement can be sought from the Commission. Submissions will be considered on a case-by-case basis for health service organisations moving into new facilities, redeveloping facilities or facilities with planned redevelopment.

Health service organisations that are newly established and undergo interim accreditation to the NSQHS Standards are expected to comply with requirements of relevant national or international standards.

Health service organisations that access reprocessing equipment from a third party provider are to ensure the provider supplies the organisation with evidence of full compliance with relevant national or international standards.

Where visiting health professionals supply their own sterile equipment or sterile loan equipment is used, organisations are required to assure and seek evidence that the equipment was reprocessed, transported and stored in compliance with relevant national or international standards.

Accrediting agencies are required to:

- Assess and rate health service organisations compliance with Action 3.17 in accordance with the requirements set out in this Advisory.