

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE



ADVISORY

TITLE	Reprocessing of reusable medical devices in health service organisations
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Replaces	AS18/07 version 5.0 published on 16 March 2020
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 (second edition): Preventing and Controlling Healthcare-associated Infections Standard
Attachment	n/a
Notes	Updated timelines for compliance
Responsible officer	Margaret Banks Director, National Standards Phone: 1800 304 056 Email: accreditation@safetyandquality.gov.au
To be reviewed	December 2021



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 3.14 following the introduction and subsequent revision by Standards Australia of *AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations*.

ISSUE:

Action 3.14 of the National Safety and Quality Health Service (NSQHS) Standards (second edition) 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 used by hospitals and day procedure services to meet the requirements in Action 3.14. Standards Australia released AS/NZS 4187:2014 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 [version 3] specifies the minimum requirements needed to comply with Action 3.14 in the NSQHS Standards (2nd ed.).

REQUIREMENTS:

To comply with the requirements of Action 3.14 health service organisations should:

- a. Complete a gap analysis to determine its current level of compliance with AS/NZS 4187:2014 by June 2021
- b. Develop and document an implementation plan using a quality improvement framework specifying timeframes, milestones and deliverables to support implementation for AS/NZS 4187:2014 by December 2021
- c. Demonstrate progress toward implementing the plan, noting the following:

1. Segregation of clean and dirty activities

The Commission expects organisations to comply with AS/NZS 4187:2014 requirements for effective segregation of clean and dirty activities. Compliance with Action 3.14 in the NSQHS Standards can be achieved by implementing strategies that **ensure** segregation of clean and dirty activities including unidirectional work and airflow to reduce the risk of cross contamination. These strategies must be accompanied by a detailed risk analysis and include a process map or flow diagram to indicate how risks of cross contamination are being identified and managed.

The Commission expects all health service organisations will be compliant with requirements to segregate clean and dirty activities by December 2023 through refurbishment and redevelopment of existing sterilising services, endoscopy reprocessing units and satellite services as may be required to achieve compliance by that date. All future new builds should be planned to be compliant.

Exceptions to this requirement 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

The Commission expects organisations to comply with AS/NZS 4187:2014 requirements for storage of sterile stock. Organisations need to assess the risk of humidity and temperature on stored sterile stock and ensure risks of contamination are mitigated wherever sterile stock is stored.

All sterile stock should be stored in compliant shelving. A risk analysis is required if sterile stock and non-sterile stock are co-located in a storage area.

Compliance with Action 3.14 in the NSQHS Standards in organisations that do not currently comply can be achieved by developing a plan, endorsed by the organisation's executive that includes realistic timeframes, costings and options for funding that are approved by the executive to achieve full compliance with AS/NZS 4187:2014 storage requirements by 31 December 2022. Prior to this date should an organisation not comply there should also be a risk assessment (including mitigation strategies) and documented evidence of a regular review process.

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.

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

The Commission expects organisations to comply with AS/NZS 4187:2014 requirements for cleaning, disinfecting and sterilising equipment by 31 December 2022.

Compliance with Action 3.14 in the NSQHS Standards in health service organisations that will not be fully compliant by 31 December 2022 can be achieved by developing and implementing a detailed plan that includes realistic timeframes, costings and options for funding that are approved by the executive to move to full compliance. There should also be a risk assessment, mitigation strategies and evidence of regular review and reports to the executive on progress. This detailed plan, inclusive of executive endorsement, must be in place by 31 December 2021

Whenever an organisation replaces cleaning, disinfecting and/or sterilising equipment, it must install equipment that is compliant with AS/NZS 4187:2014 and the relevant applicable ISO standard. The equipment should be operated and maintained in accordance with the manufacturer's requirements **and** AS/NZS 4187:2014, including for water quality and water monitoring. Health service organisations will also need to develop procedures for operational use of this equipment that are compliant with AS/NZS 4187:2014.

Equipment and design of all new builds, refurbishments and redevelopments of sterilising services units must comply with AS/NZS 4187:2014.

4. Monitoring requirements for water quality

The Commission expects organisations to comply with AS/NZS 4187:2014 water monitoring requirements by 31 December 2022.

Health service organisations are required to comply with water monitoring set out in AS/NZS 4187:2014 [Amendment 2] for all reprocessing equipment compliant with the applicable ISO standards.

Compliance with Action 3.14 in the NSQHS Standards in health service organisations that will not be fully compliant by 31 December 2022 can be achieved by developing and implementing a detailed plan that includes realistic timeframes, costings and options for funding that are approved by the executive to move to full compliance. There should also be a risk assessment, mitigation strategies and evidence of regular review and reports to the executive on progress. This detailed plan, inclusive of executive endorsement, must be in place by 31 December 2021.

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.

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.

Health service organisations that are newly established and undergo interim accreditation to the NSQHS Standards are expected to comply with requirements of AS/NZS 4187:2014.

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 AS/NZS 4187:2014.

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 AS/NZS 4187:2014.

Accrediting agencies are required to:

- a. Ensure a gap analysis is completed
- b. Assess progress on the implementation plan, in accordance with the requirements set out above
- c. Where appropriate, review the risk assessment, mitigation strategies and documented review processes at each accreditation assessment
- d. Rate Action 3.14 as 'met with recommendation' where a health service organisation demonstrates progress towards its implementation plan for AS/NZS 4187:2014.