

ADVISORY

TITLE	Reprocessing of reusable medical devices in health service organisations
Advisory number	AS18/07
Version number	1.0
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Publication date	October 2018
Replaces	Advisory A16/03 of the NSQHS Standards (first edition)
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	Updates related to the NSQHS Standards (second edition)
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To be reviewed	December 2020

ADVISORY

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

PURPOSE:

To describe the minimum requirements for health service organisation 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 most commonly used to meet the requirements in Action 3.14. AS/NZS 4187:2014 replaces AS/NZS 4187:2003 and became operational in December 2016. Standards Australia has withdrawn AS/NZS 4187:2003.

REQUIREMENTS:

To comply with the requirements of Action 3.14, where health service organisations apply AS/NZS 4187:2014, health service organisations will need to:

- a. Complete a gap analysis to determine the current level of compliance with AS/NZS 4187:2014 and document the findings. Access to the standard and relevant references outlined in AS/NZ 4187:2014 are also necessary to ensure that the health service organisation's action plan is comprehensive and addresses gaps within the organisation. Without access to these references the health service organisation cannot adequately assess gaps and can therefore not adequately plan for them.

- b. Develop and document a detailed implementation plan using quality improvement principles specifying timeframes, milestones and deliverables to enable full implementation of AS/NZS 4187:2014 over a five year period, from December 2016
- c. Implement the plan and demonstrate progress toward implementation.

Health service organisations undergoing interim accreditation to the NSQHS Standards are expected to substantially implement AS/NZS 4187:2014 on the establishment of the health service organisation. However, where they have not, they will be required to meet all of requirements a to c listed above for health service organisations to comply with Action 3.14.

Accrediting agencies are required to:

- a. Assess progress on implementation plan at each accreditation assessment
- b. Rate Action 3.14 as satisfactorily met only if a health service organisation demonstrates progress towards full implementation as set out in their implementation plan for AS/NZS 4187:2014
- c. Ensure the implementation plan is not repeatedly revised to delay project deliverables until the end of the five year period.