# ADVISORY

## TITLE

Reprocessing of reusable medical devices in health service organisations

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<th>Advisory number</th>
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<td>Compliance with this advisory</td>
<td>It is mandatory for approved accrediting agencies to implement this Advisory</td>
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</table>
| Information in this advisory applies to | All approved accrediting agencies  
                                      | All health service organisations |
| Attachment          | n/a              |
| Notes               | Update assessment requirements related to water quality and ongoing monitoring of water quality. |
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| To be reviewed      | January 2020     |
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 most commonly used 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 Standards Australia has withdrawn the previous version of this Standard. AS/NZS4815:2006 - 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, and is still operational.

Health service organisations and state and territory health departments have raised concerns with the Commission regarding implementation of AS/NZS 4187:2014. The Commission has commenced a review of implementation issues with AS/NZS 4187:2014. The intended outcome of the review is to clarify the minimum requirements needed to comply with Action 3.14 in the NSQHS Standards. The Commission review is expected to be completed by November 2019.
REQUIREMENTS:

To comply with the requirements of Action 3.14 until the review is complete and further advice is issued, health service organisations should:

a. Complete a gap analysis to determine the current level of compliance with AS/NZS 4187:2014 for all areas other than water quality input (Section 7 - Validation) and water quality monitoring requirements (Section 8 – Routine Monitoring and Control) and document the findings.

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 for all sections of the standards except Section 7 and 8.

c. Demonstrate progress toward implementing the plan, noting health service organisations are permitted to:
   - Return to or maintain pre AS/NZS 4187:2014 water quality input requirements and water quality monitoring requirements
   - Revise or delay implementation plans until the Commission clarifies the minimum requirements to comply with Action 3.14 in November 2019.

Health service organisations that are newly established and eligible to undergo interim accreditation to the NSQHS Standards are expected to comply with requirements a and b above.

Accrediting agencies are required to:

a. Ensure a gap analysis is completed
b. Assess progress on the implementation plan at each accreditation assessment, excluding Section 7 and 8 of AS/NZS 4187:2014.
c. Rate Action 3.14 as satisfactorily met where a health service organisation demonstrates progress towards its implementation plan for AS/NZS 4187:2014.