

# SELF ASSESSMENT SECTION 7

## AS/NZS 4187:2014 REPROCESSING OF REUSABLE MEDICAL DEVICES IN HEALTH SERVICE ORGANIZATIONS

Standard	NSQHS 3 Preventing and Controlling HAI
Auditor	
Audit Period	
LHD	
Cluster	
Facility	
Division	
Ward/Dept	
Service Type	
Audit Date	
Item Name	
Questionnaire Instruction	<p>This self-assessment is your gap analysis for SECTION 7 AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. This section is related to validation.</p> <p>Questions will be answered with: YES, NO, N/A or Work in Progress (WIP). WIP means that you are only part way through compliance for that particular question.</p> <p><b>NOTE: THESE QUESTIONS ARE FOR YOUR UNIT ONLY.</b></p> <p>You will need a copy of AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations when answering the questions as there are many references to Sections, tables and clauses within the questions.</p> <p><b>NOTE: See AS/NZS 4187:14 Guidance to Section 7, Page 95, A7.1 - 7.5.2.</b></p>

1. If any new equipment has been installed or equipment relocated since November 2014, was the following undertaken for each individual piece of equipment:
1. Was Operational Qualification performed and documented upon installation or relocation of reprocessing equipment in accordance with the applicable Standards and Manufacturers' Instructions?
  2. Was Performance Qualification performed and documented upon installation or relocation of reprocessing equipment in accordance with the applicable Standards and Manufacturers' Instructions?
- NOTE: If unable to answer YES for all equipment, document as WIP. This will need to be documented in the Action Plan for each individual piece of equipment.**
- Yes
  - No
  - N/A
  - WIP
- Comments:**

2. Does equipment purchased or relocated since November 2014 meet the manufacturers' specifications for water quality?

- Yes
- No
- N/A
- WIP

**Comments:**

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3. Is there a documented water quality testing and reporting schedule as per Table 7.2 - *Water quality used for reprocessing RMDs*?

- Yes
- No
- N/A
- WIP

**Comments:**

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4. If the water quality testing are higher than the recommended levels (as per Table 7.2), have these results been escalated and reported to the line Director?

- Yes
- No
- N/A
- WIP

**Comments:**

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5. Is planning underway for the installation of a reverse osmosis (RO) water treatment plant and the compatibility of reprocessing equipment been assessed with the reprocessing equipment manufacturer?

- Yes
- No
- N/A
- WIP

**Comments:**

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6. Is there ongoing consultation and an agreement with the supplier of local water to notify the HSO of changes likely to affect the quality of potable water?

[\(NOTE: information may be sent to Engineering Department, Local Council or Public Health Unit\)](#)

- Yes
- No
- N/A
- WIP

**Comments:**

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7. For steam sterilisers installed since November 2014, were tests conducted prior to equipment installation to demonstrate the water supplied to the steam generator is in accordance with [EN 285 Table B1- contaminants in condensate and feed water] and the results recorded?
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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8. [For Units that have a dedicated steam generator.](#)

If the feedwater is not treated chemically, is there a water testing and reporting schedule to comply with the requirements in [EN 285 Table B1 - contaminants in condensate and feed water]?

- Yes
- No
- N/A
- WIP

**Comments:**

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9. Has a steam purity and dryness tests been scheduled and performed in the Installation Qualification /Operational Qualification in accordance with EN 285 see table 10.1, Table B1 and Table E2?

[NOTE: steam quality testing does not apply to small steam sterilisers that utilise distilled or RO water for steam generation.](#)

- Yes
- No
- N/A
- WIP

**Comments:**

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10. Has Operational Qualification [OQ] been performed and documentation supplied by the reprocessing equipment manufacturer in accordance with the applicable National or International Standards? (See 7.3)

- Yes
- No
- N/A
- WIP

**Comments:**

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11. Does Operational Qualification occur following any changes, e.g. installation, modification or relocation of equipment, major breakdowns/repair, service is changed, introduction of new equipment, change to load configurations?
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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12. Is Performance Qualification [PQ] planned and performed in accordance with National and International Standards? [see 7.4, 10.5 and Table 10.1]
1. Immediately after Installation Qualification and Operational Qualification for newly installed or relocated equipment?
  2. When repairs are made or a service is changed that may adversely impact the quality of the RMD?
  3. When existing equipment is modified to deliver a new process?
  4. When introducing new or modified RMDs, packaging or loading configurations (unless there is equivalence to a previously qualified reference load, RMD/product family, packaging or loading pattern has been demonstrated)?
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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13. Are there validated cleaning processes (manual and washer/disinfector) used for RMDs – e.g. soil test, protein test, residual chemical test?
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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14. Has Performance Qualification of thermal or chemical disinfecting processes using washer/disinfectors performed in accordance with the relevant ISO 15883 series of standards? (See 1.3 - Normative References]
- Yes
  - No
  - N/A

**Comments:**

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15. Does the Unit's validation process for packaging include:
1. Sealing processes for pouches, reels and bags?
  2. Wrapping processes for folding and closing of sterilisation wraps?
  3. Processes for filling and closing of reusable containers.
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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16. Are the heat sealers tested (according to manufacturers' instructions) and results documented to indicate that they consistently produce a conforming sterile barrier system?
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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17. Has the manufacturer provided evidence that the design of reusable containers allows sterilising and maintenance of sterility within the contents of the container (see 7.4.4.4)?
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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18. Does the annual Performance Qualification (PQ) documentation include (see 7.4.5):
1. the sterility assurance level for each steriliser
  2. biological indicator results and indication of location within the load
  3. wrapping/packaging PQ
  4. the physical parameters of the sterilising process i.e. holding time, pressure and temperature
  5. load mass/contents
  6. each steriliser and cycle type
  7. cycle type performed concurrently, e.g. 3 in a row
- Yes
  - No
  - N/A
  - WIP

**Comments:**

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19. Are all product families considered for annual PQ (see 7.4.5)?

- Yes
- No
- N/A
- WIP

**Comments:**

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20. Have validation reports for each separate process been reviewed and approved by a designated person (on behalf of the Health Service Organisation) and reports are retained within the reprocessing unit?

- Yes
- No
- N/A
- WIP

**Comments:**

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21. Is a summary of the annual validation reports presented or discussed to a nominated clinical Health Service Organisation Committee e.g. Patient Safety, Infection Prevention and Control, Operating Theatre?

- Yes
- No
- N/A

**Comments:**

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**About the Healthcare Associated Infections Program**

The CEC's HAI program aims to assist local health districts and specialty health networks to improve systems to manage and monitor the prevention and control of HAIs.

For further information, please visit

<http://www.cec.health.nsw.gov.au>

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