

PEER REVIEW AUDIT

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 aim of this Peer Review Audit is to provide an independent review of your Units compliance with - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations.</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>NOTE: THESE QUESTIONS ARE FOR YOUR UNIT ONLY.</p> <p>The auditor will need a copy of AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations and access to other Standards listed on page 8 (1.3 Normative References) when answering the questions as there are many references to Sections, tables and clauses within the questions.</p> <p>The auditor(s) will also require access to your self-assessment results.</p> <p>Evidence related to any questions may need to be viewed.</p>

SECTION 1 - GENERAL

1. Does the Unit have access to the relevant Standards as specified in AS/NZS 4187:2014 - page 8 - 1.3 Normative References?
 - Yes
 - No
 - N/A
 - WIP

Comments:

SECTION 2 - QUALITY MANAGEMENT

2. Does this Unit have current Policy or Procedures or Guidelines for the recall of RMDs and includes the following (see 2.5.3.2)?
1. Examples of situations where recall of RMDs is warranted?
 2. Timeframes for recall and action?
 3. Identification of the person/s responsible for coordinating recall activities?
 4. Identification of the persons to be notified in the event of recall?
 5. Identification of the person/s responsible for retrieving distributed RMDs?
 6. Identification of the person/s responsible for reporting on recall activity?
 7. Identification of the quantities of recalled RMDs with RMD distribution records?
 8. Identification of the critical information to be included in the recall notice?
- Yes
 - No
 - N/A
 - WIP

Comments:

3. Does this Unit have current Policy or Procedures or Guidelines for training and competency assessment of staff? (See 2.2.2)
- Yes
 - No
 - N/A
 - WIP

Comments:

4. Does this Unit have current continuity plan for emergencies, e.g. equipment breakdowns, recalls? (See 2.2.2)
- Yes
 - No
 - N/A
 - WIP

Comments:

5. Is this Unit part of a documented and approved organisational structure that enables the Unit to meet the requirements of AS/NZS 4187:2014? (See 2.3.1)
- Yes
 - No
 - N/A
 - WIP

Comments:

6. To ensure products (RMDs, reprocessing equipment and their accessories) conform to specified purchasing requirements, does the policy/procedure/guideline for purchasing include:
1. Criteria for product selection and evaluations are risk based, including WHS requirements?
 2. Sterilising Manager/Supervisor involved in the selection process prior to purchase?
 3. Evaluation to ensure compatibility with reprocessing systems available within the Unit?
 4. Requirements for RMD, RMD accessories and reprocessing equipment are in the ARTG?
 5. Reprocessing equipment comply with regulatory and safety standards?
 6. Reprocessing equipment and accessories have operational instructions for use?
 7. Provision of documentation and validation reprocessing instructions in accordance with ISO 17664 - Including loan and trial RMDs?
 8. Acceptance criteria when taking delivery?

(See 2.4.2)

- Yes
- No
- N/A
- WIP

Comments:

7. Do the tracking systems for Sterilising process records (See 2.2.3(d)) identify the following for each RMD:
1. Sterilisation – Sterilising process records? (See 2.2.3(d))
 2. Date of sterilisation and batch number?
 3. Identification of steriliser?
 4. Identification of RMD?
 5. Identification of person responsible for loading RMDs?

- Yes
- No
- N/A
- WIP

Comments:

8. Does the Unit have documented evidence of action taken for non-conformance of equipment? (See 2.4.4.3)
- Yes
 - No
 - N/A
 - WIP

Comments:

9. Has a plan been developed to audit and monitor compliance with the Standards? (See 2.5.1)
- Yes
 - No
 - N/A
 - WIP

Comments:

10. Does the Unit have documented evidence and risk assessment of action taken for non-conformance of equipment? (See Appendix A2.5.2) This includes:

1. Cleaning processes?
2. Disinfecting processes?
3. Sterilising processes?
4. Packaging processes?

(See 2.5.2)

- Yes
- No
- N/A
- WIP

Comments:

11. Does the Recall policy/procedure/guideline include the following requirements for reporting of recalled RMDs:

1. Identification and circumstances that initiated a recall of RMDs?
2. Identification of the recalled RMD and reconciliation of quantities if the recall RMD with RMD distribution records?
3. Identification of patients impacted by the recall activity and follow up action?
4. Identification of the root cause for the recall?
5. Identification of corrective action taken in the relation to the recall?
6. Identification of the consequences of the recall?

(See 2.5.3.3)

- Yes
- No
- N/A
- WIP

Comments:

SECTION 3 - PROCESSING AGENT CHARACTERISATION (CHEMICALS)

12. Are all the cleaning agents, instrument grade chemical disinfectants and liquid chemical sterilising agents that are intended for use on RMDs listed on the chemical register? (See 3.1.2)

- Yes
- No
- N/A
- WIP

Comments:

13. Has the manufacturer been consulted regarding the compatibility of the available water quality with the cleaning agent (IF APPLICABLE) (See 3.1.3)?

- Yes
- No
- N/A
- WIP

Comments:

14. Are high-level instrument grade disinfectants used for disinfection of a semi-critical RMD, e.g. channelled endoscopes? (See 3.2 and Section 5)

- Yes
- No
- N/A
- WIP

Comments:

15. Does the HSO have the SDS for each sterilising agent (chemical) used in the Unit from the Manufacturer – e.g. Peracetic Acid, Aldehydes, Hydrogen Peroxide, Ethylene Oxide, Formaldehyde? (See 3.4)

- Yes
- No
- N/A
- WIP

Comments:

16. Is there documented evidence available for the compatibility of cleaning, disinfectant and sterilising agents used with the RMD and the associated equipment – e.g. Instructions for Use for the Agent, RMD and the associated equipment? (See 3.6 and 5.3)

- Yes
- No
- N/A
- WIP

Comments:

17. If the Unit is reprocessing RMDs with agents (cleaning, disinfecting, sterilising) that are NOT consistent with the validated Instructions for Use, has the following been undertaken:

1. Performance of a risk assessment, validated the process and documented the actions taken?
2. Discussed the possible effects of repeated exposure of the RMD to the proposed agent(s) and/or process with the manufacturer of the RMD and documented the outcomes?

(See 3.6)

- Yes
- No
- N/A
- WIP

Comments:

SECTION 4 - PROCESS CHARACTERISATION AND EQUIPMENT CHARACTERISATION

18. Has the Unit obtained all relevant details from the manufacturer/supplier on equipment that performs cleaning, disinfecting and sterilising? (Details include: specifications/technical information/advice - see 4.2 a-h)

(Requires evidence of a documented list with equipment, equipment type, manufacturer) (see 4.3.1 a-g)

- Yes
- No
- N/A
- WIP

Comments:

19. Can the steam steriliser be programmed to sterilise all Product families required for the HSO? (see 4.2 and 7.4.1 e) - [for central sterilising unit only](#)

- Yes
- No
- N/A
- WIP

Comments:

20. Where software is used for controlling/monitoring cleaning, disinfecting, packaging and sterilising processes, have they been validated to ensure they comply with its design intention (e.g. preventative maintenance, performance qualification, resolving software problems with the manufacturer/supplier, identification of high-risk issues such as set parameters not met)? (See 4.3.2)

- Yes
- No
- N/A
- WIP

Comments:

SECTION 5 - PRODUCT DEFINITION

21. Does the Health Service Organisation (not the Unit) have a process to classify RMDs into Critical, Semi-critical and Non-critical (as per Spaulding Classification)?

NOTE: This is to ensure that RMDs follow a validated cleaning process, it has the correctly classified reprocessing type identified and assigned? (see 5.1.2 i-iii and Table 5.1)

- Yes
- No
- N/A
- WIP

Comments:

22. Have all RMDs been classified into Product Families?

Classification of RMDs into product families will assist in developing processing conditions? (Refer to ISO/TS 17665-3 and ISO 17664 and see 5.2)

- Yes
- No
- N/A
- WIP

Comments:

23. Is there a process to identify where limiting/process values such as exposure time, pressure and temperature (see 5.3) are exceeded?

- Yes
- No
- N/A
- WIP

Comments:

24. Does the Unit have an effective segregation of clean and dirty activities and the segregation that prevents cross contamination? (See 5.6.2)

- Yes
- No
- N/A
- WIP

Comments:

25. Does the cleaning of the reprocessing area meet the cleaning risk rating and auditing requirements of NSW Health Environmental Cleaning Policy PD2012_061? (See 5.6.10)

- Yes
- No
- N/A
- WIP

Comments:

SECTION 6 - PROCESS DEFINITION

26. If the Unit has a 'flash steriliser':

1. Has it been defined and validated by the central sterilising department?
2. Have a process to document all RMDs that use this method?

(See 6.1.2)

- Yes
- No
- N/A
- WIP

Comments:

27. If the Unit has a 'fast track' process:

1. Has it been defined and validated?
2. Have a process to document all RMDs that use this method?

(See 6.1.2)

- Yes
- No
- N/A
- WIP

Comments:

28. Does the Unit have suitable reprocessing equipment for reprocessing of RMDs e.g. prior to purchasing specialised equipment, has the Unit manager assessed that it has the correct reprocessing equipment for the specialised RMDs? (See 6.2.1 and 2.2.2)

- Yes
- No
- N/A
- WIP

Comments:

SECTION 7 - VALIDATION

29. 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?
- (See 7.1)

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:

30. Manager question: 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] and the results recorded? (See 7.2.3.2)

- Yes
- No
- N/A
- WIP

Comments:

31. 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]? (See 7.2.3.2)

- Yes
- No
- N/A
- WIP

Comments:

32. For steam quality testing: 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)? (Also see 7.2.3.2)

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:

- 33.** 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:

- 34.** Is Performance Qualification [PQ] planned and performed in accordance with National and International Standards? (see 10.5 and Table 10.1)
1. Immediately after IQ and OQ 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? (See 10.5)
 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:

- 35.** Are the wrappings tested (according to manufacturers' instructions) and documented to indicate that it consistently produces a conforming Sterile Barrier System. (See 7.4.4.3)
- Yes
 - No
 - N/A
 - WIP

Comments:

- 36.** Does the annual PQ documentation include:
1. The sterility assurance level of 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?
- (See 7.4.5)

- Yes
- No
- N/A
- WIP

Comments:

37. 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? (See 7.5.2)

- Yes
- No
- N/A
- WIP

Comments:

38. 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? (See 7.5.2)

- Yes
- No
- N/A
- WIP

Comments:

39. 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? (See 7.5.3)

- Yes
- No
- N/A
- WIP

Comments:

SECTION 8 - ROUTINE MONITORING AND CONTROL

- 40.** Is there a plan for microbiological surveillance of all flexible endoscopes with channels and the AER? The plan should include:
1. Frequency
 2. Responsibility
 3. Recording if endoscope is either terminally sterilised or high level disinfection on the pathology request form
 4. Sign off of pathology reports
 5. Trend reporting to the health service organisation infection prevention and control committee (See 8.5)
-

- Yes
- No
- N/A
- WIP

Comments:

41. Does the sterilising equipment monitoring and control program comply with Table 8.2?

- Yes
- No
- N/A
- WIP

Comments:

SECTION 9 - RELEASE OF RMDs FOLLOWING REPROCESSING

42. Do the criteria for release of a RMD from reprocessing comply with Table 9.1?

- Yes
- No
- N/A
- WIP

Comments:

43. Does the Unit have a traceability/electronic tracking system? (See 9.1 - 9.4)

- Yes
- No
- N/A
- WIP

Comments:

44. Do the Unit procedures for the maintenance of the sterility of released RMDs comply with the list on page 103, A9.5 a-i?

NOTE: This list includes handling, storage and transport.

- Yes
- No
- N/A
- WIP

Comments:

45. Have the staff in the Unit been provided education of the handling, transport and storage of reprocessed RMDs?
- Yes
 - No
 - N/A
 - WIP

Comments:

SECTION 10 - MAINTAINING PROCESS EFFECTIVENESS

46. Are service level agreements/contracts in place with qualified service providers to provide the final reports [see 10.3.3] following planned:
1. Preventive Maintenance?
 2. Recalibration?
 3. Reassessment of process effectiveness?
- Yes
 - No
 - N/A
 - WIP

Comments:

47. Is preventative maintenance of all equipment planned and undertaken in accordance with documented procedures by the equipment manufacturer?

See tables:

10.1 - recommended frequency for the recalibration, preventative maintenance and testing of sterilising and associated equipment

10.2 - recommended frequency for the recalibration, preventative maintenance and testing of cleaning, disinfecting and packaging equipment

10.3 - recommended frequency for the recalibration, preventative maintenance and testing of automated endoscope reprocessors (AER)

- Yes
- No
- N/A
- WIP

Comments:

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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