ORAL HEALTH SERVICE 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	The 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. 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. NOTE: THESE QUESTIONS ARE FOR YOUR LHD/SHN. 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. The auditor(s) will also require access to your self assessment results. Evidence related to any questions may need to be viewed.

Section 1 - Governance

1. Name of Peer Review Auditor(s), Position Title and Facility

Comments:

2. Are there any further questions from the Self Assessment that the Peer Review team will follow up? (list question number and in comments, list the reasons)

Comments:

3. Does this Oral/Dental Health Service/Clinic have access to the relevant Standards as specified in AS/NZS 4187:2014? (See Table 1.3 - Normative References in AS/NZS 4187:2014?)
   ○ Yes
   ○ No

   Comments:

Section 2 - Policy, Procedures and Guidelines (2.1 - 2.2.2)

4. Does this Oral/Dental Health Service/Clinic have current Policy /Procedures for routine monitoring and control of:
   1. Cleaning processes, including compatibility of cleaning with the RMDs? (See 6.2.1)
   2. Disinfection processes - with ensuring that items are not stored in liquid disinfectant? (See 6.1.1)
   3. Sterilising processes?

   □ Yes
   □ No
   □ N/A for point 2
   □ WIP

   Comments:

5. Does this Oral/Dental Health Service/Clinic have current Policy or Procedures or Guidelines for the handling of specialised RMDs including:
   1. RMDs on loan?
   2. RMDs on trial? see 2.4.2(e)
   3. RMDs returned from repair?
   4. RMDs on consignment?

   NOTE: for those not applicable, document in Comments Section
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP

   Comments:

6. Does this Oral/Dental Health Service/Clinic have current Policy or Procedures or Guidelines for the traceability of reprocessed RMDs (critical and/or semi-critical)?
   - ○ Yes
   - ○ No
   - ○ WIP

   Comments:

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7. Does this Oral/Dental Health Service/Clinic have current Policy or Procedures or Guidelines for validation and routine control for:
   1. Cleaning processes?
   2. Disinfection processes?
   3. Sterilising processes?

   (See Figure 7.1 - validation flowchart for cleaning, disinfecting and sterilising processes)
   - □ Yes
   - □ No
   - □ N/A for point 2
   - □ WIP

   Comments:

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8. Does this Oral/Dental Health Service/Clinic have current Policy or Procedures or Guidelines for the recall of RMDs and it includes (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 critical information to be included in the recall notice?
   8. Identification of the quantities of recalled RMDs with RMD distribution records?
   9. Communication and reporting requirements, including escalation and risk assessment?
   - ○ Yes
   - ○ No
   - ○ WIP

   Comments:

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9. Does this Oral/Dental Health Service/Clinic have current Policy or Procedures or Guidelines for training and competency assessment of staff?
   - ○ Yes
   - ○ No
   - ○ WIP

   Comments:

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10. Does this Oral/Dental Health Service/Clinic have current continuity plan for emergencies – e.g. equipment breakdowns, recalls, loss of service?

- ○ Yes
- ○ No
- ○ WIP

Comments:

Section 2.2.3 - Records

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11. Does this Oral/Dental Health Service/Clinic hold records for monitoring and servicing of reprocessing equipment?
NOTE: if records are held by another department, document location in the Comments Section

- ○ Yes
- ○ No

Comments:

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12. Does this Oral/Dental Health Service/Clinic hold records for reprocessing print-outs/documentation?
NOTE: if records are held by another department, document location in the Comments Section

- ○ Yes
- ○ No

Comments:

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13. Does this Oral/Dental Health Service/Clinic hold records for the cleaning of reprocessing equipment – e.g. checklist?
NOTE: if records are held by individual clinics, document in Comments Section

- ○ Yes
- ○ No

Comments:

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14. Does this Oral/Dental Health Service/Clinic hold records for environmental cleaning audit results for each dental clinic?
NOTE: if records are held in individual clinics, document in Comments Section

- ○ Yes
- ○ No
- ○ WIP

Comments:

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15. Does this Oral/Dental Health Service/Clinic hold records for staff training and evidence of staff competency/assessments?
NOTE: if records are held in individual clinics, document in Comments Section

- Yes
- No
- WIP

Comments:

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16. Does this Oral/Dental Health Service/Clinic hold records for maintenance of RMDs or reprocessing equipment?
NOTE: if these are held onsite for individual clinics – e.g. Biomedical Engineering – document in Comments Section

- Yes
- No
- WIP

Comments:

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17. Does this Oral/Dental Health Service/Clinic hold records for Installation Qualification, Operational Qualification and Performance Qualification for reprocessing equipment?
NOTE: if these are held onsite for individual clinics – e.g. Biomedical Engineering – document in Comments Section

- Yes
- No
- WIP

Comments:

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18. Does this Oral/Dental Health Service/Clinic hold records for process deviation reports and where applicable, records of corrective action and/or preventative action?
NOTE: if these are held onsite for individual clinics, document in Comments Section

- Yes
- No
- WIP

Comments:

Section 2.2.4 - Control of documents and records

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19. Do all Policy or Procedures or Guidelines meet HSO policy/procedure/guideline frameworks (including authorisation and publication)?

- Yes
- No

Comments:

2.3.1 - Management Responsibility

20. Is this Oral/Dental Health Service/Clinic part of a documented and approved organisational structure that enables it to meet the requirements of AS/NZS 4187:2014?
NOTE: the organisational structure includes all dental clinics
- ○ Yes
- ○ No

Comments:

2.3.3 - Reprocessing within the Oral/Dental Health Service/Clinic

21. Does the person directly responsible for managing/supervising the reprocessing of RMDs:
1. Have relevant qualifications and/or experience in reprocessing RMDs?
2. Have authority to develop an implementation plan to meet the requirements of AS/NZS 4187:2014?
3. Have authority to implement policies, procedures, guidelines or SOPs to assure the quality and safety of reprocessed RMDs?
4. Have direct involvement in the supervision of the day to day activities within the reprocessing unit of this Oral/Dental Health Service/Clinic?
- ○ Yes
- ○ No
- ○ WIP

Comments:

22. Does this Oral/Dental Health Service/Clinic have a formal/planned orientation/induction, training program and competency assessment for staff who perform reprocessing?
- ○ Yes
- ○ No
- ○ WIP

Comments:

2.3.4 - 2.3.5 - Equipment and Contracts

23. Does this Oral/Dental Health Service/Clinic have external contracts/Service Level Agreements for maintenance, preventative maintenance, performance qualification and they include responsibility and compliance with AS/NZS 4187:2014?
- ○ Yes
- ○ No
- ○ WIP

Comments:

2.4 - 2.4.2 - Purchasing

See Question 34

Section 2.4.3 - 2.4.3.2 - Traceability Records

24. Does the traceability systems for Sterilising process records identify the following for each RMD:
Sterilisation
- sterilising process records? See 2.2.3(d)
- date of sterilisation and batch number?
- identification of steriliser?
- identification of RMDs?
- identification of person responsible for loading RMDs?

Other records includes [but not limited to]
- results of performance tests?
- results of chemical and biological monitoring?
- sterilising agent, batch number and expiry date?
- documented evidence of attainment of process parameters?
- identification of person responsible for releasing the RMDs?

○ Yes
○ No
○ WIP

Comments:

Section 2.4.4 - 2.4.4.3 - Monitoring and measuring equipment and documentation

25. Are records available of calibration reports from each piece of equipment, including adjustments made and certification number of the calibration device?

○ Yes
○ No
○ WIP

Comments:

Section 2.5. - 2.5.4 - Recall and preventative action

26. Is there a reporting template for reporting of recalled items and the template includes:
1. Identification of potential cause/s?
2. Implementation of a preventive action plan?
3. Documentation of action?
4. Evaluation of preventative actions?
5. Risk assessment
6. If required, implementation of additional preventative actions?

□ Yes
□ No
□ WIP
□ Will also be reported in IIMs

Comments:

Section 3 – Reprocessing Agent Characterisation

27. Have staff been provided education on sterilising/disinfectant agents and how they must not be used outside the recommended conditions specified by the manufacturer?

○ Yes
○ No

Comments:

28. Have all staff involved in the handling and use of cleaning agents, disinfectants and chemical sterilising agents been trained in:

1. Safe handling?
2. Use?
3. Storage?
4. Procedures for spills?
5. Procedures for exposure management?

○ Yes
○ No

Comments:

Section 4 – Process Characterisation and Equipment Characterisation

29. Has this Oral/Dental Health Service/Clinic 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)

○ Yes
○ No

Comments:

30. Can the steam steriliser be programmed to sterilise all Product Families required for the Health Service Organisation? (see 7.4.1 e)

NOTE: The Health Service will be required to determine what RMDs belong in a product family first

○ Yes
○ No
○ N/A
○ WIP

Comments:

31. Does this Oral/Dental Health Service/Clinic's reprocessing equipment comply with the following Standard? Steam sterilisers—Small: [EN 13060]

○ Yes
○ No
○ N/A

Comments:

Section 5 - 5.1 - 5.5.3 - Product definition

32. Have all RMDs been classified into Product Families?
NOTE: Classification of RMDs into product families will assist in developing processing conditions. [Refer to ISO/TS 17665-3 and ISO 17664 and Section 5.2]

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

33. Does this Oral/Dental Health Service/Clinic have a process to identify where limiting/process values such as exposure time, pressure and temperature (see 5.3) are exceeded?

- ○ Yes
- ○ No

Comments:

34. Is there as process to ensure that the items (RMDs and their packaging) are not compromised during all stages in the pre-disinfection and pre-sterilising workflow?

- ○ Yes
- ○ No

Comments:

Section 5 - 5.6 - 5.6.14 - Facility Design

35. Does this Oral/Dental Health Service/Clinic have an effective segregation of clean and dirty activities and the segregation that prevents cross contamination?

- ○ Yes
- ○ No

Comments:

36. Does this Oral/Dental Health Service/Clinic have a unidirectional work flow of dirty to clean?
NOTE: this minimises the risk of contamination of a cleaned, disinfected or sterilised RMD.

- ○ Yes
- ○ No

Comments:

37. Is water of the required quality & specified for reprocessing RMDs? (See Section 7.2.3.1 and Table 7.2 - check Standards Australia for a revision of this table)

- ○ Yes
- ○ No

Comments:

38. Does the cleaning of the reprocessing area meet the cleaning risk rating and auditing requirements of NSW Health Environmental Cleaning Policy PD2012_061?
NOTE: This may vary for each clinic. Use the comments section to write the details for each clinic
○ Yes
○ No

Comments:

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39. Is entry into the reprocessing facility restricted to authorised personnel and not a common walk through to other areas?
○ Yes
○ No
○ N/A

Comments:

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40. Does the ventilation in cleaning areas and sterile storage areas comply with AS 1668.2?
○ Yes
○ No

Comments:

Section 6 – Process Definition

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41. Does this Oral/Dental Health Service/Clinic have suitable reprocessing equipment for the reprocessing of RMDs (includes both routine and specialised RMDs)? (See 2.2.2)
○ Yes
○ No

Comments:

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42. Do all sterilisers have a drying cycle for wrapped RMDs? (See 6.4.1)
○ Yes
○ No
○ N/A

Comments:

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43. Does this Oral/Dental Health Service/Clinic have the manufacturer's instructions for all types of sterilisers?
○ Yes
○ No
○ N/A

Comments:

Section 7 - Validation

44. 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 Instillation 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

Comments:

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45. Does this Oral/Dental Health Service/Clinic'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

Comments:

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46. 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

Comments:

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47. Is a summary of the annual validation reports presented or discussed to a nominated clinical Health Service Organisation Committee, e.g. Patient Safety, Oral Health Management?

○ Yes
○ No
○ N/A

Comments:

Section 8 - Routine monitoring and control

48. Does the sterilising equipment monitoring and control program comply with Table 8.2 - *Requirements for routine monitoring and control of sterilising equipment*?

○ Yes
○ No
○ N/A

Comments:

Section 9 - Release of RMDs following reprocessing

49. Does this Oral/Dental Health Service/Clinic have a traceability/electronic tracking system?

○ Yes
○ No

Comments:

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50. Have this Oral/Dental Health Service/Clinic staff been provided education of the handling, transport and storage of reprocessed RMDs?

○ Yes
○ No

Comments:

Section 10 - Maintaining process effectiveness

51. Are service level agreements/contracts in place with qualified service providers to provide the final reports [see 10.3.3] following planned:

1. Preventative maintenance?
2. Recalibration?
3. Reassessment of process effectiveness?
4. Annual requalification of processing equipment?

○ Yes
○ No
○ N/A

Comments:

Notes

52. Notes from the walk around the Unit(s) - these can be risks identified, good initiatives, identified good practices or issues that may require escalation

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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