SELF ASSESSMENT SECTIONS 8 – 10

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	This self-assessment is your gap analysis for SECTIONS 8- 10 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. These sections are related to routine monitoring and control; release of RMDs following reprocessing; and maintaining process effectiveness. 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 UNIT ONLY. 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. NOTE: See AS/NZS 4187:14 Guidance to Sections 8 – 10, Page 102 A8.1 - 10.5.

Section 8 - Routine monitoring and control

1. 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

- Yes
- No
- N/A
- WIP

Comments:

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2. Is there a process to ensure that loaned flexible endoscopes or those returned from repair have microbiological testing within 72 hours of receipt?

- Yes
- No
- N/A
- WIP

Comments:

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3. Is there routine monitoring and control of packaging procedures that ensure the packaged items produced during routine operation meets the specification for:

1. wraps?
2. reusable rigid sterilising containers?
3. laminates?
4. self-seal laminates?
5. autoclave bags?

- Yes
- No
- N/A
- WIP

Comments:

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4. Is there routine monitoring and control for heat sealers (see 8.6)?

- Yes
- No
- N/A
- WIP

Comments:

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5. 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
- WIP

Comments:

Section 9 - Release of RMDs following reprocessing

6. Do the criteria for release of a RMD from reprocessing comply with table 9.1 (criteria for release of an RMD from reprocessing)?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

7. Does the Unit have a traceability/electronic tracking system?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

8. Are critical and semi-critical RMDs handled in a manner that protects the integrity of packaging until point of use?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

9. Are critical and semi-critical RMDs transported in a manner that protects the integrity of packaging until point of use?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

10. Is the storage of critical and semi-critical RMDs in a manner that protects the integrity of packaging until point of use?
    - Yes
    - No
    - N/A
    - WIP

    Comments:

11. 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:

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

    Comments:

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13. Is there a risk assessment or audit of transport systems to ensure that the systems protect the package integrity until the point of use?
    - Yes
    - No
    - N/A
    - WIP

    Comments:

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14. Is there restricted access to the Unit's storage areas for critical and semi-critical RMDs, including consumables?
    - Yes
    - No
    - N/A
    - WIP

    Comments:

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15. Are there dedicated dust free shelving, cupboards, drawers or containers for sterile RMDs and consumables?
    - Yes
    - No
    - N/A
    - WIP

    Comments:

Section 10 - Maintaining process effectiveness

16. 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
- WIP

Comments:

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17. 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:

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18. Is the outcome of assessments, including the rationale for decisions reached documented, e.g. changing of chemicals, relocating equipment, changing packaging material, major repairs, changing load configuration?
NOTE: the assessment of change may require a repeat of instillation qualification, operational qualification or performance qualification (see 10.5)

- 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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