

SELF ASSESSMENT SECTION 5

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 5 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. This section is related to the reprocessing of RMDs.</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>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>NOTE: See AS/NZS 4187:14 Guidance to Section 5, Page 86, A5.1 - A5.6.14.</p>

Section 5 - 5.1 - 5.5.3 Product definition

1. 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:

2. Are senior staff/manager within the central sterilising unit consulted regarding the Spaulding Classification requirements for all Critical and Semi-Critical RMDs to ensure that the correct reprocessing type is identified and assigned? (see 5.1.2 i-iii and Table 5.1)

NOTE: This consultation should occur for RMDs that are processed inside and outside the central sterilising unit, e.g. satellite sites such as endoscopy, cardiology, outpatient clinics, medical imaging.

- Yes
- No
- N/A
- WIP

Comments:

3. 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:

4. Does the Unit have 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:

5. 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
- N/A
- WIP

Comments:

6. Does the sterile barrier system for RMDs comply with ISO 11607-1 and ISO 11607-2.?

- Yes
- No
- N/A
- WIP

Comments:

7. Does the protective packaging protect the Sterile Barrier System (SBS) and contents until the point of use (e.g. dust cover)?
- Yes
 - No
 - N/A
 - WIP

Comments:

8. Is any protective packaging (e.g. instrument tip protectors applied prior to sterilisation) compatible with the sterilising process?
- Yes
 - No
 - N/A
 - WIP

Comments:

Section 5 - 5.6 - 5.6.14 Facility Design

9. Does the Unit have an effective segregation of clean and dirty activities and the segregation that prevents cross contamination?
- Yes
 - No
 - N/A
 - WIP

Comments:

10. Does the Unit 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
- N/A
- WIP

Comments:

11. Is the reprocessing unit free from opening windows?

- Yes
- No
- N/A
- WIP

Comments:

12. Are the finishes/ledges on the walls and other surfaces flush, smooth, non-shedding, water resistant and able to be accessed and withstand frequent cleaning?

- Yes
- No
- N/A
- WIP

Comments:

13. Are floors covered in a sealed, non-slip material that is washable?

- Yes
- No
- N/A
- WIP

Comments:

14. Are all work surfaces, fittings, fixtures, window treatment, shelving and furniture in the reprocessing unit easy to clean and maintained in a good condition?

- Yes
- No
- N/A
- WIP

Comments:

15. Is shelving designed and installed to enable safe handling practices, i.e. they have smooth surfaces that will not damage product, packaging and other materials?

- Yes
- No
- N/A
- WIP

Comments:

16. Are cleaning sink workstations:

1. Dedicated for pre-treatment and/or manual cleaning and rinsing?
2. Of sufficient depth and size to allow a RMD to be completely immersed?
3. Ergonomically designed to allow staff to both fully immerse and to retrieve an RMD safely from the sink without the potential for injury?
4. Designed to provide sufficient bench space to facilitate a unidirectional work flow and to minimise the risk of cross contamination?
5. Not used for handwashing?

- Yes
- No
- N/A
- WIP

Comments:

17. Is water of the required quality and specified for reprocessing RMDs (see Section 7.2.3.1 and Table 7.2)?

- Yes
- No
- N/A
- WIP

Comments:

18. Are workstations:

1. Supplied with sufficient electricity supply, computer terminal points to facilitate safe and effective reprocessing activities?
2. Suitably equipped for preparation and packaging?
3. An adequate size to accommodate packaging materials to be used and are height adjustable?
4. Have an adequate space between workstations for the safe movement of equipment and staff?

- Yes
- No
- N/A
- WIP

Comments:

19. Does the reprocessing facility have adequate lighting to enable thorough visual examination of RMDs?

- Yes
- No
- N/A
- WIP

Comments:

20. Is task lighting and magnification available where required?

- Yes
- No
- N/A
- WIP

Comments:

21. Are bulk storage (e.g. consumables) facilities external to the cleaning and packing areas?

- Yes
- No
- N/A
- WIP

Comments:

22. Is there a dedicated area provided within the steriliser unloading zone for cooling, and where applicable, aeration of sterilised RMDs?

- Yes
- No
- N/A
- WIP

Comments:

23. Is there a dedicated area provided for the storage of reprocessed RMDs that have been released for use?

- Yes
- No
- N/A
- WIP

Comments:

24. Have risks with loan/consignment RMD storage and workflow been resolved?

- 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?

- Yes
- No
- N/A
- WIP

Comments:

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

Comments:

27. Are there sufficient hand hygiene facilities (handwash and alcohol based hand rub) available and accessible in all work areas?
- Yes
 - No
 - N/A
 - WIP

Comments:

28. Are the alcohol based hand rubs and handwash products approved for use by the Health Service Organisation within the reprocessing unit?
- Yes
 - No
 - N/A
 - WIP

Comments:

29. Does the ventilation in cleaning areas and sterile storage areas comply with AS 1668.2?
- Yes
 - No
 - N/A
 - WIP

Comments:

30. Does the disposal of waste comply with the requirements of the local regulatory authorities, NSW Health policy and health service organisation policies?
- 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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