SELF ASSESSMENT SECTION 3

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 SECTION 3 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. This section ensure that units have information for each cleaning agent/s, disinfection and sterilising agent provided by manufacturer/supplier on site. 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 Section 3, Page 83, A3.1 - A3.7.4.

1. Are all Agents used within the Unit listed on the Australian Register of Therapeutic Goods (ARTG)?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

2. 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?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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3. Where the manufacturer of the cleaning agents make claims of their microbicidal effectiveness, do they include the evidence in their technical information? (See 3.5)
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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4. Are Safety Data Sheets (SDS) available for every agent (cleaning, disinfecting and sterilising) used within the Unit?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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5. Does the Unit have copies of the manufacturer's information available (technical information), e.g. microbial efficacy, toxicity/residues, compatibility?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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6. Are cleaning agents used in the Unit suitable for intended purpose as recommended by the manufacturer in their Instructions for Use e.g. manual cleaning, ultrasonic machine?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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7. 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:

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8. Are chemical disinfectant(s) used to process RMDs labelled as an 'Instrument Grade Disinfectant'? (NOT Hospital grade disinfectant)
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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9. Are high-level instrument grade disinfectants used for disinfection of a semi-critical RMD e.g. channelled endoscopes (See Section 5)?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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10. In this Unit, are intermediate or low-level instrument grade disinfectant used for non-critical RMD where required, e.g. tonometer prisms (see Section 5 and Spaulding's Classification System)?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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11. Have staff been provided education on sterilising/disinfectant agents and how they must not be used outside the recommended conditions specified by the manufacturer - e.g. breaking the Peracetic Acid single use cup and diluting for manual cleaning use, using AER for 'surgical instrument sterilisation'?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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12. 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 5.3)

- Yes
- No
- N/A
- WIP

Comments:

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13. 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?

- Yes
- No
- N/A
- WIP

Comments:

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14. Does the Unit have the correct storage facilities for all cleaning, disinfectant and sterilising agents?

- Yes
- No
- N/A
- WIP

Comments:

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15. Has the Unit trained staff in the correct use of PPE for handling agents and the PPE is available at the point of use?

- Yes
- No
- N/A
- WIP

Comments:

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16. Does the Unit have readily accessible information for the safe use, handling and storage of chemicals for workers and the information is available at the point of us?

- Yes
- No
- N/A
- WIP

Comments:

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17. Are staff trained to phone the Emergency Number for a Code Yellow with a large chemical spill that is unable to be contained with the Spill Kit?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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18. Are appropriate Spill Kits located near storage/use of chemical agents?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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19. Has the impact on the environment by agents which could be released during the use of cleaning, disinfectant or sterilising process been assessed to ensure compliance with local/national regulatory requirements?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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20. Are all chemical agents labelled correctly and are visible?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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21. Are monthly WHS Inspections completed and actioned?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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22. 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
- 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

March 2018