SELF ASSESSMENT SECTION 4

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 4 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. This section is on process and equipment characterisation: processing equipment (cleaning, disinfecting, sterilising) delivers safe, effective and reproducible cleaning, disinfecting and sterilising processes. 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 4, Page 85, A4.1 - A4.3.3.

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1. 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]

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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2. Do the equipment specifications include [but not limited to]:
1. Detailed description of process cycles?
2. Process parameters and their tolerances?
3. Means by which process variables may be monitored and controlled?
4. Measures that fail to achieve specified parameters and their tolerances in cleaning, disinfecting and/or sterilising are able to be identified?
5. Treatment required prior to exposure to the process to ensure its effectiveness?
6. Restrictions/limitations to size, mass, configuration or loading orientation?
7. Post cycle treatment (if applicable) – e.g. additional rinse or alcohol flush cycle for endoscopes; additional drying time?
(Requires evidence of a documented list with equipment, equipment type, manufacturer) [see 4.3.1 a-g]

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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3. Can the steam steriliser be programmed to sterilise all Product Families required for the Health Service Organisation? [see 7.4.1 e] - FOR CENTRAL STERILISING UNIT ONLY

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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4. 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)?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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5. Does the Unit's reprocessing equipment comply with the following Standards?
Washer-disinfectors: [ISO 15883]

- ○ Yes
- ○ No
- ○ N/A

Comments:

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6. Does the Unit's reprocessing equipment comply with the following Standards?
Ultrasonic cleaners: [AS 2773.1 or AS 2773.2.]
○ Yes
○ No
○ N/A

Comments:

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7. Does the Unit's reprocessing equipment comply with the following Standards?
Drying cabinets: [AS 2514.]
○ Yes
○ No
○ N/A

Comments:

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8. Does the Unit's reprocessing equipment comply with the following Standards?
Heat sealers. [Refer to ISO 11607-2 and ISO/DTS 16675-3 for guidance.]
○ Yes
○ No
○ N/A

Comments:

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9. Does the Unit's reprocessing equipment comply with the following Standards?
Steam sterilisers—Large: [EN 285]
○ Yes
○ No
○ N/A

Comments:

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10. Does the Unit's reprocessing equipment comply with the following Standards?
Steam sterilisers—Small: [EN 13060]
○ Yes
○ No
○ N/A

Comments:

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11. Does the Unit's reprocessing equipment comply with the following Standards?
Dry Heat [Refer to ISO 11607-2 & ISO/DTS 16675-3 for guidance.]
○ Yes
○ No
○ N/A

Comments:

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12. Does the Unit's reprocessing equipment comply with the following Standards?
Ethylene oxide sterilisers [EN 1422]
○ Yes
○ No
○ N/A

Comments:

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13. Does the Unit's reprocessing equipment comply with the following Standards?
Steam/formaldehyde steriliser [EN 14180]
○ Yes
○ No
○ N/A

Comments:

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14. Does the Unit's reprocessing equipment comply with the following Standards?
Peracetic acid sterilisers. [Refer to ISO 14937 for guidance.]
○ Yes
○ No
○ N/A

Comments:

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15. Does the Unit's reprocessing equipment comply with the following Standards?
Hydrogen peroxide gas/plasma sterilisers. [Refer to ISO 14937 for guidance.]
○ Yes
○ No
○ N/A

Comments:

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16. Does the Unit's reprocessing equipment comply with the following Standards?
Aeration Cabinets [Refer to ISO 25424 & ISO 11135 for guidance]
○ Yes
○ No
○ N/A

Comments:

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17. Does the Unit's reprocessing equipment comply with the following Standards?
Endoscope storage cabinets. [Refer to EN 16442 - controlled environment storage cabinets for disinfected thermo labile endoscopes (in draft) for guidance]
○ Yes
○ No
○ N/A

Comments:

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18. Does the Unit's reprocessing equipment comply with the following Standards?
Biological indicator incubators. [Refer to ISO 11138-1 or ISO 14161 for guidance.]

○ Yes
○ No
○ N/A

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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