SATELLITE SITE 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 UNIT ONLY. 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. It is recommended that an experienced infection control consultant and/or sterilising manager perform the peer review. The Manager of the Satellite site as well as the staff member responsible for teaching or performing the reprocessing should be available for the Peer Review audit.

Section 1 - Scope and General

1. Peer review auditors name(s), position title and facility/LHD

Comments:

2. Are there any questions from the Self Assessment audit that the Peer review team/person needs to follow up?
(Write the questions numbers here)

Comments:

3. Does the Unit/Department/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
   - WIP

Comments:

Section 2 - Quality Management - Policies/Procedures/Guidelines

4. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for Validation and Requalification of:
   1. Cleaning processes - for semi-critical and critical items which includes their ability to withstand the cleaning processes? See to (AS/NZS 4187:2014 - 6.1.1)
   2. Disinfection processes?
   3. Sterilising processes?
   - Yes
   - No
   - N/A
   - WIP

Comments:

5. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the initial treatment (e.g. wiping, rinsing, cleaning) and collection of used RMDs before they are transported/transferred to the processing area:
   1. Clinical Areas?
   2. Operating theatres?
   3. Procedural areas?
   4. Other areas?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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6. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the handling of specialised RMDs including:
   1. RMDs on loan?
   2. RMDs on trial? (See AS/NZS 4187:2014 - 2.4.2(e))
   3. RMDs returned from repair?
   4. RMDs on consignment?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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7. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the validated cleaning process of RMDs prior to disinfection and/or sterilisation?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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8. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the handling and transport of RMDs prior to and following reprocessing?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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9. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the cleaning of:
   1. Processing equipment?
   2. Environmental cleaning of the Unit/Department/Clinic (including project or high cleaning)?
   3. Other equipment/furniture within the Unit/Department/Clinic?
   4. Specialised cleaning e.g. air conditioning outlets, filters?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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10. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the recall of RMDs and it includes (see AS/NZS 4187:2014 - 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?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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11. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the review of deviation reports or procedural problems?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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12. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for training and competency assessment of staff?
   - Yes
   - No
   - WIP

   Comments:

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13. Does this Unit/Department/Clinic have current continuity plan for emergencies e.g. equipment breakdowns, recalls?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

Section 2 - Quality Management - Records

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14. Does the Unit/Department/Clinic hold records for purchasing of RMDs (including previous purchases)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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15. Does the Unit/Department/Clinic hold records for purchasing of reprocessing equipment?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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16. Does the Unit/Department/Clinic hold records for monitoring of reprocessing equipment and services to this equipment?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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17. Does the Unit/Department/Clinic hold records for cleaning process records which includes time, date, chemical and dosage, water temperature, person responsible signature?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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18. Does the Unit/Department/Clinic hold records for high-level disinfection including chemical/ thermal process records, MRN, time, date, person responsible loading and unloading signature(s)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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19. Does the Unit/Department/Clinic hold records for staff training records and evidence of staff competency?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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20. Does the Unit/Department/Clinic hold records for Installation Qualification, Operational Qualification and Performance Qualification for reprocessing equipment? (See definitions in AS/NZS 4187:2014 - 1.5.32; 1.5.49; 1.5.53)

- ○ Yes
- ○ No
- ○ N/A

Comments:

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21. Do all Policy or Procedure or Guideline meet Health Service Organisation policy/procedure/guideline frameworks (including authorisation and publication)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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22. Are all documents/records (electronic or paper) maintained in a designated storage area which enables retrieval, retention and archiving - e.g. electronic records kept on a network drive?

- ○ Yes
- ○ No
- ○ N/A

Comments:

Section 2 - Quality Management - Management Responsibility

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23. Is the Unit/Department/Clinic part of a documented and approved organisational structure that enables the Unit/Department/Clinic to meet the requirements of AS/NZS 4187:2014?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

Section 2 - Quality Management - Reprocessing within Unit/Department/Clinic

24. 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/NZ 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/Department/Clinic?
NOTE: If no to any questions, write the responses in the Comments section

- Yes
- No
- N/A
- WIP

Comments:

25. Does the Unit/Department/Clinic have a formal/planned orientation/induction, training program and competency assessment for staff?

- Yes
- No
- N/A
- WIP

Comments:

Section 2 - Quality Management - Equipment and Contracts/Service Level Agreements

26. Does the Unit/Department/Clinic have external Contracts/Service Level Agreements for maintenance, preventative maintenance, performance qualification etc, and these include responsibility and compliance with AS/NZS 4187:2014?

- Yes
- No
- N/A
- WIP

Comments:

Section 2 - Quality Management - Purchasing

27. To ensure products (RMDs, reprocessing equipment and their accessories) conform to specified purchasing requirements, does the policy/procedure/guideline for purchasing include:
1. Criteria for product selection and evaluations are risk based, including WHS requirements?
2. Sterilising Manager/Supervisor involved in the selection process prior to purchase?
3. Evaluation to ensure compatibility with reprocessing systems available within the Unit/Department/Clinic?
4. Requirements for RMD, RMD accessories and reprocessing equipment are in the ARTG?
5. Reprocessing equipment comply with regulatory and safety standards?
6. Reprocessing equipment and accessories have operational instructions for use (IFUs)?
7. Provision of documentation and validation reprocessing instructions in accordance with ISO 17664 - including loan and trial RMDs?
8. Acceptance criteria when taking delivery?

- Yes
- No
- N/A
- WIP

Comments:

Section 2 - Quality Management - Traceability Records

28. Does the traceability systems for high level chemical disinfection process identify the following for each RMD:
1. Type of RMD?
2. Serial Number?
3. Date of cleaning?
4. Technician/staff Responsible?
5. Identification of the automated equipment used to process the RMDs?
6. Process cycle number and date of disinfection?

- Yes
- No
- N/A
- WIP

Comments:

29. For high level disinfection, are there other records but not limited to:

- Disinfectant
  - type/brand
  - batch number
  - expiry date
  - date of opening
- Test strips
  - type/brand
  - batch number
  - expiry date
  - date of opening
  - results positive/negative
  - identification of technician/staff conducting test
- AER
  - cycle process record
  - self disinfection cycle
  - water filter pressures
  - date - chemicals
  - filter changed
  - identification of staff
- Manual immersion into disinfectant
  - temperature of disinfectant
  - time of immersion
  - time of removal
  - final rinse
  - identification of staff

○ Yes
○ No
○ N/A
○ WIP

Comments:

Section 2 - Quality Management - Monitoring, measuring equipment and documentation

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

○ Yes
○ No
○ N/A
○ WIP

Comments:

Section 2 - Quality Management - Recall and Preventative Action

31. Does the Unit/Department/Clinic have documented evidence and/or risk assessment of action taken for non-conformance of equipment? (See AS/NZS 4187:2014 - Appendix A2.5.2)
This includes:
1. Cleaning processes
2. Disinfecting processes
3. Sterilising processes
4. Packaging processes

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

Section 3 - Reprocessing Agent Characterisation

32. Are all Agents used within the Unit/Department/Clinic listed on the Australian Register of Therapeutic Goods (ARTG)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

33. 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

Comments:

34. Where the manufacturer of the cleaning agents make claims of their microbiocidal effectiveness, do they include the evidence in their technical information? (See AS/NZS 4187:2014 - 3.5)

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

35. Are Safety Data Sheets (SDS) available for every agent (cleaning, disinfecting and sterilising) used within the Unit/Department/Clinic?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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36. Does the Unit/Department/Clinic have copies of the manufacturers' information available (technical information – e.g. microbial efficacy, toxicity/residues, compatibility)?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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37. Are cleaning agents used in the Unit/Department/Clinic suitable for intended purpose as recommended by the manufacturer in their Instructions for Use and there is documented evidence that the cleaning agent(s) will not have an adverse effect on other cleaning or disinfectant agents, e.g. for manual cleaning, ultrasonic machine?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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38. Has the manufacturer been consulted regarding the compatibility of the available water quality with the cleaning agent (IF APPLICABLE) (See AS/NZS 4187:2014 - 3.1.3)?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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39. Are chemical disinfectant(s) used to process RMDs labelled as an 'Instrument Grade Disinfectant' (NOT Hospital grade disinfectant)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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40. Are high-level instrument grade disinfectants used for disinfection of a semi-critical RMD, e.g. non-channelled endoscopes? (See AS/NZS 4187:2014 - Section 5)

- ○ Yes
- ○ No
- ○ N/A

Comments:

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41. In this Unit/Department/Clinic, are intermediate or low level instrument grade disinfectant used for non-critical RMD where required, e.g. tonometer prisms? (See AS/NZS 4187:2014 - Section 5 and Spaulding's Classification System)

- ○ Yes
- ○ No
- ○ N/A

Comments:

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42. 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

Comments:

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43. 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 AS/NZS 4187:2014 - 5.3)

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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44. 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

Comments:

Section 4 - Process and Equipment Characterisation

45. Has the Unit/Department/Clinic obtained all relevant details from the manufacturer/supplier on equipment that performs cleaning, disinfecting and sterilising?
(Details include: specifications/technical information/advice) (See AS/NZS 4187:2014 - 4.2 a-h)

- Yes
- No
- N/A
- WIP

Comments:

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46. 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 AS/NZS 4187:2014 - 4.3.1 a-g)

- Yes
- No
- N/A
- WIP

Comments:

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47. 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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48. Does the Unit/Department/Clinic's reprocessing equipment comply with the following Standards? Washer-disinfectors: [ISO 15883]

- ○ Yes
- ○ No
- ○ N/A

Comments:

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49. Does the Unit/Department/Clinic'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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50. Does the Unit/Department/Clinic's reprocessing equipment comply with the following Standards? Peracetic acid sterilisers. [Refer to ISO 14937 for guidance]

- ○ Yes
- ○ No
- ○ N/A

Comments:

Section 5 - Product Definition

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51. Does the Health Service Organisation (not the Unit/Department/Clinic) 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 been correctly classified and assigned the correct reprocessing type according the manufacturer's instructions. (See AS/NZS 4187:2014 - 5.1.2 i-iii and Table 5.1)

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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52. Are senior staff/manager within the central sterilising Unit/Department/Clinic 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 AS/NZS4187:2014 - 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/Department/Clinic – e.g. satellite sites such as endoscopy, cardiology, outpatient clinics, medical imaging

- Yes
- No
- N/A
- WIP

Comments:

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53. Does the Unit/Department/Clinic have a process to identify where limiting/process values such as exposure time, temperature, humidity, immersion capability (See AS/NZS 4187:2014 - 5.3) are exceeded?

- Yes
- No
- N/A

Comments:

Section 5 - Facility Design

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54. Does the Unit/Department/Clinic have an effective physical segregation of clean and dirty activities and the segregation that prevents cross contamination?

- Yes
- No
- N/A
- WIP

Comments:

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55. Does the Unit/Department/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
- N/A
- WIP

Comments:

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56. 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 minimize the risk of cross contamination?
5. Not used for handwashing?

○ Yes
○ No
○ N/A

Comments:

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57. Is the water used of the required quality and specified for the reprocessing of your RMDs. (See AS/NZS 4187:2014 - Section 7.2.3.1 and Table 7.2)?
○ Yes
○ No
○ N/A

Comments:

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58. Is there a dedicated area provided for the storage of reprocessed RMDs that have been released for use?
○ Yes
○ No
○ N/A

Comments:

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

Comments:

Section 6 - Process Definition

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60. Does the Unit/Department/Clinic have suitable reprocessing equipment for reprocessing of RMDs – e.g. prior to purchasing specialised equipment, has the Unit/Department/Clinic manager assessed that it has the correct reprocessing equipment for the specialised RMDs? (See AS/NZS 4187:2014 - 2.2.2)
○ Yes
○ No
○ N/A

Comments:

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61. If the Unit/Department/Clinic reprocesses heat labile semi-critical RMDs (e.g. transvaginal transducers, TOE transducers), does the Unit/Department/Clinic have the following in place:
1. Identification of all RMDs that are classified as heat labile semi-critical?
2. Documented procedures for reprocessing?
3. Monitoring and documentation requirements (including tracking)?
4. Documented procedures for components of the RMD that cannot be immersed in the chemical disinfectant, e.g. hand controls?
5. Processes to ensure they do not become contaminated?

- Yes
- No
- N/A
- WIP

Comments:

Section 7 - Validation

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62. Does equipment purchased or relocated since November 2014 meet the manufacturers' specifications for water quality?

- Yes
- No
- N/A
- WIP

Comments:

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63. Is there a documented water quality testing and reporting schedule as per Table 7.2 - *Water quality used for reprocessing RMDs*?

- Yes
- No
- N/A
- WIP

Comments:

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64. Has Operational Qualification [OQ] been performed and documentation supplied by the reprocessing equipment manufacturer in accordance with the applicable National or International Standards? (See AS/NZS 4187:2014 - 7.3)

- Yes
- No
- N/A
- WIP

Comments:

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65. Does Operational Qualification occur following any changes, e.g. installation, modification or relocation of equipment, major breakdowns/repair, service changes, introduction of new equipment, changes to load configuration?

- Yes
- No
- N/A
- WIP

Comments:

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66. Has Performance Qualification of thermal or chemical disinfecting processes using washer/disinfectors performed in accordance with the relevant ISO 15883 series of standards? (See AS/NZS 4187:2014 - 1.3 - Normative References)

- Yes
- No
- N/A
- WIP

Comments:

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67. Is a summary of the annual validation reports presented or discussed to a nominated clinical Health Service Organisation Committee, e.g. Patient Safety, Infection Prevention and Control, Operating Theatre?

- Yes
- No
- N/A
- WIP

Comments:

Section 8 - Routine Monitoring and Control

Nil questions – Questions related to this section are in the staff assessment, interview and observation audit

Section 9 - Release of RMDs Following Reprocessing

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68. Have the Unit/Department/Clinic staff been provided education of the handling, transport and storage of reprocessed RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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69. Is there restricted access to the Unit/Department/Clinics storage areas for critical and semi-critical RMDs, including consumables?

- Yes
- No
- N/A
- WIP

Comments:

Section 10 - Maintaining process effectiveness

70. Are service level agreements/contracts in place with qualified service providers to provide the final reports [See AS/NZS 4187:2014 - 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:

71. Is preventative maintenance of all equipment planned and undertaken in accordance with documented procedures by the equipment manufacturer? See AS/NZS4187:2014 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:

72. Have any risks been identified during the walk around of the Unit/Department/Clinic that require escalation to the Manager?

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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