SELF ASSESSMENT SECTIONS 1 & 2

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 1 & 2 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. This section specifies the elements of the quality management system. It also identifies the governance requirements for the reprocessing unit(s). 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. 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 4187:2014 Guidance to Section 2, Page 79, A2.1 - A2.5.4. NOTE: You do not need a separate policy/procedure/guideline for each of these questions - the information may be included in a comprehensive or other policy/procedure/guideline.

Section 1 - Normative References

1. Does the Unit 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:

2. Has a plan been developed for a peer review audit to determine compliance with AS/NZS 4187:2014?
   - ○ Yes
   - ○ No
   - ○ WIP

   Comments:

Section 2 Policy, Procedures and Guidelines (2.1 - 2.2.2)

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3. Does this Unit have access to current Health Service Organisation/NSW Policy or Procedures or Guidelines which includes:
   1. Work Health and Safety?
   2. NSW Health occupational screening and vaccination?
   3. Purchasing of equipment (RMDs and equipment)?
   4. Incident Management
   5. Complaints Management
   - ○ Yes
   - ○ No

   Comments:

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4. Does this Unit have access to current Health Service Organisation Policy or Procedures or Guidelines for the purchase of critical consumables and it includes obtaining the manufacturers' instructions and validation data/report, e.g. sterile barrier systems? (See 2.4.2 and 6.4.1)
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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5. Does this Unit have current Policy or Procedures or Guidelines for qualification of equipment that includes:
   1. RMDs (including new RMDs)?
   2. Reprocessing Equipment?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

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6. Does this Unit have a current Policy or Procedures or Guidelines for categorising critical, semi-critical and non-critical RMDs according to the Spaulding classification? (See 6.3)
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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7. Does this Unit have current Policy or Procedures or Guidelines for Validation and Requalification of:
   1. Cleaning processes - for semi- critical and critical items and they are able to withstand the cleaning processes? See to (6.1.1)
   2. Disinfection processes?
   3. Sterilising processes?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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8. Does this Unit have current Policy or Procedures or Guidelines for Validation and Requalification of Product Families?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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9. Does this Unit have current Policy /Procedures for routine monitoring and control of:
   1. Cleaning processes, including compatibility of cleaning with the RMDs? (See 6.2.1)
   2. Disinfection processes - with ensuring that items are not stored in liquid disinfectant? (See 6.1.1)
   3. Sterilising processes?
   - Yes
   - No
   - N/A
   - WIP

   Comments:

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10. Does this Unit have current Policy or Procedures or Guidelines 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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11. Does this Unit have current Policy or Procedures or Guidelines for the handling of specialised RMDs including:
1. RMDs on loan?
2. RMDs on trial? [see 2.4.2(e)]
3. RMDs returned from repair?
4. RMDs on consignment?

- Yes
- No
- N/A
- WIP

Comments:

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12. Does this Unit have current Policy or Procedures or Guidelines for the cleaning of RMDs prior to disinfection and/or sterilisation?

- Yes
- No
- N/A
- WIP

Comments:

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13. Does the Unit have a Policy or Procedures or Guidelines for Immediate Use - Emergency Sterilisation (may also be called 'flash sterilisation')? (See 6.1.2)

- Yes
- No
- N/A
- WIP

Comments:

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14. Does the Unit have a Policy or Procedures or Guidelines for Emergency Sterilisation (may also be called 'fast track')? (See 6.1.2)

- Yes
- No
- N/A
- WIP

Comments:

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15. Does this Unit have a current Policy or Procedures or Guidelines for biological and chemical indicators used during validation and monitoring of the processes? (See 6.1.1 and 7.4.5)

- Yes
- No
- N/A
- WIP

Comments:

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16. Does this Unit have current Policy or Procedures or Guidelines for the inspection and assembly of RMDs prior to disinfection?

- Yes
- No
- N/A
- WIP

Comments:

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17. Does this Unit have current Policy or Procedures or Guidelines for the inspection and assembly of RMDs prior to disinfection?

- Yes
- No
- N/A
- WIP

Comments:

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18. Does this Unit have current Policy or Procedures or Guidelines for the inspection, assembly and packaging of RMDs prior to sterilisation?

- Yes
- No
- N/A
- WIP

Comments:

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19. Does this Unit have current Policy or Procedures or Guidelines for the loading and unloading of the Washer/Disinfector equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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20. Does this Unit have current Policy or Procedures or Guidelines for the loading and unloading of the RMD Drying Cabinets equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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21. Does this Unit have current Policy or Procedures or Guidelines for the loading and unloading of the Case Cart equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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22. Does this Unit have current Policy or Procedures or Guidelines for the loading and unloading of the Automated Endoscopy Reprocessors (AER) equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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23. Does this Unit have current Policy or Procedures or Guidelines for the loading and unloading of the Cabinets/ HEPA Filter Cabinets [Endoscopy] equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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24. Does this Unit have current Policy or Procedures or Guidelines for the loading and unloading of the sterilising equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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25. Does this Unit have current Policy or Procedures or Guidelines for the traceability of reprocessed RMDs (critical and/or semi critical)?

- Yes
- No
- N/A
- WIP

Comments:

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26. Does this Unit have current Policy or Procedures or Guidelines for disinfection of cleaned RMDs and/or sterilisation of cleaned RMDs?

- Yes
- No
- N/A
- WIP

Comments:

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27. Does this Unit have current Policy or Procedures or Guidelines for validation and routine control for
1. Cleaning processes?
2. Disinfection processes?
3. Sterilising processes?

(See Figure 7.1 - validation flowchart for cleaning, disinfecting and sterilising processes)

- Yes
- No
- N/A
- WIP

Comments:

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28. Does this Unit have current Policy or Procedures or Guidelines for the release of RMDs following Sterilisation?

- Yes
- No
- N/A
- WIP

Comments:

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29. Does this Unit have current Policy or Procedures or Guidelines for the handling and transport of RMDs prior to and following reprocessing?

- Yes
- No
- N/A
- WIP

Comments:

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30. Does this Unit have current Policy or Procedures or Guidelines for the cleaning of:
1. Processing equipment?
2. Environmental cleaning of the unit (including project or high cleaning)?
3. Other equipment/furniture within the unit?
4. Specialised cleaning e.g. air conditioning outlets, filters?

- Yes
- No
- N/A
- WIP

Comments:

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31. Does this Unit have current Policy or Procedures or Guidelines for the periodic preventative maintenance of processing equipment including calibration of monitoring instrumentation?

- Yes
- No
- N/A
- WIP

Comments:

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32. Does this Unit have current Policy or Procedures or Guidelines for action to be taken in the event of:
1. Biological spill and/or exposure?
2. Chemical spill and/or exposure?

- Yes
- No
- N/A
- WIP

Comments:

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33. Does this Unit have current Policy or Procedures or Guidelines for action to be taken in the event of control of non-conforming RMDs (corrective and preventative)?

- Yes
- No
- N/A
- WIP

Comments:

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34. Does this Unit have current Policy or Procedures or Guidelines for the recall of RMDs and it includes (see 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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35. Does this Unit have current Policy or Procedures or Guidelines for the review of deviation reports and other indicators of quality or procedural problems?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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36. Does this Unit have current Policy or Procedures or Guidelines for training and competency assessment of staff?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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37. Does this Unit have current continuity plan for emergencies, e.g. equipment breakdowns, recalls?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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38. Does this Unit have current Policy or Procedures or Guidelines for purchasing reprocessing equipment, RMDs and accessories required for both? (See 2.4.2)

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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39. Does this Unit have current Policy or Procedures or Guidelines for the selection and purchase of chemical agents? (See 2.4.2, 3.1.1, 3.1.2)

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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40. Does this Unit have current Policy or Procedure or Guideline for the storage, handling, decanting and disposal of chemicals? (see 3.7.3)

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

Section 2.2.3 - Records

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41. Does the Unit hold records for purchasing of RMDs?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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42. Does the Unit hold records for purchasing of reprocessing equipment?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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43. Does the Unit hold records for monitoring of reprocessing equipment and services to this equipment?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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44. Does the Unit hold records for cleaning process records?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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45. Does the Unit hold records for sterilising process records?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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46. Does the Unit hold records for high level disinfection, including chemical and thermal process records?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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47. Does the Unit hold records for microbiological surveillance testing (endoscopes)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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48. Does the Unit hold records for cleaning of reprocessing equipment checks?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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49. Does the Unit hold records for environmental cleaning audit results of the reprocessing unit?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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50. Does the Unit hold records for staff training and evidence of staff competency?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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51. Does the Unit hold records for staff rosters and allocations?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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52. Does the Unit hold maintenance records for RMDs (if these are held onsite, e.g. Biomedical Engineering - answer Yes)?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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53. Does the Unit hold records for Installation Qualification, Operational Qualification and Performance Qualification for reprocessing equipment?

- ○ Yes
- ○ No
- ○ N/A

Comments:

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54. Does the Unit hold records for process deviation reports and where applicable, records of corrective action and/or preventative action?

- ○ Yes
- ○ No
- ○ N/A

Comments:

Section 2.2.4 Control of documents and records

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55. Do all Policy or Procedures or Guidelines meet HSO policy/procedure/guideline frameworks (including authorisation and publication)?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

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56. Are all documents/ records (electronic or paper) maintained in a designated storage area which enables retrieval, retention and archiving?

- Yes
- No
- N/A
- WIP

Comments:

Section 2.3.1 - Management Responsibility

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

- Yes
- No
- N/A
- WIP

Comments:

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58. For requests for additional resources, is there a process for documenting submissions, ability to allocate a risk rating and escalation process within the Health Service Organisation?

- Yes
- No
- N/A
- WIP

Comments:

Section 2.3.2 - Resource requirements (resources include workforce, equipment, maintenance etc)

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59. Has the Unit been provided, allocated or accepted a submission for resources to implement the requirements within these standards?

- Yes
- No
- N/A
- WIP

Comments:

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60. Has the Unit been provided, allocated or accepted a submission for resources to implement the required quality management program and maintain its effectiveness through ongoing review?

- Yes
- No
- N/A
- WIP

Comments:

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61. Has the Unit been provided, allocated or accepted a submission for resources to meet regulatory and customer requirements?

- Yes
- No
- N/A
- WIP

Comments:

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62. Has the Unit been provided, allocated or accepted a submission for resources to ensure skilled staffing levels are sufficient to maintain the continuous, safe and efficient operation of the reprocessing facility?

- Yes
- No
- N/A
- WIP

Comments:

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63. Has the Unit been provided, allocated or accepted a submission for resources to maintain the buildings, workspaces and associated utilities necessary to achieve conformity with requirements for RMD reprocessing?

- Yes
- No
- N/A
- WIP

Comments:

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64. Has the Unit been provided, allocated or accepted a submission for resources to procure reprocessing equipment appropriate and compatible to purpose?

- Yes
- No
- N/A
- WIP

Comments:

Section 2.3.3 Reprocessing Unit

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65. 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?

- Yes
- No
- N/A
- WIP

Comments:

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

- Yes
- No
- N/A
- WIP

Comments:

Section 2.3.4 - 2.3.5 (Equipment and Contracts)

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67. Does the Unit have an escalation/reporting process to ensure that there is adequate reprocessing equipment and RMDs available to meet the service demands of its customers?

- Yes
- No
- N/A
- WIP

Comments:

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68. Does the Unit 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 2.4 - 2.4.2 - Purchasing

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69. 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?
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?
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 2.4.3 - 2.4.3.2 Traceability Records

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70. Do 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 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:

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71. 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 conducting test

AER

- cycle process record
- self disinfection cycle
- water filter pressures
- date
- chemicals
- filter changed

Manual immersion into disinfectant

- temperature of disinfectant
- time of immersion
- time of removal
- final rinse

  - Yes
  - No
  - N/A
  - WIP

Comments:

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72. Do the tracking systems for Sterilising process records identify the following for each RMD:

Sterilisation

- sterilising process records? See 2.2.3(d)
- date of sterilisation and batch number?
- identification of steriliser?
- identification of RMDs?
- identification of person responsible for loading RMDs?

Other records includes [but not limited to]

- results of performance tests?
- results of chemical and biological monitoring?
- sterilising agent, batch number and expiry date?
- documented evidence of attainment of process parameters?
- identification of person responsible for releasing the RMDs?

  - Yes
  - No
  - N/A
  - WIP

Comments:

Section 2.4.4 - 2.4.4.3 - Monitoring and measuring equipment and documentation

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73. Has the Unit ensured that the monitoring and measuring equipment is calibrated at specified intervals? These include:
1. Identified with calibration status?
2. Adjusted /re-adjusted as necessary?
3. Protected from adjustments that would invalidate the results?
4. Protected from damage during handling, maintenance and storage?
5. Certified by a suitable certification body/company e.g. NATA?

- Yes
- No
- N/A
- WIP

Comments:

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74. 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 2.5. - 2.5.4 - Recall and preventative action

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75. Does the Unit have documented evidence and risk assessment of action taken for non-conformance of equipment? (see Appendix A2.5.2) This includes:
1. Cleaning processes
2. Disinfecting processes
3. Sterilising processes
4. Packaging processes

- Yes
- No
- N/A
- WIP

Comments:

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76. Is there a reporting template for reporting of recalled items and the template includes:
1. Identification of potential cause/s?
2. Implementation of a preventive action plan?
3. Documentation of action?
4. Evaluation of preventative actions?
5. Risk assessment
6. If required, implementation of additional preventative actions?

- 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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