

# SATELLITE SITE SELF ASSESSMENT

## 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 Satellite Site self-assessment is your gap analysis for AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations.</p> <p>A satellite reprocessing site is a small Unit/Department/Clinic that reprocesses (sterilises or high level disinfection) a single specific type of reusable medical device e.g. transvaginal transducer, nasendoscope, flexible cystoscope, TOE transducer.</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>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 each Section. They commence on Page 79.</p> <p>NOTE: You do not need a separate policy/procedure/guideline for each of the questions relating to policy/procedure/guideline. If the information is included in a comprehensive policy/procedure/guideline, answer 'Yes' and make a notation in the Comments Section.</p> <p>NOTE: If your Unit/Department/Clinic outsources all reprocessing, auditing is not required e.g. the reusable medical device is sent to the CSD. Comments section can be used to document: policy name/links, location of evidence, recommendations, auditing programs etc.</p> <p>NOTE: RMD = Reusable Medical Devices.</p>

## Section 1 - Scope and General

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1. Describe your Unit/Department/Clinic, the reusable medical device you use and what do you use to reprocess it.

**Comments:**

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2. Does your 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:**

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3. Has a plan been developed for a peer review audit to determine compliance with AS/NZS 4187:2014?  
**NOTE:** A Peer Review audit is conducted by your experienced Infection Prevention and Control Professional, CSD Manager or experienced clinician from another unit/department/clinic the same as yours.

- Yes
- No
- N/A
- WIP

**Comments:**

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## Section 2 - Quality Management - Policies/Procedures/Guidelines

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4. Does this Unit/Department/Clinic have access to current Health Service Organisation/NSW Policy or Procedure or Guideline 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
- N/A
- WIP

**Comments:**

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5. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for validation qualification of reprocessing equipment?

- Yes
- No
- N/A
- WIP

**Comments:**

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6. Does this Unit/Department/Clinic have a current Policy or Procedure or Guideline for categorising critical, semi-critical and non-critical RMDs according to the Spaulding classification which includes their reprocessing requirements? (See AS/NZS 4187:2014 - 6.3)

- Yes
- No
- N/A
- WIP

**Comments:**

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7. 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:**

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8. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for classification and validation of Product Families?

NOTE: This is only applicable for departments/units/clinics that [sterilise](#) reusable medical devices (RMDs). It is a method for ensuring all RMDs are sterilised. Each RMD is assessed against defined criteria within a matrix: design, material, weight, packaging and estimated steam penetration resistance. They are then assigned to a product family by their score. Each product family is validated for a sterilising cycle (each will have different temperature/pressure/holding time).

- Yes
- No
- N/A
- WIP

**Comments:**

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9. Does this Unit/Department/Clinic have current Policy /Procedures for routine monitoring and control of:
1. Cleaning processes, including compatibility of cleaning agents and reprocessing equipment on the RMDs? (See AS/NZS 4187:2014 - 6.2.1)
  2. Disinfection processes - which includes RMDs not being stored in liquid disinfectant? (See AS/NZS4187:2014 - 6.1.1)
  3. Sterilising processes?
    - 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 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/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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12. 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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13. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the inspection and assembly of RMDs prior to disinfection or sterilisation?

- Yes
- No
- N/A
- WIP

**Comments:**

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14. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the loading and unloading of the Washer/Disinfector equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

**Comments:**

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15. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline 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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16. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the loading and unloading of the Cabinets/ HEPA Filter Cabinets/ TGA-approved forced air drying cabinets [Endoscopy] equipment used to reprocess RMDs?

- Yes
- No
- N/A
- WIP

**Comments:**

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17. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the traceability of reprocessed RMDs (critical and/or semi critical)?

- Yes
- No
- N/A
- WIP

**Comments:**

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18. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for disinfection of cleaned RMDs and/or sterilisation of cleaned RMDs?

- Yes
- No
- N/A
- WIP

**Comments:**

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19. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for validation and routine control and monitoring for:

1. Cleaning processes?
2. Disinfection processes?
3. Sterilising processes? (See Figure 7.1 - validation flowchart for cleaning, disinfecting and sterilising processes - AS/NZS 4187:2014)

- Yes
- No
- N/A
- WIP

**Comments:**

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20. 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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21. 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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22. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the periodic (within set timeframes) preventative maintenance of processing equipment including calibration of monitoring instrumentation?

- Yes
- No
- N/A
- WIP

**Comments:**

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23. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline 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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24. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for action to be taken in the event of control of non-conforming RMDs (corrective, preventative monitoring and review)?

- Yes
- No
- N/A
- WIP

**Comments:**

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25. 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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26. 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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27. 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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28. Does this Unit/Department/Clinic have current continuity plan for emergencies, e.g. equipment breakdowns, recalls?

- Yes
- No
- N/A
- WIP

**Comments:**

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29. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for purchasing reprocessing equipment, RMDs and accessories required for both? (See AS/NZS 4187:2014 - 2.4.2)

- Yes
- No
- N/A
- WIP

**Comments:**

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30. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the selection and purchase of chemical agents? (See AS/NZS 4187:2014 - 2.4.2, 3.1.1, 3.1.2)

- Yes
- No
- N/A
- WIP

**Comments:**

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31. Does this Unit/Department/Clinic have current Policy or Procedure or Guideline for the storage, handling, decanting and disposal of chemicals? (See AS/NZS 4187:2014 - 3.7.3)

- Yes
- No
- N/A
- WIP

**Comments:**

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## **Section 2 - Quality Management - Records**

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

- Yes
- No
- N/A

**Comments:**

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

- Yes
- No
- N/A

**Comments:**

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34. 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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35. 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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36. 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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37. Does the Unit/Department/Clinic hold records for cleaning of reprocessing equipment checks?

- Yes
- No
- N/A

**Comments:**

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38. Does the Unit/Department/Clinic hold records for environmental cleaning audit results of the reprocessing Unit/Department/Clinic?

- Yes
- No
- N/A

**Comments:**

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39. 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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40. Does the Unit/Department/Clinic hold records for staff rosters and allocations?

- Yes
- No
- N/A

**Comments:**

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

- Yes
- No
- N/A

**Comments:**

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42. 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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43. 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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44. 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:**

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## [Section 2 - Quality Management - Management Responsibility](#)

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

- Yes
- No
- N/A
- WIP

**Comments:**

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46. 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

**Comments:**

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47. Has your Unit/Department/Clinic put in a [successful](#) submission for resources to implement the requirements within these standards?

- Yes
- No
- N/A
- WIP

**Comments:**

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48. Has your Unit/Department/Clinic put in a submission for resources to meet other regulatory or customer requirements?

- Yes
- No
- N/A
- WIP

**Comments:**

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49. Has your Unit/Department/Clinic put in a [successful](#) 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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50. Has your Unit/Department/Clinic put in a [successful](#) 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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## **Section 2 - Quality Management - Reprocessing within Unit/Department/Clinic**

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51. 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:**

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

- Yes
- No
- N/A
- WIP

**Comments:**

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

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53. Does the Unit/Department/Clinic 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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**54.** Does the Unit/Department/Clinic have external Contracts/Service Level Agreements for maintenance, preventative maintenance, performance qualification etc, and they include responsibility and compliance with AS/NZS 4187:2014?

- Yes
- No
- N/A
- WIP

**Comments:**

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## **Section 2 - Quality Management - Purchasing**

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**55.** 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:**

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## **Section 2 - Quality Management - Traceability Records**

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**56.** 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:**

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57. 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:**

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

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**58.** Has the Unit/Department/Clinic 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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**59.** 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:**

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## Section 2 - Quality Management - Recall and Preventative Action

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**60.** 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:**

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61. 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:**

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### Section 3 - Reprocessing Agent Characterisation

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

- Yes
- No
- N/A

**Comments:**

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63. Are all the cleaning agents, instrument grade chemical disinfectants liquid chemical sterilising agents that are intended for use on RMDs, listed on the Chemical Register?

- Yes
- No
- N/A

**Comments:**

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64. 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:**

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65. 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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66. 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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67. 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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68. 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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69. 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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70. 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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71. In your 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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72. 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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73. 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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74. If the Unit/Department/Clinic 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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75. Does the Unit/Department/Clinic have the correct storage facilities for all cleaning, disinfectant and sterilising agents?

- Yes
- No
- N/A

**Comments:**

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76. Has the Unit/Department/Clinic 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

**Comments:**

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77. Does the Unit/Department/Clinic have readily accessible information for the safe use, handling and storage of chemicals for workers and the information is available at the point of use?

- Yes
- No
- N/A

**Comments:**

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78. 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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79. Are appropriate Spill Kits located near storage/use of chemical agents which are checked and documented on a regular basis?

- Yes
- No
- N/A

**Comments:**

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80. 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

**Comments:**

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

- Yes
- No
- N/A

**Comments:**

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82. Are monthly WHS Inspections completed and actioned?

- Yes
- No
- N/A

**Comments:**

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83. 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:**

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#### Section 4 - Process and Equipment Characterisation

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84. 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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**85.** 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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**86.** 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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**87.** 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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**88.** 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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89. Does the Unit/Department/Clinic's reprocessing equipment comply with the following Standards? Drying cabinets: [AS 2514.

- Yes
- No
- N/A

**Comments:**

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90. 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:**

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91. Does the Unit/Department/Clinic's reprocessing equipment comply with the following Standards? Hydrogen Peroxide Gas. [Refer to ISO 14937 for guidance]

- Yes
- No
- N/A

**Comments:**

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92. Does the Unit/Department/Clinic's reprocessing equipment comply with the following Standards? Aeration Cabinets. [Refer to ISO 25424 or ISO 11135 for guidance]

- Yes
- No
- N/A

**Comments:**

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93. Does the Unit/Department/Clinic's reprocessing equipment comply with the following Standards? Endoscope storage cabinets. [Refer to EN 16442 controlled environment storage cabinets for disinfected thermo labile endoscopes for guidance]

- Yes
- No
- N/A

**Comments:**

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## [Section 5 - Product Definition](#)

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**94.** Does the Health Service Organisation (not your 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 to the manufacturer's instructions. (See AS/NZS 4187:2014 - 5.1.2 i-iii Table 5.1)

- Yes
- No
- N/A
- WIP

**Comments:**

---

**95.** 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/NZS 4187:2014 - 5.1.2 i-iii 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:**

---

**96.** 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:**

---

**97.** Are there processes to ensure that RMDs are not compromised during all stages in the pre-disinfection and pre-sterilising workflow?

- Yes
- No
- N/A
- WIP

**Comments:**

---

## **[Section 5 - Facility Design](#)**

---



98. 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:**

---

99. 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:**

---

100. Is the reprocessing Unit/Department/Clinic free from opening windows?

- Yes
- No
- N/A

**Comments:**

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

- Yes
- No
- N/A

**Comments:**

---

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

- Yes
- No
- N/A

**Comments:**

---

103. Are all work surfaces, fittings, fixtures, window treatment, shelving and furniture in the reprocessing Unit/Department/Clinic easy to clean and maintained in a good condition?

- Yes
- No
- N/A

**Comments:**

---

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

- Yes
- No
- N/A

**Comments:**

---

**105.** Are cleaning sink workstations:

1. Dedicated for pre-treatment and/or manual cleaning 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:**

---

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

- Yes
- No
- N/A

**Comments:**

---

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

- Yes
- No
- N/A

**Comments:**

---

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

- Yes
- No
- N/A

**Comments:**

---

**110.** 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

**Comments:**

---

**111.** 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:**

---

**112.** Are there sufficient hand hygiene facilities (handwash and alcohol based hand rub) available and accessible in all work areas?

- Yes
- No
- N/A

**Comments:**

---

**113.** Are the alcohol based hand rubs and handwash products approved for use by the Health Service Organisation within the reprocessing Unit/Department/Clinic?

- Yes
- No
- N/A

**Comments:**

---

**114.** Does the ventilation in cleaning areas and sterile storage areas comply with AS 1668.2?

- Yes
- No
- N/A

**Comments:**

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**115.** 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

**Comments:**

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## **Section 6 - Process Definition**

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**116.** 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:**

---

**117.** Does the Unit/Department/Clinic have a process for identifying, recording, communicating and escalating issues/incidents related to transport and pre-treatment?

- Yes
- No
- N/A

**Comments:**

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**118.** If the Unit/Department/Clinic reprocesses heat sensitive semi-critical RMDs (e.g. anaesthetic equipment), does the Unit/Department/Clinic have the following in place:

1. Identification of all RMDs that are classified as heat sensitive semi-critical?
2. Documented procedures for reprocessing? (See AS/NZS4 187:2014 - 5.1.2)
3. Documented monitoring requirements? (See AS/NZS 4187:2014 - Table 6.1)
4. Documented processes to ensure they do not become contaminated?

- Yes
- No
- N/A
- WIP

**Comments:**

---

**119.** 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:**

---

**120.** If the Unit/Department/Clinic reprocesses RMDs from outside the health service organisation, has process definition and validation been undertaken for these items?

- Yes
- No
- N/A
- WIP

**Comments:**

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### **Section 7 - Validation**

---

**121.** If any new equipment has been installed or equipment relocated since November 2014, was the following undertaken for each individual piece of equipment:

1. Was Operational Qualification performed and documented upon installation or relocation of reprocessing equipment in accordance with the applicable Standards and Manufacturers' Instructions?
2. Was Performance Qualification performed and documented upon installation or relocation of reprocessing equipment in accordance with the applicable Standards and Manufacturers' Instructions?

**NOTE:** If unable to answer YES for all equipment, document as WIP. This will need to be documented in the Action Plan for each individual piece of equipment.

- Yes
- No
- N/A
- WIP

**Comments:**

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**122.** 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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**123.** 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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**124.** If the water quality testing are higher than the recommended levels (as per Table 7.2), have these results been escalated and reported to the line Director?

- Yes
- No
- N/A
- WIP

**Comments:**

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**125.** 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:**

---

**126.** 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:**

---

**127.** Is Performance Qualification [PQ] planned and performed in accordance with National and International Standards? [See AS/NZS 4187:2014 - 7.4, 10.5 and Table 10.1]:

1. Immediately after Installation Qualification and Operational Qualification for newly installed or relocated equipment?
2. When repairs are made or a service is changed that may adversely impact the quality of the RMD?
3. When existing equipment is modified to deliver a new process?
4. When introducing new or modified RMDs, packaging or loading configurations? (Unless there is equivalence to a previously qualified reference load, RMD/product family, packaging or loading pattern has been demonstrated)

- Yes
- No
- N/A
- WIP

**Comments:**

---

**128.** 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:**

---

**129.** Have validation reports for each separate process been reviewed and approved by a designated person (on behalf of the Health Service Organisation) and reports are retained within the reprocessing Unit/Department/Clinic?

- Yes
- No
- N/A
- WIP

**Comments:**

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**130.** 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:**

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### **[Section 8 - Routine Monitoring and Control](#)**

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

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### **[Section 9 - Release of RMDs Following Reprocessing](#)**

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131. Do the criteria for release of a RMDs from reprocessing within your Unit/Department/Clinic comply with table 9.1 (Page 71 - types of reprocessing and the release criteria)?

- Yes
- No
- N/A
- WIP

**Comments:**

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132. Does the Unit/Department/Clinic have a traceability/electronic tracking system?

- Yes
- No
- N/A
- WIP

**Comments:**

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133. Is the [handling](#) of critical and semi-critical RMDs handled in a manner that protects the integrity of packaging until point of use?

- Yes
- No
- N/A
- WIP

**Comments:**

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134. Are critical and semi-critical RMDs [transported](#) in a manner that protects the integrity of packaging until point of use?

- Yes
- No
- N/A
- WIP

**Comments:**

---

135. Is the [storage](#) of critical and semi-critical RMDs in a manner that protects the integrity of packaging until point of use?

- Yes
- No
- N/A
- WIP

**Comments:**

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

- Yes
- No
- N/A
- WIP

**Comments:**

---

137. 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:**

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138. Is there dedicated dust free shelving, cupboards, drawers or containers for sterile RMDs and consumables?

- Yes
- No
- N/A
- WIP

**Comments:**

---

### [Section 10 - Maintaining process effectiveness](#)

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139. 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:**

---

**140.** Is preventative maintenance of all equipment planned and undertaken in accordance with documented procedures by the equipment manufacturer? (See AS/NZS 4187:2014)

- 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:**

---

**141.** Is the outcome of assessments, including the rationale for decisions reached documented – e.g. changing of chemicals, relocating equipment, changing packaging material, major repairs, changing load configuration?

**NOTE:** the assessment of change may require a repeat of instillation qualification, operational qualification or performance qualification (See AS/NZS 4187:2014 - 10.5)

- Yes
- No
- N/A
- WIP

**Comments:**

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#### **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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