# SELF ASSESSMENT SECTION 6

AS/NZS 4187:2014 REPROCESSING OF REUSABLE MEDICAL DEVICES IN HEALTH SERVICE ORGANIZATIONS

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<th>Standard</th>
<th>NSQHS 3 Preventing and Controlling HAI</th>
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**Questionnaire Instruction**

This self-assessment is your gap analysis for SECTION 6 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. This section is related to process definition.

Questions will be answered with: YES, NO, N/A or Work in Progress (WIP). WIP means that you are only part way through compliance for that particular question.

NOTE: THESE QUESTIONS ARE FOR YOUR UNIT ONLY.

You will need a copy of AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations when answering the questions as there are many references to Sections, tables and clauses within the questions.


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1. If the unit has a ‘flash steriliser:
   1. Has it been defined and validated by the central sterilising department?
   2. Have a process to document all RMDs that use this method?
      - Yes
      - No
      - N/A
      - WIP

**Comments:**
2. If the unit has a fast track process:
   1. Has it been defined and validated?
   2. Have a process to document all RMDs that use this method?
      ○ Yes
      ○ No
      ○ N/A
      ○ WIP

   Comments:

3. Does the Unit have suitable reprocessing equipment for reprocessing of RMDs, e.g. prior to purchasing specialised equipment, has the Unit manager assessed that it has the correct reprocessing equipment for the specialised RMDs? (See 2.2.2)
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP

   Comments:

4. Does the Unit have a process for identifying, recording, communicating and escalating issues/incidents related to transport and pre-treatment?
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP

   Comments:

5. If the Unit reprocesses heat sensitive semi-critical RMDs (e.g. anaesthetic equipment), does the Unit have the following in place:
   1. identification of all RMDs that are classified as heat sensitive semi-critical?
   2. documented procedures for reprocessing? (See 5.1.2)
   3. monitoring requirements? (See Table 6.1)
   4. processes to ensure they do not become contaminated?
      ○ Yes
      ○ No
      ○ N/A
      ○ WIP

   Comments:
6. If the Unit reprocesses heat labile semi-critical RMDs (e.g. endoscopes, transvaginal probes, TOE probes), does the unit 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
   
   Comments:

7. Does the Unit have a documented criteria for the selection, purchase and evaluation for sterile barrier systems (packaging)?
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP
   
   Comments:

8. Does the Unit have a documented process for the validation of sterile barrier systems?
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP
   
   Comments:

9. Do all sterilisers have a drying cycle for wrapped RMDs? (See 6.4.1)
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP
   
   Comments:

10. If the Unit reprocesses RMDs from outside the Health Service Organisation, has process definition and validation been undertaken for these items?
    ○ Yes
    ○ No
    ○ N/A
    ○ WIP
    
    Comments:
11. Does the Unit have the manufacturers’ instructions for all types of sterilisers?
   ○ Yes
   ○ No
   ○ N/A
   ○ WIP

Comments: