### Section 8 - Routine Monitoring and Control

1. Is there a plan for microbiological surveillance of all flexible endoscopes with channels and the AER? The plan should include:
   1. frequency
   2. responsibility
   3. recording if endoscope is either terminally sterilised or high-level disinfection on the pathology request form
   4. sign off of pathology reports
   5. trend reporting to the health service organisation infection prevention and control committee

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**Questionnaire Instruction**

This self-assessment is your gap analysis for SECTIONS 8-10 - AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. These sections are related to routine monitoring and control; release of RMDs following reprocessing; and maintaining process effectiveness.

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

**NOTE:** THESE QUESTIONS ARE FOR YOUR UNIT ONLY.

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

**NOTE:** See AS/NZS 4187:14 Guidance to Sections 8 – 10, Page 102 A8.1 - 10.5.
2. Is there a process to ensure that loaned flexible endoscopes or those returned from repair have microbiological testing within 72 hours of receipt?
   - Yes
   - No
   - N/A
   - WIP
   Comments:

3. Is there routine monitoring and control of packaging procedures that ensure the packaged items produced during routine operation meets the specification for:
   1. wraps?
   2. reusable rigid sterilising containers?
   3. laminates?
   4. self-seal laminates?
   5. autoclave bags?
      - Yes
      - No
      - N/A
      - WIP
   Comments:

4. Is there routine monitoring and control for heat sealers (see 8.6)?
   - Yes
   - No
   - N/A
   - WIP
   Comments:

5. Does the sterilising equipment monitoring and control program comply with Table 8.2 - Requirements for routine monitoring and control of sterilising equipment?
   - Yes
   - No
   - N/A
   - WIP
   Comments:
Section 9 - Release of RMDs following reprocessing

6. Do the criteria for release of a RMD from reprocessing comply with table 9.1 (criteria for release of an RMD from reprocessing)?
   - Yes
   - No
   - N/A
   - WIP
   Comments:

7. Does the Unit have a traceability/electronic tracking system?
   - Yes
   - No
   - N/A
   - WIP
   Comments:

8. Are 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:

9. 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:

10. 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:
11. Do the Unit procedures for the maintenance of the sterility of released RMDs comply with the list on page 103, A9.5 a-i?

**NOTE:** This list includes handling, storage and transport.

- Yes
- No
- N/A
- WIP

Comments:

12. Have the Unit staff been provided education on the handling, transport and storage of reprocessed RMDs?

- Yes
- No
- N/A
- WIP

Comments:

13. Is there a risk assessment or audit of transport systems to ensure that the systems protect the package integrity until the point of use?

- Yes
- No
- N/A
- WIP

Comments:

14. Is there restricted access to the Unit’s storage areas for critical and semi-critical RMDs, including consumables?

- Yes
- No
- N/A
- WIP

Comments:

15. Are 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

16. Are service level agreements/contracts in place with qualified service providers to provide the final reports [see 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:

17. Is preventative maintenance of all equipment planned and undertaken in accordance with documented procedures by the equipment manufacturer?
   See 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:

18. 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 installation qualification, operational qualification or performance qualification (see 10.5)
      ○ 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

March 2018