ORAL/DENTAL HEALTH SERVICE 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	This self-assessment is your gap analysis for AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations. Questions with '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 4187:14 Guidance to each Section. They commence on Page 79. 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. If your oral/dental health service/clinic outsources all reprocessing, auditing is not required. Your Service Level Agreement will require the CSD that performs the reprocessing to be compliant with AS/NZS4187:2014. Comments section can be used to document: policy name/links, location of evidence, recommendations, auditing programs, gaps you have identified, links to Instructions for Use etc. NOTE: if there are variations between individual clinics, document in Comments Section.

Section 1 - Governance

1. Describe your oral/dental health service/clinic – e.g. number of clinics; if reprocessing is in-house; outsourced or a combination; number of clients/year; other relevant details you require for National Standard 3.

Comments:

2. Describe the reason for assessing your oral/dental health service/clinic against AS/NZS 4187:2014

Comments:

3. Does your oral/dental health service/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

Comments:

4. 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)

5. Does your oral/dental health service/clinic 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:

6. Does your oral/dental health service/clinic have access to current Health Service Organisation Policy or Procedures or Guidelines for the purchase of critical consumables? (includes obtaining the manufacturers' instructions and validation data/report e.g. sterile barrier systems) (See 2.4.2 and 6.4.1)
   - ○ Yes
   - ○ No
   - ○ WIP

   Comments:

---

7. Does your oral/dental health service/clinic 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
   - ○ WIP

   Comments:

---

8. Does your oral/dental health service/clinic 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 for point 2
   □ WIP

   Comments:

---

9. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for Validation and Requalification of Product Families?
   - ○ Yes
   - ○ No
   - ○ N/A
   - ○ WIP

   Comments:

---

10. Does your oral/dental health service/clinic 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 for point 2
- ○ WIP

Comments:

---

11. Does your oral/dental health service/clinic 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 from a clinic?

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

---

12. Does your oral/dental health service/clinic 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?

NOTE: for those not applicable, document in Comments Section

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

---

13. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the cleaning of RMDs prior to sterilisation?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

14. Does your oral/dental health service/clinic have a Policy or Procedures or Guidelines for Emergency Sterilisation (includes Fast Track)? (See 6.1.2)

- Yes
- No
- N/A
- WIP

Comments:

---

15. Does your oral/dental health service/clinic 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
- WIP

Comments:

---

16. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the inspection, assembly and packaging of RMDs prior to sterilisation?

- Yes
- No
- WIP

Comments:

---

17. Does your oral/dental health service/clinic 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:

---

18. Does your oral/dental health service/clinic 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:

---

19. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the loading and unloading of RMDs from the sterilising equipment used to reprocess RMDs?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

20. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the traceability of reprocessed RMDs (critical and/or semi critical)?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

21. Does your oral/dental health service/clinic 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 for point 2
- ○ WIP

Comments:

---

22. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the release of RMDs following sterilisation?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

23. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the handling and transport of RMDs prior to and following reprocessing?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

24. Does this your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the cleaning of:
1. Processing equipment?
2. Environmental cleaning of the oral/dental health service/clinic (including project or high cleaning)?
3. Other equipment/furniture within the oral/dental health service/clinic?
4. Specialised cleaning, e.g. air conditioning outlets, filters?

- Yes
- No
- WIP

Comments:

---

25. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the periodic preventative maintenance of processing equipment including calibration of monitoring instrumentation?

- Yes
- No
- WIP

Comments:

---

26. Does your oral/dental health service/clinic 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
- WIP

Comments:

---

27. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for action to be taken in the event of control of nonconforming RMDs (corrective and preventative)?
Note: See Glossary of Terms for definitions

- Yes
- No
- WIP

Comments:

---

28. Does your oral/dental health service/clinic 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?
9. Communication and reporting requirements, including escalation and risk assessment?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

29. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for the review of deviation reports and other indicators of quality or procedural problems?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

30. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for training and competency assessment of staff?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

31. Does your oral/dental health service/clinic have current continuity plan for emergencies, e.g. equipment breakdowns, recalls, loss of service?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

32. Does your oral/dental health service/clinic have current Policy or Procedures or Guidelines for purchasing reprocessing equipment/accessories and RMDs/accessories? (See 2.4.2)

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

33. Does your oral/dental health service/clinic 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
- ○ WIP

Comments:

---

34. 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 your oral/dental health service/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?
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
- ○ WIP

Comments:

---

35. Does your oral/dental health service/clinic have current Policy or Procedure or Guidelines for the storage, handling, decanting and disposal of chemicals? (see 3.7.3)

- ○ Yes
- ○ No
- ○ WIP

Comments:

Section 2.2.3 - Records

---

36. Does your oral/dental health service/clinic hold records for purchased RMDs?
NOTE: if records are held by another department, document location in the Comments Section

- ○ Yes
- ○ No

Comments:

---

37. Does your oral/dental health service/clinic hold records for purchased reprocessing equipment?
NOTE: if records are held by another department, document location in the Comments Section
○ Yes
○ No

Comments:

---

38. Does your oral/dental health service/clinic hold records for monitoring and servicing of reprocessing equipment?
NOTE: if records are held by another department, document location in the Comments Section
○ Yes
○ No

Comments:

---

39. Does your oral/dental health service/clinic hold records for reprocessing print-outs/documentation?
NOTE: if records are held by another department, document location in the Comments Section
○ Yes
○ No

Comments:

---

40. Does your oral/dental health service/clinic hold records for high-level disinfection, including chemical and thermal process records?
NOTE: if records are held by another department, document location in the Comments Section
○ Yes
○ No
○ N/A

Comments:

---

41. Does your oral/dental health service/clinic hold records for the cleaning of reprocessing equipment, e.g. checklist?
NOTE: if records are held by individual clinics, document in Comments Section
○ Yes
○ No

Comments:

---

42. Does your oral/dental health service/clinic hold records for environmental cleaning audit results for each dental clinic?
NOTE: if records are held in individual clinics, document in Comments Section
○ Yes
○ No
○ WIP

Comments:

---

43. Does your oral/dental health service/clinic hold records for staff training and evidence of staff competency/assessments?
NOTE: if records are held in individual clinics, document in Comments Section

- Yes
- No
- WIP

Comments:

---

44. Does your oral/dental health service/clinic hold records for staff rosters and allocations?
NOTE: if records are held in individual clinics, document in Comments Section

- Yes
- No
- WIP

Comments:

---

45. Does your oral/dental health service/clinic hold records for maintenance of RMDs or reprocessing equipment?
NOTE: if these are held onsite for individual clinics e.g. Biomedical Engineering - document in Comments Section

- Yes
- No
- WIP

Comments:

---

46. Does your oral/dental health service/clinic hold records for Installation Qualification, Operational Qualification and Performance Qualification for reprocessing equipment?
NOTE: if these are held onsite for individual clinics, e.g. Biomedical Engineering - document in Comments Section

- Yes
- No
- WIP

Comments:

---

47. Does your oral/dental health service/clinic hold records for process deviation reports and where applicable, records of corrective action and/or preventative action?
NOTE: if these are held onsite for individual clinics, document in Comments Section

- Yes
- No
- WIP

Comments:

Section 2.2.4 - Control of documents and records

---

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

- ○ Yes
- ○ No

Comments:

---

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

- ○ Yes
- ○ No

Comments:

2.3.1 - Management Responsibility

---

50. Is your oral/dental health service/clinic part of a documented and approved organisational structure that enables the service/clnic to meet the requirements of AS/NZS 4187:2014?
NOTE: the organisational structure includes all dental clinics

- ○ Yes
- ○ No

Comments:

---

51. For requests for resources to meet and maintain AS/NZS 4187:2014, does your oral/dental health service/clinic have a process for escalating risk rated submissions?
NOTE: resources include buildings, workspaces, staffing, equipment, RMDs

- ○ Yes
- ○ No
- ○ WIP

Comments:

2.3.3 - Reprocessing within the oral/dental health service/clinic

---

52. 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/NZS 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 related to reprocessing within your oral/dental health service/clinic?

- ○ Yes
- ○ No
- ○ WIP

Comments:

---

53. Does your oral/dental health service/clinic have a formal/planned orientation/induction, training program and competency assessment for staff who perform reprocessing?

- Yes
- No
- WIP

Comments:

2.3.4 - 2.3.5 - (Equipment and Contracts)

---

54. Does your oral/dental health service/clinic have external contracts/Service Level Agreements for maintenance, preventative maintenance, performance qualification and they include responsibility and compliance with AS/NZS 4187:2014?

- Yes
- No
- WIP

Comments:

2.4 - 2.4.2 - Purchasing

See Question 34

Section 2.4.3 - 2.4.3.2 - Traceability Records

---

55. Does the traceability 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
- WIP

Comments:

Section 2.4.4 - 2.4.4.3 - Monitoring and measuring equipment and documentation

56. Has your oral/dental health service/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:

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

- Yes
- No
- WIP

Comments:

Section 2.5. - 2.5.4 - Recall and preventative action

58. Does your oral/dental health service/clinic 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
- WIP

Comments:

59. 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
○ WIP
○ Will also be reported in IIMs

Comments:

Section 3 – Reprocessing Agent Characterisation

60. Are all Agents used within your oral/dental health service/clinic listed on the Australian Register of Therapeutic Goods (ARTG)?
○ Yes
○ No

Comments:

---

61. 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

Comments:

---

62. Where the manufacturer of the cleaning agents make claims of their microbicidal effectiveness, do they include the evidence in their technical information? (See 3.5)
○ Yes
○ No

Comments:

---

63. Are Safety Data Sheets (SDS) available for every agent (cleaning, disinfecting and sterilising) used within your oral/dental health service/clinic?
○ Yes
○ No

Comments:

---

64. Does your oral/dental health service/clinic have copies of the manufacturer's information (technical information) available, e.g. microbial efficacy, toxicity/residues, compatibility?

○ Yes
○ No

Comments:

---

65. Are cleaning agents used in your oral/dental health service/clinic suitable for intended purpose as recommended by the manufacturer in their Instructions for Use – e.g. manual cleaning, ultrasonic machine?

○ Yes
○ No
○ N/A

Comments:

---

66. Has the manufacturer been consulted regarding the compatibility of the available water quality with the cleaning agent? (IF APPLICABLE) (See 3.1.3)

○ Yes
○ No
○ N/A
○ WIP

Comments:

---

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

○ Yes
○ No
○ N/A

Comments:

---

68. In your oral/dental health service/clinic, are intermediate or low level instrument grade disinfectant used for non-critical RMDs where required – e.g. dental impressions? (see Section 5 and Spaulding's Classification System)

○ Yes
○ No

Comments:

---

69. Have staff been provided education on sterilising/disinfectant agents and how they must not be used outside the recommended conditions specified by the manufacturer?

○ Yes
○ No

Comments:

---

70. 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 5.3)

○ Yes
○ No

Comments:

---

71. If t your oral/dental health service/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

Comments:

---

72. Does your oral/dental health service/clinic have the correct storage facilities for all cleaning, disinfectant and sterilising agents?

○ Yes
○ No

Comments:

---

73. Has your oral/dental health service/clinic trained staff in the correct use of PPE for handling agents and the PPE is available at the point of use?

○ Yes
○ No

Comments:

---

74. Does your oral/dental health service/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 us?

○ Yes
○ No

Comments:

---

75. Are appropriate Spill Kits located near storage/use of chemical agents?

○ Yes
○ No

Comments:

---

76. 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 supplied Spill Kit?

○ Yes
○ No
○ N/A

Comments:

---

77. 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

Comments:

---

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

○ Yes
○ No

Comments:

---

79. Are monthly WHS Inspections completed and actioned?

○ Yes
○ No
○ N/A

Comments:

---

80. 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

Comments:

Section 4 – Process Characterisation and Equipment Characterisation

81. Has your oral/dental health service/clinic obtained all relevant details from the manufacturer/supplier on equipment that performs cleaning, disinfecting and sterilising? (Details include: specifications/technical information/advice) (see 4.2 a-h)

- ○ Yes
- ○ No

Comments:

82. 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)?

(Requires evidence of a documented list with equipment, equipment type, manufacturer) (see 4.3.1 a-g)

- ○ Yes
- ○ No
- ○ WIP

Comments:

83. Can the steam steriliser be programmed to sterilise all Product Families required for the Health Service Organisation? (see 7.4.1 e)

NOTE: The Health Service will be required to determine what RMDs belong in a product family first

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

84. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Washer-disinfectors: [ISO 15883]

- ○ Yes
- ○ No
- ○ N/A

Comments:

85. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Ultrasonic cleaners: [AS 2773.1 or AS 2773.2]

○ Yes
○ No
○ N/A

Comments:

---

86. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Drying cabinets: [AS 2514]

○ Yes
○ No
○ N/A

Comments:

---

87. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Heat sealers. [Refer to ISO 11607-2 and ISO/DTS 16675-3 for guidance]

○ Yes
○ No
○ N/A

Comments:

---

88. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Steam sterilisers — Large: [EN 285]

○ Yes
○ No
○ N/A

Comments:

---

89. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Steam sterilisers—Small: [EN 13060]

○ Yes
○ No
○ N/A

Comments:

---

90. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Hydrogen peroxide gas/plasma sterilisers. [Refer to ISO 14937 for guidance]

○ Yes
○ No
○ N/A

Comments:

---

91. Does your oral/dental health service/clinic's reprocessing equipment comply with the following Standards? Biological indicator incubators. [Refer to ISO 11138-1 or ISO 14161 for guidance]

- ○ Yes
- ○ No
- ○ N/A

Comments:

Section 5 - 5.1 - 5.5.3 - Product definition

---

92. Have all RMDs been classified into Product Families?
NOTE: Classification of RMDs into product families will assist in developing processing conditions. [Refer to ISO/TS 17665-3 and ISO 17664 and Section 5.2]

- ○ Yes
- ○ No
- ○ N/A
- ○ WIP

Comments:

---

93. Does your oral/dental health service/clinic have a process to identify where limiting/process values such as exposure time, pressure and temperature (see 5.3) are exceeded?

- ○ Yes
- ○ No

Comments:

---

94. Is there as process to ensure that the items (RMDs and their packaging) are not compromised during all stages in the pre-disinfection and pre-sterilising workflow?

- ○ Yes
- ○ No

Comments:

---

95. Does the sterile barrier system for RMDs comply with ISO 11607-1 and ISO 11607-2?

- ○ Yes
- ○ No

Comments:

---

96. Is any protective packaging (e.g. instrument tip protectors applied prior to sterilisation) compatible with the sterilising process?

- ○ Yes
- ○ No

Comments:

Section 5 - 5.6 - 5.6.14 - Facility Design

97. Does your oral/dental health service/clinic have an effective segregation of clean and dirty activities and the segregation that prevents cross contamination?

○ Yes
○ No

Comments:

---

98. Does your oral/dental health service/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

Comments:

---

99. Is the reprocessing unit of your oral/dental health service/clinic free from opening windows?

○ Yes
○ No

Comments:

---

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

○ Yes
○ No

Comments:

---

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

○ Yes
○ No

Comments:

---

102. Are all work surfaces, fittings, fixtures, window treatment, shelving and furniture in the reprocessing unit of your oral/dental health service/clinic easy to clean and maintained in a good condition?

○ Yes
○ No

Comments:

---

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

○ Yes
○ No

Comments:

---

104. 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

Comments:

---

105. Is water of the required quality and specified for reprocessing RMDs. (See Section 7.2.3.1 and Table 7.2 - check Standards Australia for a revision of this table)?
○ Yes
○ No

Comments:

---

106. Are workstations:
1. Supplied with sufficient electricity supply, computer terminal points to facilitate safe and effective reprocessing activities?
2. Suitably equipped for preparation and packaging?
3. An adequate size to accommodate packaging materials to be used and are height adjustable?
4. Have an adequate space between workstations for the safe movement of equipment and staff?
○ Yes
○ No
○ N/A

Comments:

---

107. Does the reprocessing facility have adequate lighting (including magnification) to enable thorough visual examination of RMDs?
○ Yes
○ No

Comments:

---

108. Are bulk storage (e.g. consumables) facilities external to the cleaning and packing areas?
○ Yes
○ No

Comments:

---

109. Is there a dedicated area provided within the steriliser unloading zone for cooling of sterilised RMDs?
- ○ Yes
- ○ No
- ○ N/A

Comments:

---

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

Comments:

---

111. Does the cleaning of the reprocessing area meet the cleaning risk rating and auditing requirements of NSW Health Environmental Cleaning Policy PD2012_061?
NOTE: This may vary for each clinic. Use the comments section to write the details for each clinic
- ○ Yes
- ○ No

Comments:

---

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

Comments:

---

113. Are there sufficient hand hygiene facilities (handwash and alcohol based hand rub) available and accessible in all work areas?
- ○ Yes
- ○ No

Comments:

---

114. Are the alcohol based hand rubs and handwash products approved for use by the Health Service Organisation within the reprocessing areas?
- ○ Yes
- ○ No

Comments:

---

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

○ Yes
○ No

Comments:

---

116. Does the disposal of waste comply with the requirements of the local regulatory authorities, NSW Health policy and health service organisation policies?

○ Yes
○ No

Comments:

Section 6 – Process Definition

---

117. If your oral/dental health service/clinic 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

Comments:

---

118. Does your oral/dental health service/clinic have suitable reprocessing equipment for the reprocessing of RMDs (includes both routine and specialised RMDs)? (See 2.2.2)

○ Yes
○ No

Comments:

---

119. Does your oral/dental health service/clinic have a process for identifying, recording, communicating and escalating issues/incidents related to transport and pre-treatment?

○ Yes
○ No

Comments:

---

120. If your oral/dental health service/clinic reprocesses heat sensitive semi-critical RMDs (e.g. relative anaesthetic tubing), does the service/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 5.1.2)
3. Monitoring requirements? (See Table 6.1)
4. Processes to ensure they do not become contaminated?

○ Yes
○ No
○ N/A

Comments:

---

121. Does your oral/dental health service/clinic have documented criteria for the selection, purchase and evaluation for sterile barrier systems (packaging)?

○ Yes
○ No

Comments:

---

122. Does your oral/dental health service/clinic have a documented process for the validation of sterile barrier systems?

○ Yes
○ No

Comments:

---

123. Do all sterilisers have a drying cycle for wrapped RMDs? (See 6.4.1)

○ Yes
○ No
○ N/A

Comments:

---

124. If your oral/dental health service/clinic reprocesses RMDs from outside the service, has process definition and validation been undertaken for these items?

○ Yes
○ No
○ N/A

Comments:

---

125. Does your oral/dental health service/clinic have the manufacturer's instructions for all types of sterilisers?

○ Yes
○ No
○ N/A

Comments:

Section 7 - Validation

---

126. 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:

---

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

- ○ Yes
- ○ No
- ○ N/A

Comments:

---

128. 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

Comments:

---

129. 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/Manager?

- ○ Yes
- ○ No
- ○ N/A

Comments:

---

130. Is planning underway for the installation of a reverse osmosis (RO) water treatment plant and the compatibility of reprocessing equipment been assessed with the reprocessing equipment manufacturer?

- ○ Yes
- ○ No
- ○ N/A

Comments:

---

131. Is there ongoing consultation and an agreement with the supplier of local water to notify the HSO of changes likely to affect the quality of potable water?
NOTE: information may be sent to Engineering Department, Local Council or Public Health LHD/SHN ORAL HEALTH SERVICE
○ Yes
○ No

Comments:

---

132. For steam sterilisers installed since November 2014, were tests conducted prior to equipment installation to demonstrate the water supplied to the steam generator is in accordance with EN 285, Table B1- contaminants in condensate and feed water] and the results recorded?
○ Yes
○ No
○ N/A

Comments:

---

133. For oral/dental health services/clinics that have a dedicated steam generator:
If the feedwater is not treated chemically, is there a water testing and reporting schedule to comply with the requirements in EN 285, Table B1 - contaminants in condensate and feed water?
○ Yes
○ No
○ N/A

Comments:

---

134. Has a steam purity and dryness tests been scheduled and performed in the Installation Qualification /Operational Qualification in accordance with EN 285 [see table 10.1, Table B1 and Table E2]?
NOTE: steam quality testing does not apply to small steam sterilisers that utilise distilled or RO water for steam generation.
○ Yes
○ No
○ N/A

Comments:

---

135. Has Operational Qualification [OQ] been performed and documentation supplied by the reprocessing equipment manufacturer in accordance with the applicable National or International Standards? (See 7.3)
○ Yes
○ No
○ N/A

Comments:

---

136. Is Performance Qualification [PQ] planned and performed in accordance with National and International Standards? [see 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

Comments:

---

137. Are there validated cleaning processes (manual and washer/disinfector) used for RMDs – e.g. soil test, protein test, residual chemical test?

○ Yes
○ No
○ N/A

Comments:

---

138. Has Performance Qualification of thermal or chemical disinfecting processes using washer/disinfectors performed in accordance with the relevant ISO 15883 series of standards? (See 1.3 - Normative References]

○ Yes
○ No
○ N/A

Comments:

---

139. Does your oral/dental health service/clinic's validation process for packaging include:
1. Sealing processes for pouches, reels and bags?
2. Wrapping processes for folding and closing of sterilisation wraps?
3. Processes for filling and closing of reusable containers.

○ Yes
○ No
○ N/A

Comments:

---

140. Are the heat sealers tested (according to manufacturers' instructions) and results documented to indicate that they consistently produce a conforming sterile barrier system?

○ Yes
○ No
○ N/A

Comments:

---

141. Has the manufacturer provided evidence that the design of reusable containers allows sterilising and maintenance of sterility within the contents of the container (see 7.4.4.4)?

○ Yes
○ No
○ N/A

Comments:

---

142. Does the annual Performance Qualification (PQ) documentation include (see 7.4.5):

1. The sterility assurance level for each steriliser
2. Biological indicator results and indication of location within the load
3. Wrapping/packaging PQ
4. The physical parameters of the sterilising process i.e. holding time, pressure and temperature
5. Load mass/contents
6. Each steriliser and cycle type
7. Cycle type performed concurrently, e.g. 3 in a row

○ Yes
○ No
○ N/A

Comments:

---

143. Are all product families considered for annual PQ (see 7.4.5)?

○ Yes
○ No
○ N/A

Comments:

---

144. 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 of your oral/dental health service/clinic?

○ Yes
○ No
○ N/A

Comments:

---

145. Is a summary of the annual validation reports presented or discussed to a nominated clinical Health Service Organisation Committee, e.g. Patient Safety, Oral Health Management?

○ Yes
○ No
○ N/A

Comments:

Section 8 - Routine monitoring and control

146. 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?

NOTE: for those listed items that are N/A, document in Comments section

○ Yes
○ No
○ N/A

Comments:

---

147. Is there a routine monitoring and control for heat sealers (see 8.6)?

○ Yes
○ No
○ N/A

Comments:

---

148. 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

Comments:

Section 9 - Release of RMDs following reprocessing

149. 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

Comments:

---

150. Does your oral/dental health service/clinic have a traceability/electronic tracking system?

○ Yes
○ No

Comments:

---

151. Is the handling of critical and semi-critical RMDs in a manner that protects the integrity of packaging until point of use?

○ Yes
○ No

Comments:

---

152. Are critical and semi-critical RMDs transported/moved in a manner that protects the integrity of packaging until point of use?

○ Yes
○ No

Comments:

---

153. Is the storage of critical and semi-critical RMDs in a manner that protects the integrity of packaging until point of use?

○ Yes
○ No

Comments:

---

154. Do your oral/dental health service/clinic's 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

Comments:

---

155. Have your oral/dental health service/clinic staff been provided education of the handling, transport and storage of reprocessed RMDs?

○ Yes
○ No

Comments:

---

156. 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

Comments:

---

157. Is there restricted access to your oral/dental health service/clinic's storage areas for critical and semi-critical RMDs, including consumables?

○ Yes
○ No

Comments:

---

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

○ Yes
○ No

Comments:

Section 10 - Maintaining process effectiveness

---

159. 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

Comments:

---

160. 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

○ Yes
○ No

Comments:

---

161. 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 10.5)

○ Yes
○ No
○ N/A

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