RICPRAC RURAL INFECTION CONTROL PRACTICE GROUP **INFECTION CONTROL AUDIT:** **Sterilizing Services: AS/NZS 4187:2014 COMPLIANCE AUDIT**

Facility:_____ Audit Date_____ Auditor Name/s_____

Abbreviations and Definitions – See page 10 (abbreviations); and pages 11-20 (definitions) of AS/NZS 4187.
'Policy' or 'procedure' : in this tool means '*policy*'/ '*procedure*'/ *work practice/ protocol/ guideline* (however it's named).
Note: the criteria are evaluating content within '*policies*' not asking for individual '*policies*'.
There is a 'policy' means the content is documented in a '*'policy''* (however named – see above).
Documented policies must meet the following requirements to pass (use the tick boxes).

i. Have defined intervals for review and are within the stated timeframe *(docs with no date or expired FAIL).*
ii. Have evidence of being approved by the HSO approval system *(unauthorised versions FAIL).*
iii. Are the only version used by the staff to guide practice *(Previous, multiple, or draft versions in use FAIL).*
iv. Records are maintained in a designated storage area for a period of time not less than that defined by regulatory authorities; or in their absence by HSO policy. Hint: *Identify where the secondary storage.*
v. Must be retrievable. Hint: *Ask staff to access a document.*

Scoring Criteria:
Not met:——score 0
Met ——score 1

These reference numbers refer to AS/NZS 4187:2014 (References to other documents are listed with the criteria)

No partial scores
Not applicable - mark N/A and score 1
(circle score)

	Evaluating detail and content in 'policy'; other documents and records	AS/NZS 4187:2014 Reference	Not met	Met
1.	There is an organisational *'policy'* for cleaning of RMDs, disinfection of RMDs and Sterilization of RMDs *Hint: – this overarching document guides reprocessing practices across the whole facility (other wards/ departments reprocessing RMD's). Detailed content in CSSD specific policies are evaluated separately.* *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2	0	1
2.	There is a *'policy'* for initial pre-treatment of used RMDs prior to their return to the reprocessing facility. The maximum period of time permitted to elapse between use; and initial cleaning of the RMD is specified. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2 6.2.2.2 5.1.3 A 6.2.2.2	0	1
3.	There is a *'policy'* for the collection and transport of ***used*** RMDs from point of use. Content includes protection of the RMD's, and prevention of contamination or harm to personnel and environment. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(g) 6.2.2.1	0	1
4.	*'Policy'* directs that all RMDs which have been opened (but not used) are subjected to all stages of the reprocessing procedures.	5.1.3(d)	0	1
5.	There is a *'policy'* for handling specialized RMDs, loan, and trial instruments. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(h) 2.4.2 5.1.3(c)	0	1
6.	There is a *'policy'* for purchasing reprocessing equipment, RMDs and accessories including critical consumables. *'Policy'* directs how new RMDs are introduced into circulation. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(b) 2.2.3(a) 5.1.3	0	1
7.	Content within the purchasing *'policy'* is consistent with 2.4.2 parts a–h. *a* ☐ *b* ☐ *c* ☐ *d* ☐ *e* ☐ *f* ☐ *g* ☐ *h* ☐	2.4.2	0	1
8.	There is a *'policy'* instructing disinfection of cleaned RMDs. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(n)	0	1
9.	There is a *'policy'* for routine monitoring and control of cleaning, disinfecting & sterilizing processes. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2 & A6.2.3	0	1
10.	There is a *'policy'* for handling, transport and storage of reprocessed RMDs. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(r)	0	1
11.	There is a *'policy'* for cleaning of reprocessing equipment. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(s)	0	1
	Page 1 Total (Possible score 11)	**Score**	**____ / 11**	

	Evaluating detail and content in 'policy'; other documents and records	AS/NZS 4187:2014 Reference	Not Met	Met
12.	There is a *'policy'* for the loading and unloading of the cleaning equipment *i.* ☐ *ii.* ☐ *iii.* ☐ *Other reference:* ***ISO 15883-2***	2.2.2(l) 6.2.3(e)	0	1
13.	There is a *'policy'* for Inspection, assembly (& testing if applicable) and packaging of RMDs prior to disinfection; and prior to sterilization. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(j) 6.4.2 A6.4.2	0	1
14.	There are documented instructions for assembly of RMD's into trays or sets. Content instructs that RMD are not packaged with tubing or textiles & RMD with hinges and ratchets are assembled in the unlocked position. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2 6.4.2 A6.4.2	0	1
15.	There is a *'policy'* guiding the use of internal indicators (if used) ☐ *Not used (not applicable-Score 1)*	8.7.6	0	1
16.	There is a '*policy*' for sterilization of RMDs consistent with parts a–e of 6.5.2. *a* ☐ *b* ☐ *c* ☐ *d* ☐ *e* ☐ *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2 & , 6.5.2	0	1
17.	There is a *'policy'* directing traceability of reprocessed semi-critical and critical RMDs. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(m)	0	1
18.	The *'policy'* for release includes documented criteria consistent with table 9.1 *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(q) 9.1–9.5	0	1
19.	*'Policy'* directs the investigation of nonconforming RMD, the action to be taken when nonconforming RMD are detected; the corrective and preventative action, recall (if necessary); review of deviation reports and indicators of non conformances and re-evaluation to verify the cause of nonconformity is resolved. *Other reference* ***ISO 14937 3.5***	2.2.2(v) 2.2.2(x) 2.5.2 2.5.3.1	0	1
20.	*'Policy'* documents the minimum cleaning and high level disinfection process when sending non conforming RMD off-site (repair or maintenance).	5.1.3(b– c)	0	1
21.	There is a '*policy*' stating that medical devices labelled single use are not reprocessed or reused.	5.1.3(f)	0	1
22.	There is a *'policy'* for qualification and requalification of reprocessing equipment (cleaning, disinfecting and sterilizing) Content includes specified procedures for requalification. *i.* ☐ *ii.* ☐ *iii.* ☐	2.2.2(c) 2.2.2(d) 10.4.2	0	1
23.	RMDs are classified into product families and the classification is documented and validated. *Other reference:* ***ISO 17664*** *and* ***ISO 17665-3***	5.2 A 2.4.1 A2.2.2(f)	0	1
24.	There is copy of the validation report in the department for each **WD**. This report indicates the WD has passed IQ, OQ & PQ. *[Note: major repairs and relocation of the WD then the IQ, OQ & PQ report must be dated after the move]* *Info: Requirements for the report are specified in section 7.5* *Other reference* ***ISO 15883-1*** *6.1* IQ: ☐ _/__/__ OQ: ☐ _/__/__ PQ: ☐ _/__/__	7.1 7.2 7.3 7.4 7.5 10.4	0	1
25.	There is a requalification report showing each **WD** has passed PQ. *(Not met if >12 months).* (*annual*) PQ: ☐ __/__/__	7.4 7.5 10.4	0	1
26.	Ancillary items for the WD have been supplied and installed in accordance with their specification. *Other reference* ***ISO 15883***	7.1.1 7.2.2 & 7.3	0	1
27.	There is copy of the validation report in the department for each **sterilizer**. This report indicates the sterilizer has passed IQ, OQ & PQ. *(Major repairs and relocation of the Sterilizer:– The IQ, OQ & PQ report must be dated after sterilizer was moved).* *Info: Requirements for the report are specified in section 7.5.* *Other reference* ***ISO 17665-1*** *6.1.1 (a-p); 6.1.3 (a-e); 6.2; 6.2.2, 9.2, & 9.3* IQ: ☐ _/__/__ OQ: ☐ _/__/__ PQ: ☐ _/__/__	7.2.2 7.3 7.5.2 (a–n) 7.5.3	0	1
	Page 2 Total (Possible score 16)	**Score**	**____ / 16**	

	Evaluating documents records and quality	AS/NZS 4187:2014 Reference	Not met	Met
28.	There is a requalification report showing each **sterilizer** has passed PQ *(Not met If >12 months)* (*annual*) PQ: ☐ __/__/__	7.4 7.5	0	1
29.	The Biological indicators used on sterilizers during PQ demonstrate compliance with parts (i–iv) of 7.4.5 & ISO 11138-1. *i* ☐ *ii* ☐ *iii* ☐ *iv* ☐ *Other reference*: ***ISO 11138; ISO 17665 – 1*** [8.5; 8.6; 8.8]	7.4.5[(i–iv)]	0	1
30.	Each type of packaging has been validated and incorporated into annual PQ. *Other reference* ***ISO 11607-1*** and ***11607-2*** [5.4]	5.5.1 5.5.2 7.4.1 10.4	0	1
31.	There is documented evidence including IQ, OQ & PQ that each **Automated Endoscope Reprocessor (AER)** and/ or other **low temperature sterilization** systems (e.g. STERIS, Soluscope, Medivator or other); have been validated. *Other reference* ***ISO 14937*** IQ: ☐ __/__/__ OQ: ☐ __/__/__ PQ: ☐ __/__/__	7.2 7.3 7.4 7.5.2 [(a–n)] 7.5.3	0	1
32.	There is a requalification report showing each **AER** and/ or other **low temperature sterilization** system has passed annual PQ *(Not met if date is >12 months).* (*annual*) PQ: ☐ __/__/__	7.4 7.5, 10.4	0	1
33.	There are records of the recalibration, preventative maintenance and testing of the **AER** and /or other **low temperature sterilization** systems in accordance with Table 10.1.	10.1	0	1
34.	(IQ) There is evidence of a 'certificate of calibration' from the heat sealing equipment manufacturer. Dated __ /__ /__	7.2.2	0	1
35.	There is a documented program of preventative maintenance for all reprocessing equipment. There are documented records of maintenance activities. *iv.* ☐ *v.* ☐ *Other reference* ***Sterilizers ISO 17665 Washer disinfectors D15883series***	2.2.2[(t)] 5.2[(e)] 10.1 Table 10.1 10.3.1	0	1
36.	The organisational monitoring and measuring equipment is calibrated using NATA accredited equipment; and as specified in section 2.4.4.1. (If using external contractors; the agency has confirmed that NATA accredited equipment is used). There are calibration reports for each piece of monitoring and measuring equipment.	2.4.4.1 2.4.4.2	0	1
37.	There is a documented contingency '*procedure*' in case automated cleaning equipment is unavailable. This instructs the acceptable alternative cleaning processes or whether an item is to wait until an automated cleaning process is available. *Confirm the sterilizing staff are aware of this process to pass.*	A 6.2.1	0	1
38.	Records are kept of the repair and action taken when non conforming and faulty equipment is identified. *iv.* ☐ *v.* ☐	2.4.4.3	0	1
39.	There are purchasing records for the RMDs; and reprocessing equipment. *iv.* ☐ *v.* ☐	2.2.3	0	1
40.	There records of periodic audits to evaluate compliance with AS/NZS4187:2014. Date of last audit: __ /__ /__	2.5.1	0	1
41.	The manager (however named) directly responsible for the reprocessing of RMDs within the facility meets the requirement specified in parts a– e of 2.3.3. *a* ☐ *b* ☐ *c* ☐ *d* ☐ *e* ☐	2.3.3[(a–e)]	0	1
42.	Staff training: There is a formal induction/orientation program as listed in Section A2.3.3.	A2.3.3	0	1
43.	Staff Training: Staff completes periodic reassessment of competencies for reprocessing activities. Documented records are kept.	2.2.2[(aa)] 2.2.3[(j & e)] A2.3.3	0	1
	Page 3 Total (Possible score 16)	**Score**	**___ / 16**	

	Evaluating Practices (and evidence of compliance with documented 'policy')	AS/NZS 4187:2014 Reference	Not met	Met
44.	Entry to the reprocessing facility is restricted.	5.6.11	0	1
45.	Hand hygiene facilities are available and accessible in all work areas.	5.6.12	0	1
46.	Hand creams are not used when performing reprocessing activities.	5.6.12	0	1
47.	Personal protective equipment (PPE) is easily accessible and worn in each of the work areas.	5.6.12	0	1
48.	The reprocessing environment has distinct and separate physical segregation of the cleaning areas from the other reprocessing areas (i.e. packing/ sterilization/ cooling/ storage). The work flow is unidirectional from dirty to clean.	5.6.1 5.6.2	0	1
49.	The reprocessing environment is protected and controlled (includes temperature 18°C-25°C, humidity 35-70%, controlled traffic flow, directed workflow from dirty to clean and airflow is from clean to dirty) so that the integrity of the sterilization process and the integrity of the packaging are not compromised. *Other reference* ***AS 1668.2***	5.4, 5.6.1 5.6.2 A9.5	0	1
50.	All work surfaces, fittings, fixtures, windows, shelving and furniture are constructed of robust non shedding materials that are easy to clean and maintain. i.e. Non opening windows, junctions between walls and floors are coved and flush.	5.6.3 5.6.4	0	1
51.	There is task lighting and magnification. Ceiling lights are flush fitting.	5.6.8	0	1
52.	Sinks are of sufficient size and depth to fully immerse the RMD. Sinks are ergonomically designed. Sinks are dedicated for pre-treatment and manual cleaning and rinsing of RMD. These sinks are not used for any other purpose.	5.6.5	0	1
53.	There are facilities to enable water or air flushing of lumened RMD at the RMD cleaning sinks.	5.6.5	0	1
54.	The reprocessing facility is cleaned in accordance with the documented '*procedure*' and schedule. The area is maintained in a hygienic state at all times. Separate dedicated cleaning equipment is provided for both dirty and clean work areas.	2.2.2$^{(s)}$ 5.6.10	0	1
55.	There are procedures for cleaning the equipment used to transport used RMD.	A6.2.2.1	0	1
56.	A dedicated area is provided for the storage of reprocessed RMDs that have been released for use. The storage areas for RMDs are controlled as per 5.6.9; and parts a–i of A 9.5. *a* ☐ *b* ☐ *c* ☐ *d* ☐ *e* ☐ *f* ☐ *g* ☐ *h* ☐ *i* ☐ *(Info: STORAGE - STERILE SUPPLIES Sterile supplies must be handled and stored in a manner that maintains the integrity of packs and prevents contamination from any source [dust, vermin, sunlight, water, condensation etc]. Storage areas must be temperature and light controlled and easily cleaned. Supplies should be stored off the floor to avoid mechanical damage during cleaning).* *Other reference:* **AUSHFG – Part B - 190.5.65** Page 290	5.6.9 A9.5$^{(a–i)}$	0	1
57.	The sterile storage area is HEPA filtered. The sterile storage room has positive pressure gradient to other rooms. Air supplied to sterile store, set-up rooms, and operating rooms is not recirculated from any other enclosure. *Other reference:* ***AS 1668.; & Victorian Design guidelines for hospitals and day procedure centres enclosure E1a***	5.6.14	0	1
58.	New RMD, RMD returned from loan/repair or loan RMD are fully reprocessed by a validated cleaning, disinfection and sterilization process in accordance with the RMD manufacturer's reprocessing instructions.	5.1.3$^{(a)}$	0	1
59.	All staff adhere to the HSO '*policy*' specifications for cleaning and disinfecting RMD. *(hint: this is asking for evidence staff practices are consistent with HSO documented 'policy/ procedures'.*	6.1.1	0	1
	Page 4 Total (Possible score 16)	**Score**	**___ / 16**	

	Evaluating Practices (and evidence of compliance with documented 'policy')		AS/NZS 4187:2014 Reference	Not met	Met
60.	RMD are disassembled prior to pre-treatment or cleaning. *(hint: this is asking for evidence staff practices are consistent with HSO documented 'policy/ procedures').*		6.2.3(a)	0	1
61.	RMD's are segregated to allocated cleaning pathways (e.g. Manual, ultrasonic/ WD or WD only). *(hint: this is asking for evidence staff practices are consistent with HSO documented 'policy/ procedures').*		6.2.3(b)	0	1
62.	Manual cleaning of an RMD is limited to pre-treatment prior to reprocessing in a washer/disinfector; or where the manufacturers validated cleaning instructions require manual cleaning only.		6.2.3(c)	0	1
63.	Cleaning and disinfection or sterilization of RMDs is performed between uses including when single use sheath/sleeve/ protective barriers are used. *(Check: Single use sheaths/sleeves/protective barriers for RMD's are not used as a substitute for reprocessing*).		5.1.3(e)	0	1
64.	RMDs are cleaned in accordance with the validated cleaning instructions provided by the RMD manufacturer.		6.2.1	0	1
65.	There is evidence that all cleaning agents, instrument grade chemical disinfectants and liquid sterilizing agents used on RMD's are registered on the Australian register of Therapeutic goods (TGA) for that purpose.		3.1.2, 3.1.3(a–i) 3.2 (a–j) 3.7.3	0	1
66.	There is evidence that RMD's are reprocessed to the highest possible level using the Spaulding classification system.		5.1.2 Table 5.1	0	1
67.	Disinfectants or sterilizing agents used outside the range of conditions specified by the supplier have undergone a full validation. Validation has proven the microbiocidal effectiveness of the disinfecting or sterilizing process. These '*procedure*s' are documented and approved by the designated responsible person.		3.5	0	1
68.	There are detailed specifications from the manufacturers for the processes delivered by the cleaning and disinfection equipment. (ultrasonic, AER, washer/disinfector).		4.2(a–h)	0	1
69.	Where the RMD's manufacturer cleaning instructions specify the use of an ultrasonic, an ultrasonic is used. *If an ultrasonic is not available where required then the compliance is scored as 'Not met'*		A 4.3.3	0	1
70.	The ultrasonic is compliant with Australian Standards and is commissioned as per AS 2773.2 section 6.3. *Other reference* ***AS 2773.2*** *6.3 and Appendix E* **CT = commissioning test*	CT* ☐ __ /__ /__ OQ: ☐ __ /__ /__ PQ: ☐ __ /__ /__	table 7.1 table 10.2	0	1
71.	There is evidence that the performance of ultrasonic cleaners is monitored each day of use. *Other reference* ***AS2773.1*** *3.21(a-d), 3.22, B5* ***AS2773.2***		8.2.4	0	1
72.	Visible soiling is removed from the RMD prior to being processed in an ultrasonic cleaner. All RMD processed in the ultrasonic are subject to a further manual or mechanical cleaning process.		6.2.3(d)	0	1
73.	Ultrasonic is emptied and cleaned at least daily and more frequently if contaminated. *Other reference* ***AS2773.1*** *B5* ***AS2773.2*** Flushing type ultrasonic cleaners are operated for a complete cycle with fresh water and detergent but without a load at the end of a day's work and then emptied and left dry until required for subsequent use.		6.2.3(g)	0	1
	Page 5 Total (Possible score 14)		**Score**	____ / 14	

	Evaluating Practices (and evidence of compliance with documented 'policy')	AS/NZS 4187:2014 Reference	Not met	Met
74.	The water supplied is of suitable quality as defined in table 7.2 for cleaning and disinfection. *Other reference* ***ISO 15883-1*** [5.23]	5.6.6 A5.6.6 7.2.3.1 table 7.2	0	1
75.	The WD manufacturer instructions regarding the water quality requirements are implemented i.e. Softened, filtered, demineralized, reverse osmosis or distilled water. (Should occur prior to WD installation). *Other reference* ***ISO15883-1*** [5.23 & 6.4]	7.2.3.1	0	1
76.	The water quality in the WD is tested monthly. (table 7.2 final rinse water) and non conformance is actioned. *Other reference* ***ISO 15883-1 ISO 15883-2***	table 7.2 Table 8.1	0	1
77.	The water temperature in the WD is checked each cycle – parameters are consistent with table 6.1. *(hint: confirm the printout has been checked and signed).* *Other reference* ***ISO 15883-1*** *and ISO* ***15883-2***	8.2.3(a–d)	0	1
78.	The inflowing water during the flushing stage of the WD is maintained below 45°C to avoid protein coagulation. *(Info: Temperatures higher that 45°C can cause protein coagulation and cleaning problems).* *Other reference* ***ISO 15883-1*** [4.2.2]	A6.2.3	0	1
79.	There is evidence that the chemical dosing volumetric test is performed quarterly on WD. *Last 2 test dates: __/__ /__ & __ /__ /__.* *Other reference* ***ISO 15883-1 ISO 15883-2***	table 8.1	0	1
80.	There is evidence a validated objective means of assessing the performance of the WD cleaning process. Using methods from ISO 15883 series – *(hint: routine regular soil [or alternative] test results).* *Other reference* ***ISO 15883-1 Annex C***	7.4.2	0	1
81.	Following automated cleaning the RMD is visually inspected and checked to ensure it is clean (soil test results "if used" pass) and dry and cycle records are checked to confirm parameters have been met. *Other reference* ***ISO 15583-1*** [4.5]	9.1	0	1
82.	Evidence is provided to indicate the quality of the final rinse water in the WD is free of chemical residue and microbial contaminants *(Info: examples could include Ph test /water testing / ATP bioluminescence).* *Other reference* ***ISO 15883-1*** [4.4.3, 6.4.2, 6.10.4]	table 8.1	0	1
83.	WD, loading racks, trolleys, ultrasonic cleaners, drying cabinets and other accessories are cleaned in accordance with manufacturer's instructions.	6.2.3(g)	0	1
84.	Brushes and other accessories used for pre-treatment or manual cleaning are cleaned and thermally disinfected or sterilized at least daily	6.2.3 (g)	0	1
85.	There is a traceability system for all high level chemical disinfection that contains all elements as listed in part a (i–ix) of 2.4.3.2 . Where electronic records are kept, there are '*procedures*' in place to verify attainment of process parameters at the conclusion of each cycle. *i* ☐ *ii* ☐ *iii* ☐ *iv* ☐ *v* ☐ *vi* ☐ *vii* ☐ *viii* ☐ *ix* ☐	2.4.3.2 (a [i–vii]) 2.4.3.2 (a [vii D])	0	1
86.	After removal of an RMD from disinfectant following manual immersion the RMD is rinsed in a sufficient volume of suitable quality water to minimize residual disinfectant on item. The RMD and disinfectant manufacturer's instructions shall be followed. *(hint: suitable quality of water as defined by the manufacturer).*	6.3.5 table 7.2	0	1
	Page 6 Total (Possible score 13)	**Score**	**___ / 13**	

	Evaluating Practices (and evidence of compliance with documented 'policy')	AS/NZS 4187:2014 Reference	Not met	Met
87.	Sterile water or water filtered through a 0.22um sterilizing grade filter is used for rinsing instruments intended for use in sterile cavities, in known immune-compromised patients, or for invasive *'procedures'* e.g. ERCP and bronchoscopy.	6.3.5	0	1
88.	Methods used for drying RMDs do not compromise the cleanliness of the RMD. *(Hint: If drying cabinets are unavailable low linting cloths or instrument grade compressed air is used).*	6.2.3 (f)	0	1
89.	Records indicate the drying cabinet is checked daily and operating within specified limits (limits are referenced to manufacturers' instructions and AS 2774 and AS 2514).	8.2.6	0	1
90.	A technical manual for drying cabinets containing all information required as listed in AS 2514 5.3 (a–j) is available. *Other reference* ***AS 2514*** *5.3*	4.3.3	0	1
91.	Each drying cabinet has passed an annual performance test on two successive occasions as listed in AS 2514 rendering the test load completely free of moisture. (*2 tests completed on: __ /__ /__ & __ /__ /__)* *Other reference* ***AS 2514*** *6.2*	4.3.3	0	1
92.	Accessories (tray liners, tip protectors and other materials) that are used for the assembly & presentation of packaged RMD are manufactured for that purpose.	6.4.2	0	1
93.	Packaging systems – PSBS (sealable pouches; reels). SBS (sterilization wraps -woven or non woven). PSBS (Reusable containers). All meet the criteria defined in TABLE 9.1.	Table 9.1	0	1
94.	Sealing methods for SBS ensure the integrity and maintain sterility of the RMD until point of use as per 6.4.2 *(Info: There should be no evidence of string, non adhesive tape, staples, pins or elasticized bands. The method of sealing should also be tamper evident).*	6.4.2 (b iv)	0	1
95.	The heat sealer has annual (or more frequent if recommended by manufacturer) thermometric testing, maintenance and re calibration. (*Date of last maintenance: __ /__ /__)* *Other reference* ***11607-2*** *and* ***16675-3***	table 10.2	0	1
96.	For heat sealed pre-formed Sterile Barrier System (SBS) the sealing process parameters and their tolerances is specified and documented as per manufacturer's instructions.	6.4.2 (b [iv])	0	1
97.	There is evidence the heat sealing equipment has undergone PQ & OQ indicating that it consistently produces conforming SBS. *Other reference* ***ISO/TS 16775:2014 including Annex D*** OQ: ☐ __ /__ /__ PQ: ☐ __ /__ /__	7.4.4.2 7.5.1 A7.4.1	0	1
98.	A daily check (of the seal of one or more samples of preformed SBS) is performed by visual assessment of seal integrity over the entire length of the seal before and after exposure to the sterilization process.	8.6	0	1
99.	Impulse and rotary heat sealers without a process record: There is a daily record of the temperature setting. Visual checks of the temperature setting are made immediately prior to each episode of sealing.	8.6	0	1
100.	Rigid reusable containers are inspected, used and cleaned according to the manufacturer's instructions.	A6.4.2	0	1
101.	The packaged RMD is labelled prior to sterilization AS PER 6.4.2.	6.4.2	0	1
102.	There is a copy of the manufacturer's specifications for the sterilizers.	4.3.1 (a–g)	0	1
	Page 7 Total (Possible score 16)	**Score**	____	**/ 16**

	Evaluating Practices (and evidence of compliance with documented 'policy')	AS/NZS 4187:2014 Reference	Not met	Met
103.	A dedicated area is provided within the sterilizer unloading zone for cooling, and where applicable, aeration of sterilized RMDs.	6.5.2(d) 5.6.9	0	1
104.	There are sterilizing process records as per 2.4.3.2 (b i–vii). *i* ☐ *ii* ☐ *iii* ☐ *iv* ☐ *v* ☐ *vi* ☐ *vii* ☐	table 8.2 2.4.3.2(b [i-vii])	0	1
105.	Prior to release of an RMD from each process i.e. cleaning, disinfection and sterilization; the cycle record is checked to verify the parameters have been met in accordance with Table 9.1. Non conforming RMD are not released.	table 9.1 9.3 & 2.5.2 A2.5.2	0	1
106.	Records are kept for the identification and traceability of semi critical RMD undergoing high level chemical disinfection.	2.2.3 2.4.3.2	0	1
107.	Routine monitoring of AER and/or other low temperature sterilization systems is conducted and recorded in accordance with Table 8.2.	8.7 table 8.2	0	1
108.	Criteria for release of the RMD using low temperature sterilization systems comply with Table 9.1. *(NB: this category includes EO, peracetic acid, hydrogen peroxide systems and low temperature steam/formaldehyde)*	9.2 table 9.1	0	1
	Page 8 Total (Possible score 6)	**Score**		**____/ 6**

Audit References:

Relevant standards and references are listed on pages 8–9 of AS/NZS4198:2014

Other references *(noted in the standard but not on pages 8-9)*

ISO/TS 16675 *Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO11607-2.*

Australasian Health Infrastructure Alliance (AHIA), Australasian HFG, *Australasian Health Facility Guidelines (AusHFG)*

Victorian Government Department of Human Services [DHS], *Design guidelines for hospitals and day procedure centres* retrieved from http://www.healthdesign.com.au/vic.dghdp/guidelines.htm on 18/12/09

	Actual Score	Possible Score
Page 1 Total		**11**
Page 2 Total		**16**
Page 3 Total		**16**
Page 4 Total		**16**
Page 5 Total		**14**
Page 6 Total		**13**
Page 7 Total		**16**
Page 8 Total		**6**
Total		**108**

Audit Total Actual Score: _____ Total Possible score 108 Compliance percentage _____%