Cleaning, disinfection and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities

Audit Form

Compliance with AS/NZS 4187 - 2003

Grampians Region Infection Control Group

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HEALTH FACILITY:	
Date:	**Auditors:**
Designated area:	

Note: Please refer to AS/NZS 4187 - 2003 when completing this audit – each element is referenced back to the appropriate section of the Standard.

SCORING SYSTEM

Scoring System:	***AS Standard Interpretation:***	***Scoring Process***
0 = ACCEPTABLE **1 = UNACCEPTABLE** **N/A = NOT APPLICABLE**	• **SHALL = Mandatory** **Score 0 or 1 as appropriate** ☺ **SHOULD = Recommended** **Mark ☑ or ☒** **Note: These points are not included in the scoring system.**	A | B **Column A = Achieved score** **Column B = Total Possible score**

Section	Standard	Compliance 0	1	N/A	Action Timeframe
2	**HANDLING OF USED ITEMS**				
2.1	*WATER QUALITY FOR CLEANING*				
	• Clean water supply of good quality **(Sample) 0/1** →		**0**		
	• Care taken with selection of detergents **1/1** →		**1**		
	☺ *Weekly testing on water hardness* **☑ or ☒**		☒		
2.2	*TREATMENT OF USED ITEMS*				
	• Gross soil is removed as close to the point of use as possible b/f being returned to CSSD →		**0**		
	• Standard precautions are used at all stages of handling used items →		**1**		
	• PPE is available and is used where appropriate. →		**0**		
	☺ *A written description of the procedures is available in all areas*		☒		
	☺ *Reusable drainage bottles are emptied at the user level, avoiding spillage.*		☑		
	☺ *Soiled drapes and linen are placed in soiled linen containers and sent for laundering.*		☑		
2.3	*DETERGENT & RINSE ADDITIVE RESIDUES*				
	• Check washing machines daily to ensure there is no chemical residue →		**N/A**		
	☺ *Instruments and equipment are free from residue after the cleaning process*		☐		
	Sub Total	**2**	**6**		

Scoring System:	***AS Standard Interpretation:***	***Scoring Process***
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Section	Standard	Compliance 0	Compliance 1	Compliance N/A	Action Timeframe
1	**SCOPE AND GENERAL**				
1.1	*SCOPE* • There is a copy of AS4187 – 2003 in the CSSD /sterilising area				
	• The standard is not applied to items intended for single use only, nor to items that may be contaminated with unconventional infective agents e.g. CJD, nor for goods such as dressings and bandages which should be obtained from commercial sources, ready for use.				
				2	
1.2	*REFERENCED DOCUMENTS*				
1.3	*DEFINITIONS*				
1.4	*PROCESSING ENVIRONMENT* • The planning and construction of any new facility or major refurbishment of existing facility includes the principles of environmental control to minimise particulate contamination and bioburden.				
	☺ *In a new or renovated facility consideration is given to workflow, with separated designated areas for cleaning, pack preparation, sterilisation and storage; wall, floor, surface finishes, airflows and air conditioning.*				
	☺ *Existing sterilising facilities make every endeavour to conform to the requirements of clause 1.4*				
				1	
1.5	*REPROCESSING OF INSTRUMENTS AND EQUIPMENT* • Prior to use or reuse, every item is cleaned, or cleaned and disinfected or sterilised as appropriate for intended use				
	• Any item used to enter a normally sterile site/tissue is sterile for use				
	• Explanted medical/dental devices are not reprocessed				
	☺ *Implantable items are purchased in a sterile condition*				
				3	
	Section 1 TOTAL			**6**	

SECTION ONE TOTAL SCORE

SECTION 1 TOTAL		**6**	

Section	Standard	COMPLIANCE			Action Timeframe
2	**CLEANING AND HANDLING OF USED ITEMS**	**0**	**1**	**N/A**	
2.1	WATER QUALITY FOR CLEANING • Clean water supply of good quality				
	• Care taken with selection of detergents and drying agents				
	☺ *Weekly testing on water hardness and records are kept*				
				2	
2.2	*INITIAL TREATMENT OF USED ITEMS* • Gross soil is removed as close to the point of use as possible, as soon as possible before being returned to CSSD - dry wiping, damp wiping and rinsing				
	• Standard precautions are used at all stages of handling used items				
	• PPE is available and is used where appropriate.				
	☺ *A written description of the procedures is available in all areas*				
	☺ *All single use items are discarded appropriately after use*				
	☺ *Soiled drapes and linen are placed in soiled linen containers and sent for laundering.*				
				3	
2.3	*COLLECTION PROCEDURES* • Procedures for the collection of used items from wards, OR and other departments have been formulated.				
	• There is separate procedures/arrangements for the collection of used itmes and the delivery of sterile items				
				2	
2.4	*COLLECTION EQUIPMENT* • Collection containers are puncture resistant**,** leak-resistant & have a lid that can be closed				
	• Container or trolley is cleaned at the end of each round				
	☺ *Containers and trolleys are metal or plastic, capable of being cleaned*				
				2	
	Section 2 Sub Total			**9**	

Section	Standard			Action Timeframe
2.5	*CLEANING AREA* • There is a physically separate cleaning area to prevent possible contamination of processed items			
	• Written policy on the methods, and frequency of cleaning the area and equipment			
	Equipment in cleaning includes (recommended): ☺ *Separate hand washing facilities*			
	☺ *Adequate bench space*			
	☺ *Smooth surfaces without crevices*			
	☺ *Good lighting*			
	☺ *Efficient ventilation – min. 10 air changes ph with –ve pressure to sterilising area - (AS 1668.2)*			
	☺ *Temperature range maintained in the range 18°C to 22°C*			
	☺ *Adequate storage space for materials and equipment*			
	☺ *Adequate waste disposal bins*			
	☺ *Non-slip flooring*			
	☺ *Sink suitable for disposal of liquid waste*			
	☺ *Cleaning sinks*			
	☺ *Ultrasonic cleaners (AS 2773*			
	☺ *Washer/disinfectors (AS 2945)*			
	☺ *Drying equipment*			
	☺ *Non-porous work surfaces for efficient cleaning*			
	☺ *Adequate plumbing with ease of maintenance*			
	☺ *Appropriate workflow and traffic flow from reception to distribution of items*			
			2	
2.6	*SORTING OF ITEMS PRIOR TO CLEANING* • All items that have been unwrapped for use are considered to be contaminated whether they have been used or not and are subjected to the full cleaning process			
	• A check of completeness and defects is made during sorting.			
	• There is written procedures for handling specialised items, including loan instruments and sets.			
	☺ On receipt, items are sorted according to type and cleaning method			
			3	
	Section 2 Sub Total		**5**	

Section	Standard			Action Timeframe
2.7	*CLEANING PRECAUTIONS* • Care is taken to avoid direct contact with skin when using detergents, disinfectants and other chemicals			
	☺ *Techniques of cleaning avoid generating aerosols*			
	☺ *Single use suction tubing is used (recommended)*			
	☺ *If accidental exposure does occur, the affected area is washed with copious amounts of clean water and treated in accordance with MSD sheets*			
	☺ *There are documented procedures to minimise risk of damage to instruments through inappropriate cleaning methods and materials*			
	☺ *Abrasive cleaners(steel wool or abrasive powders and pastes are NOT used*			
			1	
2.8	*CLEANING AGENTS* • The Material Safety Data Sheet (MSDS) is read before using agent			
	• Cleaning agents are used to remove soil - Appendix D			
	• Product Data Bulletins and MSDS are obtained for all cleaning agents and chemical and requirements are implemented			
	• Cleaning agents are dispensed in a safe manner which does not promote contamination of contents.			
	• Common household detergents are not used –high foaming, high residue			
	• Cleaning agents do not leave a residue			
	☺ *Chemical suppliers have provided evidence regarding agents compliance with Appendix D*			
	☺ *Chemical suppliers have provided chemical testing kits to test pH, chlorine content, chlorine residue, and presence of iron and water hardness.*			
	☺ *Chemical suppliers have provided training for staff*			
	☺ *Detergent used is a mild alkaline detergent – pH range 8.0 – 10.8 (Some items may require the use of neutral detergents)*			
	☺ *Acid-based agents are only used for stainless steel surfaces only*			
			6	
	Section 2 Sub Total		7	

Section	Standard			Action Timeframe
2.8 Contd	*ENZYMATIC CLEANERS* • Rubber or nitrile gloves are worn and standard precautions observed if handling enzyme cleaning agents			
	☺ *Enzymatic cleaners are not used routinely, but used to soak items where debris is congealed on them (exception - flexible endoscopes)*			
	☺ *MSDS pertaining to enzymatic cleaners are clearly displayed in work area*			
	☺ *The enzymatic cleaners used have multiple enzyme activity and are used at the correct temperature and time and within their shelf life.*			
	☺ *Different commercial products are not mixed.*			
	Agents for Manual Cleaning • Biodegradable, non-corrosive, non-toxic, non-abrasive, low foaming, free rinsing, preferably liquid and mildly alkaline			
	Agents for Mechanical Cleaning • Biodegradable, non-abrasive, low foaming, free rinsing and preferably liquid			
	Product is appropriately labelled • Product name, manufacturer's name & address, description & purpose, dilution instructions, batch number, manufacture or expiry date, advice not to mix with other chemicals, safety & first aid instructions, storage requirements.			
			4	
2.9 2.9.1	*CLEANING METHODS* *GENERAL* • Care is taken to ensure the cleaning process does not add to bioburden			
	• Cleaning methods are appropriate to the design of the items cleaned			
	• Cleaning methods are documented			
	• After cleaning the items are clean to the naked eye (macroscopic) and free from any protein residues			
			4	
2.9.2 2.9.2.1	*MECHANICAL CLEANING* *GENERAL* • Washer/disinfectors and ultrasonic cleaners are routinely cleaned and maintained to prevent colonisation and formation of biofilms			
			1	
2.9.2.2	*BATCH-TYPE WASHER/DISINFECTORS* • Mechanical washer complies with AS 2945			
	• Final rinse water temperature is between 80°C and 90°C to ensure effective function of drying agent			
	☺ *Where multi-programmable washer/disinfectors are used, strict protocols are in place for their operation and ongoing maintenance*			
			2	
	Section 2 Sub Total		**11**	

Section	Standard			Action Timeframe
2.9.2.3	*WASHER CYCLES* The washer cycle includes: • Pre-rinse, with water			
	• Warm water wash with cleaning agent added			
	• One or more hot water (80°C & 90°C) rinses with drying agent added			
	• Drain, leaving contents at a temperature for quick drying			
	• Drying, either radiant heat from an element or a hot air blast			
			5	
2.9.2.4	*SPECIFIC CONSIDERATIONS FOR BATCH-TYPE WASHERS – AS 2945-1998* • There is minimal handling of soiled items			
	• Automatic dispensers are used to add correct amount of cleaning agents			
	• Items are positioned to ensure surfaces are exposed to the cleaning process			
	• Machine is maintained by skilled personnel			
	• Internal cleanliness of machine is maintained			
	• Performance is continually monitored and documented			
	• Care is taken when unloading items capable of holding residual water			
			7	
2.9.2.5	*ANAESTHETIC AND RESPIRATORY WASHER/DISINFECTORS (AS 2945)* • Machine/cycle is used to rinse, wash and disinfect anaesthetic and respiratory equipment not required to be sterile (semi-critical items)			
	The machine operates within the temperature ranges: • Rinsing – 40°C to 50°C			
	• Washing – 50°C to 60°C			
	• Disinfecting – 70°C to 95°C			
	• Final rinsing – 80°C to 90°C			
	• Machine is routinely cleaned and maintained to prevent colonisation and formation of biofilms			
			6	
2.9.2.6	*MECHANICAL CLEANING OF ANAESTHETIC INSTRUMENTS & EQUIPMENT* • All equipment place in the washer is processed for a complete cycle			
	• All surfaces, including internal lumens are exposed to cleaning process			
	• Clean techniques are use when handling processed anaesthetic items			
	• Items are not dried in ambient air –mechanical drying is used (2.10)			
	• Hands are thoroughly clean when handling processed items			
	• Appropriate connectors are used for drying tubing & other lumened items			
	• Items not for immediate use are reassembled in a clean area			
	• Items are packed and clearly labelled for supply to user area			
			8	
	Section 2 Sub Total		**26**	

Thermal Disinfection
90°C for 1 minute
80°C for 10 minutes
75°C for 30 minutes
70°C for 100 minutes

Section	Standard			Action Timeframe
Table 7.2	*BATCH WASHERS* *CALIBRATION OF MEASUREMENT DEVICES/SYSTEMS* • On commissioning			
	• 6-12 monthly			
	• After repair			
	• Quarterly thermocouple temperature check			
			4	
	MONITORING • Documented time at temperature			
	• Check every cycle for thermal disinfection			
	• Continuous performance checks for temperature and cleanliness of items			
	• Documented daily test for detergent or rinse residue **-** processed items are selected at random, placed in a clean bowl of water, agitated and pH of water measured			
			4	
	MAINTENANCE • Quarterly preventative maintenance			
	• Descaling is performed as required			
			2	
	ROUTINE CHECKING AND CLEANING • The functions of the washer/disinfector are checked daily			
	• Check and clean jets, filters, door, door gaskets and external surfaces			
	• Check detergent and rinse dispensers are clear and functioning correctly			
	• Check filters and door seals			
			4	
	Section 2 Sub Total		**14**	

Section	Standard			Action Timeframe
2.9.2.7	*ULTRASONIC CLEANER AS2773.2 (BENCHTOP)* • Approved detergent is added after tank is filled with water			
	• Degassing is performed before instruments are processed			
	• Instruments are rinsed free of gross soil prior to immersion			
	• Instruments are placed in basket supplied by manufacturer			
	• Instrument are rinsed in warm-to-hot running water after removal from machine			
	• Where fitted, pump and associated tubing are purged of cleaning solution when the 'tub' is empty			
	• The unit is operated with lid closed to prevent emission of aerosols and to prevent damage to hearing			
	• No part of the operator's body is submerged into water during operation			
	☺ *The manufacturers' instructions are considered re. suitability of equipment for ultrasonic cleaning*			
			8	
Table 7.2	*CALIBRATION OF MEASUREMENT DEVICES/SYSTEMS* • Not applicable			
	MONITORING • Daily performance testing (Section 6, AS 2773.2) o Aluminium foil test o Pencil load test			
			1	
	MAINTENANCE • Annaul electrical safety check			
			1	
	ROUNTINE CHECKING & CLEANING • Checking filters and base plate			
	• Wiping external surfaces			
	• Emptying of tank at least daily or more frequently, as necessary			
	• Continuous checks for correct functioning of switches, gauges and lights			
			4	
2.9.3 2.9.3.1	*MANUAL CLEANING* *GENERAL* • Delicate or complex instruments are carefully hand-washed and rinsed			
	• Cleaning equipment is non-abrasive and maintained in good condition			
	• Cleaning equipment is thermally disinfected or sterilised at the end of each cleaning session			
	• When not in use, it is stored clean and dry			
	• Reusable cleaning brushes are cleaned and thermally disinfected after each use			
			5	
	Section 2 Sub Total		**19**	

Section	Standard			Action Timeframe
2.9.3.2	*The following are available (recommended):* ☺ *Clean water supply of good quality (Section 2.1)*			
	☺ *At least two sinks large and deep sinks*			
	☺ *Small brush with firm plastic bristles, able to withstand cleaning agents*			
	☺ *Light grade nylon or similar non abrasive scouring pad*			
	☺ *Cleaning agent*			
	☺ *Wire dental burr brush*			
	☺ *Non-linting clothes (adequate supply for frequent changing)*			
			0	
2.9.3.3	*METHOD OF CLEANING (For items that do not have electrical components, or are not power tools operated by compressed air) – (recommended)* ☺ *Item flushed with running water, 15°C – 30°C, to remove gross soiling*			
	☺ *Sink filled with warm water (approx 45°C) and detergent*			
	☺ *All items dismantled or opened prior to placement in cleaning solution*			
	☺ *Items held low in sink to limit generation of aerosols*			
	☺ *All surfaces, including lumens and valves, are washed*			
	☺ *Stubborn stains are removed using a non-abrasive pad or soaking in stain removing solution*			
	☺ *Items received a final rinse in warm-to-hot running water*			
	☺ *Items are dried in a drying cabinet (hollowware is inverted)*			
			0	
2.9.3.4	*MANUAL CLEANING OF ANAESTHETIC & RESPIRATORY EQUIPMENT* • Anaesthetic and respiratory equipment is washed in a mechanical washer, not washed manually			
	• Semi-critical anaesthetic and respiratory equipment is thermally			
	• Disinfected or sterilised (or both) between uses			
	• Where thermal disinfection is not available, semi-critical items are sterilised or are single-use devices			
			4	
2.10 2.10.2	*DRYING OF ITEMS* *DRYING METHODS* • A drying cabinet is used for tubing and anaesthetic equipment			
	• The cabinet operates between 65°C – 75°C			
	• Drying cabinets complies with AS 2514 or AS 2774			
	☺ *A drying cabinet is used for instruments and hollowware*			
	☺ *When manual drying a lint free cloth is used*			
	☺ *Items are not dried in ambient air*			
	☺ *Alcohol or other flammable liquids are <u>not</u> used as a drying agent (exception – endoscopes)*			
			3	
	Section 2 Sub Total		**7**	

Section	Standard			Action Timeframe
Table 7.2	*DRYING CABINET* *CALIBRATION OF MEASUREMENT DEVICES/SYSTEMS* • On commissioning			
	• 6 –12 monthly			
	• After repair			
	• Annual thermocouple check			
			4	
	MONITORING • Documented daily visual temperature check			
			1	
	MAINTENANCE • Quarterly preventative maintenance			
			1	
	ROUTINE CHECKING AND CLEANING • Daily surface clean			
	• Filters and door seals checked and cleaned			
			2	
2.11	*MONITORING OF CLEANING PROCESSES* • Detergent and rinse additive containers are replenished when necessary			
	• There is a continuous visual inspection of cleaned items			
	☺ *Instruments and equipment are free from residue after the cleaning process*			
	☺ *Commercially available soil tests are used to verify cleaning efficiency*			
			2	
	Section 2 Sub Total		**10**	

Section	Standard			Action Timeframe
App B B2	*CARE AND HANDLING OF POWERED TOOLS – INCLUDE DENTAL HANDPIECES* *CLEANING OF POWERED INSTRUMENTS AND HOSES* • Instruments kept free of gross soiling during procedure by wiping with dry sponge or a sponge moistened with sterile water			
	• In CSSD instrument is cleaned with a non-linting cloth moistened with detergent and water			
	• Powered surgical instruments and hoses are NOT immersed in water or placed in automated or ultrasonic cleaners			
	• Unless otherwise recommended by manufacturer, hoses remain attached to hand pieces during cleaning			
	• Hoses and cords are inspected for damage and wear			
	• All traces of detergent are rinsed from instruments			
	• Instruments and air hoses are wiped with a clean non-linting cloth to remove excess water			
	• A drying cabinet or second non-linting cloth is used to dry powered instruments and hoses			
			8	
B3	*LUBRICATION* • Items are lubricated only when necessary and according to manufacturer's written instructions			
	• Lubricants are not allowed into the hose when lubricating external movable fittings on air hose			
	☺ *If required, instruments are operated after lubrication to ensure dispersal of lubricant*			
	☺ *Care is taken not to generate aerosols during lubrication process*			
			2	
B4	INSPECTION AND TESTING • Instrument is tested before packaging and sterilisation			
	• Triggers and handles are in the safety position when changing attachments			
	• Medical grade compressed air or compressed dry nitrogen is used			
	• Instruments are operated at the correct pressure			
	• The rate is set while the instrument is running			
	• Damaged instruments and hoses are sent to an appropriately qualified technician or returned to the manufacturer for repair			
	• Powered tools requiring repair are cleaned and disinfected or sterilised			
	• If it is not possible to clean and decontaminate the item it is packaged in a container, sealed and labelled with the relevant hazard warning			
	• The health care facility complies with requirements for transporting biohazardous goods			
			9	
B5	STERILISATION • Powered surgical instruments are disassembled before sterilisation			
	• These items are packaged prior to sterilisation			
	• Delicate and sharp parts are protected			
	• Hoses are coiled loosely when packaged for sterilisation			
			4	
	Section 2 Sub Total		**23**	

SECTION 2 TOTAL		**131**	

Sectior	Standard	COMPLIANCE			Action Timeframe
		0	1	N/A	
3	**PACKAGING AND WRAPPING OF USED ITEMS PRIOR TO STERILISATION**				
3.1	*GENERAL* • Each material used is tested to establish penetration times and drying characteristics				
	• Materials used are compatible with the items being packed and the sterilising method selected				
	• Textile wraps are laundered prior to use				
	• Single wraps are used once and discarded				
	• Combinations of hollowware, instruments, dressings, drapes or tubing are not incorporated into a single pack				
				5	
3.2	*PACK SIZE* • Maximum size of packs has been established during the performance qualification process (Section 8 and Appendix H)				
	• If contents of pack are wet, the pack is deemed unsterile and is not used				
				2	
3.3	*LABELLING PRIOR TO STERILISATION* • Prepared labelling or non-toxic solvent-based felt-tipped pens and rubber stamps are used				
	• Labelling includes contents of pack, batch control data				
	• Sharp-tipped, water- based or ball-type pens are not used.				
				3	
3.4	*SPECIFIC REQUIREMENTS*				
3.4.1	*INSTRUMENTS* • Ratchet instruments are remain open and unlocked				
	• Multi-part instruments are disassembled or sufficiently loosed prior to packaging to allow contact with sterilisation agent				
	☺ *Sets are packed to prevent damage to delicate items*				
	☺ *Instrument trays are perforated*				
				2	
3.4.2	*HOLLOWWARE* • All openings face the same direction				
	• Items cannot move inside pack				
	• Stackable hollowware packaged together are separated by non-porous spacers when nested				
	☺ *Hollowware is placed with opening against the paper and not the plastic (Section 3.4.3.3)*				
				3	
3.4.3 3.4.3.1	*TYPES OF PACKING & WRAPPING MATERIALS* ☺*Appropriate packaging materials are selected for the different sterilisation processes (See Table Page 25)*				
	Section 3 Sub Total			**15**	

ection	Standard			Action Timeframe
3.4.3.2	*WRAPS* • Textile linen wraps comply with AS 3789.2			
	• Linen with defects such as holes and threadbare patches are not used			
	• Heavy woven fabrics such as canvas, are not used			
	• Recyclable barrier fabrics comply with AS 3789.8			
	• Paper wraps conform with AS 1079.2			
			5	
3.4.3.3	*FLEXIBLE PACKAGING MATERIALS* ☺ *Tips of sharp instruments are protected to prevent damage to laminated pouches*			
	☺ *Laminated packaging is placed on its side in the steriliser*			
	☺ *Hollowware is placed with opening against the paper and not the plastic*			
3.4.3.4	*NON-POROUS, NON-CELLULOSE BASED MATERIALS* • Except for dry heat sterilisers, nylon packaging is not used			
			1	
3.4.3.5	*Cellulose-based and non-cellulose based non-woven wraps* • Where used they conform to AS 1079.5			
			1	
3.4.3.6	*RIGID REUSABLE STERILISATION CONTAINER SYSTEMS* • Containers allow penetration and removal of sterilising agent, and maintain sterility following the process			
			1	
App E E3 E3.1	*SELECTION AND USE OF RIGID REUSABLE STERILISATION CONTAINERS* *SPECIFIC CONSIDERATONS* *ACQUISITION* • Filters adequate to ensure sterility maintenance			
	• All components are easily disassembled for cleaning, drying and storage			
	• For DD and benchtop steam sterilisers, the base and lids are perforated			
	• Containers are compatible with cleaning and sterilisation methods and equipment			
	• Cleaning, drying, storage and transport systems are compatible with additional bulk of containers			
	• Adequate trials have been undertaken to assess use of container systems			
	• On-site testing using physical and biological testing, and efficiency of drying cycle have established compatibility of container system with sterilising process			
			7	
E3.2	*INSPECTION AND MAINTENANCE* • After cleaning and drying a visual inspection is made to establish that the trays and lids are not dented and seals/gaskets are intact			
	• A check is made that correct filters are properly fastened in place			
			2	
	Section 3 Sub Total		**17**	

Section	Standard			Action Timeframe
E3.3	*LOCKING MECHANISMS* • Containers have a locking device which is tamperproof, non-resealable and has a built-in chemical indicator			
	• The manufacturer has provided education re. use of locking device			
			2	
E3.4	*VALIDATION* • On-site testing using physical, chemical and biological testing, has established that container system will achieve sterilisation of contents			
	• Seals, gaskets and filter-retention plates are visually inspected after cleaning and before each use.			
	• Any change in the use of container system is validated by biological and physical testing			
			3	
E3.5	*PACKING TECHNIQUES AND PROTECTION OF INSTRUMENTS* • Containers packed to allow for penetration of sterilising agent			
	• Containers are not overloaded			
	• Hollowware and textiles are not mixed in the same tray			
	• Lids are able to be removed without contaminating the contents			
	• Where used, internal wraps can be opened without risk of contamination of the contents			
	• Filters and retaining mechanisms are easily visible and secure			
	• Instrument retaining mechanisms are used to protect instruments			
			7	
E3.6	*MASS* • The mass of the container and content allows for sterilising parameters to be met			
	• The mass of container and contents complies with manual handling standards			
			2	
E3.7	*STORAGE* • Containers are compatible with storage shelving systems and space before and after sterilising process			
			1	
E3.8	*ERGONOMICS* • Design allows for ease of use			
	• Handles allow containers to be lifted easily			
	• Design allows for easy removal of basket and trays without contamination, damage to contents and strain to operator			
			3	
E3.9	*FILTERS – where required* • Single use filters are discarded after use			
	• For reusable filters - Written data from manufacturer has been obtained regarding validation for re-use			
	• Method for affixing filters provides reliable integrity of system			
			3	
	Section 3 Sub Total		**21**	

Section	Standard			Action Timeframe
E3.10	*TRANSPORT* • Transport systems prevent damage to containers, their lids and contents			
	• Transport system has adequate weight bearing capacity for number and type of container system used			
			2	
TABLE 3.1	*NOTE 1* • Packed and wrapped items are not sterilised in a “flash” steriliser			
			1	
3.6 3.6.1	*SEALING OF PACKS* *GENERAL* • Staples, pins, inappropriate tape or taping methods are NOT used			
	• String, non-adhesive tape and elastic bands are NOT used			
			2	
3.6.2	*HEAT SEALING - APPENDIX F (Page 115)* • Seals are checked to ensure complete seal			
	• Laminated pouch sealing complies with AS1079.4			
	☺ *Suitable heat sealing equipment is used*			
			2	
Table 7.2	*HEAT SEALER* *CALIBRATION OF MEASUREMENT DEVICES/SYSTEMS* • On commissioning			
	• 6-12 monthly			
	• After repair			
			3	
	Monitoring • Daily check of seal integrity pre and post sterilisation			
			1	
	MAINTENANCE • Adjustment of gap between heating elements at least quarterly (according to manufacturers specifications			
			1	
	ROUTINE CHECKING AND CLEANING • Daily wipe of external surfaces			
	• Continuous checks for correct functioning of switches, gauges and lights			
			2	
	Section 3 Sub Total		**14**	

Section	Standard			Action Timeframe
3.6.3	*STERILISING INDICATOR TAPE* • Tape is appropriate for the mode of sterilisation			
	• Tape is compatible with wrapping material used			
	• Tape colour change after exposure is clear, distinct and uniform and markedly different to unprocessed tape			
	• Tape has name of manufacturer, batch number and date of manufacture on the core			
	• Tape is heat stable, moisture stable and permeable to sterilising process			
	• Indicator tape is removed from textile wraps before returning to linen service			
	☺ Tape adhesive is pressure-sensitive, non-toxic and adheres to clean surfaces and leaves no adhesive residue on removal			
	☺ *The use of tape to seal bags and pouches is only used in the absence of a heat-sealing machine or when the machine is broken down.*			
	☺ *Where tape is used to seal a bag, the bag is sequentially folded over 2 – 3 times prior to taping across the entire folded edge with one continuous piece of tape extending at leat 25 mm around the back of bag on both sides*			
			6	
	Section 3 Sub Total		**6**	

SECTION 3 TOTAL		**73**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
4	**STERILISING EQUIPMENT**				
4.1	*GENERAL* • Heat bead devices, microwave ovens, pressure cookers, incubators, UV cabinets, boiling water units, ultrasonic cleaners and similar appliances are not used as sterilisers – they will not sterilise				
				1	
4.2	*STEAM STERILISERS* • An operators manual is in the vicinity of the steriliser at all times				
	• Operator has verified that the items is suitable for steam sterilisation				
	• The cycle time and temperature reflects the type of load and packaging material being processed				
	• Steam – dryness fraction of 97% or above				
	• Steam is not heated beyond 2^{o}C above sterilising temperature (superheated)				
	• Penetration times have been established and added to the holding time (121^{o}C-15 mins, 132^{o}C-4 mins, 134^{o}C-3 mins)				
	☺ *Manufacturers instructions for operating steriliser are followed*				
				6	
4.2.2	*DOWNWARD DISPLACEMENT STERILISER (HORIZONTAL)* • Complies with AS 2192				
	• Ability of steriliser to achieve sterilisation of cannulated instruments has been established at the time of validation.				
	• Drying time is determined by size and density of packs				
				3	
4.2.3	'*FLASH' STERILISER* • Complies with AS 2192				
	• Used for dropped, single instruments where there is no sterile duplicate available only				
	• Cannulated, complex instruments, suction and other tubing are not 'flash' sterilised				
	• Used for unwrapped non- porous items only				
	• The 'flash' sterilising process is monitored to ensure efficiency				
	☺ *'Flash' sterilising is not used as a convenience or as a cost saving mechanism – adequate instruments are available*				
				5	
4.2.4	*BENCHTOP STERILISER* • Complies with AS 2182				
	• Without a drying cycle – sterilise unwrapped items only				
	• Drying process via mild heating of chamber while door remains closed – used for small numbers of simple packs (scissors, forceps) packed in paper bags				
	• Portable pre vacuum sterilisers – appropriate requirements of AS 1410 are applied				
				4	
	Section 4 Sub Total			**19**	

Section	Standard			Action Timeframe
4.2.5	*PREVACUUM STERILISER* • Complies with AS 1410			
			1	
4.3	*DRY HEAT STERILISER (HOT AIR TYPE)* • Complies with AS 2487			
	• The door of the steriliser is not opened during the cycle			
			2	
4.4	*LOW TEMPERATURE STERILISERS AND LIQUID STERILANTS*			
4.4.2	*ETHYLENE OXIDE STERILISERS ISO 11135* • Gas concentration not less than 400 mg/l			
	• Temperature not less than 36°C on cool cycle			
	• Not greater than 60°C on warm cycle			
	• Relative humidity greater than 40% but less than 100%			
	• Time is appropriate for temperature and gas concentration			
	☺ Reference has been made to instrument manufacturer's instruments when using EO – gases can adversely affect some materials			
			5	
4.4.3	*HYDROGEN PEROXIDE PLASMA STERILISERS*			
4.4.4	*PERACETIC ACID STERLISING EQUIPMENT*			
4.4.5	*LIQUID STERILANTS*			
	• Any liquid sterilant used is registered with the TGA			
			1	
	Section 4 Sub Total		**9**	

Section 4 Total		**28**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
5	**LOADING OF STERILISERS**				
5.1 5.1.1	*STEAM STERILISATION* *GENERAL* • The sterilising load is commences immediately after loading				
	• Loads are not pre-heated				
				2	
5.1.2	*LOADING PORTABLE, DOWNWARD DISPLACEMENT AND PRE-VACUUM STERILISERS* • Hollowware is tilted on edge in a draining position				
	• Packs of drapes are loaded with layers vertical				
	• Items do not touch chamber walls				
	• Laminated pouches are loaded on edge with paper to laminate or flat with paper surface down				
	• Hollowware items are packed with the opening against the paper				
	• Loading carts are loosely loaded to capacity				
	• Only a single layer of packs is placed on each tray				
	☺ *Racks are used to allow for adequate separation of packaged instruments*				
	☺ *Packs of hollowware and trays of instruments are NOT place above textile packs*				
				7	
5.1.2.2	*'FLASH' STERILISERWITHOUT A DRYING STAGE* • Items are not bagged or wrapped				
	• Items placed on a perforated or mesh tray				
	• Tray placed flat on steriliser shelf				
	• A new chemical indicator is place in each tray being processed				
	☺ *Performance of specifically designed containers for sterilising and transporting 'flash' sterilised instruments has been established*				
				4	
5.2.2	*DRY HEAT STERILISATION* • Space is left between items to allow adequate circulation of air				
	• Items are not in contact with chamber walls				
				2	
5.3 5.3.2	*ETHYLENE OXIDE GAS STERILISATION* *BASKETS AND LOADING CARS* • Items are placed in a metal basket or on a metal rack or loading cart				
				1	
	Section 5 Sub Total			**16**	

Section	Standard			Action Timeframe
5.3.3	*LOADING OF BASKETS AND LOADING CARS* • Items are placed loosely within the confines of the basket or loading car			
	• Packages do not touch chamber walls			
	• Items in flexible packaging materials are loaded on edge with paper to laminate, or flat with paper down			
			3	
5.4 5.4.2	*HYDROGEN PEROXIDE PLASMA STERILISATION* • Space is left between items to allow adequate circulation of the sterilising agent			
	• Items are well away from chamber walls			
			2	
5.5 5.5.2.1	*PERACETIC ACID LIQUID CHEMICAL STERILISATION* *DIRECTED FLOW PROCESSING CONTAINER/TRAY* ☺ *Care is taken to load machine in a manner that will allow penetration of liquid sterilant to all surfaces*			
5.5.2.2	*FLEXIBLE PROCESSING TRAY* • Each instrument channel is directly connected to the machines fluid pathways via a purpose-designed tubing adaptor kit			
	☺ *Instrument manufacturer's instructions regarding leak and pressure testing are considered before loading flexible endoscopes into the machine*			
			1	
5.6	• Care is taken to ensure load content and manner of loading facilitates air removal and steam penetrations			
	☺ *For all other methods of sterilisation consideration is given to manufacturer's instructions regarding load content and loading techniques*			
			1	
	Section 5 Subtotal		**7**	

Section 5 Total		**23**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
6	**UNLOADING OF STERILISERS**				
6.1 6.1.1	*STEAM STERILISERS* *WITH DRYING STAGE* • On completion of drying stage the load is immediately removed from steriliser				
	• A visual inspection is made to ascertain that the load is dry, and the sterilising indicators have made the required colour change				
	• On removal of load the recording charts or printouts are checked and designated record sheets are signed that required parameters have been met				
	• Supervisor is notified if deviation of any parameter is detected				
	• Loading carts with cooling items are kept away from high activity areas				
	• Forced cooling with fans or boosted air conditioning is NOT used.				
	• Cooling items are NOT placed on solid surfaces				
	• Damaged, wet or dropped items are considered unsterile and are reprocessed				
	• Where unwrapped items are sterilised, appropriate handling procedures for unloading have been developed and documented				
				9	
6.1.2	*FLASH STERILISATION (without a drying stage)* • Wrapped items are not sterilised without a drying stage				
	• Procedures for unloading 'flash' have been developed and documented				
	• Sterile 'set up' personnel wear a surgical mask and full sterile attire when transferring items from steriliser to point of use				
				3	
6.5	*PERACETIC ACID LIQUID CHEMICAL STERILISATION* • When complete the air seal is released to access instruments				
	• Chemical indicator strip is visually inspected for colour change				
	• Load print out is checked to confirm parameters have been met				
	• Where instruments are transferred directly to sterile field, procedure in 6.1.2 is followed				
	• Attachments for purging of chemical steriliant are checked to ensure they have remained attached to instrument throughout cycle				
				5	
6.6	*MONITORING OF UNLOADING PROCEDURE* • Procedures for unloading each type of steriliser have been developed and documented				
	• Compliance with procedures are monitored (section 8)				
				2	
	TOTAL SECTION 6			**19**	

SECTION SIX TOTAL SCORE	**Section 6 Total**		**19**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
7	**PURCHASING, COMMISSIONING, CALIBRATION, PERFORMANCE TEST, MAINTENANCE AND VALIDATION**				
7.1	*GENERAL* *All stages of the sterilisation process have been developed and documented to ensure that the items can be sterilised* • Cleaning				
	• Inspection				
	• Assembly				
	• Packaging				
	• Loading				
	• Sterilisation Cycle				
	• Calibration, routine monitoring and recording				
	• Unloading				
	• Storage				
	• Distribution				
	• Validation of the process				
	• The process can be reliably reprocessed				
	• The process is routinely monitored to the desired probability of a non-sterile item				
				13	
7.2	*PURCHASING* • All new sterilisers and associated equipment purchased complies with appropriate Australian Standards ➢ AS 1410 – Pre vacuum Steriliser ☐ ➢ AS 2182 – Sterilisers-Steam-Benchtop ☐ ➢ AS 2192 – Sterilisers-Steam-Downward displacement ☐ ➢ AS 2437 – Flushers/sanitisers for bedpans & urine bottles ☐ ➢ AS 2487 – Dry heat sterilisers ☐ ➢ AS 2514 – Drying cabinet for medical equipment ☐ ➢ AS 2773.1 – Ultrasonic cleaner-non portable ☐ ➢ AS 2773.2 – Ultrasonic cleaner-benchtop ☐ ➢ AS 2774 – Drying cabinet for respiratory equipment ☐ ➢ AS 2945 – Batch-type washer/disinfector ☐ ➢ AS 3836 – Rack conveyor washers ☐				
	☺ *Installation qualification and operational qualification are included as part of the purchasing agreement with the supplier of all associated equipment*				
				1	
7.3 7.3.2 7.3.2.1	*VALIDATION* *COMMISSIONING OF STERILISERS* *GENERAL* • The tests and check to be performed during commissioning are specified, documented and recorded				
				1	
	Section 7 Sub Total			**15**	

Section	Standard	Carried Forward		Action Timeframe
7.3.2.1 Contd	• These include: ➢ calibration of all gauges, recording equipment and indicators, ☐ ➢ parameter monitoring, ☐ ➢ specific steriliser performance tests, and ☐ ➢ any process indicator tests ☐			
			1	
7.3.2.2	*INSTALLATION QUALIFICATION* • IQ demonstrates the steriliser and the area in which it is installed comply with the manufacturer's specifications			
			1	
7.3.2.3	*OPERATIONAL QUALIFICATION* • OQ demonstrates that installed equipment operates within predetermined limits when used in accordance with its operational procedures			
			1	
7.3.3	*PERFORMANCE QUALIFICATION* • PQ demonstrates the attainment of the required sterilising conditions throughout the specified load(s)			
	• PQ has been achieved through: o Verification of physical parameters o Demonstration of microbiological lethality			
	• If used – process challenge devices are in accordance with EN 867-5			
	• Each sterilisation process and each type of steriliser load and loading pattern for the PQ process is specified and documented			
	• PQ is performed after completion of commissioning and ➢ On the introduction of new or modified items, ➢ New or modified packaging/loading patterns, ➢ New or modified or processing parameters (unless equivalence, either to validated reference loads or cycles or to a previously validated product, packaging or loading pattern, is demonstrated)			
			5	
7.3.4	*CERTIFICATION OF PERFORMANCE QUALIFICATION OF STERILISER* • Reports on commissioning, PQ, recommissioning and performance requalification have been prepared and signed and a copy filed in the sterilising processing facility			
			1	
7.4 7.4.1	*RECOMMISSIONING AND PERFORMANCE REQUALIFICATION* • The recommissioning and performance requalification process is documented and a copy filed in sterilising facility			
			1	
	Section 7 Sub Total		**10**	

Section	Standard			Action Timeframe
7.4.2	*RECOMMISSIONING* • Recommissioning is performed if: ➢ Changes or engineering work is carried out on equipment which could effect the performance of the steriliser ➢ A review of records indicated unacceptable deviation(s) from data determined during validation			
	• The responsibility for determining the necessity and extent of repeating elements of commissioning is assigned to a designated person trained in this speciality			
	• Recorded data for each type of test or check during recommissioning is within specified limits of the data recorded during commissioning			
			3	
7.4.3	*PERFORMANCE REQUALIFICATION (PReQ)* • PReQ is performed at least annually and whenever a change is made to a steriliser load which is not within the limits specified in the performance qualification report			
	• The responsibility for determining the necessity and extent of repeating parts of PReQ is assigned to a designated person trained in this speciality			
			2	
7.5	*CALIBRATION OF STERILISER* • A calibration schedule, based on the steriliser history, has been established and maintained			
	• Documentation is requested from the service provider that includes: o Actual and adjusted values			
	• When faults arise corrective action is taken			
	☺*Routine calibration checks and maintenance of all measuring devices, timers, gauges and displays on steriliser are checked by a trained competent person*			
	☺*Measuring equipment is certified by a recognised certification body e.g. (NATA)*			
	☺*The report is made available and includes the certification number of the calibration device used*			
			3	
7.6	*MONITORING OF STERILISER* • Routine sterilisation cycle performance is monitored accordance with the test frequencies specified in Table 7.1 (attached)			
			1	
	Section 7 Sub Total		**9**	

Section	Standard			Action Timeframe
7.7	*MAINTENANCE OF STERILISERS* *A preventative maintenance schedule, based on the history of the equipment is established and maintained.*			
	• Where faults arise, corrective action is undertaken			
	• A preventative maintenance contract is entered into with a trained competent maintenance contractor or the equipment manufacturer			
	• Where this is not possible a skilled person has been trained for the task			
	• Filters on equipment are checked every 6 months and results recorded			
	• A program of routine replacement or revalidation of filters has been established			
	• A cleaning and maintenance program is in place			
	• After repairs testing is done to establish compliance with original installation or operation qualification specifications			
	• Repairs are assessed to establish if they have altered the performance of the equipment since most recent validation			
			8	
7.8 7.8.1	*ASSOCIATED EQUIPMENT* *GENERAL* • This may include: ➢ Drying cabinets ☐ ➢ Aeration cabinets ☐ ➢ Batch washers ☐ ➢ Rack conveyor washers ☐ ➢ Ultrasonic cleaners ☐ ➢ Heat sealer ☐			
			1	
7.8.2	*VALIDATION OF PROCESSES* • Processes for associated equipment have been established, documented and validated			
			1	
7.8.3	*COMMISSIONING* • All associated equipment has under gone a commissioning process ☺ *Reference is made to the applicable Standard and the manufacturer's operational instructions for guidance on the commissioning procedure for each type of associated equipment*			
			1	
	Section 7 Sub Total		**11**	

Section	Standard			Action Timeframe
7.8.4	*PERFORMANCE QUALIFICATION* • The PQ consists of the following three steps: ➢ Choice and performance and practical test(s) to evaluate proper functioning ➢ Determination that operating conditions are being reliably achieved ➢ That gauges, where fitted, are indicating accurately ➢ Test results are documented (Not all associated equipment can undergo PQ – refer to applicable Standard for guidance)			
			1	
7.8.5	*RECOMMISSIONING AND PERFORMANCE QUALIFICATION* • Where performance or qualification procedures are not applicable recommissioning (usually only OQ) is undertaken at least annually • Where applicable, performance requalification is undertaken annually			
			2	
7.8.6	*CALIBRATION, MONITORING AND MAINTENANCE* • A preventative maintenance contract is entered into with a trained competent maintenance contractor or the equipment manufacturer • Or a skilled person has been trained for the task • Calibration, monitoring and maintenance of associated equipment is performed in accordance with Table 7.2 (attached)			
			3	
	Section 7 Sub Total		**6**	

TOTAL SECTION 7		**51**	

Pre-vacuum Steriliser – AS 1410

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	IQ, OQ, PQ, recommissioning and PReQ 3, 6, 12 monthly – depending on calibration history
MONITORING	Daily: External chemical indicator Leak rate test where no air detector Bowie Dick test Weekly: Leak rate test if air detector fitted Every Pack: External chemical indicator Every Cycle: Electronic printout Optional: Biological/enzymatic indicator Internal chemical indicator Process challenge devices Electronic data loggers
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris Chamber drain and filter are clear Correct functioning of recording devices, gauges and timers Door gasket – undamaged Cleaning: Loading tray and external surfaces cleaned daily Steriliser chamber cleaned weekly
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Packaged items dry and intact Correct result of BI/EI, process devices or data loggers

DOWNWARD DISPLACEMENT (JACKETED) (AS 2192) AND PORTABLE BENCHTOP (AS 2182) WITH DRYING CYCLE

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	IQ, OQ, PQ, recommissioning and PReQ 3, 6, 12 monthly – depending on calibration history
MONITORING	Every Pack: External chemical indicator Every Cycle: Electronic printout Optional: Biological/enzymatic indicator Internal chemical indicator Process challenge devices Electronic data loggers
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris Chamber drain and filter are clear Correct functioning of recording devices, gauges and timers Door gasket – undamaged Cleaning: Loading tray and external surfaces cleaned daily Steriliser chamber cleaned weekly Water reservoir emptied and cleaned – portable type
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Packaged items dry and intact Correct result of BI/EI, process devices or data loggers

DOWNWARD DISPLACEMENT (NON JACKETED) (FLASH) WITHOUT DRYING CYCLE (AS 2192)

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	IQ, OQ, PQ, recommissioning and PReQ 3, 6, 12 monthly – depending on calibration history
MONITORING	Every Cycle: Electronic printout Chemical indicator (Class 4,5,or 6) Optional: Biological/enzymatic indicator Process challenge devices Electronic data loggers
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris Chamber drain and filter are clear Correct functioning of recording devices, gauges and timers Door gasket – undamaged Water reservoir (portable types) Cleaning: Loading shelves and external surfaces cleaned daily Steriliser chamber cleaned weekly Water reservoir emptied and cleaned – portable type
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Correct result of BI/EI, process devices or data loggers

PERACETIC ACID

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	According to manufacturer's recommendations
MONITORING	Every Cycle: Electronic printout Chemical indicator Daily: Diagnostic cycle Weekly: Biological indicator
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor (or both)
ROUTINE CHECKING AND CLEANING	Daily Check: (According to manufacturer's recommendations) May include: Drip pan, Chamber drain, Water filter, Air filter, Recording device, Lid seal and carrier Cleaning: Carriers, containers and external surfaces cleaned daily
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators

COMMENTS:

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HYDROGEN PEROXIDE PLASMA

Table 7.1	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	According to manufacturer's recommendations
MONITORING	Every pack: External chemical indicator Every Cycle: Electronic printout Weekly: Biological/enzymatic indicator Optional: Internal chemical indicator Process challenge device
AFTER REPAIR OR MODIFICATION	Recommissioning or PReQ as required depending on the extent of the repairs or modification (7.4)
MAINTENANCE	Monthly, quarterly or annually – as established by HCF in conjunction with manufacturer or maintenance contractor (or both)
ROUTINE CHECKING AND CLEANING	Daily Check: Floor is free of debris (According to manufacturer's recommendations) May include: Chamber drain, Air filter, Recording device, Lid seal and carrier, Vaporizer system Cleaning: Carriers, containers and external surfaces cleaned daily
CRITERIA FOR RELEASE OF PROCESSED ITEMS	Achievement of set cycle parameters Correct colour change of chemical indicators Packaging intact Correct result of process challenge devices

COMMENTS:

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BATCH WASHER – AS2945 -1998

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning 6 - 12 monthly After repair Quarterly thermocouple temperature check
MONITORING	Documented time at temperature Check every cycle - thermal disinfection required Continuous performance checks for: - temperature - cleanliness of items Documented daily test for chemical residue
MAINTENANCE	Quarterly preventative maintenance Descaling preformed at required
ROUTINE CHECKING AND CLEANING	Daily: Check and clean jets, filters, doors, door gaskets and external surfaces Check detergent and rinse dispensers are clear and functioning correctly Check door seals

COMMENTS:

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ULTRASONIC CLEANER – AS 2773

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	Not applicable
MONITORING	Daily performance testing • Aluminium foil test or • Pencil load
MAINTENANCE	Annual electrical safety check
ROUTINE CHECKING AND CLEANING	Daily: Check filters Check base plates Wipe external surfaces Empty tank at least daily or more frequently, as necessary Continuous: Correct functioning of switches, gauges and lights

COMMENTS:

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DRYING CABINET – AS 2514 or AS 2774

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning 6 - 12 monthly After repair Annual thermocouple temperature check
MONITORING	Daily visual temperature check
MAINTENANCE	Quarterly preventative maintenance
ROUTINE CHECKING AND CLEANING	Daily: Surface cleaning Check and clean filters Check and clean door seals

COMMENTS:

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INCUBATORS FOR SELF CONTAINED BIOLOGICAL INDICATORS

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	Annual temperature check
MONITORING	
MAINTENANCE	Following of manufacturer's guidelines
ROUTINE CHECKING AND CLEANING	Following of manufacturer's guidelines

COMMENTS:

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HEAT SEALER

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning 6 - 12 monthly After repair
MONITORING	Daily check of seal integrity pre-and post-sterilisation
MAINTENANCE	Adjustment of gap between heating elements in accordance with manufacturer's specifications, at least quarterly
ROUTINE CHECKING AND CLEANING	Daily: wiping of external surfaces Continuous checks for correct functioning of switches, gauges and lights

COMMENTS:

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AUTOMATED ENDOSCOPE REPROCESSOR (WASHER/DISINFECTOR)

Table 7.2	ACTION REQUIRED
CALIBRATION OF MEASURMENT DEVICES/SYSTEMS	On commissioning After repair Annually
MONITORING	Daily check of chemical levels Every cycle: Check process recorder for critical process parameters – time, temperature, chemical concentration, and, where possible, flow rate and pressure Monthly: Microbial monitoring of rinse water quality of the automatic endoscope reprocessor (refer to GENSA guidelines)
MAINTENANCE	Check and change internal water, chemical and air filters according to manufacturer's instructions Treatment of external water filters by heat or chemical means is essential – frequency depends on local conditions and water quality Descaling of machine lines and tanks according to manufacturer's instructions
ROUTINE CHECKING AND CLEANING	Daily: Cleaning of soak basins Lids and All surface areas of machine

COMMENTS:

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Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
8	**QUALITY MANAGEMENT**				
8.1	*FACILITY MANAGEMENT* • The person in charge of sterilising facility has specific qualifications and experience in sterilising technology				
	• Person in charge has the authority to implement the requirements of AS4187				
	• Is actively involved in supervising the day-to-day activities of the CSSD				
	☺ The sterilising services line of responsibility is directly to the executive director (or director) of clinical services to ensure neutrality of service				
				3	
8.2	*DOCUMENTATION* • Policies and procedures for all activities in the processing of sterile items are documented				
	• Records are maintained and reviewed at frequent intervals and dated				
	• Records are kept for a period of time not less than that defined by regulatory authorities or Health Care Facility				
	• Records include: o Daily production statistics				
	o All tests performed on equipment				
	o Steriliser cycling records				
	o Employee training records				
	o Staff work rosters				
	o Incident reports				
	o Quality and procedure/operational manual				
	o Maintenance records				
	o Certification of validation – IQ, OQ and PQ data				
	o ☺ Tray/instrument tracking records				
				4	
8.3	*PERFORMANCE MANAGEMENT* • Staff qualifications and staffing levels are sufficient to ensure continuous, safe and efficient operation				
	• There are written job descriptions for each category of staff				
	• The manager is qualified to appropriate level by education, training and experience in sterilising processes				
	☺ There is a system for assessing staff performance after orientation and at regular intervals				
				3	
8.4	*EDUCATION AND TRAINING* • There is a formal orientation program in place for new staff				
	• Formal orientation is followed by on-the-job practical training				
	☺ *Staff members are encouraged to participate in appropriate external education courses*				
				2	
	Section 8 Sub Total			**12**	

Section	Standard			Action Timeframe
8.5	*MATERIAL MANAGEMENT* • There are protocols for inventory control			
			1	
8.5.2 8.5.2.1	*PRODUCT IDENTIFICATION AND TRACEABILITY* *BATCH CONTROL NUMBERS* ☺ Procedures are in place to link steriliser cycle batch information to items that have been sterilised, to the patient			
	• Each packaged item is labelled with a batch control identification:- o Steriliser number or code			
	o Date of sterilisation			
	o Cycle or load number			
	o ☺ Manufacturers batch/lot no. of any unsterile commercially prepared implantables placed in pack			
			1	
8.5.2.2	*STERILISATION CYCLE RECORDS* • Date of cycle			
	• Steriliser number or code (if > one steriliser)			
	• Cycle or load number (if > one load)			
	• Exposure time and temperature			
	• Name of loading operator			
	• Name of person releasing load			
	• Specific contents of load			
	• Results of physical, chemical and biological monitoring			
			8	
8.5.3	*DEVIATION AND FAULT ANALYSIS* • A procedure is in place to review any quality or procedural problems			
			1	
8.5.4	*PRODUCT COMPLAINTS* • A complaints procedure is in place and corrective action taken is documented			
			1	
8.5.5	*RECALL PROTOCOL* Recall policies and procedure are in place and include:- • Criteria for issuing recall notice			
	• Person responsible for issuing notice			
	• Person responsible for reporting on recall activities			
	• Persons to be notified when recall event occurs			
			4	
	Section 8 Sub Total		**16**	

Section	Standard			Action Timeframe
8.5.6	*RECALL NOTICE* includes: • Name of person or department for which notice is intended			
	• Sterilisation batch information			
	• Product name and quantity of products returned			
	• Specifies action to be taken by persons receiving the notice, e.g. return or destruct or hold			
			4	
8.5.7	*RECALL REPORT* includes: • Circumstances that initiated need for recall			
	• List of total number of products for recall and actual number located and recalled			
	• Identifies the number of patients potentially exposed and action taken			
	• Provision to document the actions taken to prevent a similar situation from occurring in the future (if necessary)			
			4	
8.6 8.6.1	*MONITORING STERILISER CYCLES* (see table 7.1 attached) *PHYSICAL INDICATORS* • Parameters are measured with continuous automatic permanent monitoring			
	• No permanent record – readings from gauges and devices are documented for every cycle at intervals of 10 seconds (steam)			
	• Record chart is examined and labelled with operators identification at the end of each cycle			
	• Any variations from normal is noted and action taken			
	• Where no record of physical parameters is obtained a BI/EI or a Class 4, 5 or 6 chemical indicator is used with each load			
			5	
8.6.2	*CHEMICAL INDICATORS* • *Used as recommended in table 7.1*			
			1	
8.6.3	*BIOLOGICAL/ENZYMATIC INDICATORS* • *Used as recommended in table 7.1*			
			1	
8.6.4 8.6.4.1	*SPECIAL PERFORMANCE TESTS FOR PRE-VACUUM STEAM STERILISERS* *- Used as recommended in table 7.1* • Leak rate test			
8.6.4.2	• Bowie Dick type test			
8.6.4.3	• Air detector function test			
8.6.4.4	• Air detector performance test			
			4	
	Section 8 Sub Total		**19**	

Section	Standard			Action Timeframe
8.7	*VALIDATION PROCESS – detail of process in Appendix H* • The sterilisation process has been validated			
	• The results have been documented			
			2	
8.8	*CRITERIA FOR RELEASE FOR PROCESSED ITEMS*			
8.8.1	• Prior to release there is evidence to indicate that the process has met all specified requirements			
	• The person responsible for authoring release has full knowledge of all aspects of the validation process			
	• The person responsible for authoring release is satisfied that monitoring and control of the entire process has met specifications			
			3	
8.8.3	*PARAMETRIC RELEASE (if used)*			
	• The process record shows compliance with all processing specifications achieved during performance qualification			
	• The process record shows compliance with processed used in:- o Cleaning o Packaging o Loading o Unloading o All cycle parameters			
	• There is evidence that the equipment control and any associated monitoring devices have continuously recorded all stages of the sterilisation cycle – record comply with specifications			
	• Equipment and component parts are current in terms of calibration and maintenance			
			4	
8.8.4	*NON-PARAMETRIC RELEASE*			
	• Biological/enzymatic and chemical indicators are used to determine that the sterilisation process has met processing specifications			
	• The load is not released until the results of tests are interpreted as successful			
			2	
8.8.5	*RELEASE DOCUMENTATION*			
	• The are records of items released			
	• The record includes identification of items, identification of cycle, time of release and name of person authorising release			
			2	
	Section 8 Sub Total		**13**	

Section	Standard			Action Timeframe
8.9	*MONITORING OF PACKAGING PROCESS* Continuous checks are made of: • Integrity of outer wrap & seals			
	• Correct labelling			
	• Correct colour change of external indicator			
	In addition, the end user knows to check sterilised packs for: • Integrity of outer wrap & seals and correct labelling			
	• Ease of opening			
	• Correct packaging techniques			
	• Correct contents			
	• Correct layout of contents			
	• Condition of contents – cleanliness, alignment and function			
	• Correct performance of internal indicator (if used)			
			10	
8.10 8.10.1	*OCCUPATIONAL HEALTH & SAFETY* • Staff are immunised in accordance with immunisation guidelines			
	• Immunisation records are kept in staff files			
	☺ If immunisations are declined this recorded			
	Staff health is monitored to ensure: • Superficial skin lesions are covered by an occlusive dressing and staff are made aware of cross infection hazards			
	• Accidents are recorded and treatment is provided as required			
	☺ *Staff with dermatitis, skin infections or infected lesions are examined by a MO*			
			4	
8.10.2	*STAFF ATTIRE* • A clean uniform is worn for each shift			
	• Hair is safely secured and covered while preparing items for sterilisation			
	• PPE is worn when handling used/soiled items			
	☺ *Hand and wrist jewellery including plain wedding bands are NOT worn*			
	☺ *Nail polish or acrylic nails are not worn, nails are kept short*			
	☺ *Uniforms worn in sterilising department are not worn outside the health care facility*			
			3	
	Section 8 Sub Total		**17**	

Section	Standard			Action Timeframe
8.10.3	*HANDWASHING* • Handwashing techniques and the importance of handwashing are taught to all staff during orientation and reiterated regularly			
	• Single use towels are used			
	• Hand creams are NOT used by staff on arrival at work & whilst on duty			
	☺ *Mechanical hot air drying is NOT used*			
			3	
8.11	*ENVIRONMENTAL CONTORL* • Work practices and stock control ensure that sterile and clean items are separated from soiled items			
	• Environment is in a hygienic state at all times			
	• Adequate facilities for personal hygiene are readily accessible			
	• Efficient ventilation is in place			
	• Lint production is minimised			
			5	
8.12	*EVALUATION, FEEDBACK & OUTCOMES* • Processes and procedures are evaluated			
	• Regular audits provide a mechanism for analysis, feedback and quality improvement			
			2	
	SECTION 8 Sub Total		**10**	

TOTAL SECTION 8		**87**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
9	**STORAGE & HANDLING OF STERILE ITEMS**				
9.1 9.1.1	*GENERAL* *STERILE ITEMS* • Sterile items are stored and handled in a manner that maintains the integrity of pack and prevents contamination				
	• This applies to items sterilised by facility and commercially procured items				
	• Policies and procedures for storage, handling and issuing of sterile stock have been developed and documented				
	• Items to remain sterile for use are NOT stored in ultraviolet cabinets or in disinfectants				
				4	
9.1.2	*STORAGE OF UNWRAPPED CRITICAL MEDICAL ITEMS* • Items stored unwrapped are cleaned and sterilised before storage				
	• Items are cleaned and resterilised immediately prior to use				
				2	
9.1.3	STORAGE OF UNWRAPPED SEMI-CRITICAL AND NON-CRITICAL MEDICAL ITEMS • After processing, items are stored in clean, dry, dust free, dedicated containers/drawers to protect them from environmental contamination				
	• If necessary they are reprocessed prior to use				
				2	
9.2	S*TORAGE AREA* • Sterile storage areas are dedicated to that purpose only				
	• Clearly sign-posted & traffic flow controlled/restricted				
	• Dust free, insect free & vermin free				
	• Open shelves - 250mm above floor level & 440mm below ceiling level				
	• Items protected from sunlight				
	• Storage containers are kept clean, dry and in good condition				
	• Cardboard boxes are NOT used as storage containers *(porous, cannot be adequately cleaned and may harbour organisms)*				
	• Commercial dispenser boxes are not topped up or reused				
	• Walls, floors, ceiling lights and work surfaces are constructed so that difficult-to-clean corners are minimised				
	• Surfaces non-porous & smooth & easily cleaned				
	☺ Overhead lighting is fitted flush with ceiling to minimise dust entrapment				
	☺ *Air-conditioning – 18°C – 22°C (Complies with AS 1668.2)*				
	☺ *Ventilation – RH 35% – 68% (Complies with AS 1668.2)*				
				10	
	Section 9 Sub Total			**18**	

Section	Standard			Action Timeframe
9.2.2	*ACCESS TO STORED ITEMS* • Access to sterile store area is restricted to those who have had adequate education and training in handling of sterilised items			
	• Who do not have discharging or open wounds, abrasions or scaling skin disorders and;			
	• Who have washed and dried their hands			
	• Access is restricted			
	☺ *Traffic within area is controlled – minimise movement of airborne contaminants*			
			4	
9.3	*PLASTIC DUST COVERS* • Plastic (polyethylene) used is new, clean and intact and of sufficient strength			
	• Covers are applied immediately they are cool, in a clean environment using clean techniques			
	• Dust covers are sealed (sealing by hermetic means is recommended)			
	• All batch information is marked on the packaged and not on dust cover			
	☺ *Items are placed in dust covers within 2 hours of sterilisation*			
			4	
9.4	*TRANSPORT/DISTRIBUTION OF STERILE ITEMS* • Sterile items transported outside the HC facility are packaged securely and protected against damage and contamination during transport			
	• All transport equipment is maintained in a clean, dry state and in good working order			
	☺ *A system has been instituted that provides a record as to stock levels and to the disbursement of items to users*			
	☺ *Transport vehicle has adequate segregation and meets the requirements of Clause 9.2.1*			
	☺ *Equipment used to move and transport items is dedicated to that purpose and is kept clean*			
	☺ *It is not used to collect used items, transport food or garbage*			
	☺ *Where unsterile but clean linen, such as instrument wraps, are transported with sterile items, the sterile items are separately protected e.g. in a plastic bin with lid*			
	☺ *Care is taken to ensure stock is not tightly packed into storage containers or shelving, or wrapped with elastic bands*			
			2	
	Section 9 Sub Total		**10**	

Section	Standard			Action Timeframe
9.5	*COMMERCIALLY PREPARED ITEMS* • Dust is wiped from the store pack before it is opened			
	• Sterile items are removed from the store pack before entering clean area			
	• Sterile items from external suppliers are inspected for cleanliness and/or damage to unit packs or their contents			
	☺ *Grossly soiled or damaged store packs are not accepted – return to supplier for replacement or refund*			
			3	
9.6 9.6.1	*SHELF-LIFE/STOCK ROTATION* *GENERAL* • Shelf life is event related			
	• A stock rotation system is based on the date of sterilisation			
	• Stock is maintained at adequate levels (do not overstock)			
			3	
9.6.2	*STOCK WHICH IS NONCONFORMING* • A package is considered nonconforming (non sterile and not fit for use) when:- ➢ It is incorrectly wrapped ➢ Damaged or open ➢ Water after the sterilisation cycle or comes in contact with wet surface ➢ Is placed or dropped on a dirty surface (e.g. floor or sink area) ➢ It has no indication of having been through a sterilising process			
	• Nonconforming stock is totally re processed as soon as identified			
			2	
9.6.3	*FACTORS WHICH COMPROMISE STERILE STOCK* • Processes and procedures are in place to protect sterile stock from the following factors that will compromise sterile stock ➢ Incorrect cleaning procedures in storage areas ➢ Moisture or condensation ➢ Incorrect temperature ➢ Excessive exposure to sunlight and other sources of ultraviolet light ➢ Vermin and insects ➢ Inappropriate packaging materials ➢ Incomplete sealing ➢ Sharp objects or rough handling or use of elastic bands which may cause damage to packaging materials ➢ Incorrect handling during transportation			
			1	
	SECTION 9 Sub Total		**9**	

TOTAL SECTION 9		**37**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
10	**DISINFECTION**				
10.1	GENERAL • Sterilisation is used for all reusable instruments and equipment that can withstand the process				
	• Disinfection is not carried out as a substitute for sterilisation – disinfection is not a sterilising process				
	• Items for disinfection are clean and able to withstand the process				
	• Items are not stored in disinfectant before or after any form of processing				
				4	
10.2 10.2.1	MEANS OF DISINFECTION THERMAL DISINFECTION • Item is thoroughly cleaned before disinfection				
	• All parts of the item is subjected to moist heat at or above the recommended temperature for the recommended duration (see below)				
	Surface temperature / Minimum disinfection time (minutes) 90°C / 1 80 °C / 10 75 °C / 30 70 °C / 100				
				2	
10.2.2 10.2.2.1	CHEMICAL DISINFECTION GENERAL • Chemical disinfection is only used when thermal disinfection is unsuitable				
	• Any chemical disinfectants used are registered with the TGA in Australia				
				2	
10.2.2.2	INSTRUMENT GRADE DISINFECTANTS • Only disinfectants labelled as '**instrument grade disinfectant**' are used for reprocessing reusable instruments				
	• A high-level instrument grade disinfectant is the minimum level used for semi-critical instruments which contact unbroken mucous membranes that are not normally sterile				
	• A intermediate-level or low-level instrument grade disinfectant is used for disinfection of non-critical instruments which contact unbroken skin				
	• Care is taken to follow manufacturers specific instructions				
	• Directions for use are not interchanged between formulations				
	• Relevant OH&S regulations are follow MSDS are available				
	• Extreme care is taken when using instrument grade disinfectants				
	☺ *Where practicable, the concentration of the solution is monitored at least daily in line with manufacturer's instructions*				
				7	
	Section 10 Sub Total			**15**	

TOTAL SECTION 10		**15**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
11	**CLEANING OF THE STERILISING PROCESSING FACILITY AND ASSOCIATED EQUIPMENT**				
11.1	*GENERAL* • Routine and special-purpose cleaning is performed to prevent cross-contamination				
	• There is a policy documenting areas and equipment to be cleaned, the methods used and the frequency of cleaning				
	• Completion of cleaning activities is documents				
	• Surfaces are impervious and intact to allow effective cleaning				
	• Blood and body spills are wiped up and the area washed with detergent and water				
	• Standard precautions are taken				
				6	
11.2	EQUIPMENT There is written procedures for all sterilising and ancillary equipment indicating:-				
	• Method,				
	• Frequency,				
	• Manufacturer's instructions and				
	• Cleaning agents and materials				
				4	
11.3	WASTE DISPOSAL • Waste disposal is in accordance with local regulations				
	• Waste is placed in appropriate containers				
	• Waste is not transferred from bag to bag during collection				
	• Sharps containers are available (comply with As4031 or AS/NZS4261				
	☺ *Waste is removed via designated disposal exits*				
				4	
	Total Section 11			**14**	

TOTAL SECTION 11		**14**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
12	**SELECTION AND CARE OF INSTRUMENTS**				
12.1	GENERAL • Those responsible for reprocessing instruments are involved in the selection process				
	• It is established that the cleaning methods used are compatible with the instrument to be purchased				
	• It is established that the cleaning agents or available water will not cause removal of surface finishing, corrosion or pitting				
	• Where manufacturers make claims or recommendations for reprocessing of their items, details of validation of the reprocessing procedure is obtained in writing				
				4	
12.2	GENERAL CONSIDERATIONS				
12.2.1	GENERAL • Staff responsible for instrument reprocessing have had appropriate education and training				
	• Instrument repairs are performed by qualified instrument technician				
				2	
12.2.2	IDENTIFICATION ☺ *A system for identifying instrument is established* ☺ *Engraving is not used* ☺ *High quality etching is used to mark instruments* ☺ Care is taken when using colour coded devices – may detach during surgery and may habour m/organism beneath adhesive layer				
12.2.3	REMOVAL OF SOIL • Removal of soil is performed at point of use				
	• Cannulated instruments are not allowed to become dry				
	☺ *Saline is not used to rinse or wipe instruments*				
				2	
12.2.4	SORTING INSTRUMENTS AND INSPECTION • Light or delicate instruments are kept separately from heavy instruments				
	• Instruments that can be taken apart are disassembled prior to terminal cleaning and inspected				
	• Any defective instruments are cleaned, dried and sterilised prior to being sent for repairs				
	• A validated and documented process is used for multi-part instruments and equipment designed not to be disassembled - according with manufacturer's instructions				
				4	
12.2.5	INSTRUMENT (FLASH) STERILISATION ☺ *Cleaned items are not 'flash' sterilised prior to further cleaning*				
	Section 12 Sub Total			**12**	

Section	Standard			Action Timeframe
12.2.6	LUBRICATION • When required lubricants are water miscible, compatible with the sterilising process and used according to manufacturer's instructions			
	• Lubrication is not used to overcome inadequate cleaning practices			
	Note: Stiffness may be due to - ❖ 'flash' sterilisation ❖ exposure to saline solutions ❖ inadequate cleaning ❖ malalignment and will not be corrected by lubrication			
			2	
12.3	SPECIAL CONSIDERATIONS The following are considered in the continued care and maintenance of all instruments:-			
	• Instruments are free from soil, rust or line			
	• Lumens, grooves and articulations are free of debris. A stillette is able to be passed through the lumen wherever applicable			
	• Joints are free of debris and move freely			
	• All surfaces and edges are smooth, well finished, un-pitted and free of burrs			
	• Tips of instruments are not hooked, snagged and approximate accurately			
	• Jaw serrations are visible along length – instruments with worn areas are sent for repair (qualified repairer)			
	• Stiff or loose instruments are sent for repair (qualified repairer)			
	• Cutting edges are sharp – sharpness is tested according to manufacture's instructions			
	• Valves move freely and are left in the 'on' position			
	• All multi-part components of instruments are present			
	• Components are reassembled correctly			
	• Instruments are tested to ensure they are functioning correctly			
	• Fine instruments and their tips are protected in a manner that does not inhibit the sterilisation process			
	• Templates are used to check shape and tips of fine instruments			
			14	
12.4	SPECIALISED INSTRUMENTS			
12.4.1	MICROSURGICAL INSTRUMENTS – care according to manufacturer			
12.4.2	INSULATED INSTRUMENTS - care according to manufacturer			
	Section 12 Sub Total		**16**	

Section	Standard			Action Timeframe
12.4.3	INSTRUMENTS ON LOAN • Loan instruments undergo a complete routine cleaning and processing prior to sterilisation by the wrapped method			
	• Perceived lack of time does not permit the cleaning process to be bypassed			
	• Any soil or debris found on the instruments is reported to the supplier			
	• All instruments are subjected to the full cleaning process and sterilised before being returned to their source			
	• Loan instruments are not interchanged between human, necroscopy and animal use			
	☺ *There is a contracted arrangement in place to define the responsibilities of the supplier and the health care facility*			
			5	
12.4.4	HANDPIECES - care according to manufacturer			
12.4.5	ASPIRATION SYSTEMS FOR DENTAL PROCEDURES - care according to manufacturer			
12.4.6	TRIPLEX SYRINGE FOR DENTAL PROCEDURES - care according to manufacturer			
12.4.7	ULTRASONIC SCALERS FOR DENTAL PROCEDURES - care according to manufacturer			
12.5	USE OF INSTRUMENT SHEATHES/SLEEVES • Sheaths/sleeves for instruments and equipment are not used as a substitute for cleaning, disinfection or sterilising procedures			
			1	
	Section 12 Sub Total		**6**	

TOTAL SECTION 12		**34**	

Section	Standard	Compliance			Action Timeframe
		0	1	N/A	
13	**USE OF OPERATING ROOM TEXTILES**				
13.1	GENERAL • Where the laundry is attached to the HCF the processing of operating room textiles is under the direction of the sterilising manager				
	• Laundry processing is in accordance with AS/NZS 4146				
	• Textiles used for draping and surgical gowns comply with As 3789.2 and AS 3789.6				
				3	
13.2	SPECIFIC CONSIDERATIONS • Inspection, folding and assembly of linen is performed in a dedicated area which is separated from others				
	• Air conditioning and air extractors are installed to assist in removal of airborne lint				
	• Linen is discarded if patches exceed more than 1% of total drape or garment				
	• Linen is discarded if there are signs of deterioration (threadbare)				
	• Linen is re-laundered if there are visible signs of dirt, stains, grease or oil				
	• Gauze swabs and abdominal sponges are not incorporated into linen packs				
				6	
13.3	INSPECTION • Linen required to be sterile, including wrapsper, is inspected over an illuminated table to determine presence of holes or other damage				
				1	
13.4	MENDING • Mending is done using textile patches with thermally-setting adhesive				
	• Patches are round in shape, 10mm – 20mm in diameter and attached to one side only – they do not represent more than 1% of total area				
	• Patches are not applied to seams but re-seamed if in need of repair				
	• Fenestrated openings are not repaired – when in need of repair a new fenestration is fitted or item is condemned				
	• Patches that are lifting are not accepted				
	• Linen is laundered after repair				
				6	
13.5	EQUIPMENT				
	• Light table complies with AS 3789.2				
	• Patching machine complies with AS 3789.2				
	• Machines have preventative maintenance in accordance with manufacturer's recommendations				
	• There are handwashing facilities within the OR textile area				
				4	
	Section 13 Sub Total			**20**	

TOTAL SECTION 13		**20**	

OVERALL SCORE SHEET

TOTAL SCORES	A	B	%
COLUMN A = TOTAL ACHIEVED SCORE **COLUMN B = TOTAL POSSIBLE SCORE**			
Section One		6	
Section Two		131	
Section Three		73	
Section Four		28	
Section Five		23	
Section Six		19	
Section Seven		50	
Section Eight		87	
Section Nine		37	
Section Ten		15	
Section Eleven		14	
Section Twelve		34	
Section Thirteen		20	
TOTAL SCORE		537	
% = A ÷ B x 100	**A**	**B**	

The audit can be scored to provide a basis for comparison over time and to answer the question 'do we comply with AS/NZS 4187-2003?'

The scoring system is based on the Cleaning Standards for Victorian Public Hospitals audit system where compliance with a criteria is deemed to be acceptable then no demerit points are deducted. If a criteria is deemed to be non compliant then it will score 1 or one demerit point.

AUDITORS COMMENTS:

SECTION	COMMENTS
ONE	
TWO	
THREE	
FOUR	
FIVE	
SIX	
SEVEN	
EIGHT	
NINE	
TEN	
ELEVEN	
TWELVE	
THIRTEEN	