SSU Quality Audit Tool

Overview

This document

This audit tool has been developed to aid in the review of Sterile Services Units cleaning, disinfection and sterilization procedures and processes of reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

Contents

This document contains the following topics

SSU Quality Audit Tool

Introduction

Purpose

This document was prepared by New Zealand Sterilization Services Association [NZSSA]. It documents the audit findings of *[insert hospital name]* Sterile Supplies Unit [SSU] and its recommendations.

Scope

This audit was conducted of the Sterile Services Unit located at *[insert hospital name]*.

Associated documents

The table below identifies associated documents.

Type	Title/Description
Standard	AS / NZS 4187:2003 Cleaning, Disinfecting and Sterilising Reusable Medical and Surgical Instruments and Equipment, and Maintenance of Associated Environments in Health Care Facilities NZS 8134:2001 Health & Disability Sector Standards NZS 4304:2002 Management of Healthcare Waste SNZ HB 8149:2001 Microbiological Surveillance of Flexible Hollow Endoscopes
Guidelines	Infection Control in Endoscopy 2nd Edition – Gastroenterological Nurses College of Australia Inc.

Acknowledgements

The authors would like to thank M. Smith, Regional Infection Control Practitioner, Australia for the original audit which was revised in the development of this audit tool.

SSU Quality Audit Tool

Compliance Review Audit

Standards	The AS / NZS 4187:2003 Cleaning, Disinfecting and Sterilising Reusable Medical and Surgical Instruments and Equipment, and Maintenance of Associated Environments in Health Care Facilities Standard was used in development of this audit tool. This Standard is considered to be the Australasian minimum standards in the processing of items which are required to be clean, disinfected or sterilised.
Date	The audit was conducted on *[insert date]*.
Review Team	The auditors consisted of the following: *[insert name, position title, company name]* *[insert name, position title, company name]* *[insert name, position title, company name]* *[insert name, position title, company name]*
Health Facility	This audit review was conducted for the Sterile Services Unit [SSU] at *[insert hospital name]*.

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Background Information

Facility

This department offers *[insert brief description of scope of service for the SSU being audited]*.

Hours of Operation

The current hours of operation *[insert operational hours for the SSU being audited]*.

Service Provision

The current service provision includes:

- Decontamination of items such as:

  For example:

  - *Bedpans, baby baths, theatre trolleys through the cart washer*
  - *Anaesthetic equipment such as laryngeal masks*
  - *Resuscitation equipment such as ambubags*
  - *Surgical instruments*

- Sterilisation of items such as:

  For example:

  - *Instrument sets*
  - *Specialty packs*
  - *Single instruments*
  - *Sterilisation is achieved through either Steam or Ethylene Oxide gas*

Specialities

The *[insert hospital name]* SSU currently provides services to the following specialty areas:

For example:

- *Theatre Suite – Orthopaedics, General Surgery, Urology, Gynaecology, ENT and Anaesthesiology specialities.*
- *Warkworth and Wellsford Birthing Units*
- *District Nursing Satellite Units*
- *Independent Midwives*

Staffing

The budgeted FTE for *[insert financial year]* is *[insert FTE numbers]*.

Staff Position	FTE
Service Manager	
Quality Manager	
Team Leader	
Supervisors	
Technicians	
Clerical	

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A. Decontamination

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	*AS/NZS 4187:2003* ***Standard Interpretation*:** < **SHALL = Mandatory** ☺ **SHOULD = *Recommended***	*[DHB logo inserted here]*

Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
A1	**COLLECTION PROCEDURES**				
A1.1	2.3	< Procedures for the collection of used items from wards, Operating Theatre and other departments have been formulated and documented.			
A1.2	2.2	< Soil is not allowed to remain on items.			
A1.3	2.2	< All items intended for single use are discarded at point of use.			
		Comments: •			
A2	**COLLECTION EQUIPMENT**				
A2.1	2.4	< Collection containers are puncture resistant, leak-proof & have a lid that can be closed.			
A2.2	2.3	< Separate systems exist for collection of used items & delivery of sterile items.			
A2.3	2.4	< Container or trolley is cleaned at the end of each round.			
A2.4	2.4	☺ *Containers and trolleys can be cleaned.*			
		Comments: •			
A3	**INITIAL TREATMENT OF USED ITEMS**				
A3.1	2.2	< Gross soil is removed as close to the point of use as possible (before being returned to SSU).			
A3.2	2.2	< Standard precautions are used at all stages of handling used items.			
A3.3	2.2	< Personal Protective Equipment is available and is used where appropriate.			
A3.4	2.2	☺ *A written description of the procedures is available in all areas.*			
		Comments: •			
A4	**SORTING OF ITEMS PRIOR TO CLEANING**				
A4.1	2.6	< A check of completeness and defects is made during sorting.			
	2.6	There are written procedures for handling the following specialised items:			
A4.2		< Powered tools.			
A4.3		< Endoscopes.			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
A5	**WATER QUALITY FOR CLEANING**				
A5.1	2.1	< Clean water supply of good quality.			
A5.2	2.1	< Care taken with selection of detergents and drying agents.			
A5.3	2.1	☺ *Weekly testing and recording of water hardness.*			
		Comments: •			
A6	**CLEANING AREA**				
A6.1	2.5	< There is a dedicated cleaning area to prevent possible contamination of processed items.			
A6.2	2.5	< Written policy on the methods, and frequency of cleaning the area and equipment.			
	2.5	Equipment in cleaning includes:			
A6.3		☺ *Separate hand washing facilities*			
A6.4		☺ *Adequate bench space*			
A6.5		☺ *Smooth surfaces without crevices*			
A6.6		☺ *Good lighting*			
A6.7		☺ *Efficient ventilation – a minimum of 10 air changes per hour with negative pressure to sterilising area (AS 1668.2)*			
A6.8		☺ *Room temperature maintained in range 18 - 22º C*			
A6.9		☺ *Adequate storage space*			
A6.10		☺ *Adequate waste disposal bins (AS/NZS 3816)*			
A6.11		☺ *Non-slip flooring*			
A6.12		☺ *Sink suitable for disposal of liquid waste*			
A6.13		☺ *Deep, double sink cleaning*			
A6.14		☺ *Drying equipment*			
A6.15		☺ *Non-porous work surfaces*			
A6.16		☺ *Adequate plumbing*			
A6.17		☺ *Appropriate workflow and traffic flow from reception to distribution of items.*			
		Mechanical equipment meets relevant AS/NZ Standards:			
A6.18		< Washer/Disinfectors - AS2945			
A6.19		< Ultrasonic cleaners - AS2773.			
		Comments: •			
A7	**CLEANING PRECAUTIONS**				
A7.1	2.7	< Care is taken to avoid direct contact with skin when using detergents, disinfectants and other chemicals.			
A7.3	2.7	< Techniques of cleaning avoid generating aerosols.			
A7.4	2.7	☺ *Abrasive cleaners are NOT used (steel wool or abrasive cleaning*			

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Audit Ref	Standard Ref	Standard	Compliance 0	1	N/A
		powders/pastes).			
		Comments: •			
A8	**CLEANING AGENTS**				
A8.1	2.8	< Cleaning agents are used to remove soil.			
A8.2	2.8	< Material Safety Data Sheets are available for all chemicals.			
A8.3	2.8	< Cleaning agents are dispensed in a safe manner which does not promote contamination of contents.			
A8.4	2.8	☺ *Chemical suppliers have provided validation regarding agents.*			
A8.5	2.8	☺ *Chemical suppliers have provided chemical testing kits to test pH, chlorine content, chlorine residue, and presence of iron and water hardness.*			
A8.6	2.8	☺ *Chemical suppliers have provided training for staff.*			
A8.7	2.8	☺ *Detergent used is a mild alkaline detergent with a pH range of 8.0 – 10.8*			
A8.8	2.8	☺ *Manual cleaning agents are biodegradable, non-corrosive, non-toxic, non-abrasive, low foaming; free rinsing, preferably liquid and mildly alkaline.*			
A8.9	2.8	☺ *Mechanical cleaning agents are biodegradable, non abrasive, low foaming, free rinsing and preferably liquid.*			
A8.10	2.8	< Product is appropriately labelled and includes product name, manufacturer's name & address, description & purpose, dilution instructions, batch number, manufacture or expiry date, advice not to mix other chemicals, safety & first aid instructions and storage requirements.			
		Comments: •			
A9	**CLEANING METHODS**				
A9.1	2.9	< Thorough cleaning reduces the bioburden, care is taken not to add to bioburden.			
		Comments: •			
A10	**MANUAL CLEANING**				
A10.1	2.9.3.1	< Cleaning equipment is non-abrasive.			
A10.2	2.9.3.1	< Cleaning equipment is rinsed and stored dry when not in use.			
A10.4	2.9.3.1	< Materials such as brushes are cleaned and thermally disinfected after each cleaning session.			
A10.5		< Protective water-resistant clothing and gloves are worn during all cleaning procedures.			
A10.5		< Hot and cold water are available.			
A10.6	2.9.3.1	☺ *There are at least two large, deep sinks.*			

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			0	**1**	**N/A**
A10.7	2.9.3.1	< Appropriate cleaning equipment is available.			
A10.8	2.9.3.1	< Appropriate cleaning agents are available.			
A10.10	2.9.3.3	☺ *Items are flushed in running water to remove gross visible soiling.*			
A10.11	2.9.3.3	☺ *Use warm water and detergent (approximately 45ºC).*			
A10.12	2.9.3.3	☺ *All items are dismantled or opened.*			
A10.13	2.9.3.3	☺ *Items are washed thoroughly avoiding aerosols.*			
A10.14	2.9.3.3	☺ *All hollow lumens are brushed through.*			
A10.15	2.9.3.3	☺ *Stubborn stains are removed using a scouring pad.*			
A10.16	2.9.3.3	☺ *Items are rinsed in warm-to-hot running water.*			
A10.17	2.9.3.3	☺ *Items are dried and checked for cleanliness.*			
		Comments: •			
A11	**MECHANICAL CLEANING**				
A11.1	2.9.2.1	< Mechanical Batch Washer complies with AS 2945			
A11.2	2.9.2.1	< Tunnel Washer complies with AS 3836			
A11.3	2.9.2.1	< Ultrasonic cleaner complies with AS 2773			
A11.4	2.9.2.1	< Mechanical washer (Respiratory) complies with AS 2945			
A11.5	2.11	< Check mechanical washers daily to ensure there is no chemical residue			
A11.6	2.11	☺ *Instruments and equipment are free from residue after the cleaning process*			
		Comments: •			
A12	**ULTRASONIC CLEANERS**				
A12.1	7.8.6	< Performance test performed daily (AS 2773).			
A12.2	2.9.2.7	< External tank, lid and gaskets are cleaned at least daily.			
A12.3	7.8.6	< Water strainers and drain filters visually inspected and cleaned – ***daily.***			
A12.4	7.8.6	< Water filter are visually inspected and clear - ***as necessary.***			
A12.5	7.8.6	< Base plates are not excessively eroded.			
A12.6	7.8.6	< Switches, gauges and lights functioning correctly.			
A12.7	7.8.6	< Electrical safety check has been done within last 12 months.			
		Comments: •			
A13	**MECHANICAL WASHERS**				
A13.1	7.8.6	< Written records of daily and monthly maintenance are kept.			
A13.2	7.8.6	< Visual inspection of items being processed – each load.			
A13.3	7.8.6	< Thermocouple testing to check all operating temperatures of washer – quarterly.			

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			0	1	N/A
A13.4	7.8.6	☺ *Check for detergent residues & pH of residual rinse solution – daily.*			
A13.5	7.8.6	< Jets, filters, door and door gaskets and external surfaces cleaned – ***daily.***			
A13.6	7.8.6	< Detergent and rinse dispensers are clear and functioning correctly.			
A13.6	7.8.6	< Performance tests for temperature and successful cleaning – ***continuous.***			
A13.7	7.8.6	< Gauges and timers are functioning correctly.			
A13.8	7.8.6	< Check machine is not leaking.			
		Comments: •			
A14	**DRYING**				
A14.1	2.10.2	☺ *Drying cabinets are used for drying instruments and hollowware, tubing and anaesthetic equipment.*			
A14.2	2.10.2	< Drying cabinet operates between 65º and 75ºC.			
A14.3	2.10.2	< Drying cabinet complies with AS 2514 or AS 2774.			
A14.4	2.9.3.3	☺ *Hollowware is inverted.*			
A14.5	2.10.2	☺ *A lint-free cloth is used for manual dying.*			
A14.6		☺ *Items are not dried in ambient air.*			
A14.7	7.8.6	< Documented daily visual temperature check.			
A14.8	7.8.6	< Daily surface cleaning.			
A14.9	7.8.6	< Filters and door seals are routinely checked.			
		Comments: •			
A15	**GENERAL COMMENTS**				
	•				

B. Preparation & Packaging

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			0	1	N/A
B1	**INSTRUMENTS**				
B1.1	3.4.1	< Ratchet instruments are left open and unlocked.			
B1.2	3.4.1	< Multi-part instruments are disassembled or sufficiently loosed to allow contact with sterilisation agent.			
B1.3	3.4.3.3	☺ *Sharp instruments are packaged so that the tips are exposed to the sterilising agent but will not perforate the packaging material.*			
B1.4		☺ *Sets are packed to prevent damage to delicate items.*			
B1.5		☺ *Instrument trays are perforated.*			
		Comments: •			
B2	**HOLLOWWARE**				
B2.1	3.4.2	< All openings face the same direction.			
B2.2	3.4.2	< Items cannot move inside pack.			
B2.3	3.4.2	< Stackable hollowware packaged together are separated by non-porous spacers.			
		Comments: •			
B3	**TYPES OF PACKING & WRAPPING MATERIALS**				
B3.1	3.1	< Materials are compatible with the item being packed and the sterilising method selected.			
B3.2		< Packaged items are not processed in a ‘flash’ steriliser.			
		Comments: •			
B4	**WRAPS**				
B4.1	3.4.3.2	< Textile linen wraps comply with AS 3789.2			
B4.2	3.4.3.2	< Linen with defects such as holes and threadbare patches are not used.			
B4.3	3.4.3.2	< Heavy woven fabrics are not used.			
B4.4		< Textile outer wraps are double thickness.			
B4.5	3.4.3.6	< Rigid reusable containers allow penetration & removal of the sterilizing agent.			
		Comments: •			
B5	**SEALING OF PACKS - GENERAL**				
B5.1	3.6.1	< Staples, pins, inappropriate tape are NOT used.			
B5.2	3.6.1	< String, non-adhesive tape and elastic bands are NOT USED			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
		Comments: •			
B6	**HEAT SEALING**				
B6.1	3.6.2	☺ *Suitable heat sealing equipment is used.*			
B6.2	7.8.6	< Seals are checked daily to ensure complete seal.			
B6.3		< Laminated pouch sealing complies with AS 1079.4			
B6.4	7.8.1	< Test pieces processed and examined for integrity and strength before and after sterilisation – daily.			
B6.5		< Complete mechanical service – 12 monthly.			
B6.6		< Machine is checked to ensure it is clean with no loose fibres or lint present – daily.			
B6.7		< An Electrical Safety check has been performed and is current.			
B6.8		< Continuous sealers- checked and gap between heating elements adjusted if required - 3 monthly.			
		Comments: •			
B7	**STERILISING INDICATOR TAPE**				
B7.1	3.6.3	< Tape is appropriate for the mode of sterilisation.			
B7.2	3.6.3	< Tape is compatible with wrapping material used.			
B7.3	3.6.3	< Tape colour change after exposure is clear, distinct and uniform and markedly different to unprocessed tape.			
B7.4	3.6.3	< Tape is heat stable, moisture stable and permeable to sterilising process.			
B7.5	3.6.3	< The name of the manufacturer, batch number and date of manufacture are clearly marked on the core of the indicator tapes in use.			
B7.6	3.6.3	☺ *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.*			
B7.7		< When tape is used to seal bags it is placed across the entire folded edge.			
		Comments: •			
B8	**ANAESTHETIC AND RESPIRATORY EQUIPMENT**				
B8.1		• Hands are washed thoroughly.			
B8.2	2.9.2.6	• Reassembled after processing in a clean area.			
B8.3	2.9.3.4	• Items are packaged and clearly labelled for supply to user areas.			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
B9	**LABELING PRIOR TO STERILISATION**				
B9.1	3.3	< Prepared labelling or non-toxic solvent-based felt-tipped pens are used.			
B9.2	3.3	< Labelling includes the contents of the pack and batch control data.			
B9.3	3.3	< Sharp-tipped, water-based or ball-type pens are not used.			
		Comments: •			
B10	**GENERAL COMMENTS**				
	•				

C. Sterilising

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
C1	**STEAM STERILISERS**				
C1.1	4.2.1	< An operators manual is in the vicinity of the steriliser at all times.			
C1.2	4.2.1	< Steam has a dryness fraction of 97% or above.			
C1.3	4.2.1	< Steam is not superheated beyond 2ºC of the saturated steam temperature.			
C1.4	5.1.2.1	< Items prone to entrap moisture are tilted on edge.			
C1.5	5.1.2.1	< Packs of drapes are loaded with layers vertical.			
C1.6	5.1.2.1	< Items do not touch chamber walls.			
C1.7	5.1.2.1	< Laminated pouches are loaded on edge with paper to laminate or flat with paper surface down.			
C1.8	5.1.2.1	< Loading carts are loosely loaded to capacity.			
C1.9	5.1.2.1	☺ *Packs of hollowware and trays of instruments are NOT placed above textile packs.*			
C1.10	6.1.1	< Prior to removal the recording charts or printouts are checked and results recorded.			
C1.11	6.1.1	< Supervisor is notified if a failure is detected.			
C1.12	6.1.1	< Load is removed from steriliser as soon as process is competed and a visual inspection is made to ascertain that the load is dry.			
C1.13	6.1.1	< Indicators are checked to ensure required colour change has occurred.			
C1.14	6.1.1	< Loading carts with cooling items are kept away from high activity areas.			
C1.15	6.1.1	< Cooling items are NOT place on solid surfaces.			
C1.16	6.1.1	☺ Damaged, wet or dropped items are considered unsterile and are reprocessed.			
C1.17	7.3.1	< There is routine calibration of gauges and sterilisation performance testing.			
		Comments: •			
C2	**DOWNWARD DISPLACEMENT 'FLASH' STERILISER**				
C2.1		< Complies with AS 2192.			
C2.2		< Drying time is determined by size and density of packs.			
C2.3		< Used for unwrapped non-porous items only.			
C2.4		< Blind-ended cannulated instruments are not 'flash' sterilised.			
C2.5		☺ *Instrument sets are not sterilised routinely by this method.*			
C2.6		☺ *Suction tubing is not processed in "flash" steriliser.*			
C2.7		☺ *Flash" steriliser is performance tested daily.*			

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			0	1	N/A
C2.8	5.1.2.2	< Items placed on a perforated or mesh.			
C2.9	5.1.2.2	< Tray placed flat on steriliser shelf.			
C2.10	5.1.2.2	< A new chemical indicator is place in each tray being processed.			
C2.11	5.1.2.2	< Items are not bagged or wrapped.			
C2.12	6.1.2	< Procedures for unloading of sterilisers without a drying stage (or "flash" sterilised) have been developed and documented (if used)			
C2.13	6.1.2	< Sterile "set up" personnel wear a surgical mask and full sterile attire when transferring items from steriliser to point of use			
		Comments: •			
C3	**BENCHTOP STERILISER**				
C3.1	4.2.4	< Complies with AS 2182.			
C3.2	4.2.4	< With drying cycle – drying time is determined by size and density of packs.			
C3.3	4.2.4	< Without a drying cycle – sterilise unwrapped items only.			
		Comments: •			
C4	**PREVACUUM STERILISER**				
C4.1	4.2.5	< Complies with AS 1410.			
		Comments: •			
C5	**ETHYLENE OXIDE GAS STERILISATION**				
C5.1	4.4.2	< Complies with the *National Code of Practice for the Safe Use if Ethylene Oxide in Sterilisation/Fumigation Processes* & ISO 11135.			
C5.2	4.4.2	☺ *Gas concentration is not less than 400 mg/L.*			
C5.3	4.4.2	☺ *Temperature is not less than 36ºC (cool cycle) and not greater than 60ºC (warm cycle).*			
C5.4	4.4.2	☺ *Relative humidity is greater than 40% but less than 100%.*			
C5.5	5.3.1	☺ *Load the steriliser fully with items having a common aeration and sterilisation time.*			
C5.6	5.3.2	< Items should be placed in metal baskets or on metal racks or loading cars.			
C5.7	5.3.3	< Items are placed loosely and do not touch the chamber walls.			
C5.8	5.3.3	< Items packed in flexible packaging are loaded on edge with paper to laminate or flat with the paper surface downwards.			
C5.9	6.3.1	☺ Manufacturer's instructions are followed when unloading.			
C5.10	6.3.2	< The minimum protection for unloading complies with national and occupational health and safety regulations.			
C5.11	6.3.3	< The transfer of items to an aerator occurs immediately after the			

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			0	1	N/A
		end of the filtered air purge.			
C5.12		SSU is covered by an Approved Handler [requirement of the Hazardous Substances & New Organisms Act], preferably a SSU staff member.			
		Comments: •			
C6	**PURCHASING**				
C6.1	7.2	< All new sterilisers and associated equipment purchased comply with appropriate Australian/New Zealand Standards.			
C6.2	7.3.2.1	< Performance testing is done before and after installation.			
C6.3	7.3.4	< Performance test outcomes are documented.			
C6.4	7.3.4	< Data is recorded and kept.			
C6.5	7.3.4	< A copy of data is kept in equipment record book.			
C6.6	7.4.1	< Ongoing records of recommissioning, performance data, maintenance, calibration and performance test results are kept.			
		The sterilisation process is validated as appropriate following:			
C6.7		< Installation of new equipment			
C6.8		< Major equipment servicing of steriliser or associated			
C6.9		< Modifications or technical changes to steriliser or associated equipment			
C6.10		< Replacement of any one piece of equipment that is used as part of the sterilisation process			
C6.11		< Changes to detergent or methods used for cleaning			
C6.12		< Changes to loading methods and load sizes of cleaning and washing equipment			
C6.13		< Changes to the methods for packaging/wrapping			
C6.14		< Changes to load size and configuration			
C6.15		< Changed to load carrying devices.			
		Comments: •			
C7	**PREVENTIVE MAINTENANCE**				
C7.1	7.5	< Routine calibration of gauges and sterilisation cycle performance testing is established and maintained.			
C7.2	7.7	< A skilled contractor or trained in-house person is used to carry out a preventative maintenance program.			
	7.1	The operator checks sterilisers to ensure that:			
C7.3		< Chamber floor is free of debris			
C7.4		< Chamber drain filter is clear			
C7.5		< Recording device is functioning correctly			
C7.6		< The door gasket is undamaged			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
C7.7		< Loading cart and external surfaces are damp dusted - daily			
C7.8		< Loading cart and internal walls are cleaned using detergent having a pH 4 – 5.5			
C7.9		< Filters are checked every 6 months and the results recorded.			
C7.10	8.5.2.3	< All records are kept for required time.			
		Comments: •			
C8	**MONITORING STERILISER CYCLES**				
C8.1	8.6.1	☺ *Physical parameters are measured with continuous automatic permanent monitoring.*			
C8.2	8.6.2.1	< Chemical indicators are used.			
C8.3	8.6.3	< Biological/enzymatic indicators are used.			
C8.4	8.6.4.1	< A Leak Rate Test is performed daily (in the absence of an air detector) or weekly (if an air detector is fitted).			
C8.5	8.6.4.2	< A Bowie Dick Type Test is performed daily at 134ºC for 3-3½min.			
		Comments: •			
C9	**BATCH CONTROL NUMBERS**				
	8.5.2.1	Each packaged item is labelled with the following:			
C9.1	8.5.2.1	< Steriliser identification number or code			
C9.2	8.5.2.1	< Date of sterilisation			
C9.3	8.5.2.1	< Cycle or load number			
C9.4	8.5.2.1	☺ *Manufacturers batch or lot no. of commercially prepared implantables in pack*			
		Comments: •			
C10	**STERILISATION CYCLE RECORDS**				
C10.1	8.5.2.2	Records are maintained for each sterilising cycle and include:			
C10.2	8.5.2.2	< Date of cycle			
C10.3	8.5.2.2	< Steriliser number or code			
C10.4	8.5.2.2	< Cycle or load number			
C10.5	8.5.2.2	< Exposure time, temperature and pressure			
C10.6	8.5.2.2	< Name or identification of loading operator			
C10.7	8.5.2.2	< Name or identification of person releasing load			
C10.8	8.5.2.2	< Specific contents of load			
C10.9	8.5.2.2	< Results of physical, chemical and biological monitoring.			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
C11	**MONITORING OF PACKAGING PROCESS**				
C11.1	8.9	Continuous checks are made of:			
C11.2		< Integrity of outer wrap & Seals			
C11.3		< Correct labelling			
C11.4		< Correct colour change of external indicator.			
C11.5	8.9	In addition, sterilised packs are selected at random & examined for:			
C11.6		< Integrity of outer wrap & seals and correct labelling			
C11.7		< Ease of opening			
C11.8		< Correct packaging techniques			
C11.9		< Correct contents			
C11.10		< Condition of contents			
C11.11		< Correct change of internal chemical indicator (if used).			
		Comments: •			
	GENERAL COMMENTS				
	•				

D. Storage

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	*AS/NZS 4187:2003* ***Standard Interpretation*:** < **SHALL = Mandatory** ☺ **SHOULD = *Recommended***	*[DHB logo inserted here]*

Audit Ref	Standard Ref	Standard	Compliance 0	1	N/A
D1	**STORAGE AREA**				
D1.1	9.2	< Sterile storage areas are dedicated for that purpose only.			
D1.2	9.2.2	< Clearly sign-posted & traffic flow controlled/restricted.			
D1.3	9.2.2	< Access to sterile store area is clearly is restricted.			
D1.4	9.2	< Dust free, insect free & vermin free.			
D1.5	9.2	< Shelves 250mm above floor level & 440mm below ceiling level.			
D1.6	9.2	< Items protected from sunlight.			
D1.7	9.2	< Storage containers are kept clean, dry and in good condition.			
D1.8	9.2	< Cardboard boxes are NOT used as storage containers.			
D1.9		< Surface seams are sealed.			
D1.10	9.2	< Surfaces non-porous & smooth & easily cleaned.			
D1.11	9.2	☺ *Overhead lighting set flush into ceiling.*			
D1.12	9.2	☺ *Temperature 18 - 22ºC.*			
D1.13	9.2	☺ *Humidity ranging from 35% -68% (complies with AS 1668.2).*			
		Comments: •			
D2	**PLASTIC DUST COVERS**				
D2.1	9.3	< Plastic used in new, clean and intact and of sufficient strength.			
D2.2	9.3	< Covers are applied in a clean environment using clean techniques.			
D2.3	9.3	< Dust covers are sealed.			
D2.4	9.3	< Dust covers are labelled 'DUST COVER ONLY'.			
D2.5	9.3	< Items are placed in dust covers immediately they are cooled.			
D2.6	9.3	< Batch information is not marked on plastic covers.			
		Comments: •			
D3	**TRANSPORT/DISTRIBUTION OF STERILE ITEMS**				
D3.1	9.4	< Equipment is maintained in a clean, dry state and in good working order.			
D3.2	9.4	< Sterile items transported outside the health care facility are packaged securely and protected against damage and contamination during transport.			
D3.3	9.4	☺ *Equipment used to move and transport items is dedicated to that purpose and is kept clean.*			
D3.4	9.4	☺ *It is not used to collect used items, transport food or garbage.*			
D3.5	9.4	☺ *Transport vehicles have adequate segregation.*			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
D4	**COMMERCIALLY PREPARED ITEMS**				
D4.1	9.5	< Dust is wiped from the store pack before it is opened.			
D4.2	9.5	< Sterile items are removed from the store pack before entering clean area.			
D4.3	9.5	< Sterile items are inspected for cleanliness and/or damage to unit packs.			
D4.4	9.5	☺ *Grossly soiled or damaged store packs are not accepted.*			
		Comments: •			
D5	**SHELF-LIFE/STOCK ROTATION**				
D5.1	9.6	< A stock rotation system is based on the date of sterilisation.			
D5.2	9.6	< Shelf life is event related not time related.			
D5.3	9.6	< Appropriate stock levels are maintained.			
D5.4	9.6	< Stock is regularly checked and is considered nonconforming where: < It is incorrectly wrapped < It is damaged or opened < It is wet after the sterilising cycle or comes into contact with a wet surface < It is placed or dropped on a dirty surface < It has no indication of having been through a sterilising process.			
D5.5	9.6	☺ *Nonconforming stock is reprocessed as soon as identified.*			
		Comments: •			
D6	**GENERAL COMMENTS**				
	•				

E. Quality Management

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	*AS/NZS 4187:2003* ***Standard Interpretation*:** < **SHALL = Mandatory** ☺ **SHOULD = *Recommended***	*[DHB logo inserted here]*

Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
E6	**FACILITY MANAGEMENT**				
E6.1	1	< There is a copy of AS / NZS 4187:2003 in the SSU / sterilising area.			
E6.2	8.1	< The person in charge of sterilising facility has specific qualifications and experience in sterilising technology.			
E6.3	8.1	< The person in charge of the facility is actively involved in supervising the day-to-day activities of the sterilising facility.			
		Comments: •			
E7	**DOCUMENTATION**				
E7.1	8.2	< Policies and procedures for all activities in the processing of sterile items are documented.			
E7.2	9.1.1	< Policies & procedures for the storage, handling and issuing of sterile stock are documented.			
E7.3	8.2	< Records are maintained and reviewed at frequent intervals.			
E7.4	8.2	< Records are kept for a period of time not less than that defined by regulatory authorities or Health Care Facility.			
		Comments: •			
E8	**PERFORMANCE MANAGEMENT**				
E8.1	8.3	< Staff qualification and staffing levels are sufficient to ensure continuous, safe and efficient operation of the sterilising facility.			
E8.2	8.3	< There is a written job description for each category of staff.			
E8.3	8.3	☺ *Staff performance is assessed after orientation and at regular intervals (annually).*			
		Comments: •			
E9	**EDUCATION AND TRAINING**				
E9.1	8.4	< There is a formal orientation program in place for new staff.			
E9.2	8.4	< On the job training is provided in all relevant processes.			
E9.3	8.4	☺ *Staff members are encouraged to participate in appropriate external education courses.*			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
E10	**DEVIATION AND FAULT ANALYSIS**				
E10.1	8.5.3	< A procedure is in place for the review of deviation reports and any other quality or procedural problems.			
		Comments: •			
E11	**PRODUCT COMPLAINTS**				
E11.1	8.5.4	< A written procedure is in place to ensure that complaints or defects relating to product quality, safety or efficacy are reported and investigated.			
E11.2	8.5.4	< Corrective actions are documented.			
		Comments: •			
E12	**RECALL PROCEDURES**				
E12.1	8.5.5	< Policies and procedures for the recall of products are documented and include the following:			
E12.2	8.5.5	< Criteria for issuing recall notice			
E12.3	8.5.5	< Person responsible for issuing notice			
E12.4	8.5.5	< Person responsible for reporting on recall activities			
E12.5	8.5.5	< Persons to be notified when recall event occurs.			
E12.6	8.5.6	< A Recall Notice is written and includes:			
E12.7	8.5.6	< Name of person or department for which notice is intended			
E12.8	8.5.6	< Sterilisation batch information			
E12.9	8.5.6	< Product name and quantity of products returned.			
E12.10	8.5.6	< Action to be taken by persons receiving the notice e.g. return or destruct or hold.			
E12.11	8.5.7	< A Recall Report is completed and filed and includes:			
E12.12		< Circumstances that initiated need for recall			
E12.13		< List of total number of products for recall and actual number located and recall			
E12.14		< Identifying the number of patients potentially exposed and actions taken			
E12.15		< Documenting the actions taken to prevent a similar situation.			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
E13	**OCCUPATIONAL HEALTH & SAFETY**				
E13.1	8.10.1	☺ *Staff are immunised according to local policy and records are documented in personal files.*			
E13.2	8.10.1	< Superficial skin lesions are covered by an occlusive dressing.			
E13.3	8.10.1	< Accidents are recorded and treatment is provided as required.			
E13.4		☺ *Good Health.*			
E13.5		☺ *High standard of personal hygiene.*			
E13.6	8.10.1	☺ *Staff with dermatitis, skin infections or infected lesions are examined by a Medical Practitioner.*			
		Comments: •			
E14	**STAFF UNIFORMS**				
E14.1	8.10.2	< A clean uniform is worn for each shift.			
E14.2	8.10.3	☺ Uniforms are not worn outside the health care facility.			
E14.3	8.10.2	< Hair is safely secured and covered while preparing items for sterilisation.			
E14.4	8.10.2	< PPE (Personal Protection Equipment) is available and is worn when handling contaminated items.			
E14.5	8.10.2	☺ *Hand and wrist jewellery including plain wedding bands are NOT worn.*			
E14.6	8.10.2	☺ *Nail polish or acrylic nails should not be used, nails are kept short.*			
		Comments: •			
E15	**HANDWASHING/HAND HYGIENE**				
E15.1	8.10.3	< Handwashing techniques and the importance of handwashing are taught to all staff.			
E15.2	8.10.3	< Single use towels are used.			
E15.3	8.10.3	< Grease and oil based hand creams are NOT used.			
E15.4	8.10.3	☺ *Mechanical drying is NOT used.*			
		Comments: •			
E16	**ENVIRONMENTAL CONTROL**				
E16.1	8.11	< Work practices and stock control ensure that sterile and clean items are separated from soiled items and areas in which soiled items are handled and cleaned.			
E16.2	8.11	< Environment is clean at all times.			
E16.3	8.11	< Adequate facilities for personal hygiene are readily accessible.			
E16.4	8.11	< Efficient ventilation is in place (AS 1668.2).			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
E16.5	8.11	< Lint production is minimised.			
		Comments: •			
E17	**EVALUATION FEEDBACK & OUTCOMES**				
E17.1	8.12	< A programme of evaluation of processes and procedures exists.			
E17.2	8.12	< Regular audits provide a mechanism for analysis, feedback and quality improvement.			
		Comments: •			
E18	**GENERAL COMMENTS**				
	•				

Please refer to AS/NZS 4187:2003 when undertaking the above section of the audit.

F. Infection Control

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	*NZS 8134:2001* ***Standard Interpretation*:** < **SHALL = Mandatory** ☺ **SHOULD = *Recommended***	*[DHB logo inserted here]*

Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
F1	**CRITERIA**				
F1.1	5.6.1.	< Effective infection control is achieved by developing and implementing policies and procedures that are practical and safe, with the aim of minimizing the risk of infection to patients, staff, visitors and contractors.			
F1.2		< Infection control education, training and information is made available to staff.			
F1.3		< The effectiveness of the infection control processes is monitored and outcomes linked to the quality system.			
F1.4		< Infection control principles are integrated into the procedures and processes associated with the cleaning, disinfecting and sterilising of reusable medical and surgical instruments and equipment..			
		Comments: •			

Please refer to NZS 8134:2001 when undertaking the above section of the audit.

G. Management of Healthcare Waste

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	*NZS 4304:2002* ***Standard Interpretation*:** < **SHALL = Mandatory** ☺ **SHOULD = *Recommended***	*[DHB logo inserted here]*

Audit Ref	Standard Ref	Standard	Compliance 0	1	N/A
G1	**CATEGORIZATION OF HEALTHCARE WASTE**				
G1.1	3.2	< Has the waste products been categorized in accordance with Section 3 of the 'Management of Healthcare Waste' Standards?.			
G1.2	3.2.2	< Has the waste been correctly identified as: **Hazardous - Sharps**			
		< Radioactive			
		< Cytotoxic			
		< Infectious			
G1.3	3.3	< Has the waste been correctly identified a: **Hazardous – Non-Sharps**			
		< Radioactive			
		< Cytotoxic			
		< Infectious			
	3.3.3	< Body parts			
	3.3.2	< Other – solvents, chemicals			
		Comments: •			
G2	**WASTE GENERATOR'S RESPONSIBILITIES**				
G2.1	4.4	< There a policy in place to appropriately dispose of body parts which may be sent down on Theatre trolleys to ensure that body parts are handled in a safe and culturally acceptable manner and in accordance with relevant legislation..			
G2.2		< There is policy in place to appropriately manage waste within the Sterile Supplies Unit.			
		Comments: •			
G3	**WASTE HANDLING**				
G3.1	8.1	< Staff practice Standard Precautions in the handling of waste.			
G3.2	8.1	< Staff have undergone 'manual handling technique' training.			
G3.3	8.1	< Staff have access to an appropriate immunization programme			
G3.4	8.1	< Personal Protective Equipment [PPE] is regularly checked to ascertain it is:			
		< Appropriate for the task.			
		< Readily available and use wherever required.			
		< Complies with the relevant Standard			
		< PPE is in good working order.			
		< PPE is used correctly.			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
G3.5	8.1	< Every person involved in, or injured by coming into contact with clinical waste receives:			
		< Initial first aid treatment.			
		< Effective medical care.			
		< Confidential counselling.			
		< Records are maintained for every incident.			
		Comments: •			
G4	**TRAINING**				
G4.1	10.1	< A waste management training programme has been implemented.			
G4.2	10.3	< The waste management training programme includes:			
		< Identification of hazards associated with healthcare waste.			
		< Injury prevention and the transmission of disease from handling waste.			
		< Safety procedures for dealing with the healthcare waste.			
		< Correct use of PPE			
		< Procedures for action and notification in the event of an injury.			
		< Education on standard precautions.			
		< Cleaning up procedures.			
		Comments: •			

Please refer to NZS 4303:2002 when undertaking the above section of the audit.

H. Endoscope Cleaning

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	***SNZ HB 8149:2001*** ***Standard Interpretation*:** **< SHALL = Mandatory** **☺ SHOULD = *Recommended***	Waitemata District Health Board *Te Wai Awhina*

Audit Ref	Standard Ref	Standard	Compliance 0	1	N/A
H1	**PROCEDURE MANUAL**				
H1.1		< Copy of the relevant Standards and Guidelines available for staff to refer to.			
H1.2		< Is there a procedure manual for the cleaning and disinfecting of endoscopic equipment which includes the following:			
		< Instructions provided by the endoscope manufacturer			
		< Instructions provided by the supplier of the cleaning / disinfecting equipment			
		< Instructions for the handling of chemicals used included MSDS and Health & Safety information on the use of handling of the chemicals			
		< States who the Approved Handler is and requirements under the Hazardous Substance and New Organisms Regulations 2001			
		Comments: •			
H2	**COLLECTION PROCEDURES**				
H2.1		< Procedures for the collection / delivery of used endoscopes from procedure rooms, operating theatres and other departments have been formulated and documented.			
H2.2		< Collection containers are puncture resistant, leak-proof & have a lid that can be closed.			
H2.3		< Separate systems exist for collection of used items and delivery of decontaminate items.			
H2.4		☺ *Containers can be cleaned.*			
		Comments: •			
H3	**INITIAL TREATMENT OF USED ITEMS**				
H3.1		< Gross soil is removed as close to the point of use as possible [before being returned to scope cleaning area].			
H3.2		< Standard precautions are used at all stages of handling use items.			
H3.3		< Personal Protective Equipment is available and is used where appropriate.			
H3.4		☺ *A written description of the procedures is available in all areas.*			
		Comments: • •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
H4	**CLEANING AREA**				
H4.1		< There is a dedicated cleaning area to prevent possible contamination of processed items.			
H4.2		< Written policy on the methods, and frequency of cleaning the area and equipment.			
H4.3		Equipment in cleaning includes:			
		☺ *Separate hand washing facilities*			
		☺ *Disposable towels available and maintained*			
		☺ *Adequate bench space*			
		☺ *Smooth surfaces without crevices*			
		☺ *Good lighting*			
		☺ *Efficient ventilation*			
		☺ *Non-slip flooring*			
		☺ *Sink suitable for disposal of liquid waste*			
		☺ *Deep, double sink cleaning*			
		☺ *Drying equipment*			
		☺ *Non-porous work surfaces*			
		☺ *Adequate plumbing*			
		☺ *Appropriate workflow and traffic flow from reception to distribution of items.*			
H4.4		Mechanical equipment meets relevant Standards:			
H4.5		Waste is collected as per WDHB policy.			
		Comments: •			
H5	**CLEANING PRECAUTIONS**				
H5.1		< Care is taken to avoid direct contact with skin when using detergents, disinfectants and other chemicals.			
H5.2		< Techniques of cleaning avoid generating aerosols.			
		Comments: • • •			
H6	**CLEANING AGENTS**				
H6.1		< Cleaning agents are used to remove soil.			
H6.2		< Material Safety Data Sheets are available for all chemicals.			
H6.3		< Cleaning agents are dispensed in a safe manner which does not promote contamination of contents.			
H6.4		☺ *Chemical suppliers have provided validation regarding agents.*			
H6.5		☺ *Chemical suppliers have provided training for staff.*			
H6.6		< Product is appropriately labelled and includes product name, manufacturer's name & address, description & purpose, dilution			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
		instructions, batch number, manufacture or expiry date, advice not to mix other chemicals, safety & first aid instructions and storage requirements.			
		Comments: •			
H7	**MANUAL CLEANING**				
H7.1		< Cleaning equipment is non-abrasive.			
H7.2		< Cleaning equipment is rinsed and stored dry when not in use.			
H7.3		< Materials such as brushes are cleaned and thermally disinfected after each cleaning session.			
H7.4		< Protective water-resistant clothing and gloves are worn during all cleaning procedures.			
H7.5		< Hot and cold water are available.			
H7.6		☺ *There are at least two large, deep sinks.*			
H7.7		< Appropriate cleaning equipment is available.			
H7.8		< Appropriate cleaning agents are available.			
H7.9		☺ *Items are flushed in running water to remove gross visible soiling.*			
H7.10		☺ *Items are washed thoroughly avoiding aerosols.*			
H7.11		< Cleaning equipment [brushes] reprocessed as per policy.			
		Comments: •			
H8	**MECHANICAL CLEANING**				
H8.1		< Soloscope machine complies with ?????			
H8.2		< Procedure for changing chemicals in machine documented			
H8.3		< Routine calibration of Soloscope machine and records kept.			
H8.4		< A skilled contractor or trained in-house person is used to carry out a preventative maintenance program.			
H8.5		< Each machine has a bacterial-grade filter.			
H8.6		< Schedule for frequent routine decontamination of the internal water pipes and filter is documented and maintained.			
		Comments: •			
H9	**STORAGE**				
H9.1		< Endoscopes hang vertically, free and without kinking, during storage			
H9.2		< Chemicals are stored correctly			
H9.3		< Storage areas are correctly signed for hazardous substances			
H9.4		< Spill kits available and easily assessible			
		Comments: •			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
H10	**TRAINING**				
H10.1		< All staff have undergone formal training in all aspects of cleaning and disinfecting scopes.			
H10.2		< Training documentation is complete.			
H10.3		< Training records up to date.			
H10.4		< All staff are audited annually.			
		Comments: •			
H11	**PROOF OF PROCESS**				
H11.1		< Quality control monitoring is documented.			
H11.2		< Proof of process is document for each Endocope			
H11.3		< Documentation is available which enables retrospective identification of patient who recently have had an endoscopic procedure with any particular endoscope or with an endoscope that was processed in any particular disinfecting machine.			
		Comments: •			
H12	**MICROBIOLOGICAL SURVEILLANCE**				
H12.1		< Schedule for microbiological testing for each endoscope is documented.			
H12.2		< Cultures are taken from all endoscopes no less frequently than 3-monthly.			
		< Gastroscopes and colonoscopes are tested 3 monthly			
		< Duodenoscopes, Bronchoscopes, ERCP and Cystoscopes are tested monthly			
H12.3	10.3	< Cultures should be taken more often [e.g. monthly] if:			
		< There is a change in endoscope cleaning or disinfection practices, equipment or staff			
		< The endoscope is used for ERCP or bronchoscopy procedures			
H12.4		< Water testing is completed as per protocol			
H12.5		< Collecting a sample:			
		< Sterile gloves are used			
		< An aseptic technique is used			
		< Each channel of endoscope is flushed with 0.9% saline			
		< Clean cleaning brush is used to brush down each channel			
		< Microbiological container is appropriate labelled.			
		< Procedure is documented and available to staff			
H12.5		< Procedure documented as to steps to taken if a positive			

SSU Quality Audit Tool

Scoring System: **0 = UNACCEPTABLE** **1 = ACCEPTABLE** **N/A = NOT APPLICABLE**	***SNZ HB 8149:2001*** ***Standard Interpretation*:** **< SHALL = Mandatory** **☺ SHOULD = *Recommended***	Waitemata District Health Board *Te Wai Awhina*

Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
		microbiological result is obtained.			
		Comments: •			
H13	**STERILISATION**				
H13.1		< All biopsy equipment is sterilised by SSU			
		Comments: • • •			
H14	**DOCUMENTATION**				
H14.1		< The patient label is on the proof of process sheet.			
H14.2		< The scope number is identified.			
H14.3		< The nurse / SSU technician who cleaned the endoscope has signed in the appropriate place.			
H14.4		< The cycle numbers have been documented.			
H14.5		< Microbiological results are signed by person responsible for testing.			
H14.6		< Adverse results from microbiological tests are notified to the clinical microbiologist.			
H14.7		< Incident form is completed for all adverse events.			
H14.8		< All incidents are followed up with investigation and outcome well documented.			
H14.9		< Past microbiological test and water sample results are filed and able to be located easily.			
H14.10		< Schedule for air tests is documented.			
H14.11		< Air tests results are files and able to be located easily.			
H14.12		< Start of day Soluscope validation forms signed, files and able to be located easily			
H14.13		< MSDS for chemicals are available to staff.			
H14.14		< Soluscope machine preventative maintenance schedule documented			
H14.15		< Results from preventative maintenance on Soluscope machines filed and easy to be located.			
H14.16		< Manufacturers manuals for Soluscope machines are available to staff.			
		Comments: •			
H15	**VENTILATION**				
H15.1		< Ventilation is adequate for the type of disinfectant used			
H15.2		< Air is tested for fumes on a regular base			

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Audit Ref	Standard Ref	Standard	Compliance		
			0	1	N/A
		Comments: •			

Please refer to SNZ HB 8149:2001 when undertaking the above section of the audit.

Recommendations

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