

Documenting the Performance Evidence needed for Staff Education: -

Using Sterile Services Staff: - training tools.

18/8/2003.

Traditionally Sterile Service Departments have trained new staff members using the most common method, the "Buddy" system. This method involves using an experienced member of the staff to work beside a new staff member, with one-on-one training. The down side to this method: - there were no accurate performance checks in place or documentation.

Then the staff were sent for their formal education at TAFE/OTEN to complete their Sterilisation Certificate Course for Technical Aides.

This was, and still is; a successful method of training, but a modern SSD training programme needs more. We need an accurate method of documenting and maintaining records, to provide the evidence of individual staff's performance.

Together with an ongoing skills training programme to enable evaluation of skills learned, to process new equipment and instrumentation.

The staff were still sent for their formal education at TAFE/OTEN to complete their Sterilisation Certificate Course for Technical Aides.

The SSD Education team recognised the need to have a competency based training tool, with the performance evidence documented.

Because today's instrumentation is both complex and diverse we need a system of training that enables monitoring of the staff's work performance and delivery of the training programme to meet individual's needs.

It is also essential to provide performance evidence for accreditation.

We needed to develop tools to enable the trainers to be aware of the competence of each of the 37 staff members, and be able to adapt to new instrumentation with in-service training and to provide for individuals needs.

These tools needed to address the following training issues

- The skills level that each staff member was up to, in his or her competencies?
- Was the staff education adequate?
- Was the staff member trained in all areas of competence?
- Was the evidence transportable?
- Did the evidence show clearly the level of competence of each staff member at a glance?

We recognised the need to have documented performance evidence!

So a programme was devised to ensure that all aspects of learning were captured and the date, type and level of competencies were kept as evidence for each staff member. This was achieved by using 3 separate types of tools.

1. A New Staff Orientation Programme was devised for use, over the first 6-week period for a new staff member.
2. A system of checks was put in place, to ensure nothing was forgotten and the signing off by the Team Leader was evidence of completion.
3. These programmes are completed for all staff and after signing off, are kept in a folder as performance evidence that orientation was completed.
4. There was also a 6-week initial training programme using the "Buddy" system with a week in each of the areas of work performance.

The following was developed as a very simple, but effective way of ensuring that every staff member was informed in the same way, with the same information, and there was documented evidence to attest to it!

STERILE SERVICES ORIENTATION SCHEDULE / checklist.		
NAME:-	Date:-	
1/ TOUR OF DEPARTMENT:-		
CHANGE ROOM.		[]
TOILETS.		[]
STORAGE AREA.		[]
CONTAMINATED AREA.		[]
CLEAN AREA.		[]
TEA ROOM.		[]
STERILE AREAS/ RED LINES.		[]
2/ ADMINISTRATION/CLERICAL.		
HOW TO USE BAR CODE LABELLER		[]
USE OF PHONE.		[]
USE OF COMMUNICATION BOOK.		[]
HOUSEKEEPING/TEA ROOM.		[]
KEY PICK-UP.		[]
ROSTER INFORMATION.		[]
SICK LEAVE BOOK.		[]
MEETINGS.		[]
3/ POLICIES/PROCEDURES.		
CLEANING SCHEDULE INFORMATION.		[]
COPY OF CODE OF CONDUCT AND ETHICS (Read and sign).		[]
COPY OF LEAVE & ENTITLEMENTS INFORMATION SHEET.		[]
COPY OF JOB DESCRIPTION.		[]
PROCEDURE MANUAL.		[]
O.H. & S. MANUAL.		[]
INFECTION CONTROL MANUAL.		[]
STATEMENTS OF DUTIES MANUAL.		[]
EDUCATION SCHEDULE.		[]
HOW TO USE: BIOLOGICAL INDICATORS/BOWIE DICK TEST PACKS.		[]
CLEANING SCHEDULE TRAINING.		[]
4/ OCCUPATIONAL HEALTH AND SAFETY.		
PROTECTIVE APPAREL:- CLOTHING,GLOVES,GOGGLES,MASKS,EAR PROTECTION.		[]
STANDARD PRECAUTIONS. "EVERYTHING IS CONTAMINATED."		[]
O.H. & S. POLICY/ RESPONSIBILITIES MANUAL.		[]
MINIMISATION & MANAGEMENT OF AGGRESSION		[]
CHEMICAL HANDLING AND MATERIAL SAFETY DATA SHEETS.		[]
ACCIDENT / INCIDENT IMMS REPORTING/ INJURIES: early notification form.		[]
5/ HOSPITAL ORIENTATION.		[]
6/ MANDATORY EDUCATION.		
FIRE AND SAFETY TRAINING.		[]
CHILD PROTECTION.		[]
MANUAL HANDLING.		[]
STANDARD PRECAUTIONS.		[]
OCCUPATIONAL HEALTH and SAFETY..		[]
MINIMISATION & MANAGEMENT OF AGGRESSION.		[]
7/ SUPERVISED:- "ON THE JOB" PRACTICUM.		
WEEK 1/ DIRTY AREA:- BOWLS / ANAESTHETIC.		[]
WEEK 2/ DIRTY AREA:- INSTRUMENTATION / SPECIALS.		[]
WEEK 3/ CLEAN AREA:- BOWLS / ANAESTHETIC.		[]
WEEK 4/ CLEAN AREA:- SEPARATES / TABLE 3 / STERRAD.		[]
WEEK 5/ CLEAN AREA:- INSTRUMENTS/SET-UP TRAYS.		[]
WEEK 6/ CLEAN AREA:- STERILISATION/STERILE STORAGE.		[]
Managers sign:-		
Staff members sign:-	Date completed:	
Note:- All training for each individual staff member is kept on an education DATA BASE.		

5A.

Secondly a competency based education tool to document the cleaning process, each item is disassembled and cleaned according to manufacturers recommendations and re-assembled, then signed off by a witnessing Team Leader: 3 x times each item.

<u>Competency Based Training programme for Wash-up Area</u>	<u>DATE:</u>	<u>TIME</u>	<u>SIGN</u>	<u>DATE</u>	<u>TIME</u>	<u>SIGN</u>	<u>DATE</u>	<u>TIME</u>	<u>SIGN</u>	<u>Team Leader</u>
ORTHOPAEDIC SPECIALITY :-										
Cannulated Screw Set 3.5mm/4										
Cannulated Screw Set 7.3mm										
Cannulated Tan Femoral Nail Inst Tray #1										
Cannulated Tan Femoral Nail Inst Tray #2										
Cannulated Tan Femoral Speciality Locking Tray #1										
Cannulated Tan Femoral Speciality Locking Tray #2										
Cannulated Tan Tibial Nail Inst Set										
DHS/DCS Basic Instruments										
Dr Harris Extras										
External Fixture Tubed Tray #1										
External Fixture Tubed Tray #2										
Hoffman π Blue Tray #1										
Hoffman π Blue Tray #2										
Hoffman π Compact Gold										
Hybrid External Fixator										
Llizarov System										
Mathys Synream Intramedullary Reamers										
Mini Fragment Set #1										
Mini Fragment Set #2										
Mini Hoffman External Fixture Set										
Pelvic Implant Set										
Pelvic Instruments										
Pelvic Reduction Instruments										
Small Fragment Set										
Standard Instrument Box										
Tenxor Inst & Implants										
T-Reamer Removal/Extraction Box										
Universal Nail Insertion Set										
Universal Nail Locking Set										
Unreamed Tibial Nail U.T.N.										

5B.

And a Q.A. tool for checking and packing of Instrument trays was devised, with the documented evidence to be signed off by a witnessing Team Leader.

This programme used an average of 50 trays, from simple to complex. That must be assembled and Q.A. checked and packed 3 times each, to a high level of competence, and signed off by a witnessing Team Leader.

Each of the 37 staff must eventually complete this task, has it documented on the sheet, and this sheet is kept as performance evidence: - of completion of the Learning Programme.

This was based on a system used by TAFE.

LEARNING OUTCOME:-		Name:-							
RANGE of VARIABLES:-		Package instruments and equipment.							
PERFORMANCE CRITERION:-		Check and assemble instrument sets a							
PERFORMANCE EVIDENCE:		<u>DATE</u>	<u>I.D.</u>	<u>DATE</u>	<u>I.D.</u>	<u>DATE</u>	<u>I.D.</u>	ACHIEVED COMPETENCE:	SIGN:
1	Curette Tray								
2	Minor Tray								
3	Plastic Tray								
4	General Tray								
5	Laparotomy								
6	Tonsil Tray								
7	Minor Tray								
8	Orthopaedic Tray								
9	Cystoscopy Tray								
10	Resectoscope Tray								
11	Facio-Maxillary General Tray								
12	Cardio- Thoracic chest re-opening tray O.T.								
13	Cardio- Thoracic chest re-opening tray I.C.U.								
14	Neuro Laminectomy tray								
15	Burr Hole Tray								
16	Emergency Neuro Tray								
17	Neuro Tray								
18	Cag tray								
19	Pump A Tray								
20	Pump B Tray								
21	DHS/DCS tray								
22	Fess tray								
23	Nasal Tray								
24	Cervical Laminectomy Tray No:-1								
25	Cervical Laminectomy Tray No:-2								
26	Thoracotomy Tray								
27	VIP Tray								
28	Vascular Extra's Tray								
29	Lap-Chole Tray								
30	Micro- Laryngoscopy Tray:- Paed								
31	Micro- Laryngoscopy Tray:- Stortz.								
32	Micro- Laryngoscopy Tray:- Wolf.								
33	Oesophagoscopy Tray:- Paediatric.								
34	Oesophagoscopy Tray:- Stortz.								
35	Oesophagoscopy Tray:- Wolf.								
36	Mini Fragment Tray								
37	Small Fragment Tray								
38	Universal Nail Reaming Set								
39	Standard Instrument Box								
40	Cannulated Screw Set 3.5mm/4.00mm								
41	Cannulated Screw Set 7.3mm								
42	Intra-ocular Tray								
43	Extra-ocular Tray								
44	Crainiotome 3M Drill								
45	Drill Reamer								
46	Perforator Drill								
47	Midas Rex Drill								
48	Sternum Saw								
49	Budde Halo Retractor								
50	Naso-pharyngoscope								

Sample only!

6. The third tool was developed as an education database to enable comprehensive and accurate records of all education. Including Orientations, Mandatory education, In-service, TAFE courses and Competency Based Training Programmes.

These are all documented and are easily accessed in a list that can be printed and used as a reference if the staff member changes employment or applies for a new position!

SSD Education and Training

File Edit View Insert Format Records Tools Window Help

Switchboard

**EDUCATION AND TRAINING
DATABASE**

Enter Session Attendance Print List of all Topics

View Employees Education Preview/Print Session Attendance

View List of Sessions Showing Attendees Preview/Print Staff Education Record

Staff Training Needs

Form View

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This is a truly transportable reference of the staff member's competencies and skills!

SSD Education and Training

File Edit View Insert Format Records Tools Window Help

Switchboard

Topics attended by Each Staff Member (Read Only)

Employee Number:

Last Name: Select Staff

First Name:

Date	Topic	Presenter	Time	Duration	Coi
28-Oct-02	Laparoscopic Bi-Polar Maryla	B BRAUN	3:00 PM	30	
10-Jul-02	MANDATORY EDUC. DAY	LEARNING & DEVI	8:00 AM	480	
30-May-02	ELECTROSURGICAL TESTIM	BIOMEDICAL ENG	3:00 PM	30	
27-Feb-02	ELECTROSURGICAL TESTIM	BIOMEDICAL ENG	3:00 PM	45	
25-Feb-02	MIN & MAN OF AGRESS	EDUCATION SUPP	2:30 PM	45	
11-Sep-01	EQUIP EDUCATION	ANNE STUCKEY	3:00 PM	45	
14-Nov-00	CUSA VALLEY LAB	COMPANY REPRE	3:00 PM	30	
13-Sep-00	MIN & MAN OF AGRESS	EDUCATION SUPP	11:00 AM	60	
31-Aug-00	CHILD PROTECTION	AREA HEALTH	11:00 AM	120	
30-Aug-00	MANUAL HANDLING	EDUCATION SUPP	9:00 AM	120	
29-Feb-00	FIRE SAFETY	ALISTAIR CRAIB	10:30 AM	45	
11-Nov-99	MANDATORY EDUC. DAY	THEATRE STAFF		0	
02-Nov-99	TEAMWORK	EDUCATION SUPP	2:00 PM	30	
07-Sep-99	COMMUNICATION	EDUCATION SUPP	2:00 PM	30	
08-Aug-99	PERF.MANAG.FOR STAFF	EDUCATION SUPP		60	
27-Jul-99	RONGEUR CARE	B BRAUN	3:00 PM	60	

Record: of 50

Form View

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SSD Education and Training

File Edit View Insert Format Records Tools Window Help

Topics Presented and Attendance (Read Only)

Details of Topics Provided

Date	Topic	Presenter	Time	Duration	Attendance	Names of Staff who Attended
01-Apr-02	MANDATORY EDUC. DAY	LEARNING & DEVELOPMENT	8:00 AM	480	2	Helen Anderson
20-Mar-02	MANDATORY EDUC. DAY	LEARNING & DEVELOPMENT	8:00 AM	480	2	Rhonda Annetts
27-Feb-02	ELECTROSURGICAL TEST	BIOMEDICAL ENGINEERING	3:00 PM	45	22	Silvana Barilla
25-Feb-02	MIN & MAN OF AGRESS	EDUCATION SUPPORT	2:30 PM	45	17	Virginia Boland
22-Feb-02	Min. & man of agg/managers	EDUCATION SUPPORT	9:00 AM	180	1	Naomi Brown
06-Feb-02	MANDATORY EDUC. DAY	LEARNING & DEVELOPMENT	8:00 AM	480	2	Lisa Cheers
24-Oct-01	MAN. OH&S RISKS IN HE	EDUCATION SUPPORT	9:00 AM	180	1	Wendy El- hassan
15-Oct-01	MANUAL HANDLING	AREA HEALTH	1:30 PM	120	1	Christine Gray
11-Oct-01	MANUAL HANDLING	AREA HEALTH	9:00 AM	120	1	Sandra Hadley
25-Sep-01	Designing & Building a horr	AREA HEALTH	9:00 AM	420	1	Narelle Milan
11-Sep-01	EQUIP EDUCATION	ANNE STUCKEY	3:00 PM	45	22	Magdalen Nash
29-Aug-01	Recruitment Selection Tech	AREA HEALTH	8:45 AM	240	1	Karena Nelson
16-Aug-01	ORACLE TRAINING	EDUCATION SUPPORT	9:00 AM	60	1	June Neville
11-Aug-01	MIN & MAN OF AGRESS	EDUCATION SUPPORT	9:00 AM	60	2	Carol Parkinson
08-Aug-01	MANDATORY EDUC. DAY	DIVISION OF MEDICII	8:00 AM	480	1	Tracey Perks
06-Aug-01	MANUAL HANDLING	EDUCATION SUPPORT	9:00 AM	120	3	Librada Salvador
02-May-01	MANDATORY EDUC. DAY	DIVISION OF MEDICII	8:00 AM	480	1	Fisia Semenov
11-Apr-01	MANUAL HANDLING	ARFA HEALTH	1:30 PM	120	1	Samira Shamuel
						Angelica Sherer

Resources:

Topic Type:

Close

Form View

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The Training Team has completed approx: 70% of the competency training tools to date. But as with all education it is an ongoing ever-changing area that must adapt to the needs of the trainee and the instrumentation of the day!

“Unless you try to do something beyond what you have already mastered, you will never grow!”

Joyce Kenyon
 SSD Manager
 Liverpool Health Service
 SRACA (n.s.w.) Membership Secretary and Education Officer.

Implications of ISO 15883 for Washer-disinfectors

Written by Terry McAuley

Introduction

Washer-disinfectors are crucial pieces of equipment in today's sterile services departments. It is now widely recognised that automated or mechanical cleaning processes are preferable to manual cleaning or hand washing of modern complex surgical instrumentation.

There are several advantages to mechanical cleaning processes. Operator exposure to blood, body substances and cleaning agents is minimised, mechanical cleaning processes are able to be validated, ensuring a consistent level of cleanliness is achieved, the process can be routinely monitored and the equipment maintained to ensure ongoing optimal performance. Another advantage is the achievement of thermal disinfection of items prior to further processing.

In New Zealand and Australia, washer-disinfectors were commonly expected to comply with the relevant Australian Standards, AS 3836 for Rack conveyor washers and AS 2945 for Batch type washer/disinfectors. Whilst these two Australian Standards are yet to be superseded, most health care facilities will look towards the newly published international standard, ISO 15883 for washer disinfectors for guidance on the requirements and specifications for washer-disinfectors and how to effectively validate and monitor cleaning processes.

ISO 15883 consists of five parts. These are:

- Part 1:** General requirements, terms and definitions and tests
- Part 2:** Requirements and tests for washer-disinfectors (WD) employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware etc
- Part 3:** Requirements and tests for WD employing thermal disinfection for human waste containers
- Part 4:** (draft) Requirements and tests for WD employing chemical disinfection for thermo-labile endoscopes
- Part 5:** (TS) Test soils and methods for demonstrating cleaning efficacy

The ISO 15883 Part 1 is a lengthy and complex document. This Standard is primarily designed to be used by the equipment manufacturers, however end users must also be well informed with respect to the general requirements for washer-disinfectors, particularly when making a decision to purchase a new machine and also to ensure that validation and routine monitoring of the cleaning process occurs in conformance with the Standard.

It is not the intention of the author to reproduce the entire content of this Standard, therefore the presentation of the specifications in this paper are indicative only in order to raise the awareness of the reader as to some of the key requirements in this document.

What is a washer-disinfector?

ISO 15883 Part 1 defines a washer –disinfector as “a machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice”. This paper will focus on the general requirements for washer-disinfectors as specified in Parts 1 and 2 of ISO 15883 as these apply most directly to the context of automated cleaning processes used in sterile services departments.

Any item that has been processed in an ISO 15883 compliant washer-disinfector will have been cleaned, disinfected, rinsed and when appropriate, dried. The performance requirements of the machine will depend on a range of factors, for example:

- Nature of items to be processed
- Level of disinfection efficacy necessary
- Nature of soils to be removed
- Consideration of any pre-treatments activities
- Cleaning chemistries employed

Specifications for washer-disinfectors

ISO 15883 compliant washer-disinfectors will have been designed and constructed in a manner that will include the following desirable features:

- Smooth, easy to clean surfaces
- Free draining so that no moisture will collect in hard to reach places and pose a potential risk of contamination to subsequent load items
- Minimise particulate &/ or microbial contamination from any source
- Easily accessible components for operator conducted routine tasks
- Withstand the rigours of intended use/ purpose for a minimum of 10,000 cycles
- Load carriers must have minimal contact with the items to be cleaned
- Entry port for temperature sensors to be inserted into the chamber
- Access port for testing of final rinse water
- Door interlock that prevents opening until cycle completion and cycle cannot be initiated until doors are locked
- In double opening machines – both doors cannot be opened simultaneously
- Spray nozzles must ensure all parts of the load are reached and be protected from blockage
- Chemical dosing systems under the control of the automatic controller and be able to be adjusted
- Dosing systems must be monitored directly or indirectly to ensure the volume and timing of dosing is in accordance with specifications
- Machine must indicate low volume levels

- Multi chamber washer-disinfectors must be designed so that the washer-disinfector itself, the load carriers and the load cannot be recontaminated whilst other loads are being processed simultaneously
- The cleaning chamber(s) must be capable of being disinfected under the control of the automatic controller and single chamber machines must have this as part of their normal operating cycle

What are the stages involved in an automated cleaning process?

The operating cycle itself must be under automatic control and includes four basic stages. These are:

1. Cleaning

This may incorporate several stages for example:

- **Flushing stage:** In-flowing water in this stage must not cause coagulation of proteinaceous soils therefore temperatures are usually below 35⁰ Celsius as temperatures over 45⁰ Celsius can cause protein coagulation and thereby compromise cleaning efficacy
- **Washing stage:** The temperature of the water, cleaning agent and / or other solutions in contact with the load must be controlled within the limits specified by the washer-disinfector and / or the detergent manufacturer.

2. Disinfecting

- Thermal disinfection is essential for instrument washer-disinfectors

3. Rinsing

4. Drying (when appropriate)

Why do we need thermal disinfection for instrument washer-disinfectors?

Like the concept of sterility assurance used to design sterilisation processes, it is assumed that bioburden on items to be processed through the washer-disinfector is far in excess than that which would be reasonably expected to occur under normal operating conditions.

The concept of A_0 is based on thermal inactivation of reference microorganisms and is used as a basis to assume achievement of a level of assurance that disinfection has been achieved.

The expected level of A_0 will depend upon:

- Intended use of the load
- The materials of which the load items are made
- The nature and extent of the bioburden

Thermal disinfection of the load, its carrier and the chamber walls must be verified through testing procedures. ISO 15883 advocates achievement of a disinfection level of at least A_0 of 600 up to a maximum of A_0 of 3000.

By using a properly validated automated cleaning process using a washer-disinfector designed to comply with ISO 15883, it could be assumed that minimal microorganisms will remain at the end of the cleaning and disinfection process.

Final rinsing and water quality

The environment in which the final rinse and drying stage takes place must be controlled in terms of chemical and microbiological purity. This means that any fluids, air or other materials that contact the load must not adversely affect the items being processed or impair the intended use of those items. To facilitate checking of this, a means to take samples of final rinse water is necessary either prior to its entry into the washer-disinfector or from the discharge point into the chamber from the holding tank if one is fitted.

The rinsing stage must reduce the residual concentration of any process chemicals to a safe level appropriate to the intended use of those items and this must also be verified by testing.

Where included the drying stage must remove surface moisture from the load. If hot or compressed air is used for this purpose the quality of the air must not adversely affect the load in terms of cleanliness and microbial contamination. Filters may be used for this purpose and may or may not require periodic testing.

The quality of the water required for the effective operation of the washer-disinfector is specified by the manufacturer. Often the water quality necessary for the cleaning processes is normal, potable water, however for the final rinse stages, manufacturers of washer-disinfectors are now often specifying treated water, such as reverse osmosis or de-ionised water.

Conformance testing and compatibility with reprocessing medical devices

Manufacturers of washer-disinfectors must demonstrate that flushing, cleaning, disinfection, rinsing and drying stages meet the comprehensive test specifications outlined in ISO 15883 Part 1. The manufacturer is required to supply documentary evidence that the machine complies with the applicable parts of the Standard and has passed the necessary conformity tests. Upon purchase of a washer-disinfector, end users should request a copy of this certification.

Manufacturers must also show cleaning and disinfection efficacy testing for specific claims of performance for reprocessing certain types of medical devices or specified loads. Therefore if a manufacturer claims that their washer-disinfector can be used to reprocess cannulated medical devices, for example, they must have performed tests to demonstrate the efficacy of the cleaning process, which may have been used in combination with particular load carriers and chemical agents.

The manufacturer of the chemicals used in cleaning processes must also specify the tests which can be used to detect the process residuals. This test can then be utilised as part of ongoing routine monitoring of the cleaning process.

Manufacturers of medical devices can also make claims for process efficacy in cleaning of their medical devices according to ISO 17664. However, it is acknowledged that some medical devices may require pre-treatment prior to being exposed to automated cleaning processes for that process to be completely effective.

Validation and routine testing of the cleaning process

Validation is a process that consists of a number of interrelated activities, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Annex A in ISO 15883 Part 1 provides a comprehensive list of the tests required to be performed during all stages of the validation process and the reader is referred to this resource when determining their approach to validation of their cleaning processes. The tests performed by the manufacturer should be retained and compared to the results of tests conducted during validation and any tests performed thereafter.

The basic testing schedule includes such activities as measurement of temperature on the chamber walls, load, load carrier and internal surfaces of medical devices in addition to checks for correct operation of safety door interlocks, fault indicators, chemical dosing alarms and air quality for the drying stage of the process.

During PQ, it is important to note that tests must be carried out for each different cycle intended to be used during normal production, however, if the cycles are the same except for the duration of each stage or are used for the same type of load configuration, then the shortest cycle can be used for validation purposes, as this would pose the greatest challenge or could be viewed as the “worst-case”.

Performance qualification at a minimum must consist of three consecutive cycles of visual confirmation of normal load cleanliness plus secondary confirmation of the result by residual protein testing in accordance with Annex C of ISO 15883 Part 1.

Verification of achievement of thermal disinfection on the chamber walls and the load and confirmation of load dryness is also a requirement, as is detection of any process residuals. Alignment of load carriers and verification that the spray system is capable of removing specified test soils (ISO 15883Part 5) from chamber walls, load carrier and a reference load is also included as part of PQ.

Requalification must be performed at least annually and whenever:

- Changes or engineering work is carried out that may affect the performance of the washer-disinfector
- A review of the records shows unacceptable deviations from validation data

- Process chemicals are changed
- The performance of the machine is unacceptable

Cleaning efficacy tests must be performed on a

- Daily basis via visual inspection
- Quarterly basis using a specified test soil

Residual protein testing is optional according to this Standard.

Thermometric testing is performed on the following basis:

- Quarterly testing of the load achievement of disinfection temperature
- Quarterly testing that the flushing and washing stages operate at the correct temperature and verification that the rate of temperature change is within the limits specified by the WD manufacturer

Other tests must be undertaken which include but may not be limited to:

- Quarterly checks of door interlocks
- Quarterly tests of accuracy of chemical dosing and low level indicator operation
- Quarterly verification of calibration
- Quarterly tests of spray system efficacy by use of specified test soil

Process Verification

ISO 15883 Part 1 describes three levels of process verification. The level of verification that is necessary is dependent upon the nature of the intended use of the items being processed and the level of risk associated with the reuse of that items should a failure of the cleaning process occur.

Obviously for medical devices, process verification may need to be very stringent in terms of semi-critical items that may only be subject to the cleaning process, including thermal disinfection and then returned to the end users for reuse. Some examples of these types of items may be respiratory and anaesthetic equipment.

Other items may not need this level of stringency, as they will be subject to thorough visual inspection and subsequent sterilisation processes and yet others may not be able to be thoroughly visually checked for cleanliness, as the nature of the device may prevent visual inspection, in which case a higher level of stringency may be necessary.

The levels of process verification as described in ISO 15883 Part 1 are:

- **Level 1:** Verification by the operator of attainment of thermal disinfection via inspection of the cycle recorder
- **Level 2:** Verification by an *independent* process record of achievement of thermal disinfection.

- Cleanliness must be established by visual inspection
- **Level 3:** Verification by an *independent* process record of achievement of all process variables affecting cleaning and disinfection processes
 - Essential where visual inspection cannot be achieved – i.e. internal lumens of hollow devices
- **Level 4:** Process record that is *independent* of the process *control* systems
 - Variables measured must include:
 - Temperature of water and air in the chamber in each of the operating stages
 - Volume of process chemicals admitted
 - Temperature of the water in each storage tank
 - Pressure +/- flow of process chemicals supplied to chamber during operating stages
 - Electrical conductivity of final rinse water

Implications of ISO 15883

The implications of the publication of ISO 15883 are significant for modern sterile services departments. Validation of the sterilisation process has only just been accepted as a routine part of the day to day functioning of a department. Managers and their staff now have to acknowledge that validation of cleaning process is also a requirement and therefore a greater awareness and understanding of the cleaning process and the equipment used to achieve it is necessary to provide reliably cleaned, disinfected and sterilised reusable medical devices.

ISO 15883 Part 1 and 2 specify some tests and tests frequencies that currently are not included as requirements in AS/NZS 4187 and the applicable equipment Standards. However it is anticipated that the requirements of ISO 15883 will in future largely replace the current Australian Standards for washer-disinfectors, therefore it is necessary to commence examining our processes, testing and documentation protocols.

The move towards automation of cleaning processes needs to be embraced by our industry and manual cleaning restricted to those items that are not compatible with mechanical cleaning.

Conclusion

ISO 15883 is a long anticipated Standard. The contents of the Standard are technical in nature and are directed towards manufacturers of washer-disinfectors. However, sterile services managers and their staff need to become familiar with the requirements of this Standard in relation to making informed purchase decisions when evaluating new equipment and preparing schedules for validation and routine testing of cleaning process.

However it must be noted that it is still largely up to the end users to determine what methods of routine testing they may need to implement in addition to daily visual inspection for cleanliness, checking of process parameters every cycle and performance of daily routine cleaning and maintenance tasks.

References

AS 2945 *Batch type washers/disinfectors for health care facilities*. Standards Australia; Homebush.

AS 3836 *Rack conveyor washers for health care facilities*. Standards Australia; Homebush.

AS/NZS 4187 *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment and maintenance of the associated environment in health care facilities*. Standards Australia; Homebush.

ISO 15883 *Washer-disinfectors*

- Part 1:** *General requirements, terms and definitions and tests*
- Part 2:** *Requirements and tests for washer-disinfectors (WD) employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware etc*
- Part 3:** *Requirements and tests for WD employing thermal disinfection for human waste containers*
- Part 4:** *(draft) Requirements and tests for WD employing chemical disinfection for thermo-labile endoscopes*
- Part 5:** *(TS) Test soils and methods for demonstrating cleaning efficacy*

International Standards Organisation; Switzerland

WHY ULTRASONIC CLEANING ?

Sterilising is the third stage of a process. It is important to recognise that the first essential step, is to ensure that instruments have all contaminants effectively dislodged before attempting to wash away. Micro-organisms that cannot be seen by the naked eye, are found in serrated edges, knurled handles, screw threads and fine micron scratches. Ultrasonic activity, followed by a rinse is the only economical way to penetrate those hidden areas to achieve the desired result.

An autoclave or steriliser provides the means to sterilise, but is not a cleaning machine. A washer/rinser while effective in dealing with exposed surfaces does not always reach concealed locations or breakdown dense soiling. Only cavitation can be relied on to do this effectively. Cavitation is not a magical force, but does have the ability to clean narrow crevices and small holes, even internal surfaces, that would not be easily accessible by a spray washer or other method of cleaning

Contamination, if still present on instruments when being sterilised, creates a risk of bacterial/viral organisms being protected from heat kill in an insulating cocoon. It is not a valid argument to claim, "*... even though a few instruments get through the best cleaning systems with human debris stuck to them, the debris is sterile !*" (as reported in a NZ Herald article 13/12/04)

"Sterilising a dirty instrument once, is to ruin it forever." Most instruments for sterilising are of stainless steel manufacture so it is also essential to remove all surface contaminants before autoclaving to prevent those impurities leaving a baked-on deposit. The same circumstances can also have a detrimental effect on the life of the steriliser.

An opinion that ultrasonic baths are an unnecessary expense, is often based solely on capital expenditure considerations, or occasionally a limited understanding of the need for a comprehensive cleaning/sterilising regime. A wider view is that the outlay is an investment in labour saving, effective results, staff and patient safety and the life of equipment.

Garry OWEN (*Ultrasonic Cleaning Advisor*)
Providing SOUND CLEANING options

Standards Talk

The website for accessing all standards, national and international, is;
<http://www.standards.co.nz>

There are monthly updates available on this website so you can keep up to date with changes. The complete address is;
<http://www.standards.co.nz:81/news-and-seminars/standards+update/>

The latest standard to come into print of interest to sterile services is that relating to Sterilization of health care products – Radiation. This standard has come out in three parts as listed below;

AS/NZS ISO 11137.1.2006 Requirements for development, validation and routine control of a sterilization process for medical devices

AS/NZS ISO 11137.2.2006 Establishing the sterilization dose

AS/NZS ISO 11137.3.2006 Guidance on dosimetric aspects

A copy of these are being purchased by the Association and will be held with the Association Library. The library is now managed by Alison Stewart at Wellington Hospital.

Association Library

Hi I'm Alison Stewart and I am going to be the new librarian for the Association. The library is in the process of being transferred from Dunedin to Wellington. When this is done I will inventory everything and provide a full list of the books, videos and standards held. This list will be placed on the NZSSA website and included in future Supplyline magazines.

My contact details are:

alison.stewart@ccdhb.org.nz

04 385 5923

027 285 6524

NZSSA NATIONAL CONFERENCE

14th, 15th and 16th November 2007

***Napier War Memorial Conference Centre
Marine Parade
Napier
Hawke's Bay***

Theme - "MOVING WITH THE TIMES"

***Come and enjoy the 2007 National Conference in our beautiful
Art Deco City.***

***The venue is situated on the ocean edge and in close proximity
to the CBD.***

***Accommodation has been booked at the lovely Te Pania Hotel,
situated across the road from the conference venue.
A special conference rate has been negotiated. Be sure to mention this at
the time of booking.
Alternative accommodation will be sourced. Cost and contact details will
be advised at a later date.***

***NZSSA Executive Meeting will be held on Tuesday November 13th.
The Managers Forum will be held on Wednesday November 14th.
The Graduation Dinner will be held on Friday evening at the conclusion
of the conference.***

See the next Supplyline for further details

We look forward to seeing you all in Napier

Lorraine and Jackie

NZSSA 2006 Annual Conference DVD

The NZSSA are delighted to be able to offer for purchase a DVD of the 2006 NZSSA Annual Conference. This DVD features all the speakers' presentations that made the conference a success.

The cost of the DVD is NZD \$65.00 GST inclusive. If you would like a copy please complete the information below and send it through to Daniel Phillips, 228 Talbot Street, Invercargill. Please make all cheques out to the "NZSSA".

Name: _____

Mailing Address: _____

Office Use Only:

Date Received: _____

Signed: _____

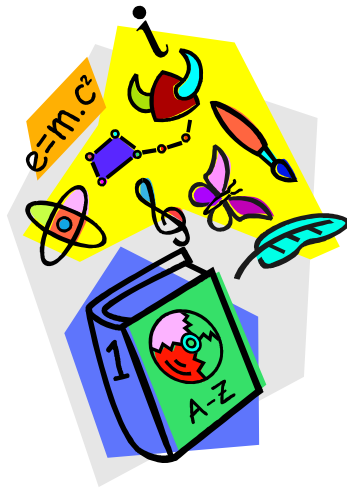
DVD Sent:

Date Sent: _____

Signed: _____

DESIGN A NEW SUPPLYLINE COVER COMPETITION

\$250.00



CRITERIA

The new Supplyline cover must:

- Look professional
- Identify clearly that the magazine is about the Decontamination and Sterilisation of medical and surgical instruments and equipment
- Reflect the role and responsibilities of Sterilising Personnel
- Be suitable for sterilising personnel in both public and private Healthcare Facilities
- Reflect NZ's distinct multi-cultural society
- Have the NZSSA logo
- Be 30cm x 21cm

Entries to be submitted to Lorraine Eldershaw, editor of Supplyline by the 11th May 2007. See Supplyline for mailing details. The executive committee will be the judging panel. The cover awarded the best, will win a prize of \$250.00. This money is being sponsored by the NZSSA.

RECOMMENDED WEBSITES

By Jackie Skudder

Article / Subject	Author	Website
The New View on Latex Allergies	Kathy Dix	http://www.vpico.com
Preventing Patient Thermal Burns from Electrosurgical Instruments	Anne Reed	http://www.mobileinstrument.com/article_preventing.php
Surgical Instrument Repair – Art or Science	Anne Reed BS and Beverley Dysert	http://www.mobileinstrument.com/article_surgical.php
Communique Questions and Answers (All related to Sterile Services Work)	IAHCSMM	www.iahcsmm.com/q_and_a_archive.htm