Section 1 - Overview

Key Points

- Reusable medical devices are processed to the level for their intended use:
  - Sterile for critical items
  - High level disinfection for semi-critical items
  - Low level disinfection for non-critical items
- Reusable medical devices undergo cleaning process prior to disinfection or sterilisation
- Single use medical devices are not reused
- Only Sterilising Services (SS) that meet the minimum requirements for cleaning, disinfection and sterilisation are able to undertake sterilisation services
- Flash sterilisation is only to be used as an emergency for single instruments eg. dropped single instrument
- SS is consulted when purchasing instrumentation
- Education, training and written instructions are to be provided to SS staff when new instrumentation or equipment is purchased
- SS is involved in operating theatre scheduling to maximise instrumentation utilisation

Introduction

The effective use of disinfection and sterilisation and procedures is important in preventing healthcare associated infections. Numerous published articles documenting infection after improper reprocessing of reusable medical equipment have emphasised the requirement for all health care services to use appropriate disinfection and sterilization techniques.

Scope of this document

The content of this document covers a number of the key issues related to cleaning, disinfection and sterilization of instruments and equipment in a variety of healthcare settings. It is intended as a guide for the practical implementation of the Centre Healthcare Related Infection Surveillance and Prevention (CHRISP) resources, such as Easi-Sterilise, for sterilizing units and the relevant Australian Standards (Australian/New Zealand Standard AS 4187- 2003 ‘Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities’ [AS4187] and Australian/New Zealand Standard 4815:2006 : ‘Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment’ [AS4815]).
For the purpose of the document the Sterilizing Services (SS) refers to any area that reprocesses medical devices.

Gastroenterological Nurses College of Australia Inc and the Gastroenterological Society of Australia published “Infection Control in Endoscopy” (2nd edition, 2003) guidelines which includes comprehensive instructions for the cleaning, disinfection and testing requirements for endoscopic reprocessing, these guidelines form the basis for practice within Queensland Health facilities.

**Sterilizing Services**

**The role of Sterilizing Services**

The sterilizing service (SS) is responsible for preparing, processing, and distributing sterile and non-sterile medical and surgical supplies and equipment required for patient diagnosis, treatment and ongoing care. SS is responsible for removing or destroying potentially infectious material on reusable devices, and distributing appropriately processed items throughout the health care facility.

The importance of the SS role is clear; reusable medical instruments improperly handled, cleaned, disinfected or sterilized are a source of infection risk to both patients and staff.

**Clinical Services Capability Framework**

*The Clinical Services Capability Framework* review of 2008/2009 has included in the Perioperative Services Module (formally the Operating Suite Services module) information relating to Sterilizing Services. This section will include service level descriptors and mandatory requirements for each level of Perioperative Services, 1(one) – 6(six).

The service provided by Sterilizing Services extends beyond the hospital walls; however, Operating Suite Services is a major stakeholder and to ensure continuity of service delivery there must be direct links between Sterilizing and Operating Suite services. In instances whereby both units are onsite is it preferable that they are co-located to assist in communication and the transfer of dirty, clean and sterile equipment and instruments. Operating theatre scheduling is to take into account the numbers of sterile instruments/trays, equipment and stock to negate the use of routine “flash” sterilizing.

Communication between the operating suite and sterilizing services shall be a high priority for the manager of Perioperative Services and staff of sterilising services.
It is essential that Sterilizing Services are included/ but not limited to being consulted in the following instances:

- Operating Theatre scheduling;
- Procurement of reusable instruments and equipment;
- Perioperative/Operating Suite management meetings;
- Perioperative education and training;
- Changes in models of care and processes across Perioperative services;
- Plans for the redevelopment, refurbishment and/or redesign and commissioning of new operating theatres and sterilising services

**The role of infection control**

The role of infection control is primarily to prevent healthcare associated infections, necessitating a close working relationship with the SS. Infection control co-ordinators and sterilizing service staff must jointly be involved in the development of facility sterilization and disinfection policies and guidelines. Establishment of committee structures and other means of formal and informal communication between infection control and sterilizing services staff will ensure provision of appropriately processed equipment in health care facilities.

It also follows that sterilizing service should be aware of local and state wide infection control policies that may affect the service they provide. They have a responsibility for achieving consistent production and management standards in the reprocessing of reusable instruments and equipment.

**Education and courses in sterilizing technology**

Staff who undertake reprocessing of reusable medical devices must be trained in the necessary procedures. This training should be formal and provided by a registered training authority.

**STERILIZING TECHNOLOGY**
Southbank Institute of TAFE (Brisbane)
Phone: 07 3244 5165
Facsimile: 07 3244 5152

**Mayfield Education Centre**
Client Services Officer
Phone: 03 98827644
[www.mayfield.edu.au](http://www.mayfield.edu.au) (internet access only)

**NSW ‘OTEN’ Course**
Project Manager, Audiology
Tel: (02) 9715 8529
Rationalising sterilizing services

When designing or redeveloping a SS consideration needs to be given to the changing patterns in healthcare delivery. Planning and design should also include input from relevant experts, e.g., CHRISP, including those involved in processing of reusable medical items, engineering, and infection control. In addition, in some Health Service Districts, the potential exists for centralising the provision of sterilizing services through one facility with a properly designed and equipped sterilizing unit that is able to meet the sterilizing needs of a number of other facilities. There are significant advantages to be gained from this allocation of resources, and appropriately high standards of processing can be more consistently achieved. Each District is to consider the rationalisation of their sterilizing units as an alternative to the upgrading of several units.

Design issues

The health care facility shall have separate systems for the collection of used items and the delivery of sterile items (AS 4187). Criteria for workflow patterns are included in the Australasian Health Facility Guidelines at http://www.healthfacilityguidelines.com.au/ (internet access only).

SS hand washing sinks

A clinical hand basin should be located at the entry of the cleaning area. The location of a hand basin for the packaging and storage areas must take into consideration the risk of sink splash contacting preparation areas and sterile consumables or packs (linen wrapped). If a clinical hand basin is unable to be located in this area, a hand basin should be located outside the room in close proximity to the entry (refer Queensland Health Capital Works Guidelines), consideration may also be given to the use of alcoholic hand gel in consultation with the Infection Control Co-ordinator.
Spaulding’s classification

Overview

Spaulding’s classification provides a simplified outline of the recommended processing methods for items of patient care equipment, based on the intended use of the item. Depending on the intended use of an item, medical and surgical equipment may be required to undergo the following processes between uses on different patients:

- cleaning, followed by sterilization
- cleaning, followed by high, or intermediate level disinfection
- cleaning alone

<table>
<thead>
<tr>
<th>Classification</th>
<th>Item use</th>
<th>Goal</th>
<th>Appropriate Process</th>
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<tbody>
<tr>
<td>Critical items</td>
<td>Items entering sterile tissue, the body cavity, the vascular system and non intact mucous membranes eg surgical instruments</td>
<td>Objects will be sterile (free of all microorganisms including bacterial spores)</td>
<td>Sterilization (or use of single use sterile product)</td>
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<td></td>
<td></td>
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<td>- steam sterilization</td>
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<td>- low temperature methods (ethylene oxide, peracetic acid, hydrogen peroxide plasma)</td>
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<td>Semi-critical items</td>
<td>Items that make contact, directly or indirectly, with intact mucous membranes or non intact skin eg endoscopes, anaesthetic equipment</td>
<td>Objects will be free of all microorganisms, with the exception of high numbers of bacterial spores</td>
<td>High level disinfection</td>
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<td></td>
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<td>- thermal disinfection</td>
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<td></td>
<td></td>
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<td>- chemical disinfection (glutaraldehyde, OPA)</td>
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<td>*It is always preferable to sterilize semi-critical items whenever they are compatible with available sterilization processes</td>
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<tr>
<td>Non-critical items</td>
<td>Objects that come into contact with intact skin but not mucous membranes eg crutches, BP cuffs, tabletops</td>
<td>Objects will be clean</td>
<td>Low level disinfection</td>
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<td>- cleaning (manual or mechanical)</td>
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Standard precautions

Standard precautions are safe work practices required to minimise the risk of infection to both patients and staff. They include good hygiene practices, particularly hand hygiene, the use of personal protective equipment, appropriate handling and disposal of waste, adherence to the principles of asepsis and maintenance of a clean environment. Refer to section 2, Queensland Health Infection Control Guidelines Standard Precautions for more detail.

Personal protective equipment (PPE) required for equipment reprocessing

Protective clothing should be worn to protect the health care worker from contact with blood and body fluids; it is also worn in this setting to avoid contributing to the bioburden on articles during their preparation for sterilization or subsequent storage.

Protective attire worn during cleaning of used equipment includes waterproof outer wear (gown or apron with impervious arm protection), supplemented by heavy-duty gloves and safety glasses and masks, or face shields for manual or ultrasonic cleaning. This attire must be removed when leaving the area and replaced with fresh items on returning. Staff are to wash their hands after glove removal and all cuts and skin abrasions are to be covered with a waterproof dressing.

In line with occupational health and safety requirements, staff should wear shoes with non-slip soles, strong enough to protect against injury if articles are dropped accidentally. Consideration may be given to staff wearing ear protection but this will be dependent on noise levels within the area. Hair and beards should be covered and the wearing of jewellery when on duty discouraged.

Adverse effects of cleaning agents and disinfectants

Strong detergents and disinfectants may have adverse effects on the skin. Any skin contamination should be washed off immediately and managed as per Material Safety Data Sheet instructions.

On-site laundering of operating theatre linen

The preparation of sterile drapes and gowns (‘linen’) for operating room use is becoming less of an aspect of SS activities due to the cost benefits associated with using single use drapes and gowns. Woven polyester-cotton textiles which require separate transport, laundering, checking and pack preparation from the processing of operating room instruments.

Some facilities receive a service of laundered linen (or sterile linen packs) from an external organisation eg Brisbane Metropolitan Linen Service or Wide Bay Linen Service. However, there are some health care facilities laundering their operating room linen within the facility.
After laundering, linen is passed to the SS for checking, pack preparation, sterilizing and storage, or delivery as sterile packs.

Where laundering of operating theatre linen is on site, the SS is a significant stakeholder in the standard being routinely attained by those laundry processes, despite the laundering occurring ‘outside’ the SS. It follows that the SS needs to be able to refer to the appropriate Australian Standards governing these laundry practices and ensure that all linen products meet the requirements.

**Laundering standards**

Wherever operating room linen is laundered on-site, the following standards must be present so that reference can be made to them for quality management of the linen service.

**Australian Standard AS 3789.2 Textiles for Health Care Facilities and Institutions. Part 2:**

Theatre linen and pre-packs:
- This Standard specifies requirements for the following items of theatre linen for health care facilities and institutional uses: drapes, fenestrated drapes, theatre gowns, hand towels, leggings (mayo table covers), and wrappers. Requirements for the inspection and repair of used theatre linen and for the assembly of theatre linen pre-packs are also provided. This Standard applies to theatre linen for use in all areas of health care facilities and institutions where surgical procedures are performed.

**Australian/New Zealand Standard AS/NZS 4146 Laundry Practice:**
- This Standard refers to textile articles used in commercial, industrial, hospital and institutional organisations which are subjected to repetitive laundry processes to remove soiling, staining and various contaminants which, if not removed, will result in the article being not only aesthetically unacceptable but also a theoretical health risk.
- Includes general guidelines and recommendations for laundries including design and management, collection and transport, storage prior to laundering, general operational points and storage and packing of cleaned linen, specific requirements for operating theatre linen, disinfection, and record keeping.
- Appendices covering soil types, stain removal, care of particular types of textile, wash formulas, guides to whiteness, assessing chemical and mechanical wear, and safety with laundering chemicals are included.

**Laundry procedures**

- Laundries should adopt rigorous inspection procedures to ensure that cleaned operating theatre linen has minimum staining and textile damage prior to sterilization.
- Particular attention should be given to procedures which minimise the problem of linting and static electricity.
- Effective liaison and communication between SS and laundry personnel will be invaluable to mutual achievement of the necessary standards.
- Written protocols for the day to day functioning of laundries which process operating room linen need to be established.
Transportation of contaminated equipment and sterile supplies

The criteria for collection of used and sterile items for return to a SS are described in AS 4187 and are also described in the Queensland Health “Capital Works Guidelines Building and Refurbishment Infection Control Guidelines” (2002).

**General Design features for trolleys or transport containers:**
- equipment must be dedicated for this purpose i.e. separate equipment for the transportation of used and sterile items;
- the trolley should be covered or closed with a solid bottom shelf;
- the trolley is able to be maintained in a clean, dry state and in good working condition
- the trolley can be easily manoeuvred and is fitted with brakes
- bottom shelf of the trolley should be solid
- Occupational Health and Safety (OH&S) considerations need to be taken into account to minimise the potential to lift items above a person’s shoulder
- the containers should be puncture-resistant and leak-proof and made of either plastic or metal, with a lid or liner that can be closed

**Transport of sterile supplies**

The maintenance of sterility depends primarily on the conditions of storage and the frequency of handling.

Design features related to transport of sterile supplies:
- transport containers/systems must allow articles to be handled with care and inspected as necessary;
- boxes or bags used should not cause packages be crushed together;
- sterile items transported to an external facility must be able to be securely packaged to protect against damage and contamination.

A manual trolley wash area is required for SSs. In large teaching hospitals an automatic trolley wash should be considered.