

DISINFECTION & STERILIZATION

INFECTION CONTROL GUIDELINES

DISINFECTION & STERILIZATION INFECTION CONTROL GUIDELINES

SECTION 1 OVERVIEW

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 sterilization 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 it is 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 (internet access only)

NSW 'OTEN' Course

Project Manager, Audiometry

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, eg 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

| Classification | Item use | Goal | Appropriate Process |
|----------------------------|--|--|--|
| Critical items | Items entering sterile tissue, the body cavity, the vascular system and non intact mucous membranes eg surgical instruments | Objects will be sterile (free of all microorganisms including bacterial spores) | Sterilization (or use of single use sterile product) <ul style="list-style-type: none"> • steam sterilization • low temperature methods (ethylene oxide, peracetic acid, hydrogen peroxide plasma) |
| Semi-critical items | Items that make contact, directly or indirectly, with intact mucous membranes or non intact skin eg endoscopes, anaesthetic equipment | Objects will be free of all microorganisms, with the exception of high numbers of bacterial spores | High level disinfection <ul style="list-style-type: none"> • thermal disinfection • chemical disinfection (glutaraldehyde, OPA) <p>*It is always preferable to sterilize semi-critical items whenever they are compatible with available sterilization processes</p> |
| Non-critical items | Objects that come into contact with intact skin but not mucous membranes eg crutches, BP cuffs, tabletops | Objects will be clean | Low level disinfection <ul style="list-style-type: none"> • cleaning (manual or mechanical) |

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 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 persons 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.

DISINFECTION & STERILIZATION INFECTION CONTROL GUIDELINES

SECTION 2 CLEANING & PACKAGING

Section 2- Cleaning and Packaging

Cleaning of instruments and equipment

Cleaning is defined as the removal of all adherent visible soil from the surfaces, crevices, joints, and lumens of instruments, and it is normally accomplished using water with detergents or enzymatic products. Meticulous physical cleaning must precede disinfection and sterilization procedures. The [Infection control guidelines for the prevention of transmission of infectious diseases in the healthcare setting](#) (CDNA, 2006, p16-7) states that “if an item cannot be cleaned it cannot be disinfected or sterilized”.

Ward areas

Regardless of the type of cleaning method used, gross soil should first be removed by rinsing with water, a detergent solution or a detergent/disinfectant formulation. Soaking in an enzymatic solution may be required if the exudate has dried. The initial pre-cleaning may be carried out in the area where the equipment was used otherwise it should be cleaned in the central sterilizing department. Direct dispatch to SS should be in closed, leak proof containers.

When carrying out cleaning procedures, protective apparel complying with AS 2161.2 (2005) shall be worn, as stated in AS 4187, the cleaning of instruments in a ward area should be performed in a designated area to prevent possible contamination of clean or processed items. There should be a designated clean area and dirty area for processing instruments, and the area should ideally include the requirements as stated in AS 4187 eg hand washing facilities, good lighting etc.

Operating rooms

Cleaning of instruments within the operating theatre should comply with current Australian Federation of Operating Room Nurses (AORN) Standards, Guidelines and Policy Statements. Gross soil is to be removed first prior to the transportation of used instruments to SS in lidded containers or covered trolleys.

Water quality

The quality of water is integral to the cleaning process. Routine water testing is often conducted by engineering staff and or engineering contractors, and the utilisation of such a resource would be preferable. Opportunities to share services should be considered in order to prevent duplications and conserve resources. Useful information on the quality of water may be obtained from the local water authority or Population Health Unit and will assist in determining appropriate cleaning agents required for the SS.

Water hardness is determined by the amount of calcium and magnesium ions present in the water. Water hardness reduces the rate of kill of certain disinfectants and generally reduces the efficiency of cleaning chemicals. This occurs because divalent cations (eg magnesium and calcium) interact with some chemicals to form insoluble precipitates and a white-grey residue on the instruments.

Possible interactions between very hard water, or water with elevated levels of dissolved chemicals justify the attention required here to the quality of water used for cleaning. These dissolved components of reticulated water have the potential to seriously retard the effectiveness of some cleaning agents and may damage instruments. Also, drying of instruments following a post-cleaning rinse with impure water can produce undesirable precipitated residues of the salts and other elements dissolved in the water.

In some cases where further filtration is required to remove the likes of chlorides, etc, systems such as Reverse Osmosis filtration are employed. This quality of water would normally only be used for final rinse applications.

Water and resource economisation should not take precedent over operational imperatives such as water quality and critical parameters for processes.

Selection of cleaning agents

Deposits of dust, soil and microbial residue on equipment can contribute to healthcare associated infections. Cleaning agents remove organic, inorganic and microbial contaminants. No single compound has all the properties that are required to remove all fractions of soil deposits. The first step in cleaning is the use of surfactants or surface active agents to reduce surface tension, which assists in soil being held in the cleaning solution.

Chemical suppliers shall provide Product Data Bulletins and Material Safety Data Sheets (MSDS) for all cleaning agents. A guide for selecting cleaning agents can be found in AS 4187.

Chemical storage

Chemicals classified as hazardous by Worksafe Australia (as indicated on the Material Safety Data Sheet, or MSDS) should be registered within a facility and stored appropriately. Detergents, disinfectants and chemicals with high acidity or alkalinity should be stored in a chemical storage cabinet and each MSDS for chemical incompatibilities are to be reviewed before storing different chemicals together.

Material safety data sheets

Material Safety Data Sheets (MSDS) provide important information about chemical substances. Suppliers of chemical agents shall provide Product Data Bulletins and the MSDS for all cleaning agents and provide the user with validation that the cleaning agent complies with the recommendations of AS 4187.

Copies of all MSDS should be available to all employees at all times in a designated register so that appropriate action can be taken in case of exposure to a hazardous substance. If information is incorporated into work instructions it is important to use the original wording and refer to the MSDS.

Chemical spills

The degree of hazard from a spill depends on the nature of the substance and the amount spilled. All chemical spill management procedures, including spill kits, should be developed in accordance with the MSDS for the particular substance, or other relevant policies. Spill kits should be provided for each cleaning agent that may be hazardous, as well as for blood (refer 'blood spill cleaning procedure'), asbestos and glutaraldehyde. Contact the facility Workplace Health and Safety Officer for advice.

Detergents

A mild alkaline detergent is preferred for manual cleaning, ultrasonic cleaning, or one of the several types of instrument washers. Mild alkaline detergents (pH range 8.0 – 10.8) are more efficient cleaning agents for surgical instruments than neutral pH detergents or surfactant based detergents. It is recommended that facilities work with chemical suppliers to determine the best detergent required as this will be dependent on the facilities water quality.

The term pH refers to a scale which measures acidity or alkalinity:

- pH 0-6.9 = acid
- pH 7.0 = neutral
- pH 7.1-14.0 = alkaline

Information on detergents to be used in ultrasonic cleaners is described in: AS 2773.1, Ultrasonic cleaners for health care facilities, Part 1, Non-portable; and AS 2773.2, Ultrasonic cleaners for health care facilities, Part 2, Benchtop.

To assist in preventing detergent or rinse residue on the instruments the functions of the washer/disinfectant and detergent dispenser should be checked daily. Chemical residue has the potential to cause tissue irritation.

Enzymatic (proteolytic) cleaners

Gross soil should first be removed by rinsing with detergent and water. If blood or exudates have dried or hardened, soaking in a warm solution of an enzymatic cleaner is required.

Cleaning agents, containing enzymes for breaking down proteinaceous matter, may be used for sensitive equipment if the equipment manufacturer approves their use. Rubber or nitrile gloves are required when handling enzymatic solutions as the enzymatic cleaner will degrade latex gloves.

Disinfectants

Disinfectants are not needed during the cleaning of surgical instruments and equipment. Nor are disinfectants required for general environmental cleaning.

Manual cleaning

Manual cleaning can be labour and time intensive but the practice may still be recommended by the manufacturers for the cleaning of items that are delicate or complex. Items that require manual cleaning must be separated from other items when they are received into SS. Prior to cleaning the item is to be checked for completeness. Manufacturer's instructions must be followed. Manual cleaning is not appropriate for anaesthetic equipment or equipment where thermal disinfection is required.

Staff who undertake manual cleaning should undergo appropriate training and instructions for the dismantling and reassembly of complex instruments should be available for reference.

The manual cleaning process usually involves a system of two, preferably three sinks; one for washing with the aid of a soft bristled brush; the second for the first rinse with tap water; and the third for the final rinse. For the process for manual cleaning including cleaning lumen instruments refer to the Standard Operating Procedures and Workplace Skills Assessments as part of Easi-Sterilise (http://www.chrispqld.com/easi_sterilise/easi-sterilise.html).

Highly caustic agents, abrasive pads and powders must not be used during the manual cleaning process as they have the potential to cause damage to instruments due to abrasions or leave residue on the instruments.

During the manual cleaning process staff must wear appropriate personal protection which includes waterproof apron, rubber gloves (strong enough to prevent punctures or cuts) and eye and face protection. All of these items should be changed when the staff member leaves the cleaning area.

Brushes and accessories for cleaning

The criteria for cleaning equipment are per AS 4187. Cleaning accessories should be capable of withstanding thermal disinfection, or they should be single use only. Adequate supplies of disposable non-linting cloths or swabs should be available to allow frequent changing. Cleaning brushes and accessories should be inspected regularly, not used if visibly contaminated and replaced when worn or kinked. At the completion of each day all reusable cleaning accessories should be cleaned and thermally disinfected or sterilized.

Some equipment may be supplied with appropriate cleaning adapters eg endoscopes. Substitute cleaning equipment should not be used unless approved by the manufacturer of the instrument.

Mechanical cleaning

Mechanical cleaning using washer/disinfector machines (either batch or multi-chambered design) removes soil from instruments. They offer a number of advantages including: an automated and controlled process, lack of aerosol generation, and reduced staff contact with contaminated instruments.

Washer/disinfectors usually operate within the following temperature ranges:

- Rinsing 40°C - 50°C
- Washing 50°C - 60°C
- Disinfecting 70°C - 95°C
- Final rinsing 80°C - 90°C

For thermal disinfection the following times and temperatures must be achieved:

- 🕒 70° for 100mins
- 🕒 75° for 30 mins
- 🕒 80° for 10 mins
- 🕒 90° for 1 min

Maintenance of mechanical cleaners such as ultrasonic cleaners, batch type washers and multi-chambered washers should follow manufacturer's instructions as well as the relevant sections in AS 4187.

When procuring new equipment consideration should be given to systems that employ automation for the conveying of items offers advantages by increasing efficiency by maximising machine utilisation also reduces the risk of manual handling injury by reducing the need to double handle instruments or trays.

Ultrasonic cleaning

Ultrasonic cleaning is generally used as a supplement to manual or mechanical cleaning or to clean delicate tubes or other hollow instruments such as special syringes or needles. Manual cleaning is to precede ultrasonic cleaning.

Ultrasonic cleaners work by subjecting instruments to high frequency, high energy sound waves that dislodge soil from the surfaces and crevices of the articles placed in the cleaning fluid. A neutral or alkaline, low foaming detergent is suitable; foam is undesirable because it settles on instruments when they are removed from the tank. Rubber and polyvinyl chloride (PVC) cannot be cleaned ultrasonically because these materials absorb the vibrations that are created.

The operation and maintenance of ultrasonic cleaners should comply with the manufacturer's instructions and with AS 2773. The process for ultrasonic cleaning and specific considerations on the use of ultrasonic cleaners can be found in AS 4187.

Batch washers

Mechanical cleaning via specifically designed machines such as batch type washer/disinfectors or multi-chambered washer/disinfectors is available. These machines are used for cleaning instruments and utensils, complex equipment such as anaesthetic breathing circuits, flexible fibre optic endoscopes, and laboratory glassware.

Batch type washers clean baskets of instruments by forced spraying from fixed or rotating arms in a closed chamber; refer to AS 2945 describing Batch-type washer/disinfectors for health care facilities.

Details for washer cycles and specific considerations for batch type washers can be found in AS 4187.

Continuous Process (multi-chambered) Washer/Disinfectors

These machines have several stages/chambers with different cleaning, rinsing and drying conditions. They perform a continuous process in which the articles being cleaned proceed on a moving belt/conveyor through a series of chambers on racks or load carriers. AS 3836 provides basic requirements for this type of machine.

The rack conveyor system extends from before the input window of the machine to past the output window to facilitate manual handling of the racks and the items being cleaned.

Drying of instruments

Drying reduces the risk of re-contamination during inspection and assembly of instruments, and minimises rusting and staining. Residual moisture interferes with the sterilization process, and can damage instruments. Following any method of cleaning (pre-cleaning, manual, mechanical and ultrasound) instruments need to be dried.

If a mechanical washer (batch or continuous process) has a drying cycle; during validation of the machine it is important to identify what items the process can effectively dry. If there is ever a need to transfer these identified items to a dryer because of residual moisture there is potentially a malfunction in the drying cycle and the machine needs to be serviced and revalidated.

Drying cabinets should be used for drying instruments, hollow ware, tubing and anaesthetic equipment. Drying cabinet operating temperatures shall be within the range 65°C to 75°C. Refer to AS 2514 and AS 2774 for drying cabinets.

Hot air drying may also occur during the last stage of the cycle of washer/disinfectors machines, batch washers or multi stage rack conveyor machines. Drying cabinets, and or compliant drying systems must be used for drying of tubing. Alcohol is recommended as a drying agent only for endoscopes, and only if recommended by the manufacturer.

Packaging & wrapping materials and techniques

The purpose of packaging and wrapping of items for sterilization is to provide an effective barrier to maintain sterility following processing prior to use and to permit aseptic removal of the contents from the pack.

Packaging materials

A wide range of packaging materials are available for use in SS. Packaging materials are selected according to size, shape, weight and the intended sterilization process. Packaging material must:

- be compatible with the sterilization process;
- be suitable for closing and sealing;
- free from loose fibres and particles;
- free from toxic ingredients and non-fast dyes;
- be compatible with pack contents under the proposed sterilization conditions

The requirements of a packaging material include:

- permeability to air, steam and gaseous sterilants (i.e. allows removal and penetration to steam) (does not apply to dry heat or ionising radiation);
- resistance to penetration by micro-organisms following sterilization

In relation to microbial penetration, non-porous materials are solid barriers while porous materials are effectively 'filters' manufactured to have good control over the probability of penetration by micro-organisms, even at small rates of air flowing through the material, as long as it is kept dry.

Australian Standard 1079 covers several generic types of packaging used in sterilizing services. These and the textile related standards for sterilizing packaging materials are:

| | |
|----------------------|--|
| AS1079.1 | Selection of packaging materials for goods undergoing sterilization |
| AS1079.2 | Non-reusable papers - for the wrapping of goods undergoing sterilization |
| AS1079.3 | Paper bags – for single use in healthcare facilities |
| AS1079.4 | Flexible packaging systems – for single use in hospitals |
| AS1079.5 | Non reusable, non woven wrapping materials – for goods undergoing sterilization in health care facilities |
| AS3789.2 | Theatre linen and pre-packs |
| AS3789.8 | Recyclable barrier fabrics |
| AS1079 Part 1 | Is a 'Guide to the selection of packaging materials' which describes to potential manufacturers of sterilising packaging systems the general conditions and requirements they will need to meet during the intended use. |

Other packaging materials or systems include rigid reusable sterilization container systems, containers for dry heat sterilization, aluminium foil and polyethylene film.

Appropriate processes for different packaging materials

Not all packaging materials or systems are appropriate for all sterilization processes used in health care facilities. AS 4187 describes the different process for which particular packaging materials are appropriate.

Nylon film (sometimes offered for sale in Australia) is inappropriate for use in most in-facility sterilization processes due to problems of air removal and sterilant penetration.

Care needs to be taken in the use of flexible packaging materials in steam Sterilizers. The non-porous web (usually 'see-through') is impermeable to steam, air and condensate. Care needs to be taken in the placement of packs made from this material in a Sterilizer; place the pack so that the plastic layer is generally vertical. After sterilization, packs need to be closely inspected for moisture.

If a facility is changing the class of wrapping material eg linen inner and outer paper to an all paper wrapping system; the Sterilizer/s must be revalidated and the drying capacity of the machine checked and adjusted accordingly.

Resistance to punctures and tears

One significant factor in the choice of a particular packaging material for a pack intended for sterilization is the need for the finished sterile pack to resist damage that may occur during handling. Punctures and tears can easily occur to many porous packaging materials, but some are more resistant than others.

Health facility personnel need to monitor the occurrences of damage that do occur and decide on appropriate actions, which may involve the selection of an alternative material.

Papers

Papers including bleached crepe paper and wraps combining cellulose and synthetic fibres are commonly used packaging materials for steam, dry heat and ethylene oxide sterilization. They are permeable to steam, air and chemical vapours and provide an effective barrier if the packs are stored in clean, dry conditions. Medical grade paper is free from loose particles but frees particles if packs are opened by tearing, cutting or by opening a fibre tear seal.

It is important that the paper wraps used within the facility are used inline with the manufacturer's recommendations, the use of double peel is not recommended as a wrapping method as this increases the probability that the steam may not penetrate the packing material.

Paper is unsuitable for use in the hydrogen peroxide plasma method of sterilization as it absorbs the hydrogen peroxide vapour from the chamber space, thus interfering with subsequent generation of hydrogen peroxide plasma during the cycle.

Reusable rigid container systems

Reusable rigid containers are used for the steam sterilization of large sets of surgical instruments. They are made from metals, aluminium, high-density polymers, or metals and plastic in combination. Perforations in the base and lid are lined with a steam permeable high-efficiency filter material. These containers should be properly loaded in terms of density to avoid problems of moisture retention and increased drying times. After use these containers should be disassembled and cleaned by washing with detergent and water before sterilization. Routine inspection and maintenance of these containers is essential in ensuring their ongoing effectiveness. Container systems are to be validated before use.

Woven fabrics

Woven cotton or cotton/polyester material can be used for heavy packs that are sterilized in pre-vacuum or downward displacement steam sterilizers. They are less resistant as a bacterial barrier than crepe paper but they are more resistant to tearing. Two layers of cloth, or one of cloth and one of paper, with the textile configured as an inner wrap, should always be used. Defects in the fabric, such as holes and threadbare patches, render the wrap ineffective. All textile outer wraps shall be of double thickness. The performance of woven cotton or polyester/cotton materials as microbial barriers is not as good as the many single-use wraps, but in clean, dry storage conditions these wraps should maintain sterility for several weeks.

If woven cotton/polyester materials are used, there should be facilities and procedures in place to inspect and assess the quality and suitability of such fabrics for use and reuse.

Very tightly or thick woven materials may impede air removal and steam penetration, and thus should not be used. The exception is the introduction into the Australian market of 'recyclable barrier fabrics' made from wholly synthetic materials. These are very durable and thus attractive for use, but validation of the attainment of sterilization conditions and reliable drying should be locally established before they are adopted in a facility.

Non-perforated containers of glass or metal

Glass tubes closed with non-absorbent cotton wool plugs or crimped foil caps may only be used for dry heat sterilization of glass syringes and needles. Because glass is a poor conductor of heat, heat penetration investigations need to be performed. Needles should be supported so that the tip does not contact the wall of the container. Glass bottles, vials and ampoules may be used for the steam sterilization of aqueous liquids by laboratories, and lidded jars may be used for dry heat sterilization of oils. Non-perforated metal containers are only suitable for dry heat sterilization.

Aluminium foil may be used as a wrapping material for large articles, such as surgical drills, which are sterilized by dry heat. Pinholes may occur in the creases and thus a grade of foil thicker than the common 'domestic' grade needs to be selected (~75µM). Metals are impervious to steam and gas sterilizing agents.

Wrapping technique

A package should be designed to minimise the risk of contamination during opening and removal of contents. All principle features of a sterile pack such as sealing and layers of packaging material may be compromised by careless opening of the pack.

Individual products may be enclosed in a single layer of wrapping material or they may be double wrapped to reduce the likelihood of contamination when the package is opened. The outer wrap is sealed and provides the bacterial barrier. The inner wrap, which is unsealed, acts as a protective cover during the removal of the article. Wrapping methods are outlined in AS4187.

Sealing, indicators and labelling

- Adhesive tapes, such as 'sterilization indicator sealing tape' which are commonly used to fasten wrappings also incorporate a chemical indicator, usually comprising diagonal stripes which darken or change in colour during the sterilization process. Tape adhesive must be stable under the conditions occurring during sterilization and be permeable to the sterilizing agent.
- Heat sealing of flexible packaging materials is the best method for these materials. Seal the laminate to the paper with a continuous adhesive seal of 3-15mm. In the event of breakdown of the heat sealer a seal may be formed by first folding the corners of the open end inwards, then making two or three width-wise folds of the entire open end of the pack followed by securing of the folds with adhesive tape (which could be 'autoclave' indicator tape).
- Self sealing packages are to be used in accordance with manufacturers instructions.
- Staples must never be used because they perforate the packaging material
- Labelling of packs should be prior to sterilization using non-toxic, solvent based felt tip marking pens. Labelling should occur on the sterilization indicator sealing tape securing wrapped packs. Pouches should be labelled outside the heat seal line' and on the clear (laminate) side as the ink may penetrate the paper. Commercially prepared self-adhering labels may be used, with the advantage that they may be pre-printed and/or computer generated.
- A piggyback batch control label system or computer generated system is to be used on all items that are to be used as a sterile product (refer to [CHRISP "Recommendations for manual batch labelling and manual tracking of instruments trays for Operating Suite"](#)), this label is to be placed in the patient's procedural record by operating suite staff to assist with the ability to recall items. Minimum labelling requirements as described in AS4187 include:
 - Sterilizer identification number or code
 - Date of sterilization
 - Cycle load or number

Specific guidelines for packaging for low temperature processes

The low temperature sterilization processes each have special requirements or limitations for packaging materials. Short descriptions follow:

Ethylene oxide

Many porous packaging materials and sealing styles may be used in ethylene oxide, except for cotton or polyester/cotton textiles which absorb moisture needed for reliably killing microorganisms. Sealed containers must not be used. Different packaging materials (as well as the goods being sterilized) will absorb differing amounts of ethylene oxide during sterilization. Removal of this absorbed gas is a slow process requiring a specific aeration stage and equipment. Packaging materials can have a significant effect on the efficacy of the sterilization process and any change requires that the process be revalidated.

Hydrogen peroxide plasma

Only purely synthetic packaging materials can be used in hydrogen peroxide plasma sterilization. This is because there is no absorbed moisture in the packaging material, very small quantities of which would interfere with the attainment of the deep vacuum and the generation of plasma used in this process. Suitable materials may be selected from the range of non-woven wraps and non-cellulose flexible packaging materials available and are sealed at 120°C.

Peracetic acid

Peracetic acid sterilization utilises a liquid sterilant, therefore porous packaging materials cannot be used because at the end of the process they would be completely saturated with liquid.

This process is intended for sterilization of unwrapped instruments with only a very short distance for transport of goods from the sterilizer to the place where they are used. For this purpose, the load carrying 'cassette' offers some protection following sterilization, similar to the way packaging materials function, but these machine specific load-carrying systems are not intended to maintain sterility longer than a few minutes after sterilization.

Heat sealing of packaging material

Heat sealers are used to seal paper to paper (eg bags or pouches), film to paper (eg laminates, flexible packaging systems) and plastics. Heat sealing involves pressing the lacquered surfaces between heated plates. The temperature, pressure and contact times must be constantly monitored. Creases, thickness and type of material used may result in faulty seals. Seals should always be checked on opening to ensure that the seal has been maintained.

Heat sealers shall undergo a complete mechanical service, including temperature calibration, at regular intervals not exceeding 12 months.

Test pieces for each type of packaging material used shall be processed daily on each heat sealer and examined for integrity and strength of seal before and after being subjected to a steam sterilization process.

Various types of heat sealers are available – refer to AS 4187. Heat sealers are either of the jaw-type or of the continuous type. For each type of heat sealer, the operator shall on a daily basis check the following:

- the machine is in a clean condition with no loose fibres or lint present; and
- element covers, where fitted, are in a good condition, and are replaced immediately when damaged

In addition, the operator shall, every three months, check and adjust the gap between the heating elements to ensure that it is within the manufacturer's recommendations.

The effect of the sterilization process on the seal must be taken into consideration. Heat seals are weakened during steam sterilization but usually return to the normal condition on cooling. Sterilization by ethylene oxide, hydrogen peroxide plasma or radiation does not have a significant effect on seals.

State purchasing contract – SOA 7

The Queensland Health Services Purchasing and Logistics Unit administers a whole-of-state 'Standing Offer Arrangement' for consumables that are routinely used by sterilizing services. 'SOA-7' provides access to tried and tested sterilizing materials and monitoring consumables for use throughout all Queensland Health facilities. SOA-7 includes:

- plastic, paper bags for wrapping/sterilization with or without indicators
- packaging and wrapping systems – flexible, heat sealable and paper
- sterilization monitoring systems – chemical and biological
- sterilization accessories - sealing tape, instrument tips and tray liners.

DISINFECTION & STERILIZATION INFECTION CONTROL GUIDELINES

SECTION 3 STERILIZATION

Section 3 - Sterilization

Definition and Overview

Sterilization involves the complete destruction of all forms of microbial life, including bacteria, viruses, and spores. To be effective, sterilization must be preceded by meticulous cleaning (mechanical or manual) to remove all foreign material from objects prior to undergoing sterilization.

All items introduced into normally sterile tissue, sterile cavities or the bloodstream ('critical' sites) must be sterile. Sterility is also preferred for items used in 'semi-critical' sites (refer to 'Spaulding's classification').

There are a variety of sterilizing methods suitable for health care facilities including steam sterilization (autoclaving), dry heat sterilization, and low temperature sterilizing processes (ethylene oxide, peracetic acid and hydrogen peroxide plasma). The sterilization method chosen must be compatible with the item to be sterilized to avoid damage. Manufacturer's recommendations are to be followed when determining the method of sterilization for individual items. Single use sterile equipment is an alternative in settings unable to undertake sterilization processes.

Steam sterilization

Steam sterilization involves the use of steam under pressure, delivered at a particular temperature for an appropriate time. Sterilization occurs as the latent heat of condensation is transferred to the load causing it to heat rapidly. Heating denatures any microorganisms remaining following the cleaning process. Wrapped and packaged items must be thoroughly dry prior to removal from the autoclave and procedures must be in place to monitor the sterilization process.

Types of steam Sterilizers

In health care facilities, four generic types of steam Sterilizer may be found:

- the pre-vacuum steam Sterilizer (for porous and cannulated loads) – AS/NZS 1410-2003.
- the downward displacement steam Sterilizer with drying stage (for porous loads) - AS/NZS 2192-2002
- the downward displacement 'flash' steam Sterilizer (for unwrapped instruments) - AS/NZS 2192-2002
- the benchtop steam Sterilizer (which is only suitable for porous loads if it has a suitable drying stage) – AS/NZS 2182-1998

Steam quality

Steam quality affects the degree of sterilization and dryness of processed materials. When materials such as dressings, linens, and outer wrappings are sterilized, the fabrics can become saturated with moisture. This in turn hinders diffusion of air from the load and therefore any trapped air can significantly reduce the rate at which a dense porous load will heat.

There are three categories of steam quality that will hinder the efficacy of the sterilization process:

- moisture content of steam (dryness fraction)
- non-condensable gases, e.g.: air content of steam
- particulate or chemical contamination carried in the steam arising from an impure water supply (from which the steam is generated) or improper operation of the boiler or steam generator.

Moisture content

A continuous supply of dry saturated steam is required for reliable steam sterilization. This is steam that is not too wet and not too dry. Excess moisture carried (suspended or entrained) in the steam may cause wet loads, while superheated steam is a problem for reliable sterilization because it is dry and needs to cool before its moisture (necessary for fast killing of microorganisms) becomes available. Steam in the Sterilizer may become superheated during expansion into the chamber from a much higher pressure, or it may be produced through malfunction of some Sterilizer or steam supply components.

The moisture content of the steam (dryness fraction) is measured as the weight of dry steam present in a mixture of dry saturated steam and entrained water. Ideal steam for sterilization is 100% dry saturated steam, although in practice, values greater than 97% are considered acceptable. Inferior moisture content quality can occur due to factors such as boiler priming and poorly trapped steam supply lines. Similarly, superheated steam is to be avoided.

Non-condensable gases

Non-condensable gases are those which do not exhibit a change between gas and liquid states in the normal operating range of temperatures of a steam Sterilizer. They seriously interfere with the heat plus moisture conditions necessary for microbial death.

Air is generally 'incondensable' and may be trapped in steam being delivered to a Sterilizer. Other Non-condensable gases may arise from boiler water treatment regimens, or residues of chemicals used to treat the interior of steam supply pipes. Non condensable gas entrainment can be minimised though the correct chemical treatment of boiler water. The removal of non-condensable gases can be facilitated by the installation of air vent assemblies at high points on the steam line before the sterilizer.

Contaminated steam

Steam should not be contaminated by chemical or particulate matter. Chemical contamination may arise from small amounts of 'carry over' of chemical laden boiler water during steam generation, while particulate contamination may arise from release of corrosion or precipitated materials in steam supply pipes. It is necessary to remove this contamination in order for reliable sterilization to take place.

The maximum level of contamination given in European Standard EN 285 is 1.0 mg/kg. The qualities of non-condensable gases and physical contamination will largely depend on the quality of the boiler water. In the case of electric benchtop sterilizers, the purer the water supply, the purer the steam will be. This is also true for steam generators and steam boilers, however, steam quality is not solely dependant on the feed water quality, but an overall program including appropriate servicing and maintenance of equipment including a suitable water treatment program where applicable. The only method of removing physical and particulate matter from the steam supply is by filtration.

Steam quality testing

In order to ensure that the end product is as pure as possible, a number of tests can be performed to test steam quality. Results within the specified acceptable levels will show that the quality of steam introduced into the Sterilizer is not harmful to the load.

Steam quality testing is recommended during the commissioning of a Sterilizer and or Steam boiler to establish base line data. Steam quality testing may be considered as part of investigations aimed at pin pointing steam supply issues, but not be considered as definitive proof that a given system will achieve the desired results. Tests have proved that steam systems with a measured dryness fraction of in excess of 98% - delivered to the sterilizers, were still unable to produce suitably dry loads.

Information describing practical methods for testing Sterilizer steam quality can be found in Australian/New Zealand Standard 1410.

Steam sterilization parameters

The fundamental minimum times for reliable sterilization by dry saturated steam at different temperatures usually used for health care facility Sterilizers are set out in AS 4187. The term 'time at temperature' is often used. These times commence only after air removal from the Sterilizer chamber and load have been achieved, which means that the time taken for pack centres, and or product internals, to reliably attain the intended sterilizing temperature need to be determined and known. This determination is an essential part of 'validation' of the steam sterilization process.

For each working temperature there is a corresponding working steam pressure (when steam is 'dry saturated steam'), without which, the continuity of the intended temperature could not be guaranteed. Refer AS 4187 to determine temperature for each working pressure.

The time and temperature parameters for steam sterilizing are regarded by microbiological authorities as defining 'overkill processes'. This is necessary in the typical situation where the number of packs and pack size per load vary.

Load dryness testing

The dryness test for pre-vacuum sterilizers, benchtop steam sterilizers and downward displacement steam sterilizers is documented in AS 1410, AS 2182 and AS 2192 respectively under the relevant sections for testing.

The dryness test should have been carried out pre-delivery during evaluation for 'type' acceptance, and it should be one of the 'on site' tests conducted during commissioning and validation.

The dryness test is essentially the same for benchtop steam sterilizers, and may be carried out by comparing the dryness of a load of sterilized porous articles, after they have returned to ambient temperature following the sterilization process, with the dryness of similar porous articles which have not been sterilized, at the same temperature.

Fault Finding

Determination and location of sterilizer failure and faults often requires the cooperation and consultation over many disciplines. It is imperative that when SS recognise a sterilising failure or fault the Sterilizer is placed out of action until Engineering Services has been consulted. Fault finding should follow a logical sequence of investigation and confirmation of factual information and data. A flow chart (Sterilizer Fault Finding- Flowchart) has been provided in Appendix 1 to assist in the formulation of an investigative process.

To facilitate a consistent approach to the technical support for sterilising and maintenance departments a Sterilising Maintenance Network of Advisors has been established with representatives from AMU, District BEMS staff and CHRISP. The Sterilising Maintenance Network of Advisors is a single point of contact for the provision of advice and guidance for Queensland Health facilities experiencing problems with sterilising equipment and steam supply. For further information please refer to the CHRISP website: http://www.health.qld.gov.au/chrisp/sterilising/sterile_support.asp

Wet pack problem in steam sterilization

Wrapped items need to be dry on removal from a steam sterilizer. Sterilizing and engineering/maintenance personnel can productively work to reduce the occurrences of wet loads and to eliminate problems that have been identified.

Sterilization by steam under pressure works best when steam is of high quality, i.e.: in the range 97% to 100% dryness fraction; steam of this dryness fraction does not deliver excess moisture to the packs being sterilized.

The drying stage of a steam sterilizer, whether a downward displacement or a pre-vacuum type, cannot be relied upon to dry off more moisture than the Sterilizer imparts to packs (by condensation of steam) when it sterilizes them using steam of this quality. For this reason, all items must be suitably dry before being processed by the sterilizer. In either type of sterilizer, the drying stage immediately follows the sterilization stage. During the drying stage, the heat in the load plus the heat that is radiating inwards from the hot chamber walls (heated by steam in the jacket), combine to evaporate residual moisture in all parts of the load. A vapour removal process, usually involving a vacuum in the chamber to lower the boiling temperature thus allows evaporation to continue during the drying stage by removing the water vapour as it is being formed.

There are three areas requiring investigation when persistent wet pack problems occur:

- the quality of the steam supplied to the Sterilizer
- the effectiveness of the Sterilizer (including its various components)
- the methods used by the Sterilizer operators in loading the Sterilizer, including different types of packaging materials.

All three areas may need to be investigated in a particular problem situation refer to Appendix 2 A and B: Troubleshooting of Wet Packs.

Addressing the real cause of wet pack problems

Remedial actions suggested above and in Appendix 2 (A&B) must follow a thorough investigation. The following actions, while common, may not necessarily address the real cause of wet pack problem(s):

- covering loaded lower shelves of sterilizer loading trolleys with a textile sheet or drape to minimise the occurrence of drops of condensate falling onto load items from the shelves above
- extending the drying stage time without carrying out other investigations
- changing the packaging materials in use without carrying out other investigations
- pre-heating the load by leaving it in the sterilizer chamber for a short time prior to the actual commencement of the automatic cycle of the sterilizer. Pre-heating is sometimes successful in minimising the occurrence of wet packs, but it raises a number of unknowns relating to reliable timing and the effect of the preheating period on the long term performance of the sterilizing packaging materials used.

The following points are often erroneously implicated in the occurrence of wet loads:

- superheated steam in the sterilizer chamber (however this is a concern for reliable sterilization)
- the sterilization stage time being longer than necessary for reliable sterilization
- the appearance of wet loads with one packaging material and not others, when in fact the problem is elsewhere in the overall operation of the Sterilizer

For further information, contact [Centre Healthcare Related Infection Surveillance and Prevention, Queensland Health](#).

Flash sterilization

'Flash' sterilization is a common term which has arisen to describe the practice of fast sterilization of non-porous and or non-cannulated surgical instruments in an unwrapped condition in downward displacement steam instrument sterilizers located close to point where the instruments will be used immediately. In the past, 'flash' sterilization was the predominant way of providing sterile instruments for surgery. 'Flash' sterilization delivers the instruments wet and very hot into the operating room environment.

'Flash' versus pre-pack

The alternative approach to 'flash' sterilization is to provide instruments in a wrapped, dry and cool condition (temperature depending on the time since steam sterilization). This is possible when there is sufficient inventory of instruments and equipment to allow 'turn around' time for reprocessing (such as pre-vac sterilizers with fast cycles) in a well-appointed and staffed SS. In smaller surgical facilities, the SS activities often occur in the operating room area; however this represents a compromise of several desirable standards of control of particulate and microbial contamination in the area where sterile packs are being produced.

There is now a strong movement towards routinely preparing sterile instruments in a wrapped, dry and cool condition for use in the operating room. This is because:

- there are immediate advantages to case by case organisation of sterile instruments by operating room personnel
- the typical operating room suite is not designed or equipped to clean instruments as reliably and consistently as a properly appointed SS; there are concerns regarding the adequacy of cleaning and drying of instruments in the operating room prior to 'flashing'
- sterility of sets of instruments can be uncertain following the use sterilizers designed and intended only for single dropped instruments; they should not be used for routine sterilization of instrument sets
- the sterilizer may not be located in an area immediately adjacent to the operating room; the delivery of flash sterilized devices to their point of use compromises their sterility
- patient injury has occurred from flash sterilized items including: full thickness burns resulting in permanent scars, *Pseudomonas aeruginosa* meningitis from flash sterilized implantable devices, and surgical site infection.

A compromise is the method of delivery of 'flash' sterilized instruments in an enclosed container (with valves that automatically close at the end of steam sterilization) is commercially available (FLASH-PAK™). AS 4187 recommends that the use of such containers are specifically validated. Manufactures recommendations should be observed in relation to minimum time at temperature exposure time. Inspection and maintenance of such systems should be carried out on a regular basis as recommend by the manufacturer.

Monitoring of flash sterilization

Due to time constraints, no reliable biological means of verifying sterilization of instruments or devices can be used. In addition to the use of minimal cycle parameters (ie time, temperature, and pressure) in flash sterilization and the lack of protective packaging, lack of a biological 'flash-verifier' further reduces the inherently low margin of safety in 'flash' sterilization.

The emergency instrument ('flash') Sterilizer should be performance tested daily to ensure the efficacy of the sterilization process (i.e. time at temperature), when:

- biological indicator testing is not performed daily, or
- the Sterilizer does not maintain a permanent record of each cycle
-

A chemical indicator must be used for each load. Refer to AS 4187.

'Flash' sterilization recommendations

- restrict use to emergencies, such as unexpected surgery, or dropped instruments. 'In most emergency situations, the risk/benefit ratio is low enough that the use of flash sterilized objects is justifiable. In non-emergency situations, however, the risk/benefit ratio is higher, particularly when implantable devices are involved' (Manian)
- 'flash' sterilizers must never be used for implantables, suction tubing or cannulars or any other product not specifically validated for the "flash" process

Minimising 'flash' sterilization

The following points should be considered for action to minimise routine 'flash' sterilization:

- increase available inventory of particular instruments, particularly rigid endoscopes
- replace older design instruments with newer design, steam sterilizable ones
- provide more instrument sets in wrapped form, focusing on the advantages this provides both during surgery and for management of the operating room suite
- ensure appropriate design of the sterilizing department or sterile processing area to optimise the production and timely delivery of wrapped instrument packs
- organise better shared use of expensive instrument inventory belonging to the District
- manage operating theatre case lists in a way that optimises use of the available instruments in association with their sterile processing requirements

Dry heat sterilization

Dry heat sterilization is only minimally used in health care facilities today. Whereas steam sterilization is fast due to steam delivering both heat and moisture to the items being sterilized, dry heat sterilization subjects items to dry hot air for a long length of time. It is more commonly seen in use in laboratories for sterilization of some glassware items.

Advantages

Advantages of dry heat sterilization include:

- the ability to sterilize goods in sealed or non-porous containers
- the ability to sterilize complex goods while assembled
- the ability to sterilize goods which are impossible to dry in a steam sterilizer or which may be damaged/corroded by the moisture of steam sterilization
- the relative mechanical simplicity of a dry heat sterilizer

Disadvantages

Disadvantages of dry heat sterilization are:

- long times involved in heating, sterilizing and cooling goods being sterilized
- possible damage to packaging materials or to some of the items themselves arising from the high temperatures used
- close monitoring and control of sterilization conditions within packs being sterilized can be very time consuming
- due to the high temperature, dry heat sterilizers provide the greatest potential for injury to personnel following contact with parts of the sterilizer or the goods being processed (while they are hot), compared to the other in-facility sterilization processes
- equipment at the 'low cost' end of the market does not adequately maintain constant temperature conditions within the sterilizer. Purchasers may not be adequately aware.

Sterilization parameters for dry heat

Dry heat sterilization parameters are simply time and temperature. After attaining the sterilization temperature, the temperature must be maintained for a minimum length of time. This 'time at temperature' must be demonstrated to occur in the case of every pack placed in the sterilizer.

While even higher temperatures (for shorter times) may be used, in health care facilities it is usual to only use the time at temperature combination of 160°C for 120 minutes (plus penetration time). Penetration of heat into packs prior to commencement of this minimum time at temperature must have been assured.

Monitoring of dry heat sterilization

- temperature measurement using thermocouples is the best method of assessing the attainment of time at temperature conditions and validation of the process
- biological indicators may be used, but containing a different type of micro-organism to those used to monitor steam sterilization (refer AS 4187)
- chemical indicators used in dry heat sterilization are useful only for determining the 'sterilized' or the 'not yet sterilized' status of goods to which they are attached

Low temperature sterilization processes

The increasing use of rigid and flexible endoscopic instruments which may be damaged when exposed to the temperatures achieved in steam and dry heat sterilization (121°C and 160°C) has driven the development of alternative reprocessing methods for heat-sensitive equipment. While steam sterilizable rigid endoscopic instruments have been developed, the need to reliably sterilize many other types of heat sensitive instruments still remains.

There are three low temperature sterilization processes identified by AS4187 for use in health care facilities to sterilize items at temperatures of 55°C or lower. The active sterilants of these processes are ethylene oxide, hydrogen peroxide plasma, and peracetic acid. All liquid sterilants shall be registered with the TGA.

The immediate advantage of the low temperature processes is that heat-sensitive items can be sterilized within health care facilities. However, because of the significantly higher costs of operating low temperature sterilization processes, items for sterilization should be steam sterilized where possible.

Ethylene Oxide (EO)

After an air removal stage using a vacuum, sterilization is achieved by ethylene oxide gas in controlled conditions of humidity, temperature, time and gas concentration. Gas is supplied in canisters that are used one per cycle. Aeration of all load items is required after sterilization. Risk of personnel exposure to ethylene oxide demands environmental control equipment be in place. There is a very limited availability for this type of processing within Queensland and consideration must be given to procuring instruments or items that can undergo other processing methods other than EO.

Hydrogen peroxide plasma

After air removal by a very deep vacuum and plasma stage, sterilization is achieved through generation of a plasma of hydrogen peroxide vapour within the load by radio frequency excitation. The sterilizer monitors and controls the rate of attainment and depth of the vacuum drawn, energy required to initiate plasma within the chamber, and duration of each stage. ('Plasma' is matter excited to a higher energy state than its gaseous form).

At the end of the cycle hydrogen peroxide vapour is replaced by filtered air, and the hydrogen peroxide vapour is converted back into water and oxygen. Automated machines using hydrogen peroxide plasma to chemically process medical and surgical instruments are currently available. This method is normally used for wrapped items.

Peracetic acid

Peracetic acid, or peroxyacetic acid, in low concentrations is characterised by a very rapid action against all microorganisms including bacterial spores. Peracetic acid remains effective in the presence of organic matter and is sporicidal even at low temperatures.

Little is known about the mechanism of action of peracetic acid, but it is believed to function in a similar manner to other oxidising agents. It denatures proteins, disrupts the cell wall permeability, and oxidises sulph-hydryl and sulphur bonds in proteins, enzymes, and other metabolites.

Sterilization is achieved by contact of every part and surface of each item with a 0.2% solution of peracetic acid. The sterilizer creates a fresh sterilant solution from water combined with a powdered concentrate supplied in a single usage container. During the cycle, temperature (50°C-56°C), concentration of peracetic acid and time of exposure (12 minutes) are controlled, and sterilant is circulated throughout instruments being sterilized. A chemical neutralising agent is used in the final stage of the process to return items to a useable condition. Several different load carrying trays or containers are available to accept a variety of instruments being processed.

Automated machines using peracetic acid to chemically process medical and surgical instruments such as endoscopes and arthroscopes are available. Manufacturer's data demonstrate that this system inactivates *Bacillus subtilis* and *Clostridium sporogenes* when the solution is heated to 50°C with an exposure time of 12 minutes or less. These systems have been registered by the Australian Therapeutic Goods Administration as a sterilization process when used according to its manufacturer's recommendations. They are 'point of use' Sterilizers for unwrapped items as recommended by the manufacturer only.

Loading and unloading of sterilizers

The principles governing loading and unloading of sterilizers vary according to the type of sterilizer. In most cases involving wrapped sterilization, a significant difficulty for reliable sterilization exists when packs are loaded into the sterilizer such that they are pressed together.

Instead of the load being several smaller packs, the sterilizer 'sees' such a load as one large pack, requiring a longer sterilant penetration time than is needed for each of the packs by itself. The total sterilizing stage time may not be long enough to reliably sterilize this dense load and, for steam sterilization, drying of the load after sterilization may be ineffective.

Final assessment of reliable sterilization is determined when the sterilization process is being validated (refer AS 4187). Information related to loading and unloading of sterilizers is presented in AS 4187. Specific considerations for the different sterilizing processes follow.

Loading and unloading in steam sterilization

- heavy instrument sets (which generate large quantities of liquid condensate) should be placed on lower shelves if the condensate cannot be diverted away from lower items. This may avoid wetting of other packs
- items need to be placed in such a way that air and steam can move between and past them. Light contact is possible and likely but it should not affect sterilization
- non-perforated trays, hollowware and other containers must be placed in such a way that liquid or air (heavier than steam) is not likely to be retained e.g. tilted on the edge to facilitate air removal, entry of steam and removal of condensate
- flexible packaging material should be loaded on edge paper to laminate or flat with the paper facing downwards
- when unloading sterile instruments from a 'flash' steam sterilizer and when they are about to be used sterile, locally valid policy should be developed to ensure a low probability of recontamination of the instruments as they are transferred to the sterile field

Loading and unloading in dry heat sterilization

- packs or other items being sterilized need simply to be placed on the perforated shelves of the sterilizer without contact between each other

Loading and unloading in ethylene oxide gas sterilization

- items need to be placed in such a way that air and ethylene oxide can move between and past them. Light contact is possible and likely but it should not affect sterilization

Loading and unloading in hydrogen peroxide plasma sterilization

- items need to be placed in such a way that gaseous movement can occur between and around the items, refer to manufacturers recommendations. Light contact should not affect sterilization

Loading and unloading in peracetic acid sterilization

- the Sterilizer manufacturer's load carrying trays (specifically designed for particular types of instruments) must be used in order to achieve thorough sterilant contact with all instrument surfaces
- when unloading instruments from a peracetic acid sterilizer and when they are about to be used sterile, local policies should be developed to ensure a low probability of recontamination of the instruments as they are transferred to the sterile field

Cooling practices following sterilization

For items wrapped in porous packaging materials, the period of time between their removal from a Sterilizer (any type) and their return to room temperature is the most critical time with respect to assurance of sterility. Cooling generates a tiny flow of room air into the pack at flow rates demonstrated to breach porous packaging materials leading to their failure to provide a microbiological barrier.

Correct cooling practice is essential to maintain sterility. When a sterile item is not cooled in the correct manner the article can have moisture build up, which can contaminate stock. The item should be discharged if the packaging is torn, punctured or wet.

Before any sterilized items is used it is necessary that the item be in the temperature range of 18-22°C with relative humidity of 35-70%. In general this can be achieved with a cooling time of two hours however it does depend on the density of the item processed.

AS 4187 recommends that at the end of the sterilization process, stock should be removed and inspected for signs of moisture. Sterile packs removed from a steam sterilizer should be cooled on a mesh surface to prevent the packaging from sweating.

Do not place items on a solid surface or use forced cooling methods including fans or boosted air conditioning. If a plastic dust cover is to be applied, it needs to be applied after the sterile item has completely cooled.

The equipment storage area must be free from dust, draughts, dampness and high traffic activity to minimise bioburden and environmental contamination. All sterile packages should be handled as little as possible to decrease risk of contamination.

Rejection of items intended to be sterile

AS 4187 lists conditions under which a product is considered non-sterile. These may be summarised as items that:

- are incorrectly wrapped
- are damaged or opened
- are still wet after the sterilizing cycle or comes into contact with a wet surface
- have been placed or dropped on a dirty surface
- have no indication of having been through a sterilizing process

Storage of sterile stock

Immediately following sterilization, items should be minimally handled and stored in a low traffic area while cooling (refer AS 4187). Objectives related to sterile storage are:

- to manage sterile stock maintaining the requirements of AS 4187
- to provide end users with a product that has been reliably sterilized, and maintained in a sterile state
- to apply sound techniques of inventory management and infection control

Storage conditions

Ideally, sterile storage areas should be air-conditioned with minimal air turbulence created by fans. The following points are minimum requirements whether or not storage conditions are air-conditioned:

- area to be dedicated for sterile stock storage
- free from dust, insects and vermin
- temperature range to be between 18°C to 22°C with a relative humidity ranging from 35% to 68%
- possible deterioration of materials and/or components of sterile articles must also be considered. Manufacturer's instructions as to the likely life of an item's components (eg latex, or maximum recommended number of wash cycles) need to be considered

Shelving, containers and handling

- consideration should be given to wire rack compactor systems as these increase efficiency and storage space
- shelving systems are to be designed and constructed to avoid inaccessible corners, with sealed seams, having non-porous surfaces which facilitate damp dusting and vacuum cleaning
- shelving to be 250 mm above the floor and 440 mm from the ceiling
- area to be protected from direct sunlight
- sterile items are to be stored within the original packaging or decanted into receptacles which are enclosed and able to be cleaned to reduce risk of contamination and/or damage
- reusable cardboard boxes should not be used as storage containers as they are porous and cannot be adequately cleaned and may harbour organisms
- a system of inventory review and stock rotation based on the date of sterilization must be developed
- routine cleaning with detergent and water to be scheduled and procedures to be documented

Transporting sterile stock

In order that protection of sterile stock is 'seamless', the same factors which may compromise storage of sterile stock need to be addressed when it is being transported.

The following are important:

- avoid moisture and condensation
- avoid incorrect temperature
- avoid excessive exposure to sunlight and other sources of ultraviolet light
- avoid exposure to vermin and insects
- containers used during transportation need to be such that sterile stock does not experience extremes of storage or handling. Assessment and planning is required in order to determine the most appropriate container for the particular situation. Strong, easily cleaned, plastic containers with clip on lids are often necessary, depending on the distance transported and the training of the personnel who may be involved in transport of containers of sterile stock
- transport vehicles must have a dedicated space for containers of sterile stock

Access to sterile stock storage area

- access to the area shall be clearly defined
- traffic should be controlled to minimise the movement of airborne contaminants
- adequate education and training must be given to all staff in handling sterilized articles

Shelf life and event related sterility

The use of time-related expiration dates for the determination of shelf life for sterile items has been widely recognised as meaningless (Gardner & Peel, 1998). For many years a sterile storage time of four weeks has been the tradition, followed by recall, repacking and reprocessing of all facility manufactured stock not used within four weeks of sterilization.

The alternative is a system called 'event related sterility' which declares that the sterility of an item depends on the events occurring during storage of that item. Possible and probable events compromising sterility vary from one facility to another; therefore sterility maintenance must be viewed as a quality management exercise in each facility, comprising monitoring, evaluation, planning and instigation of changes as necessary.

Events that could compromise package sterility may arise from:

- the type(s) of packaging materials or packaging system in use
- package design
- the after effects of any failure(s) during cleaning and/or sterilization of the item(s)
- conditions occurring during storage and handling eg packaging damage, soiling, becoming wet, exposure to vermin, etc.
- materials deterioration of the product or its component parts

As part of the quality management process, any or all of these factors may be altered to improve the likelihood of maintenance of sterility for long lengths of time. Another factor important in establishing an 'event related sterility regime' is education of all personnel involved in handling sterile stock, including users (medical and nursing personnel).

In practice, the introduction of an event related sterility regime is a major exercise involving detailed assessment of all areas in which sterile stock is stored. There is a need to both influence and control the conditions of storage and all handling 'experiences' endured by stock during storage.

Broad steps towards the introduction of an event related sterility program are:

- evaluate the present situation in every user area where sterile stock is stored
- plan stages and timing of implementation, including on-going monitoring of sterile storage conditions and problem reporting mechanisms will be implemented
- raise awareness of the concept of event related sterility amongst all sterile stock users and the need for their involvement, and local plans for its introduction
- educate users as to their responsibilities for assessment of sterile packaging integrity every time they open a packaged sterile item (both in-hospital and commercially made), particularly in relation to providing feedback to the SS
- pilot the introduction in one user area for six months, utilising the date of sterilization as a reference for the length of time packs have remained on shelves
- determine the potential for adjustment and management of numbers of packs needing to be stored in each user area
- evaluate potential for more widespread introduction throughout the facility, involving assessment of observed condition of all packs
- modify (if necessary) plans for full introduction
- introduce event related sterility programme facility wide
- monitor and evaluate on a regular basis, documenting all data, observations and user reports to facilitate later quality improvements
- implement improvements as necessary on a continual basis

It should be noted that it is not possible to clearly interpret results of attempts by hospital laboratories to evaluate microbiological contamination in packs that have been sterilized, to either support or not support the introduction of an event related sterility program. Such assessment is of less importance to the program's introduction than careful monitoring and evaluation of the events that sterile packs experience during storage.

Where an 'event related sterility' regime has not been properly instituted, observance of the 'traditional' four week shelf life with repacking and reesterilization each time is the only alternative.

DISINFECTION & STERILIZATION INFECTION CONTROL GUIDELINES

SECTION 4 QUALITY MANAGEMENT IN STERILIZATION

Section 4 - Quality Management in Sterilization

Quality management in sterilizing services

Quality management: checking instrument integrity

The SS provides a valuable service to the operating suite through routine checking of the integrity of surgical instruments, replacement where possible and reporting of damage to the operating room personnel.

Due care of instruments by SS personnel requires the availability of photographic instrument identification information, as well as training in the necessary checks and tests that sometimes need to be performed to evaluate the working integrity of instruments being processed. It also involves the design and application of cleaning procedures and equipment appropriate to the range of instruments being processed.

Quality management in cleaning

Bioburden, by definition, is the number and types of microorganisms found on devices prior to sterilization (AS 4187). An awareness of the average level of contamination on a 'cleaned' batch of articles is an essential component of sterilization process design because it controls the severity of treatment that will be needed to assure sterility. Sterility assurance is the probability that a microorganism may survive the sterilization process, which corresponds to the proportion of processed articles that may not be sterile.

Visual inspection is the commonly practised method for assessing cleaning efficacy. AS 4187 provides more information.

Australian Standard 2945, 'Batch-type Washer Disinfectors for Health Care Facilities', describes a 'Soil Removal Test' which may be utilised within facilities to assess cleaning effectiveness. A standardised test soil and cleaning machine for 'test pieces' has become commercially available. Personnel in facilities may use either of these approaches to routinely assess and manage the efficacy of cleaning, particularly by mechanised cleaning equipment.

The Therapeutics Goods Administration recommends that purchasers of all surgical instruments ensure that the instruments are able to be adequately cleaned and dismantled prior to disinfection or sterilization. Manufacturers of instruments should provide the purchasing facility with the recommendations regarding requirements for reprocessing of reusable medical devices. Consultation with SS when purchasing new instrumentation is imperative to ensure that existing sterilizing services has the capacity to reprocess instrumentation.

Washer/disinfectors easily remove excessive amounts of dried organic material from instruments. The number of water jets and the degree of agitation of the water are such that instruments are thoroughly cleaned without causing damage. Monitoring the cleaning efficacy of washer/disinfectors through microbiological testing has not been validated and is therefore not recommended.

Quality management in packaging

Quality of packaging in sterilizing services incorporates management of the following aspects:

- selection and purchase of packaging materials or sterile packaging systems according to appropriate standards of packaging manufacture and sterilizing practice
- selection of packaging materials or systems appropriate to the intended final design of the pack, the sterilization process to be used, the amount of handling and transport that the pack will have to endure before use
- consistency in the preparation of packs prior to sterilizing
- on-going monitoring of the performance of packaging materials and/or packaging systems, and implementation of improvements as necessary
- documentation of decisions relating to the above steps in order to facilitate on-going improvements
- any changes to packaging materials or load configurations requires performance requalification of the Sterilizer

Quality management in sterilization

Sterilizer loading

- the articles for sterilization should be cleaned and inspected
- hinged instruments should be opened
- articles should be positioned so that air flows out by gravity

Sterilization process

The following stages are carried out under automatic control (steam sterilization):

- removal of air and heating of the chamber to sterilization temperature
- sterilization for an appropriate time and temperature; e.g: the sum of the penetration time as establish during performance qualification , and the sterilize hold time including safety factor; 3 minutes at 134°C or for 4 minutes at 132°C, etc
- restoration of the chamber to atmospheric pressure by rapid exhaustion of steam
- an effective drying stage (if fitted) Chamber contents returned to atmospheric pressure via the introduction of air through an biological filter (if fitted)
- The chamber should be vented and opened immediately because delay increases the wetness of the load and negative pressure in the chamber can cause an inrush of non-sterile air. However, if a drying stage is provided, the door remains closed and a drying process is activated and operates until the load is dry.

For flash sterilization aseptic transfer of the sterilized articles must be carefully planned. Ideally, where the Sterilizer opens into an operating room area, they may be placed directly on an appropriate sterile field (see note regarding cooling of instruments).

Monitoring and validation of sterilizers overview

Monitoring and validation of Sterilizers are very important activities in sterilizing services. No matter whether Sterilizers are small or large, and no matter whether they use steam or another sterilizing agent, the results of monitoring and validation activities are vital in achieving assurances within health care facilities that items for use on patients that are processed in Sterilizers are reliably sterile.

This section explains monitoring and validation, and attempts to assist sterilizing service personnel to implement the requirements of relevant standards in this area. AS 4187 and ISO 13683 establish the requirements for monitoring and validation of all Sterilizers used in health care facilities. Failed tests that occur during the monitoring and validation process are to be logically investigated, please refer to Appendix 1: Fault Finding of this document.

Definitions – monitoring and validation

These ISO definitions have been adopted by Australian Standards writers:

Monitoring: A programmed series of checks and challenges, repeated periodically, and carried out according to a documented protocol which demonstrates that the process being studied is both reliable and repeatable.

Validation: Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications. Validation covers three activities: commissioning, verification of process specification, and performance qualification.

The monitoring activities in use in a particular facility should have been decided upon and confirmed during validation of the Sterilizer(s) in that facility.

Sterilizer maintenance and calibration

A fundamental starting point is that every sterilizer needs to be working properly in accordance with the manufacturer's specification. This necessarily requires maintenance, testing, and calibration by personnel skilled in sterilizer operation. Unless all mechanical components and control systems of a sterilizer are functioning properly and consistently, there is no certainty regarding the sterility of product. Records of all sterilizer maintenance need to be kept.

Similarly, unless the Sterilizer instrumentation which control, display, and record physical conditions during the sterilizer cycle (particularly during the sterilization stage) are known to be accurate, there is again no chance of being able to assure that goods processed through the sterilizer are reliably sterile. Calibration (the checking and adjustment of accuracy of indication of this instrumentation) is a vital part of the maintenance necessary for every sterilizer in a health care facility. Thus routine maintenance includes calibration.

Monitoring sterilization

Monitoring of sterilization may be by physical, chemical and/or biological means and a variety of monitoring methods are available. In practice, a combination of physical, chemical and biological methods of monitoring is required. AS/NZS 4187 – Section 7, specifies the requirements for routine monitoring for each type of sterilizer.

Requirements of Australian Standard 4187 for monitoring

As steam under pressure is by far the most common method of sterilization in use in health care facilities, and as there are several styles of steam Sterilizer, AS 4187 devotes a significant amount of attention to steam sterilization.

A basic summary of the monitoring requirements for steam sterilizers is listed below:

| Process Recorder ³ | Temperature Measurement ^σ | Chemical Monitoring | Other | Optional Monitoring |
|-------------------------------|---|--|--|---|
| Every cycle. | Only during calibration and performance qualification of Sterilizer | Every load and if required, every item | <ul style="list-style-type: none"> Pre-vacuum Sterilizers - Weekly leak rate if sterilizer fitted with an automatic air detector, otherwise daily Biological Indicator for emergency - non validated loads | <ul style="list-style-type: none"> Biological Indicators^Σ Process Challenge devices Electronic Data Loggers Internal Chemical Indicators |

³ The condition here is that the record is generated automatically by the sterilizer controller system, and crucial details of every cycle are recorded in a permanent form. AS 4187, Section 8 makes note that existing sterilizers without process recorders need to be upgraded or replaced to ensure automatic parameter monitoring.

^Σ any of the three types of biological indicators for steam sterilization available in the Australian marketplace may be used, subject to sterilizer operators demonstrating the value of their contribution to sterilizer monitoring.

^σ This involves use of an independent means of temperature measurement and the introduction of electronic temperature measurement leads (thermocouples) into the sterilizer chamber. The aim is to measure during the sterilizing stage, the chamber temperature and the inside temperature of a test pack/packs. Note; the placement of thermocouples within packs should be done considering the complexity of the contents; e.g insert thermocouples into cannulas and like places where steam penetration is likely to be impeded.

Thermocouples and similar devices compliant with the recommendations set out in AS1410 are preferred because of their small physical size, high sensitivity, and ability to display and record real time data which is critical in comparing measured parameters with the sterilizers built in monitoring devices during testing. Sealed data loggers are better suited to routine monitoring – See table above.

Sterilizers should be fitted with a means of introducing test equipment such as thermocouples into the chamber, and the absence of such facilities may necessitate the replacement of the sterilizer. Refer to AS 4187, and AS1410.

This schedule of monitoring is appropriate for all types of steam sterilizer used in health care facilities:

- downward displacement porous load steam sterilizers
- downward displacement emergency instrument ('flash') steam sterilizers
- pre-vacuum porous load steam sterilizers
- portable ('bench-top') steam sterilizers
- specialised 'cassette based' steam sterilizers

The most common testing procedures performed for sterilizers include but are not limited to:

- (a) Leak rate test.
- (b) Bowie Dick type air removal test
- (c) Chemical Indicators
- (d) Biological indicators
- (e) Enzymatic indicators are no longer available.
- (f) Process challenge devices
- (g) Physical tests.

Leak Rate Tests

This test is mandatory for pre-vacuum sterilizers and is to be carried out once a week if the sterilizer is fitted with an automatic air detector.

If the sterilizer is not fitted with an air detector the leak test should be done daily.

The test should be done when all parts of the chamber is hot, usually during the drying cycle.

A leak test failure, which is an increase of more than 134 Pa per minute after stabilisation of the pressure gauge, must be reported to the line manager immediately.

Bowie Dick Air Removal Type Test

This test is mandatory for pre-vacuum sterilizers and is to be carried out on a daily basis before the processed load. A warm up cycle should be run first to properly heat the sterilizer and flush the steam lines.

The Bowie Dick Air Removal Type Test is used to provide evidence that air is being displaced by steam in porous items or provides information about the conditioning phase of the sterilizer.

It does NOT verify the time and temperature parameters.

The Bowie-Dick test should be carried out during initial sterilizer installation and after relocation, sterilization process failures and major repairs of the steam sterilizer. In these circumstances, three consecutive empty cycles should be run, each containing one Bowie-Dick test pack.

The Bowie-Dick is not applicable to downward displacement sterilizers as these have a longer cycle which can cause change to the indicator even there is air present.

If a fail result is obtained, the sterilizer must not be used until the cause is found.

Chemical indicators

Monitoring using chemical indicators involves the use of purpose designed chemical preparations which change in consistency or colour when exposed to particular sterilizing agents.

Many chemical indicators produce a colour change before minimum sterilization conditions are attained, and thus are only suitable for sorting of processed goods from those not yet processed. Most commonly, chemical indicators for steam sterilization are printed inks on packaging materials, or paper strips on which the chemical indicator is printed. A feature of paper strip indicators is that they can be placed inside packs being sterilized and thus checked by the end user.

Different types of chemical indicators are required for different types of sterilization process such as steam heat, dry heat, ethylene oxide, plasma and paracetic acid.

External indicators

These indicators are intended only to identify packs which have been through a sterilization process. They may reveal gross equipment malfunction but do not verify conditions within the sterilizer chamber or the load.

External indicators may come in the form of paper bags, pouches, autoclave tape, all of which darken in colour during the sterilization process.

Chemical indicators in the form of adhesive tapes or inks printed on packaging materials are only used on the outside of packages. Adhesive indicator tape is often used to help seal wrapped packs, in addition to its indicating function.

Internal indicators

Chemical indicators in the form of paper or cardboard strips are designed to be placed inside wrapped packs where (typically) sterilization is likely to have been more of a challenge. The person opening the pack or the pack user is then able to check for the desired colour change of the indicator. Some examples of this type may also be suitable for use during 'flash' instrument sterilization.

Purchasers should select chemical indicators based on the intended interpretation of the colour change produced by the indicator. Very few chemical indicators are designed and calibrated to only show a complete colour change when proper minimum sterilization conditions are attained.

The need to sort processed goods from unprocessed suggests a need for only low cost indicators. The desire for a good indication that sterilization was achieved for all items associated with each individual indicator suggests a need for the more expensive indicators, which provide more precise information in relation to attaining the conditions required for sterilization.

A less common type of chemical indicator is in the form of a small sealed glass vial of indicator liquid. Whilst being responsive to heat only (as distinct from heat plus moisture), this type of chemical indicator is invaluable in dry heat sterilization, or in steam sterilization of aqueous preparations in laboratories where the liquid being sterilized assures the presence of moisture during sterilization.

Biological monitoring

Biological monitoring is the use of living microorganisms for checking and challenging a sterilization process. The goal in using biological indicators is to determine whether all of the microorganisms have been killed during the sterilization process.

The microorganism based biological indicator is a system in which a large number of living hard-to-kill spores of a chosen bacterial species are presented either in a small paper envelope or in a self-contained vial. As described in AS 4187, *Bacillus stearothermophilus*, a hardy spore, is the organism of choice when monitoring steam sterilization. Different organisms are used for the different methods of sterilization (refer AS 4187). The deactivation of spores during the sterilization stage is indicated by their inability to grow in a suitable growth medium over a long incubation time (8 to 72 hours) following the sterilization cycle.

Depending on the type of steam Sterilizer and the other method(s) of monitoring also in use, AS 4187 currently recommends that biological indicators are optional with the exception of emergency loads or loads not previously validated. Biological indicator(s) are to be used for emergency loads, (Loads not previously validated). The number of biological indicators to be used will depend on the sterilizer's chamber volume (refer AS 4187, Section 8, and AS1410, Section 6.6.6)

Whether the chosen indicator is in the form of a small paper envelope or a self-contained vial, the challenge indicator(s) are strategically placed in the sterilizer and the chosen sterilization cycle is operated.

Following completion of the sterilizer cycle, the operator retrieves the indicator and commences or arranges for the incubation of the strip or vial in a controlled temperature environment.

For paper strips, transfer to the incubation medium, and the incubation process itself, must be performed in a suitably equipped laboratory. On the other hand, self-contained vials (containing a small quantity of growth medium and an indicator which shows a colour change if and when any microorganisms grow) may be incubated by the sterilizer operator if a specially designed incubator unit is also available. Demonstration that all of the microorganisms have been killed is the absence of any growth of the 'sterilized' microorganisms on the paper strip or in the self-contained vial, during the time of incubation.

When using this type of biological indicator, it is necessary to demonstrate that live microorganisms were present before the challenge was placed in the sterilizer. This is achieved through use of a 'control', an additional strip or vial from the same batch of indicators that has not been subjected to the sterilizing process. The 'control' is incubated at the same time as the strips or vials used to challenge the sterilizer(s), and a definite growth of the 'control' is reasonable evidence that viable microorganisms were present in the challenge strips or vials placed in the sterilizer. Only one control indicator strip or vial from each batch of indicators in use needs to be incubated on any day that biological indicators are used.

A drawback of this type of biological indicator is the long delay between performing the test/challenge and the gaining of the assurance that the result of the test is negative. Nevertheless, this traditional type of biological indicator is very widely used.

Physical monitoring

Physical monitoring involves independent temperature, pressure and vacuum measurements performed automatically by the sterilizer by gauges and data loggers throughout its cycle. Temperature and pressure readings should be taken at least three or four times during the sterilizing cycle and the records kept until all tests are completed.

Gauges and recorders should be calibrated at regular intervals against standard instruments.

Process control devices

Process control devices are specially designed monitoring 'systems' which can be used routinely to obtain an indication that desired air removal and time at temperature conditions are likely to have been attained inside the packs being sterilized. There are presently a number of these on the Australian market.

The decision by a health care facility to use a process control device, and the interpretation of the results generated, needs to be based upon the results of studies of Sterilizer performance during validation.

European Standard (EN 867-5) is the only document describing the performance requirements of process control devices.

Monitoring other methods of sterilization

For other methods of sterilization, monitoring should also be in accordance with the recommendations in AS 4187. A summary is included below.

Dry heat

For dry heat, following necessary mechanical maintenance, calibration and the assurance of even temperature distribution within the sterilizer chamber, a combination of temperature measurements and use of biological indicators is required. A different bacterial spore type *Bacillus subtilis var. globigii* is necessary for use with dry heat which may limit the method of incubation of test spores to a microbiological laboratory.

Chemical indicators appropriate for dry heat are available for indicating 'processed' goods but they are not accurate as indicators of sterilization conditions. Steam process 'autoclave' tape is commonly used because it does produce a distinctive 'total' colour change, but some chemical indicators specifically designed for dry heat are available. As in the case of steam, chemical indicators need to be used for every item in every sterilized load combined with an electronic printout of sterilization parameters for each load.

Low temperature sterilization processes

For the three low temperature sterilization methods, ethylene oxide, peracetic acid and hydrogen peroxide plasma, maintenance (including calibration) is necessarily only to be performed by the sterilizer manufacturer or his agent. Equipment now in use for sterilization by these methods always generates a printed record of the physical conditions during each cycle and this is an important monitoring record. For chemical and biological indicators, only those designed for use in the particular process being monitored are to be used. These are supplied by the sterilizer manufacturers / suppliers. As with the other methods of sterilization, chemical indicators need to be used on every item in every load.

AS 4187 also requires that biological indicators be used during every cycle of an ethylene oxide sterilizer, but only weekly (by a note to the table) for peracetic acid or hydrogen peroxide plasma sterilizers which produce a printed record of the attainment of critical physical stages and conditions (which in turn control and assure sterilization) for each sterilizer cycle.

Validation of sterilization

Sequence of events

Building on the internationally recognised definition of validation given at the beginning of this section, validation of sterilization in a particular sterilizer becomes a sequence of events, all thoroughly documented. These are:

- 1) Determining or deciding on the 'specifications' or sterilization conditions intended to be achieved in load items subjected to the process in the Sterilizer (this necessarily involves attention to every aspect of processing, not just sterilization, because other aspects eg cleaning and packaging, do impinge upon sterilization efficacy)
- 2) 'Commissioning' of the sterilizer ie demonstrating that the sterilizer is functioning as intended by the designer/manufacturer, that it is able to generate the specified sterilization conditions, that the sterilizer will detect any shortcomings in attaining the intended sterilization conditions, and that all gauges and process recording equipment are accurate
- 3) Verifying that the intended sterilization conditions are being achieved in all load items in the loading configuration(s) to be used in the sterilizer, and that interpretation of the results from chosen routine physical, chemical and/or biological monitoring methods is valid
- 4) Demonstrating that the intended sterilization conditions will be consistently achieved during repeated operation of the sterilizer.

These principles are applicable to validation of any method of sterilization. Some of the information called for in the above four steps has to be obtained by on site measurement, some from persons conducting sterilizer Performance Qualification tests, and some data may already be obtained during regular maintenance and monitoring activities by Sterilizer operators. AS 4187 describes many of the points that may impinge upon reliability of the overall process surrounding sterilization. It is necessary to consider the possible impact on the 'validated' state of the sterilizer arising from all of the factors listed in that clause. These are summarised by: (a) the mechanical state of the sterilizer, (b) the sterilization process programmed into the machine, (c) packaging of the goods to be sterilized, including sizes of packs, (d) loading of the sterilizer, and (e) other factors (eg cleaning methods) which have an effect on the reliability of the overall sterile production process.

International Standard 13683

AS 4187 directs readers to ISO 13683 for information on validation of steam sterilization in health care facilities. This International Standard gives guidance for the application of ISO 9000 series quality management principles to the specialised situation of moist heat (steam) sterilization.

A 'validated' process is necessary to assure that sterilization occurs reliably and the process is consistently repeated. ISO 13683 draws attention to all points that must be considered in achieving these ends, and is recommended as a resource for those with educational qualifications in the field.

Validation requirements

Validation is an intensive exercise involving planning, evaluation of test methods and systems, acquisition of data from persons performing the testing of the Sterilizers and other related products, combined with the results from repeated physical and microbiological testing and considerable record keeping. The overall approach is more rigorous than routine monitoring activities. AS 4187 recommends that validation is done at least annually.

There are different requirements for different steam sterilizer types and AS4187 and ISO 13683 provides guidance in assessing the different types. Essentially, the principles are the same but the application varies between different types of steam sterilizers.

Revalidation

Revalidation is the repetition of part or of all of the tests done for 'validation', for the purpose of reconfirming reliability of the overall process of sterilization. AS 4187 sets the requirement for annual revalidation of each Sterilizer, if there have not been any significant changes to any of the factors listed in the Clause which may impinge on reliability of the overall sterilization process. Revalidation may be required more frequently, following every incidence of change to one or more of these factors during a particular year.

Monitoring of sterilizers in office based practice

Australian Standards and other guidelines

Australian Standard 4815 should be obtained and referred to. The Royal Australasian College of General Practitioners has developed 'Sterilization/Disinfection Guidelines for General Practice' (2000).

Sterilization in office practices should be no different from sterilization in other areas of health care. It is essential that personnel operating (and testing) sterilizers in office practices receive the training required to perform this function.

Most office practices will use steam Sterilizers of the bench-top type ('autoclaves'). A few office practices may have bench-top dry heat sterilizers, but as the required tests are performed, many will find that sterilization conditions are more reliably achieved in a steam sterilizer than in a dry heat sterilizer.

It is necessary that the sterilizer be serviced by skilled and experienced service people at least annually, and that this servicing involve checking the accuracy (calibration) of the temperature and pressure gauges and the readout given by any process recorder fitted or connected to the sterilizer.

Studies to determine penetration times of heat into examples of packs being sterilized are necessary for regular revalidation of each bench-top steam sterilizer (refer to AS 4817). It will usually be necessary for the owners of such sterilizers to have an outside contractor perform this type of testing. Firms providing this service and preventative maintenance of bench-top steam sterilizers should be able to do this testing during their regular visits. Records of results for all tests performed need to be maintained for each sterilizer in use.

Package size (time at temperature) testing

'Time at temperature' is the time during which the measured temperature is above the desired sterilizing temperature for the particular test thermocouple location or locations being assessed. Time at temperature testing makes it possible to verify the attainment of sterilizing conditions in packs or items being sterilized, and to determine:

- a. the maximum pack size that should be placed in a particular Sterilizer
- b. and or the maximum complexity of item that should be placed in a particular sterilizer e.g length and complexity of cannulars, lumens, should be considered.
 - time at temperature testing is used for steam or dry heat Sterilizers
 - temperature measurement is achieved by the use of temperature sensors, eg thermocouples, placed at specific positions in the Sterilizer
 - because of the density of textiles, maximum size and mass of textile packs are determined by the ability of the sterilizing agent to penetrate the load and the efficiency of air elimination from the load
 - thermocouples should be placed into torturous paths such as canulas and like places where steam penetration is likely to be impeded .
 - refer to AS 4187 for a detailed description of methods of temperature testing

Record keeping for sterilizing services

A significant part of any quality managed production system is the documentation of all that should be occurring, and documentation of what has been occurring, including all deviations from the norm. For hospital sterilizing services, this necessarily includes:

- investigations leading to decisions about pack specifications and design
- validation and routine monitoring records for sterilizers
- details of the contents of each sterilizer load (including traceability information)
- documentation of production problems and faults
- reports of difficulties experienced by users whenever they occur
- records of responses to all problems
- sterilizing personnel records including training received by each staff member plus occupational health and safety records

[Queensland Health Policy Statement: Retention and Disposal of Clinical Records Policy](#) provide the timeframe for the retention of clinical records (which includes sterilizing service records) for QH facilities.

Documentation: use and maintenance of equipment

It is important for the smooth operation of sterilizing services that the mechanical operating condition of all sterilizing and related equipment is assured and maintained. This is especially the case due to the critical nature of the items undergoing sterilization processes in health care settings. Validation of the process demands reliable and consistent operation of the equipment in use.

Reliable and consistent operation involves direct sterilizing process function as well as the function of both automatic and manual monitoring systems/components associated with the equipment. AS 4187 describes a range of tests for sterilizers and their recommended frequency, as well as recommended maintenance and monitoring activities for common equipment associated with sterilizing services.

Written and orderly records need to be kept of all routine maintenance provided to each piece of sterilizing equipment and each piece of associated equipment. These maintenance records are of importance equal to the records of measurement of the attainment of sterilization conditions in packs/loads being sterilized.

Records of the use of sterilization equipment will naturally be generated by the batch sterilization records and product recall requirements described above. These records need also to be retained for reference within the health care facility.

Product recall

Sterilizing services involve not just the production of sterile goods but management of the quality of processes involved in production. The ability of Queensland Health facilities and Districts to successfully defend possible litigation following patient infection which might be traceable to non-sterility of a product which should have been sterile depends in part on the maintenance of suitable and accurate records by the sterilizing service. One significant feature that should be present in any system is the ability to recall 'Sterilized' product (if necessary) after it has been issued by the sterilizing service to a 'user area' of the health care facility.

AS 4187 establishes minimum criteria governing the monitoring of Sterilizers in health care facilities and the records associated with in-hospital production of sterile goods. Queensland Health recommends a manual system using piggy back labels that are placed in the patient's peri-operative medical record as a cost effective system for product recall for further information refer to [CHRISP "Recommendations for manual batch labelling and manual tracking of instruments trays for Operating Suite"](#).

Product/equipment specification, selection and purchase

Planning

Determination for specification and purchase of equipment should be resultant on a facility capacity study, and an engineering feasibility study. Such studies will facilitate a holistic approach to purchasing and will ensure that the specification for new equipment will include any structural and or supply service considerations.

Capacity Study

A capacity study is an audit of the facilities current and future processing needs to determine the nature and volume of items to be processed. The capacity study may include but not be limited to:

- Total volume for each classification of product to be processed
- Maximum product volume to be processed per day or shift
- Current available resources for processing
- Condition audit of existing equipment
- Future changes in processing needs
- Size and complexity of reusable items for processing

Engineering Feasibility Study

An engineering feasibility study should include but not be limited to the investigation and documentation of:

- Building elements critical to the housing of equipment such as:
 - Floor space
 - Structural suitability
 - Access for both installation and maintenance
 - Air conditioning and ventilation

- Availability and suitability of support services such as:
- Electrical supply, both essential and non-essential
 - Water supply – Potable, non-potable, softened, Demineralised, hot, cold etc.
 - Chilled or heated process water.
 - Drainage, and venting
 - Medical gases
 - Fuel or gas
 - Compressed air
 - Special services such as fire systems, Building Management systems, security systems, data and communication systems

The Engineering Feasibility study should include general information on the availability of all related building elements and services and a basic condition audit of all critical items. From this report a determination can be made in relation to any new proposed equipment and this equipment's impact on the building and or working environment. For example; the installation of an additional steam sterilizer could require the subsequent need for the upgrade of steam supply services, or additional heat load may be generated from the equipment and an increase in air conditioning capacity will be required.

In addition to the following considerations a template for the procurement of sterilising and related equipment is available on the CHRISP website: refer to http://www.health.qld.gov.au/chrisp/sterilising/sterile_support.asp

General Considerations

Total Life Cycle Cost

The purchase and installation cost of new equipment represent a proportion of the equipments' "Total Life Cycle Cost". Calculations and comparisons should be made comparing these costs during the selection process. "Total Life Cycle Cost" could be calculated as follows:

$$\text{Total Life Cost} = P + I + [(Con + En + M) \times SL]$$

Where:

| | | |
|-----|---|--|
| P | = | Purchase cost of equipment |
| I | = | Installation cost (Including staff training) |
| Con | = | consumables cost per annum |
| En | = | Energy cost per annum |
| M | = | annual maintenance costs |
| SL | = | Expected Service life of Equipment |

Human Resource Management

The introduction of new equipment and technology can also impact upon human resources. For example:

- Automated processing may decrease the total amount of labour required
- An increase in departmental capacity through redesign may require a subsequent increase in human resources.
- Introduction of new technology and or equipment may require the up skilling and or training for operational, and Maintenance staff
- The redesign of a work place or addition or replacement of equipment may require a process of stakeholder consultation.

Purchase of sterilizers and associated equipment

Where appropriate standards are available, purchases and installation of Sterilizers and any associated equipment associated with sterilizing services shall comply.

Where an appropriate standard is not available, efforts should be made to determine current best practice in the processing step intended to be performed by the equipment. This should be followed by an assessment of the performance and design of available equipment in terms of the desired best practice.

The purchasing of water saving devices for steriliser and related equipment is best done at the time of procuring the new equipment. In the event that facilities are investigating the feasibility of installing water saving devices on current sterilizers and associated equipment consultation needs to occur between SS, engineering staff, service contractors and the manufacturer.

Purchase of ultrasonic cleaners

Purchase and installation of Ultrasonic cleaners and any associated equipment should meet the requirements of AS 2773.1 for 'non-portable' ultrasonic cleaners (covering 'built in' or 'console' types of machine), or AS 2773.2 for bench top sized machines. Any additional features intended to assist the cleaning of cannulated items in the ultrasonic cleaner should be assessed for their effectiveness by practical trial at the time of purchase or by obtaining reports from existing users of similar technologies.

Purchase of washer or washer/disinfector machines

Purchase of rack transport system washers ('tunnel' washers) and any associated equipment rack transport system washers ('tunnel' washers) should meet or exceed the requirements of AS 3836. The standard of control over cleaning achieved by 'indexing' rack transport washer systems compared to lower priced machines should be determined based on the intended level of cleanliness of the equipment being processed.

Purchases and of installation of batch washers and any associated equipment should be according to AS 2945, particularly with respect to load carrying equipment and the machines' ability to clean the intended variety of load being processed. Full thermal disinfection conditions are not necessarily required for every load type. Lack of this feature in the specification may alter the available choices of machine.

The type, size and number of washer or washer-disinfector machine(s) should be carefully assessed according to present and future sterilizing services workload as well as the processing capacity of the available machines. Architectural requirements, features and limitations may also be significant when a choice is being made. The ability of several batch washers to provide flexibility and temporary coverage for machine 'down time' should also be considered.

Ability to effectively dry instruments after washing should also be assessed, primarily in relation to drying effectiveness but also with respect to energy consumption and thermal 'load' on the air conditioning of the room in which the cleaning machine is located.

Consideration should be given to the capacity of the machine vs the total energy, requirements including but not limited to electrical power consumption, water usage, total amount of waste generated etc.

Purchase of drying cabinets

Drying cabinets for heated air drying of instruments should meet AS 2514. The intended variety of load items to be dried will dictate different features of the drying cabinet being purchased in terms of distribution of shelves, the presence of hanging space, and the ability to circulate heated air through particular types of items required to be dry.

Purchase of heat sealers

There is presently no Australian Standard for heat sealing equipment for use in sterilizing services. However, AS 4187 does provide some useful information about possible design and features of heat sealing machines.

Single use and single patient use items

In July 2006 the TGA issued a statement on the regulations for sterilization of single use devices:

“The TGA's policy is that if there is to be re-use it can only be done in premises licensed by the TGA and any re-manufacturing that takes place must be in accordance with the standards that apply to the original manufacture of the device. In other words, the sterilized SUDs must be of the same quality, performance and safety as the original device.”

The likelihood of an existing Queensland Health care facility meeting these standards is low.

In October 2006 the Therapeutic Goods Administration (TGA) also published Fact sheet 44 clarifying definitions relating to the regulation of the re-manufacture of single use medical devices.

Definitions that required clarification include:

Single Use:

Single-use means the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

Some single-use devices are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.

Single Patient use:

Single-patient use means more than one episode of use of a medical device on **one** patient only, the device may undergo some form of reprocessing between each use in accordance with the manufacturers instructions for reuse on the same patient.

Reuse:

Reuse means the repeated use or multiple use of any medical device which has undergone some form of reprocessing (cleaning, disinfection or sterilization) between each episode of use.

Open-but-unused:

Is the term used to refer to a SUD where the packaging has been damaged or opened but the device not used and/or did not come in contact with blood, tissue or body fluids.

Used:

For medical devices that are supplied sterile:

- The device has been placed into a wound or body cavity and comes into contact with blood or body fluids; or
- Has been opened but cannot be reprocessed because the manufacturer did not provide instructions on how to reprocess the device if the packaging is opened or damaged.

For medical devices that are supplied non-sterile:

- The device has been applied for its intended use.

Re-manufacture:

Refers to one or more of the following activities carried out on SUDs supply for reuse:

- Assembly the device; or
- Packaging the device; or
- Processing the device; or
- Fully refurbishing the device; or
- Labelling the device; or
- Assigning the device a new intended purpose by means of information supplied by on or in the labelling the instructions for use or advertising material;
-

In the process, the person responsible for undertaking these activities on a SUD has:

- Changed the intended purpose of the device;
- Certified the device is suitable for reuse; and
- Assumed the legal liability for the quality, safety and performance of the device.

Clarification has also been provided in relation to the fact that “the single act of cleaning a SUD is not to be regulated as a manufacturing activity”. A specific example of this type of item is crutches.

The TGA are discussing the possibility of recommending quality assurance processes to enable facilities to reprocess specific high cost items such as external fixation devices and halo braces for reuse.

Because the device was never intended or labelled as suitable for multiple reprocessing and multiple uses, the technical requirements which must be assured for safe multiple uses need to be checked and tested by the reprocessing facility.

Thus for the purposes of the present Queensland Health Infection Control Guidelines, re-use is not recommended. Exceptions to this recommendation are in particular device situations where full quality control measures are in place, and where the final quality assured cost per device of the proposed reuse is found to be less than the cost of using each device once only. QH is examining the possibility of putting in place Quality Assurance processes and a list of exempt devices where QH accepts responsibility for the reprocessing and reuse.

Further information may be obtained by contacting The Medical Device Governance Unit of Biomedical Technology Services.

Management of surgical instruments

Procurement

The procurement of surgical instruments has traditionally been the role of operating theatres and surgeons. Over time surgical instruments have become more sophisticated and intricate and are a costly asset to health care facilities. With this in mind it is imperative that surgical instruments are appropriately maintained, cleaned, disinfected or sterilized as per the manufacturer’s instructions.

Problems have arisen in facilities that do not have a co-ordinated and consultative approach when procuring surgical instruments. Issues such as inability to for sterilising services to adequately process the instruments or damage that is inadvertently caused to instruments during use or processing has been frequently reported and can be very costly to a healthcare facility.

It is recommended that when procuring surgical instruments the following strategies should be considered:

- Establishment of an Instrument Management Committee with representatives from key stakeholders eg Operating Theatre, Sterilising Services and asset managers and Utilisation of Instrument/Tray Purchase Checklist. For further information refer to CHRISP sample template “Terms of Reference Instrument Management Committee”:
http://www.health.qld.gov.au/chrisp/sterilising/sterile_support.asp
- All materials (including base materials and implants), used in manufacture of surgical instruments must meet internationally recognised material standards.

- The external surface of both the instruments should be a matt finish, minimising distortion from reflected light. The overall finish of the instruments shall be to a high quality, with no rough or sharp edges, visible rust, pitting or defects of any variety.
- The following design elements must be considered when procuring instruments:
 - the action of the instrument must be smooth.
 - where a box or screw joint is included in the design of the instrument, it shall not allow for movement at the joint in opposition to the action of the instrument.
 - the jaws of the instrument must close in apposition.
 - where the instrument includes toothed jaws in its design, there shall be no gaps in the teeth section when the jaws are closed.
 - where a ratchet is included in the design of the instrument, this shall allow for the clamping and unclamping of the ratchet with one hand and the design of the ratchet must prevent over-clamping.
 - where the design of the instrument includes teeth or blades these must not grate or catch when closing the instrument or during use.
 - where the design of the instrument includes a spring action with a pin, this pin must extend beyond the opposing shank when the instrument is compressed.
- Each instrument shall be unconditionally guaranteed against defects in material and workmanship. The item shall be replaced or repaired at no cost to the purchaser, when said instrument has been cared for according to the manufacturer instructions, and such a defect arises.
- Manufacturer of the instrument to provide training and training material (including assessment tools) to all relevant staff e.g. Sterilising Services and Operating Theatre
- Ensure that the surgical instrument has the following warranty requirements (which is to be provided without charge to the facility):
 - the surgical instrument shall be free from defects in materials and workmanship for at least twelve months from the date of acceptance of the equipment by the facility.
 - the renewal or replacement of any parts which are, or become defective, during this period
 - the cost of any maintenance specified by the manufacturer to be performed during this period; and
 - the cost of any labor and travel associated with fulfilling the warranty service.

Maintenance of surgical instruments

To ensure that the surgical instrument maintains its functionality a comprehensive care and maintenance program is required. Common issues associated with surgical instruments include rust and discoloration, damage to fine tips and contaminated cannula (e.g. orthopedic reamers) following reprocessing. In order to prevent damage it is essential that key stakeholders develop guidelines for the management and transportation of surgical instruments following use.

The most significant strategy to minimize potential issues is the removal of gross soil (blood and body fluids) at the point of generation. The following is a list of contributing factors is:

- allowing blood or body fluid to dry onto the instruments
- soaking the instruments in water
- soaking instruments in saline
- any and all long term soaking
- sterilizing instruments with ratchets closed
- improper use of the instrument
- rough handling/dumping of the instrument
- incorrect cleaning solutions and lubricants
- allowing water to dry on instruments
- instruments not being maintained (either by the manufacturer or a recognised instrument repairer e.g. Biomedical Technology Services)

Loan sets

Requirements for reprocessing loan sets

There are logistical constraints on the processing of loan surgical instrument sets caused by the pressure for the instruments to be used with as little delay as possible between facilities. However, these constraints should not compromise the processing of loan instruments. A good working relationship between the company/facility loaning the instruments and your facility's sterilizing department and operating suite is essential to facilitate the appropriate and timely processing of these sets.

Difficulties in steam sterilizing of loan instrument sets include the following:

- often inadequate time for the set to be properly processed either before or after the intended surgical case, or both
- uncertainty about the adequacy of instrument cleaning given in a previous facility
- sets are large and often transported in container systems which impede steam sterilization and/or effective drying, meaning that the set of instruments needs to be completely repacked into smaller trays for wrapped sterilization in the facility
- instruments are often specially designed and different from those usually processed, meaning that there may be delays as sterilizing personnel learn to identify a new range of instruments

Australian Standard 4187 (Clause 12.4.3) establishes a high standard to be attained in the processing of loan instruments:

'On receipt into the health care facility, loaned instruments shall undergo a complete routine cleaning and processing prior to sterilization in a pre-vacuum or downward displacement sterilizer. Lack of time shall not permit the cleaning process to be bypassed. Following use, all loaned instruments shall be subjected to the full cleaning process and sterilized as part of the decontamination process, before being returned to their source.'

This level of processing ensures that an adequate level of control over the processing of loan sets is assured in each facility using them, and that the instruments are not being transported in an inadequately cleaned and potentially damaging state.

A record of the processes given to a set of loan instruments by a previous facility should accompany its arrival in a new facility. Similarly, such a record should be generated by each facility when returning a loan set to the managing company/facility. These records should include the following:

- name of set and supplier
- name of facility processing the set
- method(s) used for cleaning eg manual, ultrasonic, batch washer (simple or multi-cycle), tunnel washer, and results of monitoring of this step (if available)
- results of monitoring of the steam sterilization cycle used to finally sterilize the loan instruments ('flash' or porous load cycle)
- name and signature of the person in the user facility responsible for final assurance that the loan instruments are ready for despatch

Loan instruments should not be 'flash' steam sterilized prior to use (AS 4187), however the sterilization process prior to return of instruments to the supplying company or facility may be 'flash' steam sterilization.

Detailed instrument identification, re-processing requirements, care and assembly information, should be supplied by and obtained from the company/facility supplying the loan instruments.

The size and complexity of pack and or products, making up the loan instruments being steam sterilized should not exceed the size and complexity of packs and or products in which sterilization conditions are known to be reliably attained in each facility. Pack sizes and or instrument complexity should not exceed the size established in each facility for the production of reliably dry wrapped sets of instruments. Maintaining the wrapped integrity of weighty loan instrument sets is also an issue, potentially requiring use of heavy duty wraps.

The potential for the mass of loan instrument sets to cause injuries to staff (eg back and wrist injuries) should be addressed. The maximum mass of individual sets needs to be locally determined.

DISINFECTION & STERILIZATION INFECTION CONTROL GUIDELINES

SECTION 5 THERMAL & CHEMICAL DISINFECITON

Section 5- Thermal and Chemical Disinfection

Thermal and chemical disinfection overview

A disinfection process is one that is intended to significantly reduce the number of pathogenic microorganisms on instruments by removing and/or killing them. Bacterial spores are not necessarily killed by disinfection, however their numbers may be reduced as a result of the cleaning process.

Disinfection may be high level, intermediate level or low level (refer to 'Equipment reprocessing: cleaning, disinfection and sterilization'). The level of disinfection required is governed by the intended use of the item, namely in a 'non-critical', 'semi-critical' or 'critical' site (refer to 'Spaulding's classification').

High level disinfection of previously cleaned instruments and equipment will produce items with very low likelihood of any pathogenic microorganisms remaining.

Disinfection: key points

- disinfection may involve chemical or thermal means. Thermal disinfection, where items can withstand it, is always preferable to chemical disinfection
- disinfection by any process is not appropriate where sterilization is necessary, i.e.: instruments or equipment used in invasive procedures ('critical' sites)
- where sterilization is possible, sterilization is preferable to high level disinfection
- disinfection is preceded by thorough mechanical or manual cleaning
- the method of disinfection chosen must be compatible with the particular equipment and suitable for the intended use of the equipment

Efficacy of disinfection

The efficacy of disinfection depends on:

- the number of microorganisms present on items to be disinfected
- biocidal action of the disinfectant or disinfection process (chemical concentration, pH, temperature, water quality, humidity)
- effective contact between the biocidal agent and the microorganisms (presence of crevices, lumens, hinges)
- biocidal agents and apparatus being appropriate for the item(s) being disinfected

Consider the manufacturer's directions for use, and the material safety data sheet for each disinfectant regarding the need for fume extraction. This is usually achieved using a fume extraction hood or by use of a recirculating fume cabinet using an activated charcoal filter.

Thermal disinfection

Thermal disinfection achieves high level disinfection when surfaces are in contact with heated water for an appropriate length of time. Shorter times are required at higher temperatures than at lower temperatures. Draft International standards will precipitate changes to conditions required for disinfection by thermal means using circulating hot water in a mechanical cleaning machine. AS 4187 will include the following instrument surface temperatures and times for washer/disinfectors:

- 70°C for 100 minutes, or
- 75°C for 30 minutes, or
- 80°C for 10 minutes, or
- 90°C for 1 minute

Indications for use

Thermal disinfection is recommended for reprocessing of:

- anaesthetic equipment and apparatus
- laundering (eg linen, mop heads)
- eating and drinking utensils including infant feeding equipment

Methods of thermal disinfection

- washer/disinfector machines are designed for cleaning instruments and utensils, complex equipment, such as anaesthetic breathing circuits, and laboratory glassware
- some washer/disinfectors clean baskets of instruments by impingement (forced spraying) from fixed or rotating arms in a closed chamber. This is a batch process
- continuous process washer/disinfectors provide a continuous process of washing and (usually) disinfection during which articles on a moving belt proceed through a series of chambers. The 'indexing' washer achieves complete isolation of each sequential stage, and can be programmed so that different loads receive different treatments. The different treatments may involve different degrees of thermal disinfection

A typical washer/disinfector cycle includes the following stages:

- cold water rinse
- warm water wash, with cleaning agent
- hot water rinse, with disinfection (eg 80-85°C for 2 minutes, or other intended conditions)
- drying by radiant heat or hot air

GENCA infection control guidelines

Flexible endoscopic instruments are particularly difficult to clean and disinfect, and easy to damage because of their intricate design and delicate materials. Gastroenterological Nurses College of Australia Inc (GENSA) 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 and can be located via the CHRISP website at http://www.health.qld.gov.au/EndoscopeReprocessing/documents/ic_guide_endo_2ed.pdf

Chemical disinfection

Chemical disinfection is the application of a liquid chemical agent to eliminate the majority of pathogenic microorganisms, with the exception of bacterial spores, on inanimate objects or surfaces. Chemical disinfectants:

- may be inactivated in the presence of organic matter; thorough cleaning of the item must occur prior to contact with chemical disinfectants for the agent to be effective
- must be suitable for the intended use of the equipment (i.e.: choice of disinfectant and process depends on whether low, intermediate or high level disinfection is indicated)
- must be compatible with the particular equipment
- must be used in the appropriate concentration, and have sufficient contact with all surfaces of the item for an appropriate length of time.

Examples of use in health care settings

- endoscopic equipment (where unable to be sterilized)
- disinfection of environmental surfaces (where indicated)
- disinfection of 'non-critical' equipment
- disinfection of intravenous access devices/'ports', medication vials
- preservation of specimens

Alcohol

Alcohols (ethyl and isopropyl alcohol) are rapidly bactericidal, tuberculocidal, fungicidal and virucidal, but not sporicidal. They denature protein through dehydration. The optimum concentration is 60-90% by volume. Alcohol is used to:

- disinfect the surface of ampoules/vials prior to access
- disinfect cleaned surfaces (following initial clean with detergent and water) eg trolleys, counter tops, laboratory benches where required
- disinfect surfaces of some equipment eg stethoscope diaphragm, resuscitation manikins
- assist in the drying of some equipment surfaces
- disinfect skin prior to invasive procedures (refer to 'skin antisepsis')

Comments:

- evaporates at room temperature. The concentration of alcohol diminishes as it evaporates and the action may be bacteriostatic at concentrations below 50%
- flammable at concentrations recommended for disinfection; precautions are required to prevent accidental ignition; unsuitable for use in operating rooms
- inactivated by organic material; prior cleaning is required
- inexpensive and readily available
- there is no residual activity after the alcohol has completely evaporated
- generally unsuitable for application to mucous membranes
- damages materials such as rubber, plastics. The lens cement of optical equipment is weakened by disinfection with alcoholic solutions.

Chlorine (sodium hypochlorite)

Sodium hypochlorite has broad spectrum antimicrobial activity; however it is inactivated in the presence of organic matter. It is used for the treatment of water, disinfection of laundry items, dental appliances and clean environmental surfaces.

Comments:

- sodium hypochlorite is inactivated by organic material; prior cleaning is required for chlorine compounds to be effective
- low concentrations of sodium hypochlorite are effective and rapidly disinfect clean surfaces
- hypochlorite solutions may bleach and damage the texture of fabrics and corrode or damage materials eg stainless steel instruments and utensils
- solutions are unstable; are to be prepared fresh for use and to be used within 24 hours
- requires direct contact with surfaces (unsuitable for channels/crevices etc) for up to a maximum of 10 minutes
- affected by temperature and water pH
- concentration of chlorine-based disinfectants refers to available chlorine, which is a measure of oxidising power. The available chlorine content of a concentrated solution is expressed as percent w/v or, part per million (ppm). One percent corresponds to 10,000 ppm available chlorine

| | Available Chlorine (parts per million) | | | | |
|-------------------|--|---------|---------|--------|--------|
| | 10,000ppm | 5000ppm | 1000ppm | 500ppm | 125ppm |
| Household bleach* | 1:5 | 1:10 | 1:50 | 1:100 | - |
| Milton** | 'neat' | - | 1:10 | - | 1:80 |

*Household bleach (5%± sodium hypochlorite) = 50,000 ppm available chlorine

**Milton (1% sodium hypochlorite) = 10,000 ppm available chlorine

Formaldehyde

The liquid form is bactericidal, tuberculocidal, fungicidal, virucidal and sporicidal. However, its carcinogenic properties limit its use. The aqueous solution (Formalin) contains 37-40% w/v formaldehyde. Formaldehyde is classified as a high level disinfectant and is chiefly used to preserve anatomical specimens.

Comments:

- vapour is extremely irritating to the eyes and respiratory tract at low concentrations (1-5 ppm) which can also be detected by smell
- care must be taken to avoid contact between any free source of free chlorine, including chlorine disinfectants, and formaldehyde eg in histopathology laboratories and mortuaries

Glutaraldehyde

Glutaraldehyde is a liquid disinfectant recommended for the purposes of high level disinfection of heat-sensitive endoscopic instruments (refer GENSA Infection Control Guidelines).

Comments:

- refer to manufacturers directions for use of CIDEX™ and AIDAL™ as these products differ in relation to activation, duration of use and monitoring of in-use concentration
- care must be taken to avoid the introduction of organic material or excess water by unclean or wet instruments which will reduce the concentration of glutaraldehyde
- aldehydes fix protein to instrument surfaces; meticulous cleaning must occur prior to immersion
- workplace health and safety issues are well-documented

Indications for use of glutaraldehyde

There are two fundamental issues important to the use of glutaraldehyde, and both must be addressed by users:

- whether sterility is required for the instruments/equipment being processed, as distinct from high level disinfection; and
- whether there is adequate workplace protection available for people who are using glutaraldehyde

Glutaraldehyde as a sterilizing agent

It is technically possible to achieve sterilization by immersing items in glutaraldehyde, however, this requires many hours to accomplish and is not a practical means for achieving sterilization. Users need to consult manufacturers' data on this point. Glutaraldehyde is more commonly used for short immersion times to produce high level disinfection.

Items requiring sterility (eg arthroscopes, hysteroscopes, laparoscopes and their accessories, cystoscopes and all other instruments entering normally sterile locations in the body) must have been processed by a recognised sterilization method. Steam sterilization, or one of the three low temperature sterilization methods are suitable to achieve this end.

Glutaraldehyde as a disinfecting agent

In cases where sterility is unnecessary and thermal disinfection is inappropriate (a good example is the reprocessing of gastrointestinal flexible endoscopes), high level disinfection using a TGA registered instrument grade liquid chemical disinfectant is indicated.

NOTE: The strong and appropriate recommendation (from a number of sources) is for instruments to be meticulously cleaned prior to immersion in the disinfectant. They are then rinsed free of residual glutaraldehyde (using water of known microbiological quality) after disinfection to protect both patient and staff from contact with the irritant and hazardous active agent of the disinfectant solution.

NOTE: Temperature requirements and other factors affecting the efficacy of glutaraldehyde should be reviewed prior to use. Consider manufacturer's directions.

Efficacy of glutaraldehyde

The Therapeutic Goods Administration (TGA) governs the marketing in Australia of all therapeutic goods including liquid sterilants and 'instrument grade disinfectants', such as glutaraldehyde. At the present time no new glutaraldehyde preparations are allowed to be marketed without TGA registration involving evaluation of their efficacy, adequacy of labeling, and assurance of Good Manufacturing Practice in their manufacture. Continued marketing of glutaraldehyde preparations which were on the Australian market prior to 1 January 1998 is occurring with 'sponsoring' firms already having submitted applications for retrospective registration. Through this process of TGA registration users can now be assured of the efficacy of glutaraldehyde preparations on the Australian market.

Soaking times/immersion times

The issue of soaking times for instruments being disinfected in glutaraldehyde is somewhat controversial. Many factors influence successful disinfection. The time for which an instrument is soaked in glutaraldehyde is but one factor, and is inversely governed by the temperature and concentration of the disinfectant solution. However the relationships are not linear.

Differences in recommended soaking times are seen between different manufacturers of glutaraldehyde disinfectants as well as between professional organisations representing users of the disinfectant. AS 4187 recommends that users consider manufacturers' recommendations (requiring users to note the instructions for the particular glutaraldehyde preparation in use).

The infection control literature recommends a soaking time of 20 minutes for all endoscopic equipment undergoing high level disinfection, following careful cleaning, to satisfy the time requirements for inactivation of mycobacteria (Alvarado and Reichelderfer, APIC Guidelines for infection prevention and control in flexible endoscopy. AJIC 2000;28:138-155). The GENSA Guidelines for Infection Control in Endoscopy (1999) recommend a soaking time of 10 minutes for endoscope disinfection following a meticulous and repeatable regime of cleaning, with the exception of bronchoscopes, which require a soaking time of 20 minutes to inactivate mycobacteria.

Regardless of the soaking duration chosen, users must ensure that all equipment is meticulously cleaned prior to immersion and that the solution is in contact with all surfaces of each instrument during immersion, avoiding air bubbles trapped inside lumens.

Glutaraldehyde concentration

Whether glutaraldehyde preparations are acid or alkali based, the recommended in-use concentration of each preparation is an important point for effectiveness as a disinfectant. In order to achieve a nominal in-use concentration, manufacturers design their chemical formulation so that the concentration commences at an elevated level. As the concentration of active glutaraldehyde decreases over time, it remains above the minimal effective concentration up until the manufacturers recommended date of discard. Other factors will shorten the time that a solution can be used, as concentration will be affected by evaporation, dilution and carry-over.

‘Evaporation’ is simply the loss of glutaraldehyde from the solution through the process of conversion to a gaseous state and subsequent release into the air above the solution. This is the major factor requiring proper ventilation of any area in which glutaraldehyde is used.

‘Dilution’ is the reduction of the concentration of glutaraldehyde in the disinfectant solution due to the presence of droplets of water adhering to instruments following the final rinse of the cleaning stage. These droplets lower the concentration of glutaraldehyde in the disinfectant solution by a small amount by increasing the ratio of water to active ingredient.

‘Carry over’ is the gradual loss of disinfectant solution due to adherence of some of the solution to the surfaces of each instrument as instruments are removed from the solution. This residual material is toxic and must be rinsed off the instrument(s) after disinfection.

It follows that with evaporation, dilution and carry over, there is for each situation a point in time after commencement of use at which the concentration of glutaraldehyde is no longer reliable for disinfection and the solution must be replaced. This ‘end point’ will vary according to the type and number of instruments being immersed, as well as the number of days that have elapsed since use of the solution commenced. To avoid this potentially serious situation occurring, users must follow procedures involving monitoring of liquid concentration and replacement of the disinfectant with fresh solution at a frequency based on the results of concentration monitoring.

With relatively small numbers of instruments being processed, safe usage for as long as four weeks is possible with some brands of glutaraldehyde solution. Common practices used to avoid the ‘end point’ even being approached are to replace glutaraldehyde solutions on a weekly basis, or even daily in known high usage situations. Solutions are also discarded on a daily basis after use if the disinfectant is not stored in its in-use receptacle, as Workplace Health and Safety regulations prohibit recanting of solutions.

Monitoring glutaraldehyde concentration

Determining the replacement frequency requires measurement of in-use concentration. Monitoring strips ('dip in the solution' type) are available from the various suppliers of glutaraldehyde preparations. However, the strips need to be chosen to be compatible with the particular chemical formulation of the preparation in use. Chemical analysis of sample(s) of the solution in a laboratory is the only alternative to monitoring strips. Whilst laboratory analysis is more accurate than the available monitoring strips, the accuracy afforded by use of properly chosen strips is adequate for most purposes. Laboratory monitoring does provide a method for checking the accuracy of the monitoring strips where this is questioned.

Workplace health and safety issues

The workplace health and safety issues associated with use of glutaraldehyde disinfectants are significant as evidenced by the number of documented cases of skin and/or respiratory sensitisation reported by personnel involved in their handling or use. Staff wearing contact lenses who work in settings where glutaraldehyde is used should consult an ophthalmologist regarding the suitability of their lenses. Such staff may experience eye irritation or find that lenses become discoloured due to impregnation with glutaraldehyde. The issues are covered in detail in a report prepared in 1994 under the National Industrial Chemicals Notification and Assessment Scheme.

Glutaraldehyde is classified as a hazardous substance when its concentration is greater than 0.1% w/w, according to the National Occupational Health and Safety Commission's Approved Criteria for classifying hazardous substances. If a substance is classified as a hazardous substance, then its use is regulated by Part 13 of the Workplace Health and Safety Regulation 1997. This requires that a worker is not exposed to more than the maximum allowable exposure standard relevant to that substance. In the case of glutaraldehyde this is the airborne concentration in the worker's breathing zone, and workers need to be aware that maximum exposure limits exist. The Regulation governs all of the exposure standards, labelling, surveillance, personal protective equipment, training, management of spills, record keeping relevant to both employers and employees, and readers of this section are referred to it for further information.

In relation to employers' responsibilities to protect workers from exposure to hazardous substances, the Division of Workplace Health and Safety has prepared a useful 'Case Study' that demonstrates the steps an employer must take to comply with the Regulation as it applies to a facility using glutaraldehyde for disinfection. It follows that there may be requirements for monitoring and health surveillance if the risk assessment process described in the Case Study indicates a significant risk.

For advice on these issues, contact the Division of Workplace Health and Safety on telephone Freecall 1800 177 717.

Ventilation and air quality monitoring

All areas where glutaraldehyde is used should be properly ventilated. This may be by means of controlled air flow that exhausts to atmosphere or by purpose designed recirculating fume cabinets with activated charcoal chemical vapour absorbent filters. If recirculating fume cabinets are being considered, their ability to maintain adequately low levels of glutaraldehyde vapour in the breathing zone of operator(s) needs to be assured prior to installation. There is also a need for the activated charcoal cartridge within a recirculating fume cabinet to be regularly replaced. The frequency of its replacement needs to have been specifically determined based on the amount of usage of the fume cabinet and the level of control of atmospheric glutaraldehyde required.

Where ventilation is unable to control the operator's exposure to glutaraldehyde from inhalation, personal protective equipment such as a respirator may be necessary.

Whichever ventilation method is used, an assessment by a skilled occupational hygienist who is able to measure the concentration of glutaraldehyde vapour in the operator's normal breathing zone is necessary when an installation is first completed (or if it has never been tested before). Testing involves setting up equipment capable of sampling air in the breathing zone and the taking of a number of 15 minute samples in various locations.

To discuss and/or have this testing performed, contact Public Health Services Laboratories, Queensland Health, at Coopers Plains, Tel: (07) 3274 9106, Fax: (07) 3274 9177, or the Safety in Mines Testing and Research Station (SIMTARS), Redbank, Tel: (07) 3810 6336; Fax: (07) 3810 6388. These specialists provide a written report covering the results measured as well as recommendations about workplace health and safety issues observed at the time of testing in the facility. The cost of having this on-site analysis done will vary depending on factors such as location, number of sites, number of samples needing to be taken, and travel and accommodation costs (if applicable).

At the time of preparation of this section, the average cost for testing for a survey in the Brisbane area was \$700 - \$1000. This covers collection of samples, laboratory analysis, and written report containing results, observations and recommendations. Where testing is done for Queensland Health facilities by Centre for Public Health Services Laboratories' personnel, only travel and accommodation costs will have to be met. It would be best for individual facilities or Health Services Districts to seek a quotation. Some savings could possibly be made by way of a number of facilities in a geographical area arranging for testing at the same time.

Costs of this testing can be significant but repeated testing is only needed when there is a variation in the equipment, layout or ventilation system or an employee believes they are being exposed. Due to the limited number of testing personnel available in Queensland and the impracticality of frequent repeat testing, a policy of testing once only (provided there is no subsequent change in the process or the ventilation installation) is regarded as adequate monitoring of this issue. Some facilities may decide to have more frequent monitoring performed, but this is not required if there has been no change.

Monitoring of the reliable operation of ventilation systems, knowledge of the effectiveness of recirculating fume cabinets and/or observance of the recommended regimen for replacement of activated charcoal filters (where used) assures the continuing minimisation of hazard to workers due to glutaraldehyde vapour in the breathing space.

Personal protective equipment

Gloves of material impermeable to glutaraldehyde, full facial shield and water proof gowns or aprons are necessary for personal protection wherever glutaraldehyde preparations are used. Also, careful design of the area where disinfection is being performed and the procedures used will minimise the likelihood of skin exposure to glutaraldehyde.

Glove materials may be nitrile or latex with nitrile having more resistance to glutaraldehyde 'break through'. The use of single-use gloves (changed with each procedure) avoids many of the problems of 'break through'. Users of latex gloves need to be aware that the time for glutaraldehyde 'break through' may vary widely but is usually greater than one hour. Glutaraldehyde also 'breaks through' nitrile glove material following repeated use without washing residual disinfectant off gloves prior to storage between procedures.

The 'sleeve length' of gloves influences the risk of exposure to glutaraldehyde as well as the work practices aimed at minimising the risk of skin contact along the arms or wrists.

A suitable 'spill kit', designed for appropriate action in the case of a spillage of glutaraldehyde, is advisable. One supplier of spill kits suitable for spills up to 15 litres is Endomed Pty Ltd, 1/18 Paisley Drive, Lawnton, 4501, Telephone (07) 3881 1883.

Continued use of glutaraldehyde: difficult in-use situations

Difficulties in bringing under control the workplace health and safety issues relating to protection of health care worker(s) from exposure to glutaraldehyde as a hazardous substance may preclude its use in some situations. Employer responsibilities towards employees may lead to a decision in some situations to eliminate glutaraldehyde from a facility. In addition, practical issues precluding the use of glutaraldehyde where sterility is required may result in a decision to avoid its use in some situations.

These difficulties have created the impression that a state-wide or national 'ban' on the use of glutaraldehyde is imminent. This is not the case. Safe use of glutaraldehyde is technically and practically feasible, and in view of this Queensland Health has no plan to generally limit its use in facilities over which it has jurisdiction.

Eliminating the use of glutaraldehyde for sterilization purposes

Where surgical procedures are invasive, instruments must be sterile. In previous years glutaraldehyde has been widely used for processing heat sensitive invasive equipment but it is now a Queensland Health risk management priority that use of glutaraldehyde for this purpose be eliminated. The following points should be considered for action to eliminate the use of glutaraldehyde:

- increase available inventory of heat sensitive instruments, particularly rigid endoscopes
- replace older design instruments by newer design steam sterilizable ones and use steam sterilization
- install low temperature sterilization equipment appropriate for the instruments in use
- organise better shared use of expensive instrument inventory belonging to the District
- manage operating theatre case lists in a way that optimises use of the available instruments in association with their sterile processing requirements

Ortho-phthalaldehyde (OPA)

Ortho-phthalaldehyde (OPA) is an instrument grade liquid disinfectant recommended for the purposes of high level disinfection of heat sensitive instruments. The increased level of microbial activity of 'OPA' lends itself to shorter disinfection immersion times than other available high level chemical disinfectants.

'OPA' (0.55%) is a high level disinfectant suitable for reprocessing clean, heat sensitive, semi-critical medical and dental devices. It does not sterilize devices; items requiring sterilization should undergo an appropriate, biologically monitored sterilization process.

The minimum effective concentration (MEC) of 'OPA' is 0.3%. The solution may be reused for a maximum of 14 days, and should be monitored using Solution Test Strips to ensure that the MEC is above 0.3% during this time. No activation of the product is required. Once opened, the shelf life of the unused portion can be stored in the original sealed container for up to 75 days prior to use. Prior to disposal, the solution must be inactivated using Glycine. The product is designed to be used in both manual (bucket and tray) systems as well as automated endoscope reprocessors. The manufacturer's instructions should be consulted.

Thorough cleaning of instruments, including all lumens, prior to immersion should involve the use of a near neutral, low-foaming and easily rinsed detergent. Any residual contamination reduces the effectiveness of 'OPA'. The item is to undergo cleaning and drying prior to immersion in 'OPA', immersed completely for at least 10 minutes at 20°C (room temperature), and rinsed according to manufacturer's instructions. Tests have shown that 'OPA' is a more rapid tuberculocidal agent than other high level chemical disinfectants; this is achieved following immersion of a thoroughly cleaned instrument for 10 minutes.

Comments:

- stable over a wide pH range
- does not fix proteinaceous material to instruments
- is compatible with a wide range of instrument models and materials
- does not require activation
- non-irritating to personnel
- stains skin and surfaces
- costly in comparison to glutaraldehyde

Workplace health and safety

Direct contact with 'OPA' may cause irritation to eyes and skin, and temporary staining of the skin. Repeated contact may cause sensitisation. Personal protective equipment (eg gloves with sleeve length to protect arms or wrists made of latex, nitrile, butyl rubber or synthetic copolymer; full face shield; fluid resistant gowns) should be used in concordance with AS 4187 requirements.

'OPA' vapours may cause respiratory and eye irritation. The agent should be used in a well-ventilated area in closed containers with tight-fitting lids. Local exhaust hoods may be required if the area is not adequately ventilated.

Peroxygen biocide

The one available peroxygen disinfectant (Virkon™) may be used on environmental surfaces; however surface disinfection is not routinely required in health care settings.

Phenolics

Phenolics are classified as low level disinfectants. They are absorbed by porous materials, and the residual disinfectant may cause tissue irritation. Phenolics are bactericidal, virucidal, fungicidal and tuberculocidal.

Comments:

- mainly used for environmental disinfection of non-porous surfaces, such as laboratory surfaces
- not for routine hospital use

Quaternary ammonium compounds

Suitable for low-level disinfection of clean surfaces; not recommended for routine use in health care facilities. Cement, synthetic rubbers and aluminium may be damaged by quaternary ammonium compounds, especially if an anti-rust compound has been added to the solution. Inactivated in the presence of organic matter.

Purchasing chemical disinfectants

The following is a list of actions and principles to assist in rationalising the range of chemical disinfectants being purchased for use in individual facilities:

Formulate a policy for the selection and application of chemical disinfectants in the health care facility

Determine the overall use of disinfectants through a comprehensive survey of all departments and prepare a list of currently purchased products and the purposes for which they are used. The concentration in use should also be noted.

Use the list as a basis for eliminating the use of disinfectants when:

- sterilization is required
- disinfection by hot water or steam can be carried out
- the use of an antimicrobial agent is unnecessary

Develop policies for which chemical disinfectants are required (applications and in-use concentration) for disinfection of hospital equipment, for example

- phenolic disinfectant in discard jars in bacteriological laboratories
- glutaraldehyde or OPA used for disinfection of endoscopic instruments
- disinfection of the hospital environment

Disinfectants for cleaning

It has been demonstrated by Ayliffe et al (1967) and other investigators that the benefit of including an antibacterial agent in the cleaning solution is restricted to the short period of wet contact. Residual disinfectant, which may remain on the floor, is inactive in the dry state and does not retard the rate or decrease the level of re-contamination in areas where uncontrolled movement of people and equipment occurs. Sodium hypochlorite is recommended where disinfection is required following cleaning of blood spills (refer 'blood spill cleaning procedure'), and alcohol (eg isopropyl alcohol-impregnated wipes) may be used on clean trolley tops and similar surfaces that have been physically cleaned.

Other significant issues for disinfectant purchasing

- disinfectants should have TGA approval
- the successful implementation of a disinfection policy depends on the provision of information to the staff throughout the hospital
- the responsibility for preparing dilutions should be centralised and placed under the supervision of a pharmacist
- the solutions that are distributed to wards and departments should be ready for use and clearly labelled to identify the type of disinfectant
- the selection of a type or brand should be based on compatibility with materials with which it may come in contact during use, the risk of harm to the user or the articles treated, the intended purpose of the disinfection process, and cost-effectiveness

Endoscopic instruments and their accessories

Fibre-optic endoscopic instruments can be divided into rigid endoscopes (laparoscopic instruments) and flexible endoscopes. There are significant processing and usage differences between rigid and flexible endoscopes.

However, both rigid and flexible endoscopes (and their accessories) require meticulous cleaning prior to undergoing the appropriate sterilization, or high level disinfection, process.

Rigid endoscopes are categorised as 'critical' items (refer to 'Spaulding's classification'), and must be sterilized between uses. Flexible endoscopes are categorised as either 'critical' or 'semi-critical' in relation to the nature of their use. Those classified as 'critical' must be sterilized. In the case of 'semi-critical' flexible endoscopes, sterilization is preferred but not mandatory. Where sterilization of 'semi-critical' flexible endoscopes is not possible, high level chemical disinfection is required.

Both rigid and flexible endoscopes can be sterilized by low temperature processes, although some methods may be unsuitable for some flexible endoscopes. Many rigid endoscopes can also withstand steam sterilization. Endoscopes with no attached lenses, fibre-optic light carriers or cables, and suitable accessories, may be sterilized by steam (refer to 'steam sterilization' and 'low temperature sterilization processes'). In all instances, the instrument manufacturer's instructions as to the preferred method of sterilization should be followed.

A wide range of accessories is available for both invasive and non-invasive endoscopes, including forceps, laparoscopic scissors, diathermy, snares, sphincterotome knives, and lasers. Accessories used in conjunction with rigid and flexible endoscopes should be treated as 'critical' items and sterilized.

Summary of processing requirements

| | Rigid endoscopes | Flexible endoscopes | Flexible endoscopes | Accessory instruments |
|-------------------------------|---|----------------------------------|---|---|
| Spaulding's classification | Critical | Critical | Semi-critical | Critical |
| Appropriate process | Sterilization | Sterilization | -High level disinfection (sterilization where possible) | Sterilization |
| Suitable process alternatives | - Steam sterilization -Low temperature sterilization* | -Low temperature sterilization ♦ | -Chemical disinfection with glutaraldehyde or OPA -Low temperature sterilization ♦ | -Steam sterilization -Low temperature sterilization* |

* method dependent on location of sterilizing machinery and need for wrapped product (wrapped is preferred)

♦ method dependent on instrument type, materials and facilities – consult instrument manufacturer

Rigid endoscopes

Invasive ('critical') endoscopes are mainly laparoscopes, and rigid instruments with no operating channel. According to AS 4187, arthroscopes and laparoscopes which are inserted into sterile body cavities shall be sterile. Rigid endoscopes are classified as 'critical' (refer 'Spaulding's classification') and must be sterilized. Although high level disinfection has been used in the past, it is now considered inadequate.

Sterilization of rigid endoscopes

Sterilization of invasive devices attains a higher standard of infection control than high level disinfection can achieve, is more thoroughly controlled, and cycle times are comparable with immersion in disinfectants.

Low temperature sterilization methods (ethylene oxide, peracetic acid or hydrogen peroxide plasma sterilization processes) or steam sterilization may be used for rigid endoscopes. Low temperature methods are preferable as they may reduce instrument damage caused by repeated exposure to steam (even when the instrument is steam compatible). Refer to 'steam sterilization' and 'low temperature sterilization processes'.

Laparoscopes and accessory instrumentation shall be dismantled, cleaned (specially designed ultrasonic irrigators are available to assist cleaning), dried thoroughly and then reassembled prior to sterilization.

Flexible endoscopes

Flexible endoscopes can be classified according to Spaulding's classification as 'critical' (e.g. invasive) instruments that penetrate the skin or are inserted into a sterile cavity, or as 'semi-critical' (e.g. non-invasive) items that are in contact with intact mucous membranes. However, even in cases where items are not classified as 'critical', sterilization is preferable to high level disinfection.

Sterilization of flexible endoscopes

Steam sterilization is unsuitable for flexible endoscopes because they are unable to tolerate temperatures greater than 60°C. Low temperature sterilization methods are required when sterilization of flexible endoscopes is required (i.e.: flexible endoscopes categorised as 'critical') and, where sterilization is desired (i.e.: flexible endoscopes categorised as 'semi-critical') but not mandatory.

Low temperature systems such as ethylene oxide, and peracetic acid sterilization systems may be used to sterilize flexible endoscopes. However, the hydrogen peroxide plasma sterilization process is not commonly used for reprocessing flexible endoscopes due to the following technical problems:

- very long narrow lumens and those closed at one end are unsuitable for sterilization using the hydrogen peroxide plasma process
- process compatible packaging must be used
- biological indicators are required for routine monitoring with lengthy incubation periods
- entire cycle takes 75 minutes, making hydrogen peroxide plasma impractical for routine processing of most gastroenterological endoscopes

High level disinfection of flexible endoscopes

Non-invasive or 'semi-critical' items may either be sterilized or high level disinfected, however sterilization is the preferred method whenever possible. In the case of bronchoscopes that are high-level disinfected, care must be taken to observe the contact time required to inactivate *Mycobacterium tuberculosis*.

High level disinfection is a suitable process for non-invasive ('semi-critical') endoscopes such as gastroscopes, duodenoscopes, sigmoidoscopes, proctoscopes, colonoscopes, bronchoscopes, and laryngoscopes.

Reprocessing of anaesthetic and respiratory equipment

Most anaesthetic machines and breathing systems are contaminated to a minor degree with microorganisms. Equipment that is in direct contact with the patient (breathing circuits and masks) becomes more heavily contaminated.

All anaesthetic equipment that comes into contact with a patient's body fluids (including saliva) must be changed, cleaned and thermally disinfected before use on another patient. This includes equipment that has come into indirect contact with the anaesthetist's hands, which may be contaminated with blood, saliva or other body fluid. Additionally, unused items introduced into the anaesthetic work-field should be regarded as dirty and reprocessed. Attachment 3 outlines recommended processing information for anaesthetic and respiratory equipment.

To protect staff from aerosols generated during manual cleaning processes, preference should be given to the use of washer/disinfectors for the washing, disinfecting, rinsing and drying of respiratory apparatus. Most units automatically process through pre-wash, disinfection, rinse and drying cycles.

Anaesthetic equipment: cleaning methods

Thorough cleaning of all instruments and equipment is an essential prerequisite in disinfection and sterilization processes:

- all systems must be disassembled completely to allow unrestricted contact of all parts with the cleaning and disinfection process
- measuring instruments and pressure gauges must be processed separately according to the recommendations of the manufacturer
- lumens of non-disposable endotracheal tubes, airways, facemasks, laryngeal masks, anaesthetic breathing circuits and cobb's connectors are to be placed over the appropriate nozzle/water jet on the washer/disinfector to ensure proper cleaning and rinsing
- the manufacturer's instructions for cleaning and reprocessing of anaesthetic equipment should be followed
- mechanical washer/disinfectors must not be overloaded

The cleaning of external surfaces of anaesthetic machines and associated equipment should occur on a regular basis; the use of detergent and water is sufficient. The internal components do not require routine cleaning and disinfection.

Anaesthetic equipment: disinfection requirements

Anaesthetic respiratory equipment is classified as 'semi-critical' (refer to 'Spaulding's classification') and requires thermal disinfection for reprocessing. Sterilization of anaesthetic and ventilator equipment is generally unnecessary.

Refer Australian Standard AS 4187 and The Australian and New Zealand College of Anaesthetists Policy on Infection Control in Anaesthesia (1995).

Water temperatures for thermal disinfection

Rinse water temperature shall be between 80°C and 86°C (>80°C). Refer to 'Water temperature for thermal disinfection'.

Monitoring of washer/disinfectors

The requirement for routine microbiological monitoring of washer/disinfectors is unwarranted, as there are no current standards to determine if the washer/disinfector is microbiologically safe. Washer/disinfectors and instruments should be visually inspected and cycle parameters monitored to determine if the machine is functioning correctly:

- perform visual inspection and documentation of time at temperature. Instruments and equipment should be free from detergent and rinse additive residues
- presence of chemical residue (if the washing machine is functioning as designed with temperature, detergent, wash and rinse pressure all at the correct levels, there will be virtually no chemical residue left on instruments)

Standardized test devices are available for testing the effectiveness of wash processes. These tests are based on a visual indication of soil removal effectiveness.

Perform regular thermocouple testing of disinfection temperatures:

- rinsing 40°C to 50°C;
- washing 50°C to 60°C;
- disinfecting 80°C to 95°C, for up to 10 minutes

Drying

Drying reduces the risk of contamination during inspection and assembly of instruments:

- drying cabinets should be used for drying anaesthetic equipment. Drying cabinet operating temperatures shall be within the range 65°C to 75°C
- on completion of the cycle, the items shall be removed and placed in the anaesthetic apparatus drying machine (if drying cycle not installed). Tubing and other items with lumens shall be placed over appropriate connectors to ensure hot air dries all surfaces. Drying facilities may be available within the washer/disinfector

Single use items

- use single use sachets of lubricant for insertion into the patient's airway
- avoid using multi-dose vials. Such vials should always be accessed with a clean needle and syringe and dedicated for single patient use only

Soaking or 'cold sterilization'

Soaking or 'cold sterilization' (immersion of the different items in solutions containing disinfectants eg aldehydes) has a relatively high failure rate due to dosing errors, insufficient contact time (air trapping) as well as disadvantages of toxicity, skin irritation and allergy, and environmental concerns.

Management of patients with confirmed or suspected pulmonary tuberculosis

Ideally, elective operative procedures on patients who have pulmonary tuberculosis should be delayed until the patient is no longer infectious. However, if operative procedures must be performed, they should be done, if possible in operating rooms that have anterooms and staff must observe airborne precautions (refer to 'additional precautions').

For operating rooms with anterooms, the doors to the operating room should be closed, and traffic into and out of the room should be minimal to reduce the frequency with which the door opens and closes.

- a bacterial filter should be placed as close as possible to the patient to help reduce the risk of contamination of the anaesthetic equipment (ventilator and CO₂ absorbers) and prevent the discharge of tubercle bacilli into the ambient air
- preference may be given to a disposable anaesthetic breathing circuit with appropriate filters
- detergent and water is sufficient for environmental cleaning

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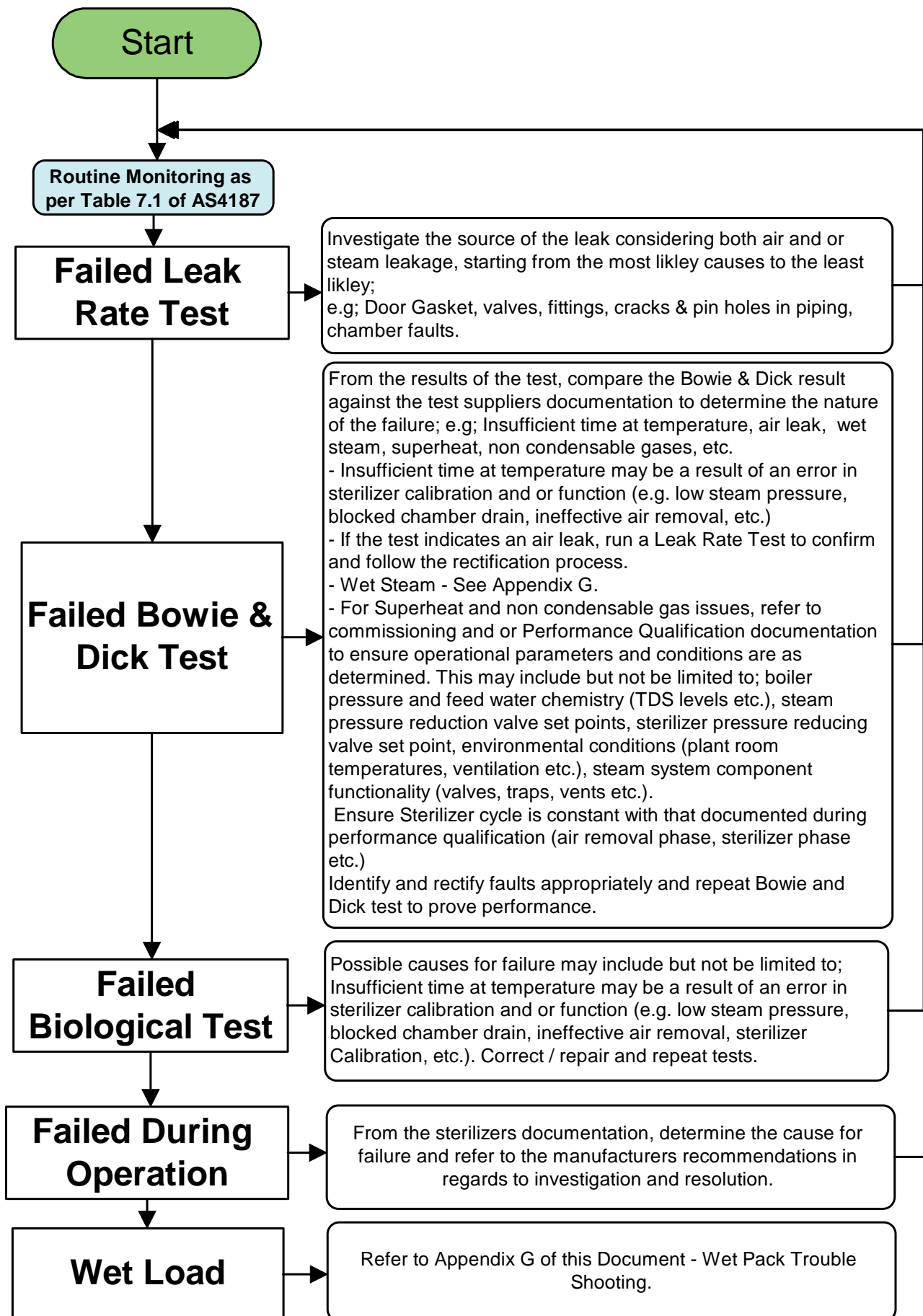
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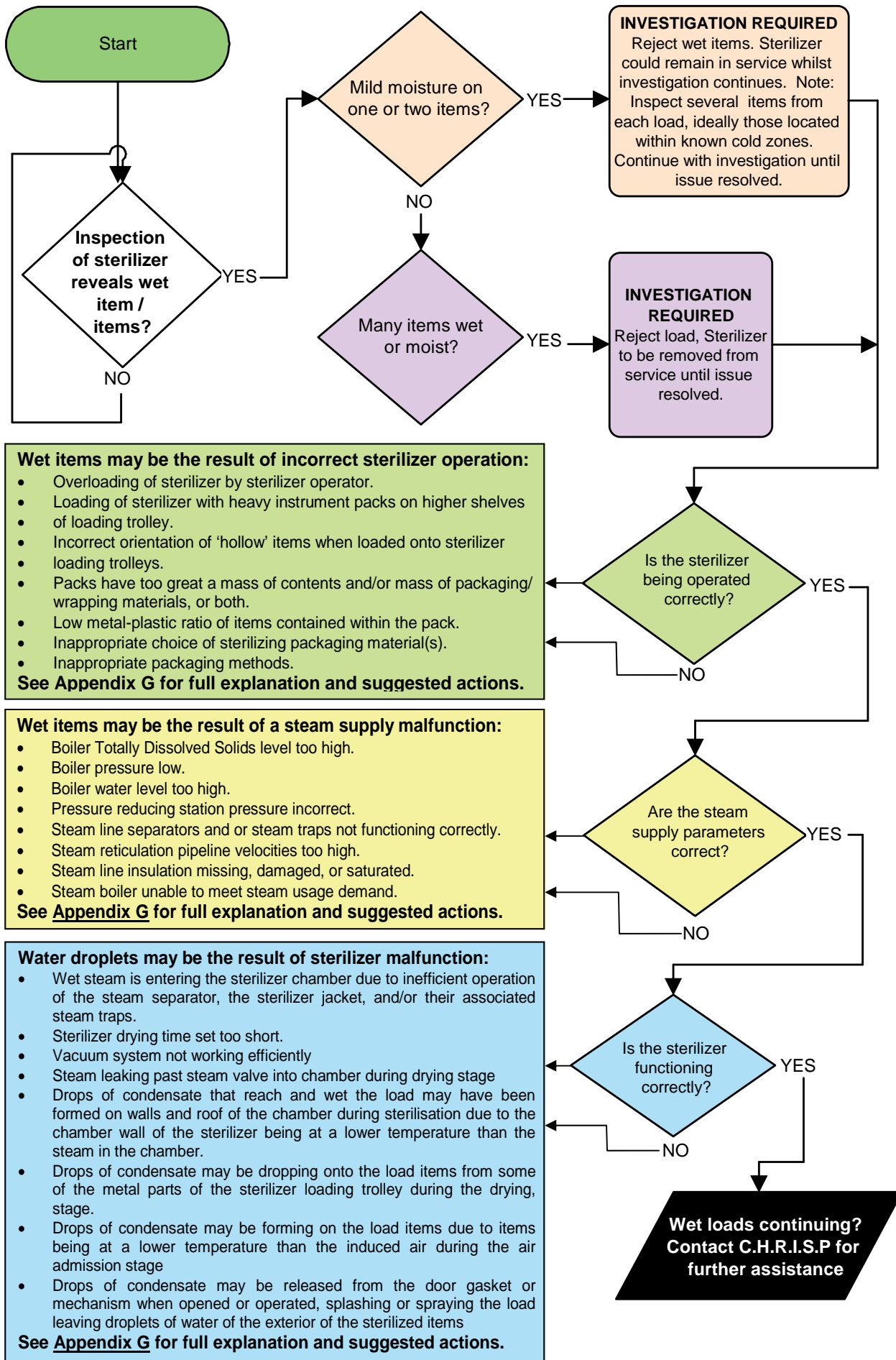
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APPENDIX

APPENDIX 1: Sterilizer Fault Finding — Flow Chart



APPENDIX 2 A: Troubleshooting of Wet Packs — Flow Chart



APPENDIX 2 B: Troubleshooting of Wet Packs

The following table presents the most common possible causes of wet packs in steam sterilisation with actions suggested for each situation:

| Possible Cause of Wet Pack | Why This May Cause Wet Loads | Suggested Course of Action |
|---|--|---|
| Overloading of sterilizer by sterilizer operator. | The placement of a larger-than-normal quantity of load items in the sterilizer is a common cause of both failure of sterilisation and difficulties in reliable drying of its load. The drying stage is less effective because there is more moisture to be removed (due to the larger load), and the moisture that is being removed is impeded by the close packing of the load items. | Sterilizer operators determine the loading pattern and loading density that leads to consistently dry results. Provide operator education and supervise to ensure consistent use of the loading pattern and maximum loading density for the particular sterilizers. Loading configuration for each product group including a maximum total weight should be determined and documented during validation |
| Loading of sterilizer with heavy instrument packs on higher shelves of loading trolley. | Instrument packs produce more condensate, when being heated in the sterilisation stage, than drape packs and soft goods. This extra water drips down onto lower shelves of the loading trolley, making it difficult for the drying stage to completely dry the load. | Routinely place instrument packs on lower shelves of the loading trolley. If instrument packs are on more than one shelf, cover the lower shelves with a textile sheet or drape. If the problem continues, investigate steam quality. Loading configuration for each product group including a maximum total weight should be determined and documented during validation |
| Incorrect orientation of 'hollow' items when loaded onto sterilizer loading trolleys. | Condensate forms all over each item in each pack, and it will pool at any possible location. Pooled condensate is more difficult to dry off than dispersed condensate. Any load item which by its shape will not drain completely will thus present a problem for reliable drying, if not placed in the sterilizer in a way that condensate will drain away. Bowls, dishes, unperforated trays and jugs are some examples of 'hollow' items. | Orientate all hollow items such that any condensate forming on them can drain away. Note that the reverse curved metal rims of some bowls and dishes may also collect liquid. Remember that items within a pack also influence its best loading orientation, and that internal items often move during handling of the pack. . Loading configuration for each product group should be determined and documented during validation |

| Possible Cause of Wet Pack | Why This May Cause Wet Loads | Suggested Course of Action |
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| Packs have too great a mass of contents and/or mass of packaging/wrapping materials, or both. | High load mass means a large amount of condensate, which in turn may create more moisture than the drying stage can consistently remove. Many layers of packaging material(s) may inhibit the rate of removal of water vapour during the drying stage. | Examine correlation between pack sizes and mass of pack contents and/or many layers of packaging material. Split excessively large packs into two or more smaller packs. Also check the quality of the available steam*. Loading configuration for each product group should be determined and documented during validation. This will include detail on the maximum weight and density of trays and testing to establish successful processing of the known "most complex" items. |
| Low metal-plastic ratio of items contained within the pack. | Due to good thermal conductivity, the heat in metal items is readily available as an energy source for pack drying whilst the heat in plastic items is not so readily available. Thus a high ratio of plastic to metal within packs can lead to wet packs. | Redesign the problem packs to increase the ratio of metal to plastic in the pack. If there is a determination to not change the metal-plastic ratio, experiment with the inclusion of porous materials in the pack to soak up and disperse condensate where it forms. |
| Inappropriate choice of sterilizing packaging material(s). | Low porosity packaging materials inhibit removal of water vapour during drying. Lack of porous material to disperse condensate within a pack may allow water to pool at some points, which the drying stage may be unable to remove. Synthetic, non-wettable barrier materials without additional porous moisture dispersing materials may also lead to pooling of condensate. | Sterilizer operator to refer to Sections 3 and 7 of AS 4187 and to do controlled testing of a variety of materials and pack design schemes so as to minimise or eliminate the effect of the chosen materials on the occurrence of wet packs. Always consider that there may be other causes of the observed wet pack problem. |
| Inappropriate packaging methods. | Lack of porous material to disperse condensate within a pack may allow water to pool at some points, which the drying stage may be unable to remove. Synthetic non-wettable barrier materials without additional porous moisture dispersing materials may also lead to pooling of condensate. Excess layers or folds of packaging materials can create drying difficulties similar to the problem of packs being too large. | Avoid any manner of pack design that may cause the gathering or retention of condensate inside packs. Experiment with judicious use of layers of moisture dispersing materials (textile or low-linting paper) within packs. Always consider that there may be other causes of the observed wet pack problem. |

| Possible Cause of Wet Pack | Why This May Cause Wet Loads | Suggested Course of Action |
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| Particular load items only | Some items, due to their design or the materials of which they are made, are inherently difficult to dry in a steam sterilizer. This will be evident where only certain items experience wet pack problems when all others are shown to be reliably dry. | Experiment with alternative and special ways of packaging the problem items. Try alternative methods of sterilisation (eg dry heat, hydrogen peroxide plasma, ethylene oxide) if they are available, but remember that the choice of packaging materials will have to be reconsidered. |
| Wet steam arriving at the sterilizer from a remote or local steam source. This could be if the steam pipes are of inadequate size, and/or if there are inadequate numbers of steam traps along the steam reticulation pipes, and/or if the insulation around the pipes is old, damaged or inadequate. | Droplets of water may be becoming transported in the steam flowing from the boiler house or steam generator. There may be so much water or the steam velocity is so high, that the sterilizer's steam separator and or jacket are unable to extract the droplets from the excessively wet steam. Some packs simply become too wet to be able to be reliably dried in the sterilizer. This fault commonly emerges during colder weather but can happen at any time. | Inspection of the steam reticulation system may reveal component malfunction, e.g. steam traps not functioning, missing or saturated pipe insulation. Repair or replace components as necessary. Careful engineering/ maintenance examination of the steam reticulation pipes may be necessary to ensure corrected fall, sizing, steam trapping and insulation of systems. Measurement of steam quality can be carried out to confirm or refute theories that steam quality is the cause of the problem, however experience has shown that measured systems with dryness fractions of in excess of 97% can still result in wet loads |
| Wet steam generated by steam generator or boiler. This could occur if the generator or boiler is of inadequate capacity for the peak steam flow demanded from it, or there is a malfunction of the generator and or water level control or boiler water treatment parameters are incorrect | Droplets of water may be becoming caught in the steam flowing from the generator due to excessive velocity, incorrect water levels, or high TDS(Totally Dissolved Solids Levels), Steam line components such as steam traps and separators are limited to how much condensate and water droplets they can remove. Steam must originate as dry as possible from the steam generator or boiler. | Careful engineering/ maintenance examination of steam generator or boiler operation is necessary. Repair and or adjust the steam generator as necessary. Operational parameters for steam generation equipment should be determined and recorded as a part of validation activities. |
| Wet steam is entering the sterilizer chamber due to inefficient operation of the steam separator, the sterilizer jacket, and/or their associated steam traps. | These components are very important in attaining steam of correct quality. If they are not working properly, or if there is too much water arriving in the steam (see above), the steam entering the chamber will still be wet. Some packs thus become too wet to be reliably dried in the sterilizer. | Check and/or replace steam traps attached to sterilizer including but not limited to the steam separator and sterilizer jacket. Ensure that the <ul style="list-style-type: none"> • steam separator is functioning correctly • All strainers are clear of debris • All condensate is directed away from steam traps without undue back pressure. |

| Possible Cause of Wet Pack | Why This May Cause Wet Loads | Suggested Course of Action |
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| Drops of condensate that reach and wet the load may have been formed on walls and roof of the chamber during sterilisation due to the chamber wall of the sterilizer being at a lower temperature than the steam in the chamber. | The temperature difference is produced by a difference in steam pressure between the jacket and the chamber during the sterilisation stage. Steam condenses back to droplets of water on the 'cooler' inside metal surfaces of the chamber, and some of these droplets fall onto parts of the load. As a result, some packs simply become too wet to be able to be reliably dried in the sterilizer. | Check that just before the end of the sterilisation stage, the jacket steam pressure is equal to the chamber steam pressure. Accuracy of the gauges on the sterilizer will also have to be confirmed through calibration. If there is a discrepancy, investigations will need to take place to determine the reason for this difference. In serious cases, a change in the sterilizer's pipe work and or control equipment has been found to be necessary. |
| Drops of condensate may be dropping onto the load items from some of the metal parts of the sterilizer loading trolley either during the drying, stage. | Condensate normally forms on the metal parts of the loading trolley during each sterilisation cycle. Normally it should drain away without wetting the load, but some droplets still may fall onto packs being sterilized. If the drops fall during the sterilisation cycle, the packs become too wet to be reliably dried. | Confirm that the water drops are definitely falling in a pattern defined by the metal structure of the loading shelves and/or other metal work of the loading trolley. Little can be done in this situation other than to cover the lower shelves with a textile sheet or drape. |
| Drops of condensate may be forming on the load items due to items being at a lower temperature than the induced air during the air admission stage | If the air drawn into the sterilizer during the air admission stage is warm and moist, this air will give up its moisture to items within the chamber. Because this occurs after the drying stage the packs will be wet on removal. | Suitable conditions must be maintained within the plant area of the sterilizer. This may be within the machine casing, or a sterilizer plant room. Ensure these areas are adequately ventilated to maintain appropriate temperature and humidity. |
| Drops of condensate may be released from the door gasket or mechanism when opened or operated, splashing or spraying the load leaving droplets of water of the exterior of the sterilized items | If water is pooling around the door gasket or door mechanism, droplets may be swept inward or drop onto the load either when the door seal is released or on removal of the load from the sterilizer chamber. | Inspection of the door gasket and door mechanisms may be required. Steam sealed door gaskets can leak producing pools of condensate in and around the sealing area. If the door seal is released with excessive residual vacuum within the chamber, there will be an inrush of air carrying water droplets into the chamber. This will also introduce air to the sterilized product which has not been filtered through the sterilizers biological air filter; this may result in a compromise to the sterile product. Replace or adjust door and pressure control components in accordance with the manufacturer's specifications. |

| Possible Cause of Wet Pack | Why This May Cause Wet Loads | Suggested Course of Action |
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| Sterilizer drying time set too short. | If the drying stage is of inadequate length, there is insufficient time for all of the moisture in every pack in the load to be removed. This may be due to changes in the type(s) of load items compared to those in use when the drying stage time was first set, or possible deterioration of the sterilizer's drying efficiency. | Compare the drying time for similar sized instrument packs in other steam sterilizers in the same facility and for similar packs in other facilities. Extend the drying time if other times are consistently longer. Re-evaluate the drying time required to consistently dry the packs currently in use. These activities should be determined and documented during validation. |
| Vacuum system not working efficiently. | Whether the vacuum system uses a steam ejector, a water ejector, or a water-ring vacuum pump, and whether or not filtered air passes into the chamber during the drying stage, wet loads are more likely when the vacuum equipment is not able to efficiently remove the water vapour produced during drying. | Maintenance personnel to test and demonstrate proper function of vacuum equipment used in the drying stage, and to report findings to sterilizing personnel. Measurement should include the minimum pressure achieved and the time taken to achieve this pressure. These parameters can be compared against benchmarks as measured and documented during validation |
| Steam leaking past steam valve into chamber during drying stage. | Steam leaking into the chamber is a significant extra load on the drying process of the sterilizer. A leaking main steam inlet valve may produce visible drops of water into an open chamber as well as audible sounds. This will only be apparent with the sterilizer door open, if the door safety interlock steam valve is also leaking. Steam sealed door gaskets can also leak into the chamber during the cycle causing the same result. | The Leak Rate Test where applicable will alert the operator of any leak of air or steam into the chamber whilst under vacuum; alternatively, the operator can check for drops of water and or steam vapour, or leaking sounds at the opening of the door of the sterilizer. Maintenance personnel to repair or replace door gasket, and or seal(s) in steam inlet valve(s), and report findings to sterilizing personnel. |