

# 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 <sup>3</sup>	Temperature Measurement <sup>σ</sup>	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"> <li>Pre-vacuum Sterilizers - Weekly leak rate if sterilizer fitted with an automatic air detector, otherwise daily</li> <li>Biological Indicator for emergency - non validated loads</li> </ul>	<ul style="list-style-type: none"> <li>Biological Indicators<sup>Σ</sup></li> <li>Process Challenge devices</li> <li>Electronic Data Loggers</li> <li>Internal Chemical Indicators</li> </ul>

<sup>3</sup> 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.

<sup>Σ</sup> 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.

<sup>σ</sup> 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](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](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.