Australasian Health Facility Guidelines

Part B - Health Facility Briefing and Planning

0190 - Sterile Supply Unit

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Australasian Health Facility Guidelines

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Index

01 INTRODUCTION

01.01 Preamble

This clause is currently not applicable, but has been included for consistent HPU clause numbering.

01.02 Introduction

GENERAL

Healthcare facilities must provide adequatefacilities for cleaning,sterilization or disinfection and storage of equipment and instruments to ensure the care and safety of patients and the safetyof staff.

This document is a resource o assist project staff, potential users and client groups in the planning, design and construction of Sterile Services Units (SSU) in the hospital setting.It should be read in conjunction with generic planning requirements and standardcomponents describedin parts A, B, C and D of these guidelines which can be found at www.healthfacilityguidelines.com.au

Facility design,must, where appropriate meet all necessary criteria to reach accreditation standardswith regards to design,equipment and safety.

This Guideline does not addressprocedural practicesand does not replace procedure manuals.

STERILIZATION

Sterilization is the 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 removeall foreign material.

There are a variety of sterilising methods suitable for healthcare facilities including steamsterilisation (autoclaving), dry heat sterilisation, and low temperature sterilising processes (ethylene oxide, peracetic acid and hydrogen peroxide plasma).

DISINFECTION

Disinfection is a process that only removes or kills organisms that are regarded likely to cause diseaseand may be achieved by either thermal or chemical methods. Thermal disinfection (hot water / pasteurisers) must be used in preference to chemical disinfection.

Chemical disinfection may only be used for items for which thermal methods are unsuitable.

The manufacturer’s instructions must be checked for compatibility of the instrument or equipment with the method of disinfection to be used.

Where thermal disinfection is used, all parts of the item must be subjected to moist heat at or above the recommended temperature for the recommended duration.

Disinfecting equipment includes anaesthetic washer / disinfectors and utensil washer / disinfectors.

01.03 Policy Framework

NSW HEALTH POLICIES

Project staff should familiarize themselves with the following:

- NSW Health, Infection Control Policy, PD2007_036, May 2007.
- NSW Health, Glutaraldehyde in NSW Public Health Care Facilities (Policy and Guidelines for Safe Use of), PD2005_108, 25 January 2005.
- Sterilising Equipment and Products - Purchase and Installation of (Non Ethylene Oxide), PD2005_055, 25 January 2005.

AUSTRALIAN / NEWZEALAND / INTERNATIONAL STANDARDS

The overarching standard for Sterile ServicesUnits is AS/NZS4187 - Cleaning, Disinfecting, and Sterilizing Reusable Medicaland Surgical Instruments and Equipment, and Maintenance of Associated Environments in Health Care Facilities, Standards Australia International Ltd, Sydney.

Sterilization outside of the hospital setting (medical, dental,surgical, allied health and skin penetration practices) is addressed in the Australian Standard AS/NZS 4815 - 'Office-based health care facilities not involved in complex patient procedures and processes - Cleaning, disinfecting and sterilizing reusable medicaland surgical instruments and equipment, and maintenance of the associated environment'.

Equipment-specific Standards are listed in Section 190.17.10of this Guideline.

01.04 Description

DEFINITION OF HEALTH PLANNING UNIT (HPU)

The Sterile ServicesUnit is a discrete unit of the hospitalwhich has the following functions:

- to process re-usableinstruments required sterile for patient care in all hospital departments including operating suites, wards and special care areas, and, depending on the Unit'srole, outlying centres;
- to disinfect selected specialised items;
- to ensurethat all processesare validated by means of qualityassurance practices;
- to ensurethat the items supplied meet the requirements of the user; and
- to providetechnical advice to users, suppliers and hospital administrators on standards for sterileproducts.

Note that it is no longer the role of the SterileServices Unit to store and distribute medical / surgical singleuse items to wards and departments or to process theatrelinen other than to sterilize packs if necessary.

THEATRE STERILIZING SERVICES UNIT (TSSU)

A TSSU processes re-usableitems for the operating suite only. Sterile storage areas may be locatedin the TSSU or in the OperatingSuite and the TSSU may contain facilities for preparation of case carts or trolleys for the itemsrequired for surgicalprocedures. Design principles are the same as for theSSU.

Because of duplication of resources, establishment of a TSSU shouldbe avoided where possible.

UNIT CONFIGURATION

With the exception of the contained Decontamination Area, the SSU should be designed as an open plan work area subdivided by benches and / or equipment into functional work areas.These work areas are to be linkedby circulation space and arranged to allow for a progressive work flow that commences with a "dirty" entry and receiving area, proceeds to a cleaning, decontamination and drying area, into a sortingand packing area, through to a sterilization and cooling area, to finishwith sterile storage,distribution and exit areas.

Work flows should prohibitthe flow of non-sterilized items through areas where sterilized items are held or stored.

MAJOR SPACE DETERMINANTS

Major space determinants are:

- projected workload (throughput);
- number of operating theatres/ suites serviced;
- extent of storage required in the Operating Suite itself and in otherwards and departments. Consideration needs to be given to the provision of commercially produced sterilestores through either the SSU or the Supply Unit;
- types of cleaning equipment selected such as index / tunnelwashers or batch washers;
- number of sterilizers and whether front or double sided loading; and
- extent of staff amenities that may or may not be sharedwith the Operating Suite.

DESIGN CRITERIA

In addition, designof the unit must addressthe following:

- safety: particular attention is to be paid to chemical, biological, electrical and fire hazards, air contaminants / particulates and odor containment / removal;
- transportation systems (hoists)and equipment (trolleys);
- signposting to allow staff from user departments controlled access to the despatch and soiled goodsreception;
- cost efficiency;

- fire egress;
- access for installation and maintenance of large items of equipment; and
- infrastructure, present and future for information technology particularly with regard to quality assurance and instrument tracking.

02 PLANNING

02.01 Operational Models

HOURS OF OPERATION

Generally staff will cover two shifts per day from approximately 0800 hours to 2200 hours Monday to Friday. Night,weekend and public holidays coverage will be at the discretion of the individual health care facility.

If no 24 hour service,there will need to be arrangements for emergency services and after-hours access by authorised personnel.

SERVICE MODELS

The sterilization processmay be carried out entirelyor partially on-site,the latter relying on an external supply source to regularly restock the hospital sterile goods store.

The scale of operation can be small or large, dependent upon the requirements of the serviced departments: for example, an Operating Unit requires the services of a Theatre Sterile ServicesUnit (TSSU) or a full Sterile Services Unit,whereas an Acute Ward requiresonly a basic Sterile Services Unit.

The following models of service deliverymay apply:

- central SSU, with or without a TSSU; and
- regional servicewith collection and receipt only in outlying centres.

Where this latte rmodel is considered / adopted, care must be taken to ensure appropriate transport is available for timelydelivery and pick-upand adequate instrumentation to avoid last-minute crises. This will require considerable negotiation with surgeonsto ensure they have the necessary instruments.

STERILIZING METHODS

The following methods of sterilization are available:

- steam underpressure (moist heat);
- low temperature sterilization; and
- dry heat.

The sterilization methodchosen must be compatible with the item to be sterilized to avoid damaging the instrument and manufacturer’s recommendations should be followed.

STEAM STERILIZATION

Steam sterilization involves the use of steam under pressure, deliveredat a particular temperature for an appropriate time. Items must be thoroughly dry prior to removalfrom the autoclave and procedures must be in place to monitor the sterilization process.

Steam sterilization is suitable for all instruments capable of withstanding heat and moisture. There are two types of steam-under-pressure sterilizers for porous loads used in SSUs:

- downward displacement (gravity) sterilizers; and
- pre-vacuum sterilizers.

The two types vary slightlywith regard to temperature range and means of air extraction. Pre-vacuum sterilizers provide a more effective method of air removal thus giving a faster operating cycle and therefore greater productivity. Downward displacement sterilizers are not recommended, as theycannot sterilise cannulated (laparoscopic) instruments.

Benchtop sterilizers are not addressed in this Guideline.

LOW TEMPERATURE STERILIZATION

There are three low temperature sterilization processes identified by AS4187 for use in healthcare facilities to sterilize items at temperatures of 55ºC or lower. The active sterilants are:

- hydrogen peroxidegas plasma;
- peracetic acid; and
- ethylene oxide.

HYDROGEN PEROXIDE GAS PLASMA

An automated machine using hydrogen peroxide plasmato chemically process medicaland surgical instruments is currently available (STERRAD™). The system uses hydrogen peroxide gas plasma at low temperature for heat-sensitive and moisture-sensitive instruments with no toxic residues and is normallyused for wrapped items.

The system cannot be used to process liquids,powders, or strong absorbers (cellulosics), and there are some lumen restrictions. Also not recommended for liquids and devicesthat can be damagedphysically or changed by exposure to low pressure.

PERACETIC ACID

Peracetic acid is a low temperature chemicalsterilant and high level disinfectant. Instruments are processed unwrapped at point of use and are wet when removed from the machine. An automated machine using peracetic acid to chemically processmedical and surgical instruments such as endoscopes and arthroscopes is currently available (STERIS™). The system is most commonly used for processing endoscopes and would not normally be found in the SSU.

ETHYLENE OXIDE (ETO)

Ethylene oxide sterilizers utiliseethylene oxide gas and humidity to sterilize items that are unable to withstandtemperatures above 60°C and are therefore incompatible with steam or dry heat. They are also used for those few items that are incompatible with the gas plasmasystem e.g. lumens and lens.

The emergence of sterilants such as gas plasma has reduced the need for ETO sterilizers and the relevant Australian standards (AS 1714 and AS 1862) have been withdrawn. However, they may still be installed in approved hospitals and their use should be made available to other facilities as a regional service.

As ethylene oxide gas is toxic and is absorbed into materials during the sterilizing process, a period of aeration is essential to remove the ETO residue. Recommended aeration times are considerable and although goods may be aerated within the sterilizer, a separate aerationcabinet may be required to improve turnover time.

The following may be used as references:

- Safe Use of Ethylene Oxide in Sterilisation / Fumigation Processes National Code of Practicefor the Safe Use of Ethylene Oxide in Sterilisation / Fumigation Processes [NOHSC:2008(1992)] Australian Government Publishing Service, Canberra’
- BS EN 1422:1998: Sterilizers for medical purposes.Ethylene oxide sterilizers. Requirements and test methods.

DRY HEAT

Dry heat sterilization is only minimally used in healthcare 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.

02.02 Operational Policies

GENERAL

Operational policies have a major impact upon the planning and design and capital and recurrent costs of health facilities. Design teams should be constantly reviewing their design proposals with these in mind and be able to demonstrate that the capital and recurrent cost implications of proposed operational policies have been fully considered.

Operational Policies may have hospital-wide application or be unit-specific. A list of general Operational Policies that may apply can be found in Part B Section 80 of these Guidelines.

SSU-SPECIFIC

Operational Policies will vary from unit to unit depending on a wide range of factors. Following are examples for consideration:

- will/ will not be responsible for the emergency sterilizing required by the Operating Suite;
- will be responsible for maintaining the stock supplied for the "out of hours" cupboard;
- will/ will not be responsible for sterilizing theatre linen;
- will/ will not be responsible for processing scopes used in other hospital units; and
- will/ will not be responsible for processing respiratory tubing from critical care areas (many units will process their own and increasingly tubing is disposable).

AFTER HOURS SUPPLIES

As the majority of facilities do not operate a 24 hour sterilizing service, provision should be made to enable wards and departments to obtain sterile stock required in an emergency and there should be written procedures indicating the method by which these supplies may be obtained.

Emergency supplies should be held in a secure cupboard accessible only by authorised hospital personnel and if design permits, should be located on

the periphery of the SSU with internal access from the dispatch area.

FLASH STERILIZATION

Emergency instrument ("flash") sterilizers are designed for one-off sterilization of instruments (eg an instrument which has been inadvertently left out of a set or dropped) and are generally located in the Operating Suite.

These sterilizers should be under the control of SSU and should be performance tested daily to ensure that the parameters of the sterilizer performance comply with Australian Standard AS 4187.

HANDLING AND COLLECTION OF USED ITEMS

All users in all departments have a responsibility for the correct handling and disposal of the contents of packs after use.

Used single-use items must be discarded into appropriate containers.

Linen wraps and drapes should be placed in soiled linen containers and returned to the linen / laundry service. Soiled linen should NOT be returned to the SSU.

"Sharps" should be placed in appropriate leakproof and puncture-proof containers and should not be returned to the SSU, but in the event of this inadvertently happening, an appropriate container should be provided in the SSU.

Re-usable items should be rinsed in water (20-40°C) to remove gross contaminants and placed in the containers dedicated to that purpose for return to SSU.

INSTRUMENT CLEANING / DECONTAMINATION

Thorough cleaning / decontamination of all instruments and equipment is an essential prerequisite in the processing of items in order to remove all infectious residual soil, tissue debris, blood etc. Cleaning methods should appropriate for the item and may be mechanical or manual.

Manual methods are used for washing certain delicate or complex instruments where mechanical methods are contra-indicated. These instruments should be carefully hand-washed and rinsed.

Mechanical ultrasonic cleaners are available for use with a limited range of jointed and serrated stainless steel instruments; they usually operate with cold tap water and only detergents approved by the equipment manufacturer should be used. Items that are lensed or unable to be submerged in a solution should not be cleaned by this method.

Mechanical decontaminators are of two types:

- Batch-Type Washer / Disinfectors; and

- Index / Tunnel Washers.

These machines are used for cleaning instruments and utensils, complex equipment such as anaesthetic breathing circuits, flexible fibre optic endoscopes, and laboratory glassware.

All SSUs will require an ultrasonic cleaner or cleaners but will need to determine whether batch washers or tunnel washer or a mix of both will be the preferred mechanical equipment as this will have major implications on space within and layout of the Decontamination Area.

If a tunnel washer is the equipment of choice, there must be a secondary method available in case of equipment breakdown or down time for maintenance, whether manual or mechanical.

ll manual and/or mechanical cleaning MUST be done “As per the Manufacturers Recommendations” (AS/NZ 4187) and these recommendations MUST be kept for the accreditation process.

INSTRUMENT DRYING

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.

Drying cabinets should be used for drying instruments, hollowware, tubing and anaesthetic equipment.

Hot air drying may also occur during the last stage of the cycle of washer / disinfector machines, batch washers or multi stage tunnel washers.

INSTRUMENT TRACKING

An instrument tracking system requires that all instruments are engraved and scannable (a form of bar coding) ensure that a particular instrument may be traced back to a particular case / patient. This does not require space as such but does require that the packing tables are appropriately serviced with computers and scanners.

LOAN INSTRUMENTS

The use of surgical ‘loan sets’ is commonplace in most hospitals. The use of these sets requires careful coordination between surgical suppliers, transport companies, hospitals and their sterilizing services. The process is extremely labour-intensive, requiring repeated manual checking, unpacking and rechecking prior to return.

Delivery crates may be numerous, bulky and heavy. The contents must be unpacked and checked (and may be photographed) against the supplier’s inventory and for damage before being put through the normal sterilizing cycle. On return, they must again be checked. This delivery and checking process requires an appropriate delivery area with space to stack the crates, benches for checking and a workstation with computer for the instrument database.

The Loan Equipment Store may be incorporated into the SSU or into the Operating Suite but should be accessible from a main hospital corridor and have ready access to the SSU cleaning area. Responsibility for checking will lie jointly with SSU and OR staff.

MAINTENANCE

There must be a planned maintenance programme for all major equipment (sterilizers, washer / decontaminators, index tunnel washers).

SCOPE PROCESSING

In those health care facilities with only a small endoscopy case load insufficient to justify a dedicated Endoscopy Unit and associated scope cleaning room, facilities for scope cleaning will be incorporated into the SSU. Fume cupboard / extraction.

For details, refer to "Standards for Endoscopic Facilities and Services", Gastroenterological Society of Australia and Gastroenterological Nurses Society of Australia, February 1998.

http://www.gesa.org.au/members_guidelines/endoscopy_ps/endoscopy_stan dards.pdf

Also, equipment for processing ultrasonic intraoperative probes if used in the Operating Suite may be required.

STERILIZATION RECORDS

The use of items incorrectly processed carries inherent risks in terms of infection. It is essential, therefore, that records be kept of all items processed and all sterilizing cycles so that a defective item may be recalled if necessary and malfunctioning equipment, operator error and/or product and processing defects identified and corrected.

These records may be included in the individual sterilizer log book or in a separate record and they must be retained for fifteen (15) years following last entry or print-out in accordance with the State Records Act 1998 and State Records Regulation 2005.

STORAGE - BULK SUPPLIES

It is important to consider the overall unit's storage requirements in some detail.

Bulk storage areas should be located on the periphery of the unit so that deliveries of bulk, non-sterile, and commercially purchased sterile stocks are not delivered through the work areas, but wherever possible have controlled access from areas outside the unit into the storage area concerned.

Storage needs can be divided into:

- non-sterile stock, both "in use" and "back-up" supplies;
- non-sterile linen, both "in use" and "back-up" supplies;
- medical / surgical consumables that may be incorporated into case packs;
- packaging material (drapes, plastic bags etc);
- spare unsterilized instruments; and
- chemicals. Detergents, disinfectants and chemicals with high acidity or alkalinity should be stored in a chemical storage cabinet. Users are advised to check for chemical incompatibilities before storing different chemicals together.

STORAGE - STERILE SUPPLIES

Sterile supplies must be handled and stored in a manner that maintains the integrity of packs and prevents contamination from any source (dust, vermin, sunlight, water, condensation etc). Storage areas must be temperature and light controlled and easily cleaned.

Supplies should be stored off the floor, with the lowest shelf at least 300 mm above floor level so as to avoid mechanical damage during cleaning.

THEATRE LINEN

The preparation of sterile drapes and gowns (‘linen’) for operating room use is usually a major aspect of SSU activities. Despite a move to disposable drapes, woven textiles remain in widespread use, requiring transporting, laundering, and checking and pack preparation separate from the processing of instruments and equipment.

Some facilities receive a service of laundered linen for sterilization or already sterile linen packs from an external organisation. However, there are many health care facilities laundering their linen within the facility. After laundering, linen is passed to the SSU for checking, pack preparation, sterilizing and storage, or delivery as sterile packs. Due to linting, linen MUST be folded in a separate room with its own air conditioning system in accordance with AS/NZ 4187.

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.

Australian/New Zealand Standard AS/NZS 4146 Laundry Practice.

TRANSPORTATION SYSTEMS

Equipment and systems to collect used items from wards / departments and operating suites and to deliver sterile items to wards and departments and operating suites must be addressed. ALL soiled Instruments MUST be collected in closed puncture proof containers.

Delivery to wards and departments will be manual and will require trolleys that will be stored in the main Sterile Stock Store.

Transfer of items to/from the Operating suite will also require a trolley system whether open or closed carts and if the SSU is not on the same level as the Operating Suite, two hoists will be required, one for used items, one for sterile items.

Case management may be done in a number of ways that will affect storage requirements in both SSU and Operating Suite and may include:

- shopping trolley or similar - 1 per case;
- closed case carts - 1 per case;
- flat top trolleys - 1 per case; and
- shelved trolleys - 1 per list.

TROLLEY WASHING

All transport trolleys will need to be cleaned after each use, either by hand or by means of a trolley washing system.

WASTE DISPOSAL

Most items returned to the unit for sterilization and reissue should have the sharps, linen and biological waste removed and sorted at source. Categories of waste within the SSU will include:

- plastic aprons, gloves, cleaning cloths and some sharps;
- general office waste;
- packaging and cartons from bulk supplies stored in the unit; and
- liner bags used to collect reusable items.

Waste should be placed in the appropriate containers and should not be transferred from bag to bag during collection.

Liner bags used to collect re-usable items, and other soiled materials should be treated as contaminated waste, discarded into appropriate containers and disposed of in accordance with the facility's policy.

"Sharps" containers should be provided for disposal of condemned needles and used, single use needles and syringes inadvertently returned to the department with re-usable items.

All waste should be removed from the department via a dedicated disposal exit. Holding space within the unit prior to its collection and disposal via the hospital's waste disposal system will need to be considered by the design team.

STAFF EDUCATION AND TRAINING

There should be a formal, departmental orientation programme for new staff and a formal programme or system for continuing in-service education. Access to a tutorial room is essential.

STAFFING

Staff qualifications and staffing levels should be sufficient to ensure the continuous, safe and efficient operation of the SSU.

There should be a written job description for each category of staff.

Departments should be managed by persons qualified to the appropriate level by education, training and experience and who hold a sterilizing technology certificate. Their responsibilities may include:

- training and supervision of staff;
- allocation of duties;
- rostering and leave arrangements;
- communication and liaison with other departments and organisations;
- development and implementation of policies and procedures;
- budget management;
- maintenance of records; and
- quality assurance programmes.

The staff may include:

- Unit Manager;
- Team Leaders;
- Sterilizing Technicians; and
- Supervisor, Educator and Loan Co-ordinator particularly in centres providing a 24 hour service.

Details such as numbers of staff, shift hours, etc should be developed in accordance with individual hospital needs.

02.03 Planning Models

LOCATION

The Sterile Services Unit should be conveniently located for access to all consumer areas of the health facility and with direct or ready access to the operating suite.

02.04 Functional Areas

FUNCTIONAL AREAS

The functional requirements for the SSU may be addressed according to the various areas as follows:

- reception and administrative functions and access control;
- receiving area for soiled / used items from external sources and from the Operating Suite;
- cleaning / decontamination / disinfection area;
- checking / packing workroom;
- sterilizing area (including loading and cooling);
- sterile stock storage - OR and wards; and
- staff amenities.

All Sterile Services Units regardless of the level of service provided will require these areas in varying combinations and sizes.

RECEPTION AREA

The Reception are will/may have the following functions:

- the “public” entry point for receiving and meeting with visitors, manufacturer representatives etc;
- area for clerk / clerical duties and Unit Manager’s office or workstation;

- the distribution point for items requested by wards and departments in the form of a counter or pass-thru hatch from the external service corridor;
- may be the delivery point for clean bulk goods and couriers; and
- may act as staff entry if immediate access to change rooms without accessing the Unit proper can be achieved.

RECEIVING AREA FOR USED ITEMS

Area where all soiled articles for reprocessing are received on trolleys from the main corridor from user departments throughout the hospital and outlying centres and - by an internal route (hoists or horizontal corridor), from the Operating Suite. Here the trolleys are unloaded and sorted and trolleys washed, by hand or via trolley wash if installed. Trolleys should not be transferred into any clean zone.

CLEANING / DECONTAMINATION / DISINFECTION

Area where all articles are sorted, used / soiled material disposed, items rinsed, manually or mechanically washed and dried.

Equipment will/may include:

- unpacking bench/es;
- multiple outlet manifold with air and water under pressure for tubing cleaning;
- sink/s and ultrasonic tank/s;
- drying cabinet/s;
- pass-thru hatch to the packing area;
- index / tunnel washer and/or;
- batch-type washer / disinfectors, ideally pass-thru to the packing area; and
- handbasin.

Space to park trolleys is essential.

A trolley wash, if provided, would be accessed off this area.

CLEAN WORKROOM

Clean Workroom where clean and dried instruments, equipment and other articles are sorted, checked, scanned and packaged for sterilizing.

One or more tables will be required for instruments but as packaging needs vary, a dedicated area for holloware and dedicated areas for items intended for low temperature sterilization are recommended.

Packing tables require power and data for use with computers and instrument scanners.

Space for mobile shelving units containing the items awaiting packaging. Storage rails and shelves for packaging drapes.

Paper, laminate and heat sealers.

A handbasin should be readily accessible but location should ensure that splash contamination of clean, dry goods cannot occur.

STERILIZING AREA

Area where loading trolleys are parked, sterilizers are loaded, set into operation, unloaded for cooling and plastic wrapped as necessary following completion of the sterilizing cycle.

The size of the area will be dependent on the number and type of sterilizers installed and whether front loaded / unloaded or double-sided loaded. Access will be required to the Sterilizer Plant Room.

If loading trolleys are electric, power outlets for recharge will be required.

STERILE STOCK STORE - OPERATING SUITE

Location of the Sterile Stock Store for the Operating Suite may depend on whether Operating Suite staff or SSU staff are responsible for assembling the case trolleys. If the former, the Sterile Stock Store will be located within

the Operating Suite but must have ready internal access from the SSU; if the latter, the Store will be located in the SSU in which case direct internal access to the Operating Suite is essential.

The Sterile Store should be ventilation, humidity and temperature controlled. Supply air pressure should be positive with respect to surrounding areas and the level of filtration should equal or exceed that of the Operating Room.

Shelving may be dust-free wire fixed or mobile shelving units or compactus- style system.

Storage cupboards should be fitted with doors.

There should be space to park and manoeuvre case assembly trolleys.

Recommended 10sqm per Operating Room.

STERILE STOCK STORE - WARDS AND DEPARTMENTS

A dedicated store should be provided for the storage and issue of sterile stock to wards and departments. It should be designed so that stock can be easily rotated and issued in date order as well as facilitate safe cleaning procedures.

Direct access will be required to the external corridor and there must be space to park the trolleys.

SHELVING AND CONTAINERS

- 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 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 cannot be adequately cleaned and may harbour organism; and
- routine cleaning with detergent and water to be scheduled.

STAFF AMENITIES

Showers and toilets for staff employed in this area should be provided. These facilities should be conveniently located and may be shared with the Operating Unit staff in cases where the Sterile Services Unit is adjacent to the Operating Suite. Staff must be provided with full length lockers especially if they are to wear “theatre scrubs”.

A Staff Room may be a shared central facility outside the Sterile Services Unit.

Access to a training room in close proximity to SSU for formal training activities is essential.

Facilities should also be provided in the Change Room to store caps, overalls and footwear protection. 'Barrier' principles are observed when entering the SSU.

02.05 Functional Relationships

It is highly desirable that the SSU has immediate horizontal or vertical adjacency to the Operating Suite (with own controlled point of entry).

Ready access to:

- Critical Care Units (ICU, NICU, Birthing Suite);

- Inpatient Units;
- Emergency Unit;
- Oral Health Unit;
- Linen Handling Unit; and
- Stores / Supply Unit.

03 DESIGN

03.01 Accessibility

EXTERNAL

There should be separate and distinct entry to the SSU well separated from other hospital traffic and located to avoid entry by unauthorised personnel.

The SSU should be signposted to allow staff from user departments controlled access to the reception area only. The entry to the receiving area requires trolley access for department returns as well as returns from the operating suite.

These return entry points may be achieved by either controlled doors or vertical transport from areas outside the SSU. Both internal and external access to the sterilizing plant room should be provided. Easy route from loading docks or wherever goods being transported may occur.

INTERNAL

Where possible a direct internal point of access should be available from the dispatch area of the SSU to the sterile storage area of the operating suite. Controlled exit for trolleys reissuing sterile supplies to departments. This exit must not be used for the return of "dirty" items to the SSU which requires a separate entry to the SSU reception area.

Outside double door access to couriers for Loan Equipment Deliveries. Special attention should be given to identifying major pieces of equipment early in the design process to ensure that door openings and room dimensions will allow easy delivery and removal (from the point to entry of the building) and access to the equipment for servicing.

MAINTENANCE

Access to the sterilizer plant room for maintenance should be such that disruption to the staff and the operation of the unit is minimal; in particular, access to services should be outside "clean areas" wherever practicable and it is preferred to be away from staff work areas.

03.02 Parking

Where the SSU provides a regional service to outlying centres, there should be ready access to parking for transport vehicles along a route that ideally does not cross public corridors.

Staff parking should be provided under or within close range of the workplace. The area should be well lit and protected from the elements. In high risk areas the Car Park may need to be monitored by security personnel or cameras.

03.03 Disaster Planning

An internal or external disaster could place extraordinary demands on the SSU and plans should be in place to cater for these demands. Refer to Part B Clause 80 and Part C of these Guidelines for further information.

03.04 Infection Control

The procedural aspects of cleaning, packing and sterilizing are outside the scope of this guideline and may be found in procedure manuals.

Major planning and design factors in infection prevention and control include:

- restricted / controlled access;

- workflows that progress from dirty to clean to sterile with no cross contamination;
- appropriate air handling systems and heat / moisture management;
- storage areas and systems that prevent contamination or spoliation of all products;
- adequate number and location of hand hygiene facilities (refer below);
- provision of personal protection items i.e. gloves, masks, eye protection and plastic aprons or gowns when there is any likelihood of splashing by blood, body fluids or mucous membranes;
- suitable materials and finishes that are easily cleaned;
- appropriate facilities for cleaning and waste management; and
- provision of staff uniforms and appropriate change facilities.

Refer to NSW Health PD2007_036 - Infection Control Policy. Also refer to Part D of these Guidelines - Infection Prevention and Control.

HAND HYGIENE

Handbasins should be located so as to allow staff to wash their hands:

- on commencement and completion of duty (in change rooms);
- after using the toilet;
- before and after meal breaks;
- after working in a "dirty" area;
- before entering a "clean" area; and
- any other action which may cause heavy contamination of the hands.

However, locations must be such to ensure there is no possibility of splash contamination of clean, dry goods.

Hand hygiene techniques and their importance in reducing cross-infection should be taught during orientation programmes and stressed continually at regular intervals. Refer to AS/NZ 4187, Appendix J - Handwashing.

03.05 Environmental Considerations

AIR-HANDLING

Good ventilation is required in the sterilizing area to remove heat and airborne moisture from the sterilizers, from trolleys cooling in front of the sterilizers and from washing and drying equipment in the unit.

The control of air movements within the SSU is of major significance in controlling both the movement of steam and the spread of potential infection between the "clean" and "dirty" areas of the unit. The following factors need to be addressed:

- storage areas need to be protected from steam penetration, especially the sterile stock store; and
- positive air pressure is required in the "clean" areas of the unit to reduce air movements into these areas from the "dirty" areas of the unit.

Heat and vapour from sterilizers should be collected and exhausted without effecting the occupied environment.

LIGHTING

Natural light is highly desirable especially for the packing workroom. Artificial lighting should take into account bench layout and the occupational health and safety requirements of staff. Light fittings should be fully recessed and selected to prevent dust and insects from entering.

TEMPERATURE

Temperatures within the Unit should be maintained within the "comfort" range of 22-24°C. In storage areas, temperatures should not exceed 27°C and supplies should be protected from direct sunlight.

03.06 Space Standards and Components

HUMAN ENGINEERING

Human Engineering covers those aspects of design that permit effective, appropriate, safe and dignified use by all people, including those with disabilities. It includes occupational ergonomics, which aims to fit the work practices, FF&E and work environment to the physical and cognitive capabilities of all persons using the building.

As the requirements of Occupational Health and Safety (OHS) and antidiscrimination legislation will apply, this section needs to be read in conjunction with the section on Safety and Security in these Guidelines in addition to OHS related guidelines.

ERGONOMICS

Sterile Services Units should be designed and built in such a way that staff, visitors and maintenance personnel are not exposed to avoidable risks of injury.

Badly designed recurring elements such as height, depth and design of workstations and counters, shelving and the layout of critical rooms have a great impact on the Occupational Health and Safety (OHS) of staff. Refer to Part C Section 730.12 under Access and Mobility of these Guidelines for more details.

ACCESS AND MOBILITY

Design must comply with AS 1428 - Design for Access and Mobility. Refer to Part C Section 730 of these Guidelines for details.

BUILDING ELEMENTS

Building elements include walls, floors, ceilings, doors, windows and corridors and are addressed in detail in Part C of these Guidelines Section 710 Space Standards and Dimensions.

Doorways should be sized to admit delivery and despatch trolleys without impediment. Door and corridors must be wide enough to accommodate large items of equipment.

03.07 Safety and Security

SAFETY

Safety and security involves people and policies as well as physical aspects, but the latter must be considered as part of overall design and not superimposed on a completed Unit and a safety audit via a risk analysis of potential hazards should be undertaken during the design process.

Of concern is the necessary manual handling of what can be very heavy instrument trays and attention must be paid to maximum allowed loads on sterilizer loading trolleys, storage systems and bench heights.

The following must be addressed with regard to safety:

- choice of flooring particularly in wet areas;
- slippery or wet floors;
- protrusions or sharp edges;
- stability and height of equipment or fittings;
- adequate drainage facilities in wet areas; and
- fittings which should be well above floor level and/or waterproof.

SECURITY

The periphery of the Unit and indeed its location within the Hospital must be such as to control unauthorised access at all times. Refer to PD2005_339 - Protecting People and Property, NSW Health Policy and Guidelines for Security Risk Management in Health Facilities.

03.08 Finishes

WALL PROTECTION

These surfaces should be washable and/or scrubbable with adequate protection against damage by trolleys. Refer to Part C of these Guidelines.

FLOOR FINISHES

Non-slip flooring is essential for all wet work areas. The floor surface should be impervious, have adequate drainage and be easy to clean. Welded sheet vinyl, coved up the wall, is recommended.

Refer to Part C of these Guidelines.

CEILING FINISHES

Ceilings must be washable, impermeable and non porous. Refer to Part C of these Guidelines.

03.09 Fixtures, Fittings & Equipment

DESCRIPTION

EQUIPMENT - GENERAL

The various zones within the SSU should accommodate the equipment manufacturer's recommendations, as space requirements may vary from one manufacturer to another. All items of equipment will need to be itemised and the dimensions of large items obtained to ensure they can be suitably housed and that:

- doors are sized to allow passage of equipment;
- heat loads are estimated and catered for; and
- weight loads are estimated and checked structurally.

Equipment requiring services such as water and special power must be duly noted and passed to project engineers.

Adequate space for maintenance of major equipment must also be considered.

All sterilizers should be located to have service / maintenance access to equipment from outside the unit whenever possible.

EQUIPMENT - SPECIFIC

Equipment should be provided for washing, drying, sealing, sterilizing, storage and transport of supplies.

Equipment required for the unit may include:

- sinks, hot and cold water and brushes;
- compressed air guns;
- high pressure water equipment;
- ultrasonic washers;
- batch washers / disinfectors and/or tunnel washers;
- drying cabinets - general;
- trolley wash;

- respiratory equipment washer / disinfector and dryer;
- packing tables;
- heat sealers - paper, plastic and laminate;
- sterilizers - steam;
- sterilizer loading trolleys;
- other types of sterilizer as indicated;
- storage shelving; and
- collection / delivery equipment.

Quantity and size of equipment will be determined by the size and/or requirements of the facility.

EQUIPMENT STANDARDS

Sterilizers should comply with:

- AS 1410 Sterilizers - Steam - Pre-Vacuum;
- AS 2182 Sterilizers - Steam - Bench top;
- AS 2192 Sterilizers - Steam - Downward displacement;
- AS 2487 Dry heat sterilizers.

Washer / disinfectors should comply with:

- AS 2945 Batch-type washer / disinfectors for health care facilities;
- AS 3836 Rack conveyor washers for health care facilities.

Ultrasonic cleaners should comply with:

- AS 2773.1 Ultrasonic cleaners for health care facilities - Non- portable;
- AS 2773.2 Ultrasonic cleaners for health care facilities - Bench top.

Sterile services equipment should pass commissioning tests specified in the standards.

03.10 Building Service Requirements

GENERAL

High cost engineering areas which should receive careful consideration by design teams include:

- lighting and the impact of deep planning on lighting requirements;
- extent of the required emergency power system;
- extent of provision of emergency doors; and
- extent of provision of essential back-up systems (eg dual generators, chillers, boilers and dual electrical circuits).

INFORMATION TECHNOLOGY AND COMMUNICATIONS

The following will/may be required:

- intercom at reception entry to Packing Area;
- hands-free intercom to/from Operating Suite;
- data outlets to packing tables - ceiling-suspended; and

- general phone / data outlets to workstations.

COMPRESSED AIR

Compressed air outlets and pressure guns are required at all cleaning sinks.

HOISTS

Where hoists are envisaged as a means of transporting supplies between the SSU and other departments, especially the Operating Suite, at least two (2) hoists should be installed. One should be dedicated to the delivery of sterile items to departments, the second to the return of used items to the SSU.

The hoists should be located so as to maintain the integrity of designated 'clean' and 'dirty' areas at all department levels.

HYDRAULIC SERVICES

The trade waste plumbing and drainage system must be designed to meet the requirements of the relevant Sewerage authority and Health Department.

Information of the quality of chemicals to be used / discharged must be provided by the client to the hydraulics engineer.

Main drains should be protected from potential contaminants.

POWER SUPPLY

An emergency back-up system for the power supply should be available for high priority equipment and illumination. One sterilizer may be on uninterrupted power supply (UPS).

Power to the packing tables should be ceiling-suspended.

STEAM SUPPLY

Steam should be provided in accordance with the requirements of AS 1410 - Sterilizers-Steam-Pre-Vacuum.

Supply pipework should be correctly trapped to remove condensate and fitted with appropriate strainers.

As the SSU may be the sole user of steam in a healthcare facility and the size of the steam plant itself would be relatively small, it is important to establish early in the planning process how steam will be delivered, by gas- fired or electric generators.

If gas is selected, the generator is often located quite a distance from the SSU in a multipurpose plant area particularly if space is limited in the sterilizer plant area. If this is the case then there must be a suitable reticulation system factored into the project as a good steam supply is critical to the function of the sterilizers.

If electric is preferred, then this may require installation in close proximity to the sterilizers. Electric steam generators are compact in size (approx the dimensions of a domestic refrigerator) but require space around them for service access. This type of generator is often located in the plant room along with the steam sterilizers and hence the master plan needs to consider a larger area for plant if electric is opted for in the final plan.

WATER QUALITY

Tests should be conducted weekly on the hardness of the available water and records kept of the results. Useful information on the quality of water may be obtained from the local water authority.

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 materials.

Some cleaning agents are specifically designed for use with hard water. Information about local water quality will aid in selecting an appropriate cleaning agent, particularly in inland parts of the State.

Demineralised water will be required for ETO sterilizers (tank).

04 COMPONENTS OF THE UNIT

04.01 Standard Components

Rooms / spaces are defined as:

- *standard components* (SC) which refer to rooms / spaces for which room data sheets, room layout sheets (drawings) and textual description have been developed;
- *standard components – derived rooms* are rooms, based on a SC but they vary in size. In these instances, the standard component will form the broad room 'brief' and room size and contents will be scaled to meet the service requirement;
- *non-standard components* which are unique rooms that are usually service-specific and not common.

The standard component types are listed in the attached Schedule of Accommodation.

The current Standard Components can be found at: www.healthfacilityguidelines.com.au/standard-components

04.02 Non-Standard Components

RECEIVING AREA

Description and Function

Area where soiled articles for processing are received on trolleys from Units throughout the facility and any waste is disposed of. Will/may also contain facilities for washing trolleys.

Location and Relationships

Direct access from main corridor.

Direct access from Operating Suite either horizontally or vertically via hoists.

Adjacent to Disposal Room.

Considerations

FF&E will include:

- stainless steel bench;
- trolley washing facilities with adequate drainage;
- trolleys; and
- hand basin.

Given the weight of some of the instrument trays, consideration may be given to a roller bench that itself must be of a height to enable loading.

CLEANING / DECONTAMINATION

Description and Function

Area for the cleaning of equipment for reprocessing.

Location and Relationships

The Decontamination area should be located between the Receiving area and the Packing / Clean Workroom area.

Considertions

FF&E will include:

- stainless steel deep bowl sinks with tubing manifolds (air and water) and additional water outlets for water pistols;
- stainless steel benches;
- instrument and tubing washers / decontaminators according to service requirements plus parking space for loaded / spare trolleys;
- ultrasonic cleaner according to service requirements;
- instrument and tubing dryers, according to service requirements;
- staff hand washing basin;
- exhaust air extraction over sinks and equipment doors; and
- pass-thru hatch to the packing area.

All decontamination and washing equipment should be installed and commissioned to the requirements of all relevant Australian Standards and Occupational Health requirements, in particular AS 2773 for Ultrasonic Cleaners and AS 2945, AS 3836 for Washer / Disinfectors.

PACKING / CLEAN WORKROOM

Description and Function

Packing Area (Clean Workroom) where clean instruments, equipment and other articles are sorted, checked and packaged for sterilizing.

Location and Relationships

Located between Cleaning / Decontamination and Sterilizing Zones

Considerations

FF&E will include:

- packing tables;
- trolleys;
- heat sealers (paper);
- storage of drapes; and
- hand washing facilities.

STERILIZING AREA

Description and Function

Area where sterilizers are loaded, set into operation and unloaded following completion of the sterilizing cycle.

The cooling / unloading area needs to provide parking space for sterilizer loading trolleys holding cooling packs and a work area for plastic wrapping and sealing.

Specialised sterilizers such as ethylene oxide and low temperature plasma require separate installation and accommodation according to manufacturer's recommendations.

The size of the area will be dependent on the number and type of sterilizers installed and, importantly, whether the sterilizers are front loaded or double sided.

Location and Relationships

The Sterilizing and Cooling area should be located between the Sorting and Packing area and the Dispatch area.

Considerations

Special consideration should be given to the location of the sterilizers.

External access to a sterilizer plant is highly desirable so that repairs or routine maintenance do not interfere with the activities within the Workroom.

A duct enclosure can also minimise heat build-up within the Workroom. An exhaust over the front of the sterilizer/s should also be considered, to extract both heat (cabinet) and steam (opening door).

The air handling system should be filtered or discharged direct to the outside to prevent lint build-up and related industrial and fire safety problems.

High level supply and low level exhaust is the recommended airflow pattern, with localised high level extraction for heat removal only.

FF&E will include:

- sterilizers;
- sterilizer loading trolleys (and area for charging same);
- work station for computer and QA activities;
- wheeled trolleys;
- mobile storage shelving for stacking respiratory circuits and accessories;
- workstation for sealing sterilized packs; and
- mobile storage shelving for completed items awaiting placement into steam sterilizers.

AX APPENDICES

AX.01 Schedule of Accommodation

A Schedule of Accommodation follows and assumes 2 or 4 Sterilisers in a Unit. The schedule will need to be amended in accordance with the requirements of the Service Plan.

The 'Room/ Space' column describes each room or space within the Unit. Some rooms are identified as 'Standard Components' (SC) or as having a corresponding room which can be derived from a SC. These rooms are described as 'Standard Components –Derived' (SC-D). The 'SD/SD-C' column identifies these rooms and relevant room codes and names are provided.

All other rooms are non-standard and will need to be briefed using relevant functional and operational information provided in this HPU.

In some cases, Room/ Spaces are described as 'Optional' or 'o'. Inclusion of this Room/ Space will be dependent on a range of factors such as operational policies or clinical services planning.

STERILE SUPPLY UNIT

Department	AusHFG Room Code	Room / Space	SC / SC-D	Qty	m2	Remarks
2 Sterilisers		After Hours Cupboard		1	4	Access from inside and outside the Unit
4 Sterilisers		After Hours Cupboard		1	6	Access from inside and outside the Unit
2 Sterilisers	CLRM-5	Cleaner's Room, 5m2	Yes	1	5	Within unit
4 Sterilisers	CLRM-5	Cleaner's Room, 5m2	Yes	1	5	Within unit
2 Sterilisers		Cleaning / Decontamination		1	50	
4 Sterilisers		Cleaning / Decontamination		1	80	
2 Sterilisers	DISP- 8	Disposal Room, 18m2	Yes	1	8	Access to external corridor
4 Sterilisers	DISP- 8	Disposal Room, 18m2	Yes	1	8	Access to external door
2 Sterilisers	STGN-9	Store - General, 9m2	Yes	1	12	Bulk goods receipt, decartoning, Linen
4 Sterilisers	STGN-9	Store - General, 9m2	Yes	1	20	Bulk goods receipt, decartoning, Linen
2 Sterilisers		Loan Equipment Store		1	9	Optional; may be located in OR
4 Sterilisers		Loan Equipment Store		1	12	Optional; may be located in OR
2 Sterilisers	OFF-S9	Office - Single Person, 9m2	Yes	1	9	
4 Sterilisers	OFF-S9	Office - Single Person, 9m2	Yes	1	9	
2 Sterilisers		Packing / Clean Workroom		1	50	
4 Sterilisers		Packing / Clean Workroom		1	80	
2 Sterilisers		Receiving Area - Used Items		1	20	
4 Sterilisers		Receiving Area - Used Items		1	35	
2 Sterilisers	RECL-10	Reception / Clerical	Yes	1	9	Pass-thru hatch or counter with shutter to corridor
4 Sterilisers	RECL-10	Reception / Clerical	Yes	1	9	Pass-thru hatch or counter with shutter to corridor
2 Sterilisers		Steriliser - Low Temperature		1	6	Free standing
2 Sterilisers		Steriliser - Steam		1	20	Includes plant
4 Sterilisers		Steriliser - Steam		1	40	Includes plant
2 Sterilisers		Steriliser Cooling		1	10	If separate from loading and in sterile stock area
4 Sterilisers		Steriliser Cooling		1	20	If separate from loading and in sterile stock area
2 Sterilisers		Steriliser Loading / Unloading		1	20	Plus spare trolleys
4 Sterilisers		Steriliser Loading / Unloading		1	40	Plus spare trolleys
4 Sterilisers		Sterilising - ETO		1	9	Free standing plus aeration cabinet
4 Sterilisers		Sterilising - Low Temperature		1	6	Free standing
2 Sterilisers	STPS-8	Store - Photocopy / Stationery, 8m2	Yes	1	8	
4 Sterilisers	STPS-8	Store - Photocopy / Stationery, 8m2	Yes	1	8	
2 Sterilisers	STSS-30	Store - Sterile Stock, OR	Yes	1	40	Adjust for 10m2 per OR. For OR storage
4 Sterilisers	STSS-30	Store - Sterile Stock, OR	Yes	1	80	Adjust for 10m2 per OR. For OR storage
2 Sterilisers	STSS-30	Store - Sterile Stock	Yes	1	20	For other clinical areas
4 Sterilisers	STSS-30	Store - Sterile Stock	Yes	1	40	For other clinical areas
4 Sterilisers		Trolley Wash		1	15	Optional

STERILE SUPPLY UNIT - Staff Areas

Department	AusHFG Room Code	Room / Space	SC / SC-D	Qty	m2	Remarks
2 Sterilisers	CHST-10	Chane - Staff (Male / Female)	Yes	1	10	Could be shared with adjacent OR
4 Sterilisers	CHST-10	Staff Change		1	16	Could be shared with adjacent OR
2 Sterilisers	SRM	Staff Room	Yes	1	15	Could be shared with adjacent OR; used for training facilities
4 Sterilisers	SRM	Staff Room	Yes	1	12	
2 Sterilisers	SHST	Shower - Staff, 3m2	Yes	1	2	
4 Sterilisers	SHST	Shower - Staff, 3m2	Yes	1	2	
2 Sterilisers	WCST	Toilet - Staff, 3m2	Yes	1	3	
4 Sterilisers	WCST	Toilet - Staff, 3m2	Yes	2	3	
4 Sterilisers	MEET-12	Meeting Room, 12m2	Yes	1	12	

AX.02 Functional Relationships / Diagrams

This clause is currently under review / not applicable, but has been included for consistent HPU clause numbering.

AX.03 Checklists

For planning checklists, refer to Parts A, B, C and D of these Guidelines.

AX.04 References

Sterilization and Disinfection Core Competencies - NSW Department of Health, 2003.

NHS Estates Schedules of Accommodation v2.0, HBN13A - Sterile Services Departments.

Disinfection and Sterilisation - Extract from Infection Control Guidelines, Queensland Government, November 2001.

WA Hospital Design and Operation Guidelines for Engineering Services V2, Draft 4.

Central Sterile Supply Unit (CSSU), Design Guidelines for Hospitals and Day Procedure Units, Department of Human Services, Victoria, November 2004.