Part B – Health Facility Briefing & Design

280 Sterile Supply Unit

iHFG

International Health Facility Guidelines

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280 Sterile Supply Unit

1 Introduction

Description

The Sterile Supply Unit's role is to clean, decontaminate and store re-usable instrument, tools, equipment, medical devices and other items to ensure patient safety, compliance, efficiency and economy.

Where viable, centralised Units minimise duplication and facilitate effective auditing while delivering a one-way flow of items between soiled and clean areas.

Service planning models will determine the size of each department. Where a full service is unavailable external suppliers will be relied upon to maintain stock levels.

2 Functional and Planning Considerations

Operational Models

The Sterile Supply Unit (SSU) also referred to as CSSD, provides a sterilising service to surgical units, critical care areas and procedures/ investigation areas and other areas within the health facility. The Unit may also provide sterilising service to outlying units if local sterilising is not available according to the unit service plan. Sterilising facilities will generally be provided centrally within hospital, serving several areas rather than decentralised units in order to avoid duplication of equipment and trained staff. SSU is also required for facilities such as stand-alone Day Surgery Centres. For sterilising facilities for Dental Surgeries, please refer to the separate FPU.

The size and role of the sterile goods supply service shall be clearly defined in the Operational Policy Statement. Operational policies will be drafted on project specific basis by users and staff of the Sterile Supply Unit, the Operating unit and all other relevant staff associated with this service.

Hours of Operation

The typical Sterile Supply Unit will operate up to 10 hours per day 5 days per week to maximise Unit efficiency.

If the service model permits a 24-hour service is desirable. If unavailable, authorised access and/ or a pass-through cupboard permits a distribution point both after hours and when required in emergency use.

3 Unit Planning Models

Sterilising services may be provided on-site or off-site using external suppliers in a commercial arrangement. External supplier arrangements may include a full service for all re-usable medical devices to partial supply of sterile goods such as linen packs, instrument sets and dressing packs.

For sterilising services provided externally consideration needs to be given to ensure sufficient instruments and supplies for the expected turn-around and adequate holding and storage areas for receiving and dispatch of supplies.

The SSU located on-site should be positioned with direct access to Operating Unit. Direct access may also be provided via clean and dirty service lifts.

Functional Areas

The Sterile Supply Unit will include the following functional areas or zones:

- Receiving area including:
  - Trolley holding for returned trolleys with instruments or case carts
  - Goods Receipt/ Non-Sterile Store for consumable stock used in processing and packing
  - Loan Equipment Store for deliveries of loan sets from specialised surgical suppliers
- Decontamination area including:
  - Trolley stripping area for dismantling of trolleys

  - Cleaning/ Decontamination area where all instruments are sorted, rinsed, ultrasonically cleaned or mechanically washed then dried
  - Trolley wash area for cleaning of trolleys this may include manual washing or automated trolley washing equipment

- Sorting and Packing area including:
  - Airlock entry to maintain air pressurization within the clean zone
  - Sorting, Assembly and Packing area; this is a Clean Workroom where clean instruments, equipment and other articles are sorted, counted and packaged for sterilizing at packing workstations

- Sterilising and Cooling area including:
  - High temperature sterilizers including loading and unloading space
  - Low temperature sterilizers for items requiring this method of sterilizing
  - Plant area for access to sterilizers
  - Cooling area for trolleys unloaded from sterilizers are held while stock is cooling

- Despatch Area for distribution of sterile stock to Operating Unit or other hospital units at the same time sterile stock may also be collected from this area by hospital units if urgently required

- An After-Hours cupboard may be provided for urgent supplies of sterilized items outside of operating hours

- Support Areas including
  - Handwashing Bays; at entry/ exits to Decontamination and Sorting/ Packing areas
  - Cleaner's rooms
  - Disposal Room
  - Stores for chemicals used in processing instruments, general supplies used in the Unit and sterile stock for Operating Unit and Inpatient Units

- Administrative and Staff Areas including:
  - Offices or Workstations
  - Meeting Room or access to a Meeting room
  - Change Rooms, which may be shared depending on the size of the Unit
  - Staff Room, which may also be shared with Operating Unit if convenient

Receiving Areas

The Trolley Holding area is a lobby or holding space provided for return of used items & trolleys awaiting stripping and cleaning. Trolley Holding should be located with ready access to Trolley Wash, Decontamination and Disposal Rooms.

The receiving area is a wet area and will include a trolley dismantling area where trolleys are stripped. Dirty linen and waste is despatched for transfer to the Disposal Room. Used instruments are delivered to Cleaning/ Decontamination area.

The Non-Sterile Store will require external access for deliveries and internal access for decanting supplies to the point of use. The Non-Sterile Store will hold stock that is 'clean' but not sterile; space will also be required for storing trolleys. General unit stock which is clean but not sterile is to be stored separately from sterile stock.

The Loan Equipment Store provides a holding area for loan instrument sets and supplies from surgical suppliers. Instruments sets are bulky, heavy items, generally received in boxes or crates and will require mechanical lifters to assist is moving the equipment. The Loan store will require external access for deliveries and should be located with ready access to Decontamination areas.

Decontamination Areas

The Decontamination area is a wet area where used instruments are sorted and processed.

In the Cleaning/ Decontamination area, instruments are rinsed, ultrasonically cleaned if appropriate, washed/ decontaminated through instrument processing equipment and dried. Special instruments may be hand washed in this area. Instruments may be tracked by using an instrument tracking system.

The Cleaning/ Decontamination area shall contain benches for instrument sorting, sinks and mechanical equipment for cleaning and decontamination of reusable surgical equipment. The Decontamination functions may also be provided in a Clean-up Room in smaller units. There will be a need to provide special types of cleaning equipment dependent on the level of service such as batch washer/ disinfectors, tunnel washers, ultrasonic cleaners, anaesthetic tubing washers and dryers. An emergency eye wash facility is to be provided.

The Decontamination area should be located between the Receiving area and the Sorting/ Packing area. Convenient access to a Disposal Room for disposal of used/ soiled material will be required. The area must include hand-washing facilities.

A trolley/ cart washing area will be required for washing and disinfecting of trolleys and carts prior to re-loading carts with cleaned and sterilised equipment for return. An automated trolley washing equipment may be installed in larger Units.

Endoscope Processing

Endoscope processing may be included in the SSU rather than Day Surgery or Endoscopy Units. If located within SSU, the process should be separate to instrument processing and follow a dirty to clean pathway from cleaning to disinfection then storage.

Endoscopes, both flexible and non-flexible undergo a process of disinfection using chemical cleaning agents by manual washing or automated reprocessing machines. The process requires large sinks and tanks of disinfecting solution or automated machines. Instruments are leak tested, then manually pre-cleaned in an enzyme solution followed by high level disinfection with an approved disinfectant solution in a fume cabinet or enclosed automated machine. Compressed filtered air is required for the drying process. An ultrasonic machine is required for cleaning of accessory instruments. The process requires monitoring and documentation of quality control measures.

Endoscope processing machines require services including electrical, mechanical ventilation and hydraulics services with filtered water supply and drainage. This equipment should be installed to manufacturer's specifications.

Disinfected endoscopes are stored in endoscope cabinets that are HEPA filtered and ventilated.

Sorting/ Packing

The Sorting/ Packing area is a Clean Room where cleaned and dried instruments are removed from the decontaminating/ drying equipment, sorted, assembled into sets and packaged, ready for sterilising. Instruments in this area may be tracked by using an instrument tracking system.

The Sorting/ Packing area will be located between the Cleaning/ Decontamination area and the Sterilising area, with a unidirectional workflow from contaminated to clean areas. The Sorting/ Packing area shall be separate area to instrument Cleaning/ Decontamination.

The Sorting/ Packing area will provide packing tables and equipment for assembly of cleaned and dry instruments into sets which are then wrapped and sealed ready for sterilisation. Consideration should be given to ergonomics aspects of packing tables. Special attention should be given to the height and depth of workbenches to allow staff to work sitting or standing. Adjustable height packing tables and equipment are recommended.

Linen folding where required, shall be carried out in a separate room, preferably the laundry. The air handling system shall 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.

Views to the outside are considered highly desirable. A handwashing basin shall be provided at the entry/ exit of the room, located to avoid water contamination of wrapped instrument sets.

Sterilising and Cooling

The Sterilising and Cooling Area provides accommodation for sterilisers and parking space for steriliser and cooling trolleys. Following unloading of the steriliser, packs should not be handled until cool. Specialised low temperature sterilisers including peracetic acid models or hydrogen peroxide gas plasma require installation and accommodation according to manufacturer's recommendations. The size of the area will be dependent on the number and type of sterilisers installed.

The Sterilising and Cooling area should be located between the Sorting/ Packing area and the Despatch area. Special consideration shall be given to the location of the sterilisers. External access to the steriliser plant is highly desirable so that repairs or routine maintenance do not interfere with the activities within the workspace. A duct enclosure can also minimise heat build-up within the area. An exhaust over the front of the steriliser(s) shall also be considered, to extract both heat (cabinet) and steam (opening door).

Special equipment for incubator sterilization may be incorporated in accordance with the hospital's Clinical Service Plan.

If automated bed washing is intended it is recommended to provide a stand-alone facility in the service zone of the hospital.

Despatch Area

The Despatch area will coordinate the distribution of sterile stock to the required hospital units. It will include a counter or desk and trolley holding space for packed trolleys awaiting delivery. The Despatch area will require external access for hospital units to collect urgent stock with restricted access to the internal departmental areas.

An After-Hours cupboard may be provided in this area for staff to collect urgent supplies preferably a pass-through cabinet with internal access for re-stocking.

Support Areas

Support areas include Cleaner's rooms, Disposal rooms and Store- rooms for chemicals and sterile stock.

Cleaner's rooms should be provided separately in clean and dirty areas of the unit.

The Disposal room should be located with access to an external corridor for ease of waste removal without accessing the Unit.

Sterile Stock stores for Operating Unit and other hospital units should be provided separately. The Sterile Stock rooms will require positive pressure, filtered air with humidity and temperature control to ensure stock is maintained in a sterile condition. The level of filtration provided should equal or exceed that of Operating Rooms.

The chemical store will hold chemicals used in the washing/ decontaminating process and may be reticulated to the washing equipment. An external access is recommended for delivery of chemical supplies.

Administrative and Staff Areas

Change areas for staff will include toilets, showers, handbasins and lockers with facilities for clean linen holding. All staff working in this Unit must wear personal protective equipment and clothing, including eye and ear protection due to equipment noise in decontamination areas and hospital attire in clean areas. In large facilities, consider separate toilet and change rooms for the decontamination staff.

The Change rooms should be located with external access and convenient and separate internal access to clean and dirty operational areas. There should be no cross flows for staff accessing clean and dirty areas of the Unit. Change rooms will include storage for used clothing which will require collection and removal to the Disposal room. Change rooms may be shared with an adjacent Operating Unit if located conveniently.

Offices or workstations will be required for routine clerical/ administrative procedures, located in the staff accessed areas. Offices for the Manager/ Supervisor and should have oversight of the operational areas within the Unit. The provision of offices will depend upon the size of the Unit. An area for storage of stationery and files should be provided.

Access to a Meeting Room will be required for staff meetings and training purposes, which may be shared with an adjacent Unit.

4 Functional Relationships

A Functional Relationship can be defined as the correlation between various areas of activity whose services work together closely to promote the delivery of services that are efficient in terms of management, cost and human resources. The Sterile Supply Unit is a key service unit within the hospital, supporting Surgical, Critical Care, Inpatient and Outpatient services. Correct functional relationships are identified below:

External Relationships

The Sterile Supply Unit (SSU) should be located with direct or close access to the Operating Unit and Day Surgery Units. This may be achieved with the use of lifts.

The SSU should have ready access to:

- Service units of the hospital including Supply Unit, Linen Handling Unit and the Loading Dock for delivery of supplies
- Hospital units requiring return and delivery of sterilised items including critical care units and inpatient units, outpatient units as determined by the Operational Policy

Access to the SSU should be restricted to authorised personnel only.

These relationships are demonstrated in the Functional Relationships Diagrams below. Three Functional Relationships diagrams are provided for small, medium and large units.

The diagram demonstrates the flow of goods, staff as well as desirable relationships between external and internal zones.

The diagrams demonstrate good functional external relationships which include:

- A direct link to/ from the Operating Unit, Day Surgery and Endoscopy for goods returned and supplied; this may be by lift
- Access from hospital units to the SSU directly from a circulation corridor
- Controlled access to the Unit from circulation corridor

Endoscope processing may be included within the SSU or located as a separate discreet function within or adjacent to Day Surgery or Endoscopy Units. The hospital's Operational Policies will determine the inclusion of endoscope processing within the SSU.

Internal Relationships

A unidirectional flow for instrument processing from contaminated or dirty areas to clean and sterile areas is critical to the functioning of the Unit.

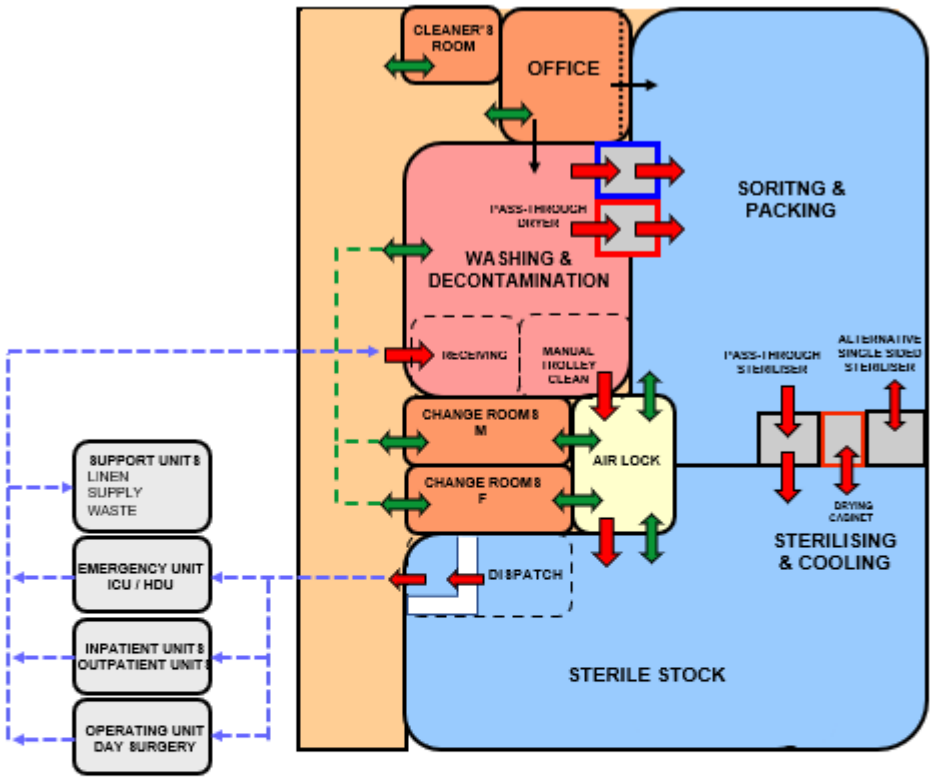
The following represents correct relationships in the processing from dirty to clean:

- Goods arrive from clinical areas to the Cleaning/ Decontamination Area - dirty zone via lifts or service corridors to a holding area
- Instruments are processed through the Cleaning/ Decontamination Area and move to the Sorting/ Packing area – a clean zone
- Trolleys are cleaned in the Cleaning/ Decontamination zone or a dedicated trolley wash and transferred to Sterile Stock/ despatch area for loading and retune to inpatient or operating units
- There is a separation between dirty and clean areas with controlled entries and no back-flow; airlocks may be required to maintain the air pressurisation of the separate zones
- Goods then flow from clean packing areas to the sterile areas and then delivered to clinical units
- Sterile stock is located adjacent to Sterilising & Cooling, with direct access to Despatch or clean lift for delivery to Units
- Incoming clean goods are taken directly to a neutral or clean zone including non-sterile supplies and loan equipment
- There is a separate entry for staff who may only enter clean areas through a controlled entry

- Staff access though a separate entry via Change Rooms and enter the dirty zone or the clean zone; Staff leaving the dirty zone re-enter via change rooms

Functional Relationships Diagrams

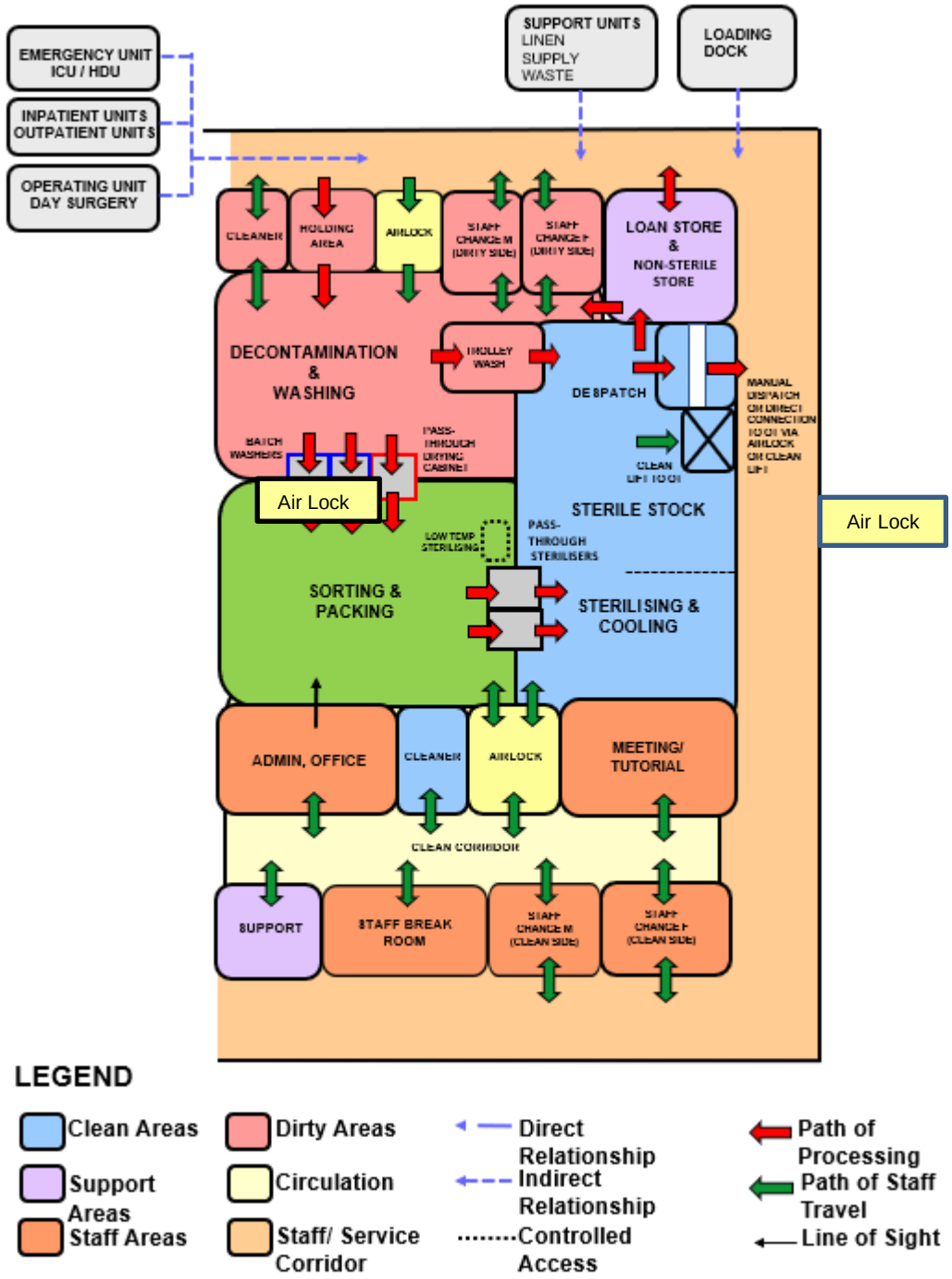
SSU Small - 1 steriliser



LEGEND

- Clean Areas
- Support Areas
- Staff Areas
- Dirty Areas
- Circulation
- Staff/ Service Corridor
- Direct Relationship
- Indirect Relationship
- Controlled Access
- Path of Processing
- Path of Staff Travel
- Line of Sight

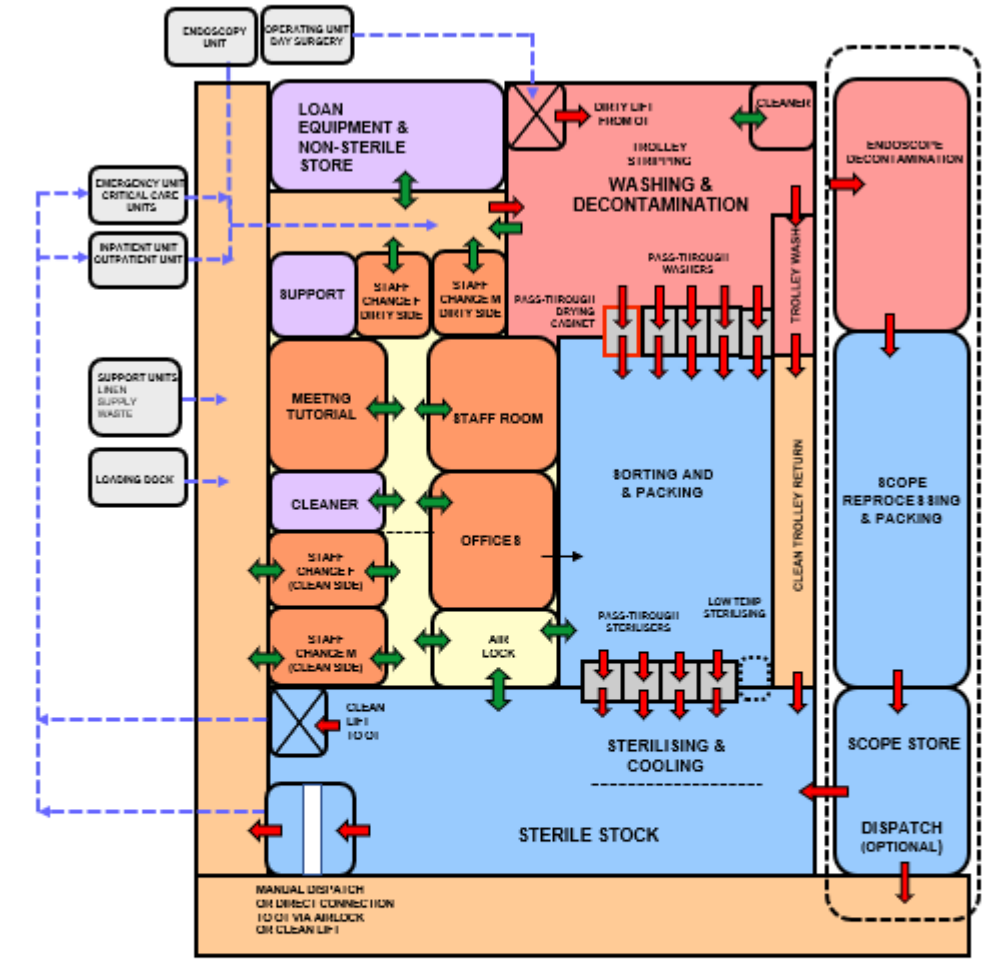
SSU- Medium - 2 sterilisers



LEGEND

- Clean Areas
- Dirty Areas
- Support Areas
- Staff Areas
- Circulation
- Staff/ Service Corridor
- Direct Relationship
- Indirect Relationship
- Controlled Access
- Path of Processing
- Path of Staff Travel
- Line of Sight

SSU - Large - 4+ sterilisers



LEGEND

- Clean Areas
- Dirty Areas
- Support Areas
- Circulation
- Staff Areas
- Staff/ Service Corridor
- Direct Relationship
- Indirect Relationship
- Controlled Access
- Path of Processing
- Path of Staff Travel
- Line of Sight

5 Design Considerations

General

Two classifications of goods are received by the SSU: contaminated items and raw materials.

Design solutions must ensure the separation of clean and dirty products avoiding routes and cross-flows which potentially could re-contaminate processed items or adversely affect the microbiology of raw materials. There must be a unidirectional workflow from contaminated to clean and sterile areas.

Adequate circulating space to accommodate trolleys and containers demanded by the departmental workload is required to ensure effective demarcation of clean and dirty areas.

Environmental Considerations

Acoustics

Provide acoustic treatment for noise generating equipment including washer/ decontaminators, sterilisers and dryers located in Cleaning/ Decontamination and Sterilising areas. Consideration should be given to acoustic privacy in Offices, Staff Rooms and Meeting Rooms.

Natural Light/ Lighting

Natural lighting aids visual inspection and has positive impact on the staff morale. Where natural lighting is not possible, glazed panels should be considered. Windows where provided must be non-opening, sealed and flush fitting except in Offices and Staff Rooms.

Task lighting including magnification inspection lights is desirable for instrument inspection. Light levels shall not be less than 400 lux at the working surface. Light fittings shall be fully recessed and selected to prevent dust and insects from entering.

Space Standards and Components

Doors

Doors used for passage of collection and distribution trolleys should be a minimum of 1200mm wide. Automatic or semi-automatic doors are recommended for ease of transit. Ergonomics/ OH&S Consideration should be given to ergonomic functionality in the Unit. Benches, sinks and packing workstations should be provided as suitable working heights. Adjustable height equipment is recommended.

The following occupational health and safety issues should be addressed during planning and design for staff safety and welfare:

- Manual handling of heavy instrument that may require lifting equipment
- Chemical agents used in Cleaning/ Decontamination processes may require specific chemical handling requirements (Refer to local regulations)
- Electrical and fire hazards related to equipment in use
- Biological hazards of contaminated equipment undergoing processing which requires stringent infection control management

Doors to areas which are likely to be used for trolley and equipment movement should include protection. The protection may include materials such as stainless steel, vinyl or proprietary materials. Protection may also extended to the door frames. Protection up to 900mm from the finished floor level is recommended.

Refer to Part C – Access, Mobility and OH&S of these guidelines for further information

Size of the Unit

The size of the SSU will be dependent on:

- The number of Operating Rooms, Procedure Rooms and clinical areas
- The clinical specialties of surgery performed e.g. orthopaedic surgery or microsurgery
- The projected workload according to the operating caseload and the specialty types

- The amount of sterile stock storage required within the Unit or decentralised to clinical Units
- The amount of commercially supplied pre-sterilised stock in use
- The provision of outsourced supplies of linen required for processing
- The number and type of cleaning/ decontamination equipment, sterilisers and dryers, single sided or pass-through models
- The ability to share areas such as Change Rooms and Staff Rooms with an adjacent Operating Unit

These aspects will be determined by the hospital's service plan and operational policies. A Schedule of Accommodation (SOA) has been provided for 1, 2 and 4 steriliser units but may be amended in accordance with each facility's service plan requirements.

Assuming a work schedule of 5 days per week for 8 hours per day. The following is a simple recommended indicator of unit size and capacity- though it is not mandatory:

- 1 Steriliser can service 2 Operating Rooms
- 2 Sterilisers can service 4 Operating Rooms
- 4 Sterilisers can service 8 Operating Rooms

Steriliser's capacity may be decided according to the project's requirements.

Safety & Security

Controlled access to prevent unauthorised entry for non-staff is highly advised. Should be located in the isolate area from general hospital traffic. Signposting should give direct access to the Sterile Supply Unit (SSU) Office/ Reception for general purposes and visitors to the Unit.

Finishes

All finishes should withstand frequent cleaning and be tolerant of surface cleaning agents. Joints should be avoided to deter moisture and organism growth. Work surfaces and sinks should have all gaps sealed. If gaps are unavoidable cleaning access is essential.

Floors

Floor finishes should be hard wearing, non-slip, easy to clean of a uniform level and suitable for heavy trolley traffic. Structural expansion points should be positioned with care in heavy traffic areas particularly where trolleys turn corners. Structural expansion points are unacceptable in the clean and sterile zones. Flooring should have integrated coved skirting continuous with the floor for ease of cleaning.

For SSU floors, fully welded vinyl floors are recommended. Alternatively industrial quality epoxy flooring may be considered. Tiled floors with joints are not recommended for SSU.

Floor scrubbing equipment is not appropriate for SSUs. If vacuum cleaners are used they should be fitted with high efficiency particulate air filters (HEPA).

Walls

Hollow wall constructions are vulnerable to trolley damage and risk pest infestation. Solid, rendered, smooth walls, epoxy coated or spray painted withstand heavy treatment and allow ease of repair. Impact resistant wall lining or wall protection should be considered if dry walls are used. In wet areas, fully welded wall vinyl may also be considered.

Ceilings

Ceilings should prohibit ingress of airborne particles or contaminants and be resistant to humidity. Ceiling should be flush, sealed against walls and easily cleaned.

Drop-in tiled ceilings are not permitted. If access hatches are required, these should be proprietary, hermetically sealed units, openable via security keys.

Fixtures, Fittings & Equipment

Shelving systems installed should be constructed of non-porous materials, dust resistant, easily cleaned and avoid inaccessible corners.

Equipment installed in the Unit including sinks, cleaning/ decontamination equipment, sterilisers, dryers, trolley washing equipment and will require mechanical, hydraulics or electrical services in accordance with manufacturers recommendations and Ministry of Health regulations.

Building Service Requirements

Communications

Voice and telephone communications should be installed within the Cleaning/ Decontamination area, the Sorting/ Packing, Sterile areas and Offices to allow contact with outside personnel and departments without breaching contaminated and clean areas.

Management Information Systems (MIS) require adequate data points and electrical points for the tracking and tracing of products and quality assurance records passing through the decontamination process including wet areas, packing areas and sterilising areas.

Heating, Ventilation & Airconditioning

The Sterile Supply Unit is a controlled environment and ventilation shall be provided by a treated air supply with compliant air-conditioning systems and HEPA filters. Positive air pressure differential should be maintained above that of the surrounding areas in Clean and Sterile zones. Negative pressure should be maintained in Cleaning/ Decontamination areas. Indicators and alarms systems to alert staff of ventilation system failure should be provided.

Humidification will be required to avoid dehydration and subsequent processing problems associated with absorbent materials.

Washers-disinfectors, sterilisers emit considerable heat and humidity affecting electronic controls.

Fully insulated pipework and machinery backed up by extract ventilation is essential to ensure tolerable working conditions, conserve energy and minimise operating costs. Heat recovery from ventilation systems should be incorporated where appropriate.

Refer to Part E - Engineering Services in these Guidelines for further information.

Engineering Services

Maintenance access to steriliser plant should be outside ‘clean’ areas and avoid disruption to the SSU and staff work areas wherever possible. Easy direct access to the front of the sterilisers in the loading/ unloading area and the discharge side for double door machines must be allowed.

Mechanical service points e.g. drainage manholes, fire hose reels etc, should be designed out of the SSU area. Sorting and packing, sterilising and cooling, and sterile stock areas should not include floor waste outlets.

Emergency power should be provided to all essential cleaning/ decontaminating and sterilising equipment.

Steam may be provided by local plant generating equipment or sterilising equipment may have integral steam generation. If steam generating plant equipment is to be installed, the location to avoid excessive distance from sterilisers.

Water quality will require investigation for efficient functioning of cleaning/ decontamination and sterilising equipment. Water filtration may be required to specific washer/ decontaminators.

Infection Control

Hand Basins

Handwashing facilities should be provided at the following locations:

- Entry and exit of cleaning/ decontamination areas
- Entry/ exit of clean and sterile areas

Handbasins should be located to avoid water splashing on clean and sterile goods.

Antiseptic Hand Rubs

Antiseptic hand rubs should be located so they are readily available for use in staff and circulation areas.

The placement of antiseptic hand rubs should be consistent and reliable throughout facilities. Antiseptic hand rubs are to comply with Part D - Infection Control, in these guidelines.

Antiseptic Hand Rubs although very useful and welcome, however cannot fully replace Hand Wash Bays.

Disaster Planning

The SSU should be capable of continued operation during and after a natural disaster. Except in instances where a facility sustains primary impact. Special design consideration is needed to protect essential services such as emergency power generation, heating and/ or cooling systems, water supply etc.

6 Standard Components of the Unit

Standard Components

Standard Components are typical rooms within a health facility, each represented by a Room Data Sheet (RDS) and a Room Layout Sheet (RLS).

The Room Data Sheets are written descriptions representing the minimum briefing requirements of each room type described under various categories:

- Room Primary Information includes Briefed Area, Occupancy, Room Description and relationships, and special room requirements
- Building Fabric and Finishes identifies the fabric and finish required for the room ceiling, floor, walls, doors, and glazing requirements

  Furniture and Fittings lists all the fittings and furniture typically located in the room. Furniture and Fittings are identified with a group number indicating who is responsible for providing the item according to a widely accepted description as follows:

Group	Description
1	Provided and installed by the Builder/ Contractor
2	Provided by the Client and installed by the Builder/Contractor
3	Provided and installed by the Client

- Fixtures and Equipment includes all the serviced equipment typically located in the room along with the services required such as power, data and hydraulics. Fixtures and Equipment are also identified with a group number as above indicating who is responsible for provision.
- Building Services indicates the requirement for communications, power, Heating, Ventilation and Air conditioning (HVAC), medical gases, nurse/ emergency call and lighting along with quantities and types where appropriate. Provision of all services items listed is mandatory.

The Room Layout Sheets (RLS's) are indicative plan layouts and elevations illustrating an example of good design. The RLS indicated are deemed to satisfy these Guidelines. Alternative layouts and innovative planning shall be deemed to comply with these Guidelines provided that the following criteria are met:

- Compliance with the text of these Guidelines
- Minimum floor areas as shown in the schedule of accommodation
- Clearances and accessibility around various objects shown or implied
- Inclusion of all mandatory items identified in the RDS

The Sterile Supply will consist of Standard Components to comply with details described in these Guidelines. Refer also to Standard Components Room Data Sheets (RDS) and Room Layout Sheets (RLS) separately provided.

Non-Standard Components

Non-Standard Components are identified in the Schedule of Accommodation as NS and are detailed below:

Receiving Area

This area will receive and hold trolleys and used instruments awaiting processing to cleaning areas. Trolleys and instruments will be sorted initially and waste removed.

The Receiving areas will be located with direct access to a circulation corridor or dirty lift from the Operating Unit. There should be controlled or automatic entry door access.

The Receiving Area will require:

- Benches and sinks with parking space for trolleys
- Hot and cold water outlets to sinks
- Smooth, impervious and easily cleanable surfaces to walls and ceiling
- Impervious and wet area non-slip finishes to the floor
- Staff handwashing basin

Decontamination Area

The Decontamination area is a dirty zone and includes cleaning/ decontamination processing and trolley washing.

The Decontamination area should be located between the Receiving areas and Sorting/ Packing areas.

The Decontamination area will require the following finishes:

- Walls and ceiling that are smooth, impervious and easily cleanable
- Impervious and wet area non-slip finishes to the floor

Fittings, Fixtures and Equipment located in this area will include the following:

- Stainless steel benches and deep bowl sinks with air and suction outlets for tube cleaning and additional water outlets for water pistols
- Instrument and tubing washers/ decontaminators according to service requirements these may be single sided, pass through or index tunnel washers
- Ultrasonic cleaner with consideration to the working height of instrument baskets
- Instrument and tubing dryers as required by the service plan
- Staff handwashing basin
- Exhaust air extraction will be required over sinks and heat/ moisture generating equipment

The trolley washing area will require hot and cold water outlets for manual washing. An-automated trolley wash unit may also be used.

Sorting & Packing

This area is a clean zone and will include a number of sorting/ packing workstations with areas for parking trolleys, heat sealing devices, examination and testing of instruments.

The Sorting/ Packing area will be located between the Cleaning/ Decontamination area and Sterilising/ Cooling area in a one-way flow. Controlled access will be required for staff.

The Sorting/ Packing area will require the following finishes:

- Walls and ceiling that are smooth, impervious, and easily cleanable
- Impervious, non-slip finishes to the floor

Requirements in this area will include the following:

- Packing tables complete with wrapping materials, tracking systems, ergonomically designed to avoid staff fatigue adjustable height stations are recommended
- Sealing equipment
- Trolleys for holding wrapped sets ready for sterilising
- Staff handwashing basin at the entry/ exit located to avoid water splashing on clean, wrapped

sets

- Positive pressure HEPA filtered air conditioning with filtration for linen

Sterilising/ Cooling

This is a sterile area and includes high and low temperature sterilisers with space for loading/ unloading and a cooling area for packed trolleys removed from sterilisers. Sterilising/ Cooling is located between Sorting/ Packing and Sterile Stock stores with a one-way flow.

The Sterilising/ Cooling area will require the following finishes:

- Walls and ceiling that are smooth, impervious and easily cleanable
- Impervious non-slip finishes to the floor

High temperature sterilisers may be single sided or pass-through. Steriliser plant equipment should ideally have external access for maintenance to avoid access to the Unit.

A workstation may be located in this area for quality assurance documentation and instrument tracking.

The air handling requirements of this area include:

- Positive pressure with HEPA filtration
- Efficient exhaust for heat/ steam generating equipment
- Filtration for lint

Low temperature sterilisers will require specialised services and should be installed to manufacturer's specifications.

Endoscope Decontamination

The Endoscope Decontamination area is a dirty zone for receiving and manual cleaning of endoscopes. The area will include stainless steel benches and sinks with sufficient space for laying flexible endoscopes without kinking delicate equipment. Staff will require access to a handwashing basin. Sinks should be large enough to hold coiled endoscopes without damage.

The area will require appropriate ventilation and exhaust for chemicals used in the cleaning process.

Endoscope Reprocessing

Endoscope Reprocessing is a clean zone for processing flexible endoscopes in automated processors. Automated processing units will be installed to manufacturer's specifications and will require appropriate hydraulic and electrical services. The area will require appropriate ventilation and exhaust for chemicals used in processing. The Endoscope Reprocessing area will include:

- Stainless steel bench and sinks for manual disinfection
- A clean area for reassembly of disinfected scopes
- A staff handwashing basin

Endoscope Store

Cupboards for endoscope storage may hold endoscopes horizontally on shelves or hanging vertically. The cupboards should be constructed of moisture resistant material that is easily cleaned. The cupboards should be well ventilated with a filtered air supply to keep endoscopes dry and an alarm system if the air supply or filtration fails. Proprietary endoscope cupboards are recommended.

Despatch

Despatch will include a staff station or counter for coordination of deliveries and space for holding packed trolleys awaiting delivery via a circulation corridor or by clean lift to Operating Unit. A double-sided after-hours cupboard may be provided for urgent collections out of operating hours.

The Despatch should be located between Sterile Stock Stores and an external circulation corridor. There should be controlled access to Despatch with a doorbell or intercom point to alert staff.

The Despatch area will require the following finishes:

- Walls and ceiling that are smooth, impervious, and easily cleanable
- Impervious, non-slip finishes to the floor

Instrument tracking facilities including computers, power and data outlets will be required in this area.

After Hours Cupboard

The After-Hours cupboard will be located in a staff accessible corridor. The cupboard will be lockable and provide a dust free, clean and dry environment for storage of sterile packs and items.

7 Schedule of Equipment & Furniture

The Schedule of Equipment and Furniture below lists the major equipment for the key rooms in this FPU.

Room/ Space	Standard Room Code	Item Description	Qty	Remarks
Cleaning/ Decontamination	NS	Bench: stainless steel	1	
		Computer: PC & monitor	1	optional
		Counter: clean-up, 2-sink	1	or 3-sink depending on the size of the unit
		Hatch: pass-through, CSSD	1	
		Rinser: spray gun, compressed air, wall mounted	1	part of clean-up counter
		Rinser: spray gun, water, wall mounted	1	part of clean-up counter
		Trolley: collection/ distribution, closed, 1200W	4	quantity may change as per operational requirements
		Trolley: loading/ unloading, height-adjustable, washer disinfector	2	
		Ultrasonic cleaning system: freestanding, dual unit, rinse & dry	1	quantity may change as per operational requirements
		Washer disinfector: pass-through	2	quantity and capacity may change as per operational requirements
		Workstation: computer, mobile	1	optional, for instrument tracking system
Instrument Sorting, Assembly & Packing	NS	Cabinet: drying, instrument, single door	1	quantity may change as per operational requirements
		Lamp: magnifying, arm-adjustable	4	may be part of instrument packing table configurations
		Package sealer	4	quantity may change as per operational requirements
		Shelving: stainless steel, wire mesh, mobile	2	
		Table: instrument packing, height-adjustable	4	quantity may change as per operational requirements

		Trolley: loading/ unloading, height-adjustable, washer disinfector	2	quantity may change as per operational requirements
		Trolley: SS, multi-purpose	4	
		Trolley: sterile wrap	2	
Sterilising – High Temperature	NS	Steriliser: steam, pass-through	2	quantity and capacity may change as per operational requirements
		Trolley: loading/ unloading, height-adjustable, steriliser	2	
Sterilising – Low Temperature	NS	Steriliser: low temperature, plasma, pass-through	1	quantity and capacity may change as per operational requirements
Store - Sterile Stock	stss-20-i similar	Bench: laminate	1	
		Chair: ergonomic, high	1	
		Computer: PC & monitor	1	
		Incubator: biological indicator, steriliser	2	1 for steam steriliser and 1 for low temperature steriliser
		Shelving: stainless steel, wire mesh, mobile	10	quantity as required
		Trolley: instrument	2	quantity as required

8 Schedule of Accommodation

The Schedule of Accommodation (SOA) identifies the rooms required in the Unit along with the quantity and the recommended room area. The sum of these room areas is the Sub Total and Total Departmental areas with a recommended circulation percentage. The circulation percentage represents the area required for internal corridors and is a target for efficient planning. SOAs and room sizes are developed for typical units and are organised into the functional zones applicable to the Unit. Not all rooms identified are mandatory requirements and optional rooms are indicated. Quantities of rooms may need to be proportionally adjusted to suit the desired unit size and service needs.

The Schedule of Accommodation for a typical Sterile Supply Unit follows. This schedule is categorised by size of the Unit rather than level of service, however this does not necessarily lead to different physical requirements. The Schedule of Accommodation lists generic spaces that form a Sterile Supply Unit. Quantities and sizes of some spaces will need to be determined in response to the service needs of each unit on a case-by-case basis.

Sterile Supply Unit for 1, 2 and 4 sterilisers

ROOM/ SPACE	Standard Component Room Codes	2 Sterilisers Qty x m^2			3 Sterilisers Qty x m^2			4+ Sterilisers Qty x m^2			Remarks
Receiving Area											
Airlock	airl-6-i similar	1	X	6	1	x	6	1	x	6	
Receiving / Office	off-s9-i							1	x	9	May be an open Workstation 5m2
Trolley Holding	NS				1	x	5	1	x	10	Increase area for case cart system
Trolley Stripping	NS				1	x	5	1	x	10	
Receiving Area - Used Instruments	NS				1	x	15	1	x	20	May include Dirty return lift
Goods Receipt – Non-Sterile Stock	stgn-20-i similar				1	x	20	1	x	25	
Loan Equipment Store	stle-60-i similar				1	x	20	1	x	30	Only if Loan Equipment used in the Facility
Decontamination Area											
Cleaning/ Decontamination	NS	1	x	15	1	x	20	1	x	50	
Trolley Wash	NS	1	x	5	1	x	8	1	x	10	May be automated trolley wash
Sorting & Packing											
Airlock	airl-6-i similar	1	X	4	1	x	4	1	x	4	To maintain air pressurisation to Sterilising Area
Instrument Sorting, Assembly & Packing	NS	1	x	25	1	x	50	1	x	100	2, 4, 8 packing tables respectively
Sterilising & Cooling Area											
Sterilising – High Temperature	NS	1	x	10	1	x	15	1	x	20	5m2 per steriliser, including area for loading sterilisers and maintenance
Sterilising – Low temperature	NS				1	x	5	1	x	10	Optional ,5m2 per steriliser, including Area for maintenance
Cooling	NS	1	x	10	1	x	15	1	x	20	With area for unloading sterilisers

ROOM/ SPACE	Standard Component Room Codes	2 Sterilisers Qty x m²			3 Sterilisers Qty x m²			4+ Sterilisers Qty x m²			Remarks
Despatch Area											
After Hours Cupboard	NS				1	x	4	1	x	4	Optional, Access from inside & outside the Unit
Despatch	NS	1	x	5	1	x	10	1	x	15	Collection and sterile stock despatch
Support Areas											
Bay – Handwashing, Type B	bhws-b-i	2	x	1	2	x	1	2	x	1	At entry/ exit to Decontamination & Packing areas
Cleaner's Room	clrm-6-i	1	x	6	2	x	6	2	x	6	Separate Cleaners room or closet in Clean areas
Disposal Room	disp-8-i similar				1	x	5	1	x	8	
Store - Chemical	stcm-i similar				1	x	5	1	x	6	Chemicals used in decontamination
Store - General	stgn-14-i similar stgn-20-i				2	x	10	2	x	20	Clean materials & sterile materials
Store - Sterile Stock	stss-20-i similar	1	x	10*	1	x	20	1	x	50	For supplying hospital units & Operating Units, OR component may be within OR Unit.*May be part of the Operating Unit
Administration & Staff Areas											
Change - Staff (Male/ Female)	chst-12-i similar chst-20-i	shared			2	x	14	2	x	20	Shower, Toilet, Lockers, Change area
Meeting Room	meet-l-15-i							1	x	15	May be shared with adjacent Unit
Office - Single Person	off-s9-i				1	x	9	1	x	9	Manager
Staff Lounge	srm-15-i similar	2	x	10	2	x	12	2	x	15	May be shared with an adjacent unit
Store - Photocopy/ Stationery	stps-8-i							1	x	8	Optional
Sub Total		**112**			**312**			**535**			
Circulation %		**25**			**25**			**25**			
Area Total		**140**			**390**			**669**			

Endoscope Processing for 2 and 4 Decontamination Units (optional, Collocated with Sterile Supply)

ROOM/ SPACE+A45:L69	Standard Component Room Codes				2 Decon units Qty x m2			4 Decon units Qty x m2			Remarks
Receiving/ Decontamination Area											
Endoscope Receiving	NS				1	x	10	1	x	15	
Cleaning/ Decontamination	NS				1	x	20	1	x	50	
Endoscope Reprocessing											
Endoscope Reprocessing	NS				1	x	20	1	x	50	Reprocessing, drying & packing/storing
Endoscope Store											
Endoscope Store	NS				1	x	10	1	x	20	May be located adjacent to Endo Procedure Rooms, storage in ventilated cupboards
Despatch Area											
Despatch	NS				1	x	5	1	x	5	Optional; Collection/ despatch of disinfected scopes
Support Areas											
Bay – Handwashing, Type B	bhws-b-i				2	x	1	2	x	1	At entry/ exit to Decontamination & Reprocessing areas
Cleaner's Room	clrm-6-i							1	x	6	May be shared with adjacent Unit
Store - Chemical	stcm-i				1	x	4	1	x	6	Chemicals used in decontamination
Store - General	stgn-8-i similar				1	x	6	1	x	10	Supplies used in processing
Administration & Staff Areas											
Change - Staff (Male/ Female)					2	x	0	2	x	0	Shared with adjacent Unit; separate for male/ female

ROOM/ SPACE+A45:L69	Standard Component Room Codes				2 Decon units Qty x m2			4 Decon units Qty x m2			Remarks
Meeting Room					1	x	0	1	x	0	Shared with adjacent Unit
Office - Single Person	off-s9-i							1	x	9	Supervisor
Staff Lounge					2	x	0	2	x	0	Shared with adjacent Unit; separate for male/ female
Sub Total					**72**			**168**			
Circulation %					**25**			**25**			
Area Total					**90**			**210**			

Please note the following:

- This SOA assumes linen is provided from external sources ready for use, and linen sorting, examination and folding areas are not required.
- Areas noted in Schedules of Accommodation take precedence over all other areas noted in the Standard Components.
- Exact requirements for room quantities and sizes will reflect Key Planning Units (KPU) identified in the Clinical Service Plan and the Operational Policies of the Unit.
- Room sizes indicated should be viewed as a minimum requirement; variations are acceptable to reflect the needs of individual Unit.
- Office areas are to be provided according to the Unit role delineation and number of endorsed full time positions in the unit.
- Staff and support rooms may be shared between Functional Planning Units dependent on location and accessibility to each unit and may provide scope to reduce duplication of facilities.

9 Future Trends

Future trends affecting Sterile Supply Units include:

- Increasing awareness of storage, ergonomics and OH&S concerns within Sterile Supply Units
- Greater reliance on outsourced sterile supplies by healthcare facilities
- Healthcare facility, consumer and specialist demands for faster instrument turnaround times placing pressure on existing Sterile Supply Units
- WHO and industry demands to ensure facilities enforce validated guidelines for cleaning, sterilisation exposure time and use of rigid transport containers
- Technological advancements made in medical instruments such as endoscopes and analysers that demand compatible sterilisers and techniques
- Demands to reduce reliance on immediate-use steam sterilisation (flash sterilisation) requiring effective policies and procedures relating to loan instrumentation
- Healthcare facility requirements to ensure Sterile Supply Unit staff have appropriate training, education and resources to follow process monitoring systems according to the manufacturer's instructions
- Continued improvements in low-temperature sterilisation systems resulting in reduced processing times and expanded capabilities for instrument reprocessing
- E-beam radiation and gamma sterilisation that are creating new opportunities for advancement in sterilisation techniques

10 Further Reading

In addition to Sections referenced in this FPU, i.e. Part C- Access, Mobility, OH&S, Part D - Infection Control, and Part E - Engineering Services, readers may find the following helpful:

- AS/NZS 4187: 2014 – 'Reprocessing of reusable medical devices in health service organizations', Refer to: http://infostore.saiglobal.com/store/details.aspx?ProductID=1773923
- Australasian Health Facility Guidelines, Part B Health Facility Briefing and Planning, Rev 5, 2016; refer to website www.healthfacilitydesign.com.au
- Guidelines for Design and Construction of Health Care Facilities; The Facility Guidelines Institute, 2014 Edition refer to website www.fgiguidelines.org

  HBN 13, 2004, Sterile Services Department, Department of Health UK, Refer to: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148489/HBN_13.pdf
- ISO Standard 14644-1: 2015 'Cleanrooms and associated controlled environments – Part 1: Classification of Air Cleanliness by Particle Concentration' http://www.iso.org/iso/catalogue_detail?csnumber=53394
- ISO Standard 14937: 2009, Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices, Refer to: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=44954
- Philip M. Schneider New technologies and trends in sterilization and disinfection , American Journal of Infection Control, Vol. 41, Issue 5, S81–S86, Refer to: http://www.ajicjournal.org/article/S0196-6553(13)00017-5/fulltext
- Rose Seavey, RN, BS, MBA, CNOR, CRCST, CSPDT Current Sterilization Trends, Challenges and Tools, Refer to: www.beckersasc.com/.../current-sterilization-trends-challenges-and-tools
- Standards for Endoscopic Facilities and Services, Gastrointestinal Society of Australia (GESA) 2011, Refer to: http://www.gesa.org.au/professional.asp?cid=9&id=131