

# DHA Health Facility Guidelines 2019

Part B – Health Facility Briefing & Design

410 – Sterile Supply Unit (SSU)



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## Executive Summary

This Functional Planning Unit (FPU) covers the requirements of a Sterile Supply Unit located on-site within a hospital. The Sterile Supply Unit (SSU) is designed to clean, decontaminate, pack, sterilise and store re-usable equipment and medical devices, in compliance with infection control principles, standards and guidelines.

The SSU service may be located on-site or off-site using commercial suppliers. Operationally, the SSU may provide a sterilising service to surgical units, critical care areas, procedures and investigation areas within the healthcare facilities and to outlying units.

The SSU is comprised of multiple functional zones to process reusable medical devices, including a receiving area for used equipment, decontamination area, sorting and packing, sterilising and cooling and a sterile stock storage/ despatch area. It is important that processing follows a one way route from dirty to clean with separation of clean and dirty functions.

The Functional Zones and Functional Relationship Diagrams indicate the ideal external relationships with other key departments and hospital services. A one way direction of travel for processing is clearly indicated.

Design Considerations address a range of important issues including separation of clean and dirty products and routes and avoiding cross-flows, ergonomics, OH&S issues in manual handling of potentially heavy instrumentation and building services requirements for the heavily serviced processing equipment.

The Schedules of Accommodation are provided using references to Standard Components (typical room templates) and Non-standard Components with quantities and sizes for typical units including 2, 3 and 4 or more sterilisers.

Further reading material is suggested at the end of this FPU but none are mandatory.

Users who wish to propose minor deviations from these guidelines should use the **Non-Compliance Report (Appendix 4 in Part A)** to briefly describe and record their reasoning based on models of care and unique circumstances.

The details of this FPU follow overleaf.



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## 410. Sterile Supply Unit (SSU)

### 1 Introduction

The function of the Sterile Supply Unit is to clean, decontaminate and store re-usable equipment, medical devices - to ensure patient safety, compliance, efficiency and economy.

Where viable, centralised Units minimize 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 & Planning Considerations

#### 2.1 Operational Models

The Sterile Supply Unit may provide a sterilising service to surgical units, critical care areas and procedures and investigation areas within the healthcare facility. The unit may also provide a 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. The SSU may be remote from the surgical facility and may be on a different site as long as transportation and storage concerns are considered.

The size and role of the sterile goods supply service shall be clearly defined in the Clinical Service Plan and Operational Policy statement. Operational policies should be drafted on project specific basis by staff of the Sterile Supply Unit in conjunction with the Operating unit and all other relevant areas served.



Loan equipment is now commonly used, which are sterilised at the facility, used, and the sent back after disinfection (not sterilised).

Transport across facilities will require rigid, sterilised, and hermetically sealed containers

### **2.1.1 Hours of Operation**

The typical Sterile Supply Unit will operate from 7am to 11pm, 5 days per week, to maximise unit efficiency. After hours and weekends will provide service on call.

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.

### **3.1 Functional Zones**

The Sterile Supply Unit will include the following functional zones:

- Receiving area with:
  - 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 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 comprising:
  - 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 with:
  - High temperature sterilisers including loading and unloading space
  - Low temperature sterilisers for items requiring this method of sterilising
  - Plant area for access to sterilisers
  - Cooling area for trolleys unloaded from sterilisers are held while stock is cooling
- Despatch Area for distribution of sterile stock to Operating Unit or other hospital units; 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

### **3.1.1 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 where and will include a trolley dismantling area where trolleys are stripped. Dirty linen and waste is dispatched 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 in moving the equipment. The Loan store will require external access for deliveries and should be located with ready access to Decontamination areas

### **3.1.2 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 in the decontamination area.

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 and an eye wash facility.

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

#### **3.1.2.1 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.

### **3.1.3 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.

### **3.1.4 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. Increasingly, sterilising linen is uncommon and disposable linen is used instead. Specialised low temperature sterilisers including peracetic acid models, hydrogen peroxide gas plasma or ethylene oxide 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.

Pass through sterilisers are mandatory for RDLs 3 to 6, and one-sided sterilising is permitted for up to RDL 2. Special provisions are required for handling ethylene oxide which is a toxic gas and installation should follow approved international standards.

Due to the hazardous conditions of the use of Ethylene Oxide (ETO), it is discouraged as far as possible.

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 work space. 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).

Staff access between sorting and packing, and the sterile store is permitted.

### **3.1.5 Sterile Stock Store**

An area for storage and holding of sterile stock within the Sterile Supply unit prior to despatch to the Operating unit or other patient treatment areas. This area may include a workstation bench as required.

### **3.1.6 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.

### **3.1.7 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.

### **3.1.8 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.

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.

### **4.1 External Relationships**

The Sterile Supply Unit (SSU) has a direct relationship with 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, inpatient units and 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 located within and adjacent to Day Surgery or Endoscopy Units. The hospital's Operational Policies will determine the inclusion of endoscope processing within the SSU.

## **4.2 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

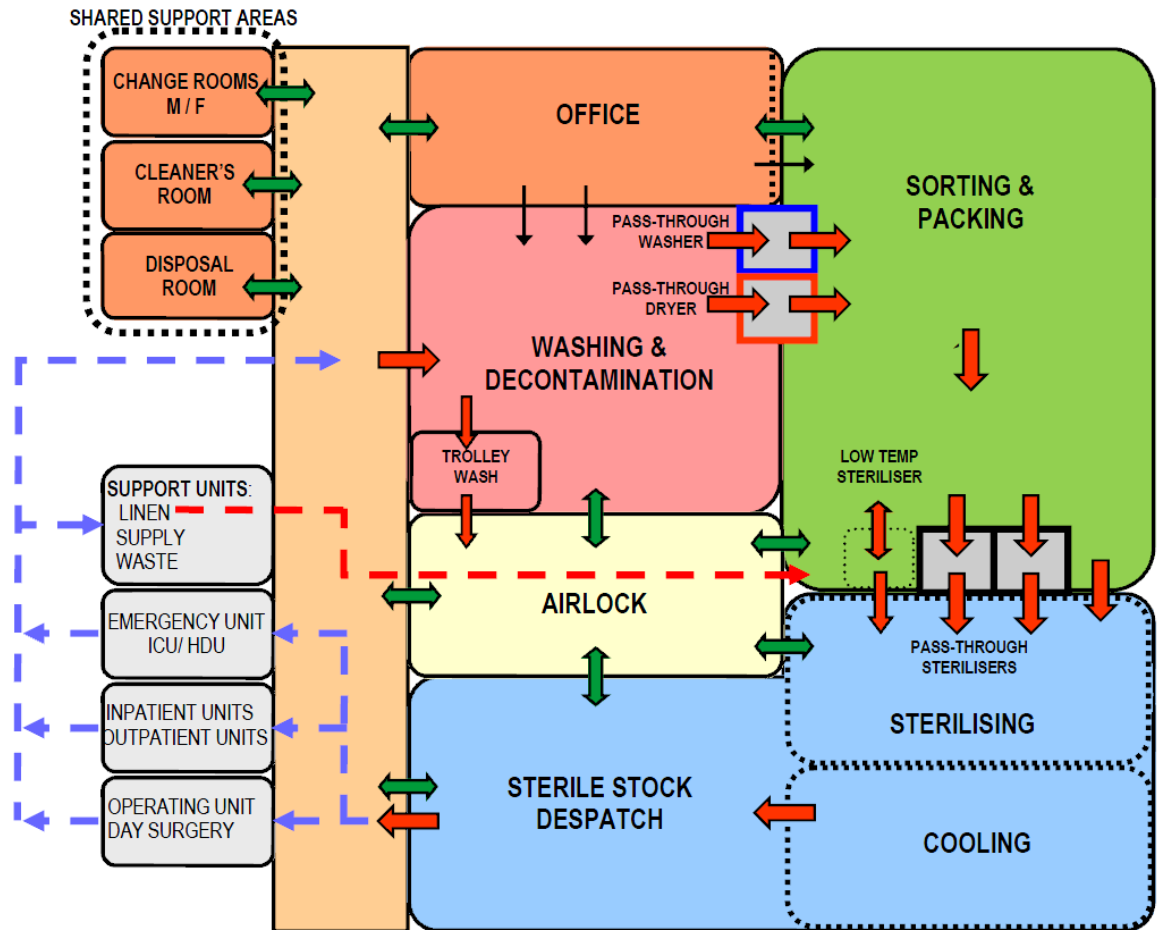


- Instruments are processed through the cleaning/ decontamination area and move to the Sorting/ Packing area – a clean zone
- Trolleys are cleaned in the Cleaning/ Decontamination zone or a dedicated trolley wash and transferred to Sterile Stock/ despatch area for loading and return to inpatient or operating 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 through 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

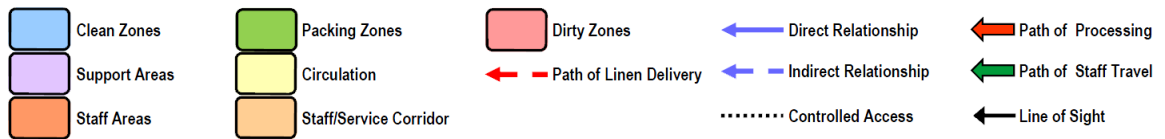


### 4.3 Functional Relationship Diagram

#### 4.3.1 Small – 1 steriliser



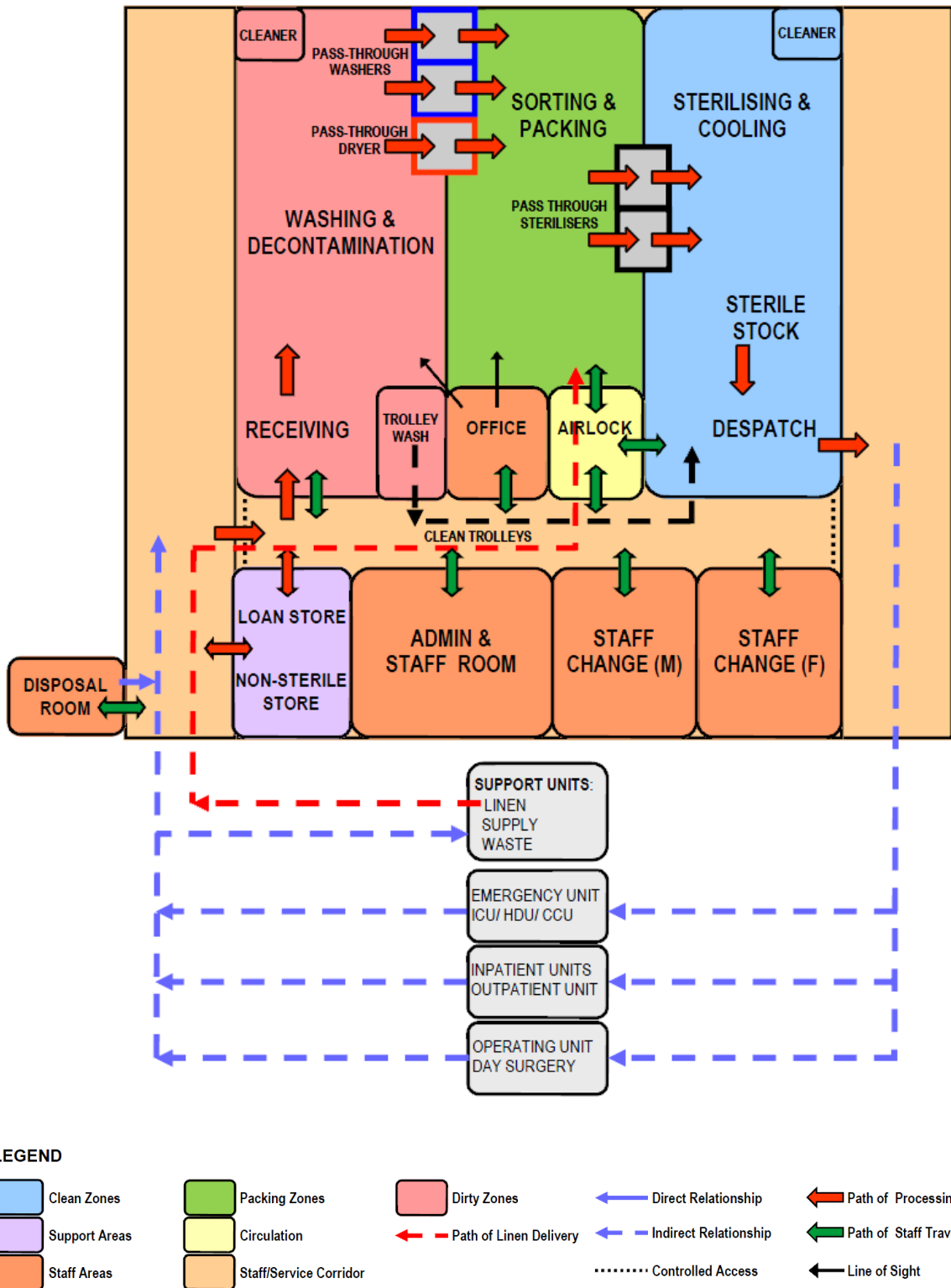
**LEGEND**





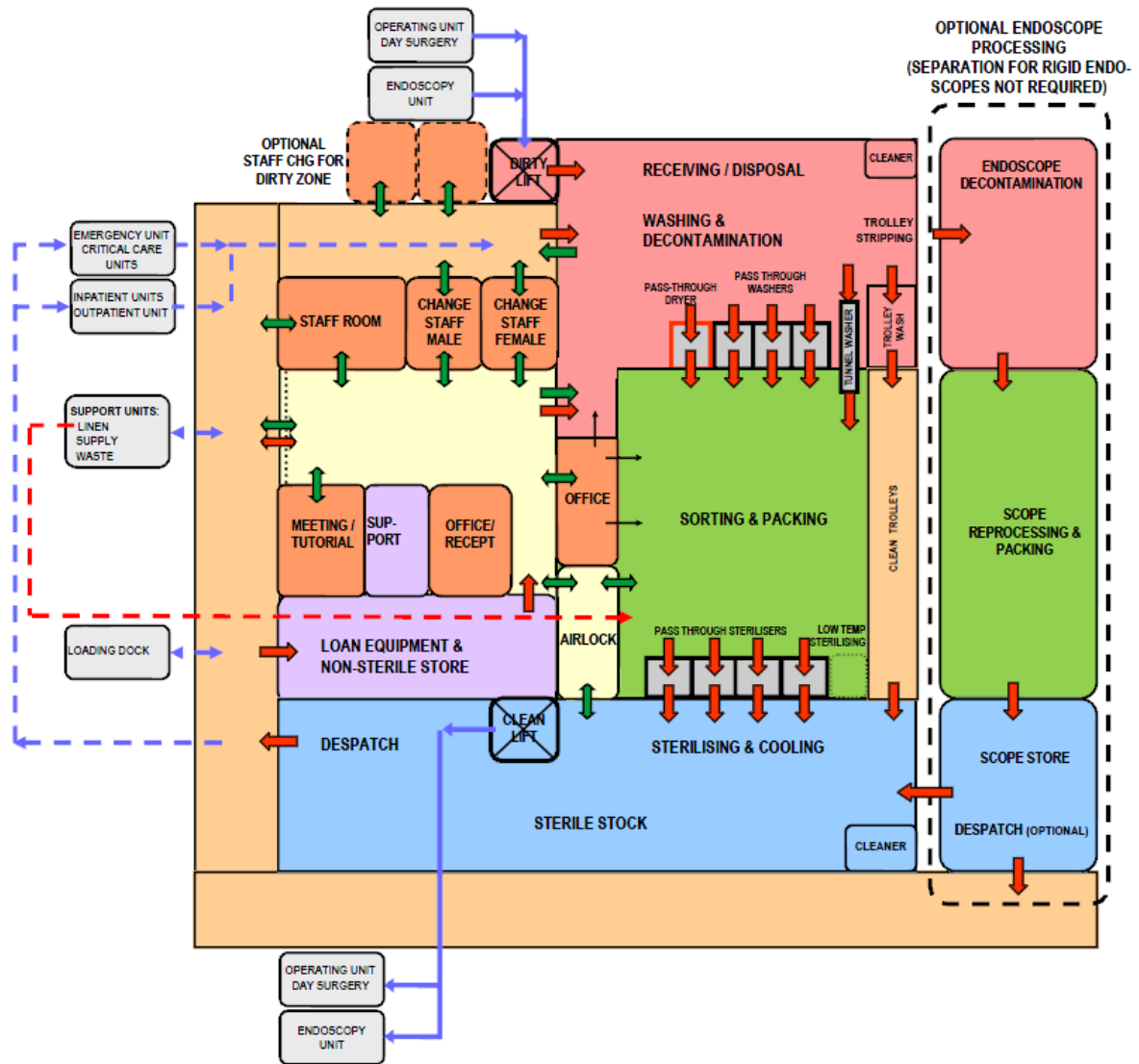


**4.3.2 Medium – 2 sterilisers**





### 4.3.3 Large – 4+ sterilisers



**LEGEND**

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



## 5 Design Considerations

### 5.1 General

Two classifications of goods are received by the SSU, namely 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.

### 5.2 Environmental Considerations

#### 5.2.1 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.

#### 5.2.2 Natural Light/ Lighting

Natural lighting aids visual inspection and has positive morale on staff. 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 fittings shall be fully recessed and selected to prevent dust and insects from entering.

### 5.3 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.



## 5.4 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

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

## 5.5 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:

- 1 steriliser can service 2 Operating Rooms
- 2 sterilisers can service 4 Operating Rooms
- 4 sterilisers can service 8 Operating Rooms

Note: A minimum of 2 sterilised per Unit is recommended to avoid shut down of service in case of breakdown of one steriliser.

## 5.6 Safety & Security

Controlled access should prevent unauthorised entry and isolate the area from general hospital traffic. Signposting should direct access to the Sterile Supply Unit (SSU) Office/ Reception for general purposes, and visitors to the Unit. Door signs should be installed on restricted access doors.

Quality indicators are to be considered for the following operations:

- Biological Incubator
- Chemical Indicator
- Barcoding System



## **5.7 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.

Beneches, cabinet etc shall be in stainless steel or resin. Shelving in sterile stock areas should ideally be perforated stainless steel.

### **5.7.1 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.

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

### **5.7.2 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.

## **5.8 Fittings, Fixtures & 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 local regulations.



## 5.9 Building Service Requirements

This section identifies unit specific services briefing requirements only and must be read in conjunction with **Part E - Engineering Services** for the detailed parameters and standards applicable.

### 5.9.1 Information and Communication Technology

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.

## 5.10 Heating, Ventilation & Air-conditioning (HVAC)

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; this includes sorting and packing areas. 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, sterilizers 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.

### 5.11 Hydraulics

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

### 5.12 Engineering Services

Maintenance access to steriliser plant should be outside clean areas and avoid disruption to the SSU and staff work area 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, sterilizing 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, location to avoid excessive distance from sterilisers will require careful consideration.

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

### 5.13 Infection Control

#### 5.13.1 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.

### 5.13.2 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, cannot fully replace Hand Wash Bays.

## 6 Standard Components of the Unit

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



2	Provided by the Client and installed by the builder
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.



## **6.1 Non-Standard Rooms**

Non-standard rooms are rooms are those which have not yet been standardised within these Guidelines. As such there are very few Non-standard Rooms. These are identified in the Schedules of Accommodation as NS and are separately covered below.

### **6.1.1 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

### **6.1.2 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 or resinate type 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, built-in, with consideration to the working height of instrument baskets
- Instrument and tubing dryers, and pass-through cupboards- 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 be used

### **6.1.3 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 lint

#### **6.1.4 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.

#### **6.1.5 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.

#### **6.1.6 Despatch**

Despatch will include a staff station or counter for coordination system if the air supply or filtration fails. Proprietary endoscope cupboards are to be provided.

The 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.

#### **6.1.7 Endoscope Decontamination**

The Endoscope Decontamination area is a dirty zone for receiving and manual cleaning of endoscopes. The area will include stainless steel or resinate type 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, and must be kept as a separate module.

#### **6.1.8 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 or resinate type bench and sinks for manual disinfection
- A clean area for reassembly of disinfected scopes
- A staff handwashing basin.

#### **6.1.9 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 recommended.



## 7 Schedule of Accommodation

The Schedule of Accommodation (SOA) provided below represents generic requirements for this Unit. It identifies the rooms required along with the room quantities and the recommended room areas. The sum of the room areas is shown as the Sub Total as the Net Area. The Total area is the Sub Total plus the circulation percentage. The circulation percentage represents the minimum recommended target area for corridors within the Unit in an efficient and appropriate design.

Within the SOA, room sizes are indicated for typical units and are organised into the functional zones. Not all rooms identified are mandatory therefore, optional rooms are indicated in the Remarks. These guidelines do not dictate the size of the facilities, therefore, the SOA provided represents a limited sample based on assumed unit sizes. The actual size of the facilities is determined by Service Planning or Feasibility Studies. Quantities of rooms need to be proportionally adjusted to suit the desired unit size and service needs.

The Schedule of Accommodation are developed for particular levels of services known as Role Delineation Level (RDL) and numbered from 1 to 6. Refer to the full **Role Delineation Framework (Part A - Appendix 6)** in these guidelines for a full description of RDL's.

The table below shows three alternative SOA's for different sized units; a small unit with 2 sterilisers, a medium sized unit with 3 sterilisers and a large unit with 4 or more sterilisers.

Any proposed deviations from the mandatory requirements, justified by innovative and alternative operational models may be proposed and record in the **Non-Compliance Report** (refer to **Part A - Appendix 4**) with any departure from the Guidelines for consideration by the DHA for approval.





### 7.1 Sterile Supply Unit for 2, 3 and 4+ sterilisers

Note: a minimum of 2 sterilisers is recommended.

ROOM/ SPACE	Standard Component Room Codes		2 Sterilisers Qty x m <sup>2</sup>	3 Sterilisers Qty x m <sup>2</sup>	4+ Sterilisers Qty x m <sup>2</sup>	Remarks
<b>Receiving Area</b>						
Receiving/ Office	off-s9-d			1 x 9	1 x 9	Optional, May be an open Workstation 5.5 m2
Trolley Holding	NS		1 x 5	1 x 8	1 x 10	Increase area for case cart system
Trolley Stripping	NS		1 x 5	1 x 8	1 x 10	
Receiving Area - Used Instruments	NS		1 x 15	1 x 15	1 x 20	May include Dirty return lift
Goods Receipt – Non-Sterile Stock	stgn-20-d similar		1 x 20	1 x 20	1 x 25	
Loan Equipment Store	stle-60-d similar		1 x 20	1 x 25	1 x 30	Size dependent on service plan, Only if Loan Equipment used in the Facility
<b>Decontamination Area</b>						
Cleaning/ Decontamination	NS		1 x 20	1 x 35	1 x 50	
Trolley Wash	NS		1 x 5	1 x 8	1 x 10	May be automated trolley wash
<b>Sorting &amp; Packing</b>						
Airlock	airl-6-d similar		1 x 4	1 x 4	1 x 4	To maintain air pressurisation to sterilising Area
Instrument Sorting, Assembly & Packing	NS		1 x 50	1 x 75	1 x 100	2, 4, 8 packing tables respectively
<b>Sterilising &amp; Cooling Area</b>						
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 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
<b>Despatch Area</b>						
After Hours Cupboard	NS		1 x 4	1 x 4	1 x 4	Optional. Access from inside & outside the Unit
Despatch	NS		1 x 10	1 x 10	1 x 15	Collection and sterile stock despatch
<b>Support Areas</b>						



Sterile Supply Unit (SSU)

ROOM/ SPACE	Standard Component Room Codes				2 Sterilisers Qty x m <sup>2</sup>	3 Sterilisers Qty x m <sup>2</sup>	4+ Sterilisers Qty x m <sup>2</sup>	Remarks
Bay – Handwashing, Type B	bhws-b-d				2 x 1	2 x 1	2 x 1	At entry/ exit to Decontamination & Packing areas
Cleaner's Room	clrm-6-d				1 x 6	2 x 6	2 x 6	Separate Cleaners room or closet in Clean areas
Disposal Room	disp-8-d similar				1 x 5	1 x 5	1 x 8	
Store - Chemical	stcm-d similar				1 x 5	1 x 5	1 x 6	Chemicals used in decontamination. If space is restricted, this may be a Sterile Supply Cupboard in the decontamination area
Store – Non-sterile General	stgn-14-d similar stgn-20-d				2 x 10	2 x 10	2 x 20	Clean materials & sterile materials
Store - Sterile Stock	stss-20-d 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
<b>Administration &amp; Staff Areas</b>								
Change - Staff (Male/ Female)	chst-12-d similar chst-20-d				2 x 14	2 x 14	2 x 20	Shower, Toilet, Lockers, Change area
Meeting Room	meet-l-15-d						1 x 15	May be shared with adjacent Unit
Office - Single Person	off-s9-d				1 x 9	1 x 9	1 x 9	Manager
Staff Room	srm-15-d similar				1 x 12	1 x 15	1 x 20	May be shared with an adjacent unit
Store - Photocopy/ Stationery	stps-8-d						1 x 8	Optional
<b>Sub Total</b>					<b>280</b>	<b>372</b>	<b>547</b>	
<b>Circulation %</b>					<b>25</b>	<b>25</b>	<b>25</b>	
<b>Area Total</b>					<b>350</b>	<b>465</b>	<b>684</b>	

**Endoscope Processing for 2 and 4 Decontamination Units**

(Optional, Collocated with Sterile Supply)

ROOM/ SPACE	Standard Component Room Codes				2 Decon units Qty x m2	4 Decon units Qty x m2	Remarks
<b>Receiving/ Decontamination Area</b>							
Endoscope Receiving	NS				1 x 10	1 x 15	



ROOM/ SPACE	Standard Component Room Codes		2 Decon units Qty x m2	4 Decon units Qty x m2	Remarks
<b>Receiving/ Decontamination Area</b>					
Cleaning/ Decontamination	NS		1 x 20	1 x 50	
<b>Endoscope Reprocessing</b>					
Endoscope Reprocessing	NS		1 x 20	1 x 50	Reprocessing, drying & packing/storing
<b>Endoscope Store</b>					
Endoscope Store	NS		1 x 10	1 x 20	May be located adjacent to Endo Procedure Rooms, storage in ventilated cupboards
<b>Despatch Area</b>					
Despatch	NS		1 x 5	1 x 5	Optional; Collection/ despatch of disinfected scopes
<b>Support Areas</b>					
Bay – Handwashing, Type B	bhws-b-d		2 x 1	2 x 1	At entry/ exit to Decontamination & Reprocessing areas
Cleaner's Room	clrm-6-d			1 x 6	May be shared with adjacent Unit
Store - Chemical	stcm-d		1 x 4	1 x 6	Chemicals used in decontamination
Store - General	stgn-8-d similar		1 x 6	1 x 10	Supplies used in processing
<b>Administration &amp; Staff Areas</b>					
Change - Staff (Male/ Female)					Shared with adjacent Unit
Meeting Room					Shared with adjacent Unit
Office - Single Person	off-s9-d			1 x 9	Supervisor
Staff Room					Shared with adjacent Unit
<b>Sub Total</b>			<b>77.0</b>	<b>173.0</b>	
<b>Circulation %</b>			<b>25</b>	<b>25</b>	
<b>Area Total</b>			<b>96.3</b>	<b>216.3</b>	

Please note the following:

- Areas noted in Schedules of Accommodation take precedence over all other areas noted in the Standard Components
- This SOA assumes linen is provided from external sources ready for use, and linen sorting, examination and folding areas are not required



## Part B: Health Facility Briefing & Design

### Sterile Supply Unit (SSU)

- Rooms indicated in the schedule reflect the typical arrangement according to number of sterilisers
- All the areas shown in the SOA follow the No-Gap system described elsewhere in these Guidelines
- Exact requirements for room quantities and sizes 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 number of approved full-time positions within the Unit



## 8 Further Reading

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

- AHIA, Australasian Health Facility Guidelines, Part B - Health Facility Briefing and Planning, 0190 - Sterilising Services Unit, Revision 6, 2016, refer to <https://healthfacilityguidelines.com.au/health-planning-units>
- 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](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148489/HBN_13.pdf)
- International Health Facility Guideline (iHFG) [www.healthdesign.com.au/ihfg](http://www.healthdesign.com.au/ihfg)
- 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](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](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=44954)
- Ministry of Health UAE, Unified Healthcare Professional Qualification Requirements, 2017, refer to website: <https://www.haad.ae/haad/tabid/927/Default.aspx>
- 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](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](http://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>
- The Facility Guidelines Institute (US), Guidelines for Design and Construction of Hospitals, 2018. Refer to website: [www.fgiguilines.org](http://www.fgiguilines.org)
- The Facility Guidelines Institute (US), Guidelines for Design and Construction of Outpatient Facilities, 2018. Refer to website: [www.fgiguilines.org](http://www.fgiguilines.org)