GUIDELINE

Storage Design for Sterile and Non-Sterile Stock for New and Refurbished Healthcare Facilities

Centre for Healthcare Related Infection Surveillance and Prevention & Tuberculosis Control
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Glossary of Acronyms, Abbreviations and Terms & Definitions

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<tr>
<td>CHRISP&amp;TB</td>
<td>Centre for Healthcare Related Infection Surveillance and Tuberculosis Control</td>
</tr>
<tr>
<td>CSD</td>
<td>Central Sterilizing Department</td>
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<tr>
<td>HEPA</td>
<td>High Efficiency Particulate Absorbing</td>
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<td>HHS</td>
<td>Hospital and Health Service</td>
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<td>OH&amp;S</td>
<td>Occupational Health &amp; Safety</td>
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<tr>
<td>OT</td>
<td>Operating Theatre</td>
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<td>RMD</td>
<td>Reusable Medical Device</td>
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<tr>
<th>Terms &amp; Definitions</th>
<th>Definitions</th>
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<tr>
<td>Deboxing</td>
<td>Is to remove commercially prepared Sterile items from shipping boxes.</td>
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<tr>
<td>Imprest</td>
<td>Generic name for a system for replenishing stock levels. Typically where an amount of stock is made available for use &amp; then topped up by what is actually used.</td>
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<tr>
<td>Sterile Stock</td>
<td>In this document refers to both reprocessed Sterile items &amp; single use commercially prepared Sterile items</td>
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<tr>
<td>Stock</td>
<td>In this document refers to any Surgical &amp; Clinical stock for patient treatment. This does not include items such as wheelchairs, bed linen, chemicals, alcohol gel.</td>
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<tr>
<td>Sufficient Segregations</td>
<td>Between Sterile &amp; Non Sterile stock should be clearly recognisable. In the areas where sterile &amp; non-sterile stock is allowed and required to be in the same room, the separation needs to be not so much physical as it needs to be visual to avoid items being placed in the wrong area &amp; subsequently taken from the wrong area &amp; assumed sterile when it may not be.</td>
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These guidelines were developed in conjunction between Centre for Healthcare Related Infection Surveillance and Prevention & Tuberculosis Control (CHRISP&TB), Queensland Health Shared Services Partner (QHSSP) Supply Services & Health Services Purchasing & Logistics (HSPL).
1.0 Introduction
Sterile items shall be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source. This requirement applies equally to items sterilized in the health care facility and to sterile items procured from commercial suppliers. Policies and procedures for storage, handling and issuing of sterile stock shall be developed and documented by the health care facility.

These guidelines provide the principles that are to be applied when selecting systems to store sterile reusable medical devices, sterile consumables and non sterile stock within a healthcare facility especially during rebuilding and redevelopment projects. For the purpose of this document sterile reusable devices and sterile consumables will be referred to as sterile stock.

The planning of stock storage areas and systems is integral in ensuring efficiency and that the sterile stock maintains its integrity, is fit for purpose and safe for patient use.

The information contained within this document pertains to the following areas is to be considered during building refurbishment and design phases:

2.0 General Principles

2.1 Storage Environment
2.2 Sterile Stock Storage System
2.3 Imprest Systems
2.4 Transportation Systems

3.0 Specific Department/Area Requirements

3.1 CSD and Operating Theatre
3.2 Endoscopy Units
3.3 Ward/Clinical Areas
3.4 Transportation (external) & Loading Dock

2.0 General Principles

2.1 Environment
The environment plays an integral role in ensuring that sterile stock maintains its integrity. To enable planning of the clinical area the following is to be considered when determining placement and space requirements of the stock storage area:

- Clinical services profile of the area
- Workflow within the clinical area
- Design that optimally utilises the area available

The following environmental requirements are to be considered with all sterile stock storage areas:

- Secured to limit access
- Environmentally controlled
- Wall, floors and work surfaces are to be non-porous, smooth, and capable of being easily cleaned
• Area should be configured so that there is limited difficult to clean corners and areas for dust to collect
• Lighting should be fitted flush into ceiling to reduce dust entrapment
• Adequate space is required around sterile product to enable air circulation
• Sterile stock storage area should be constructed that there is no risk that the sterile stock will come in contact with water
• Sterile storage area is not to be used as a shared equipment storage space (e.g. wheelchairs etc)
• There is to be an area dedicated to deboxing of commercially prepared sterile stock from outer store/transportation packaging before being brought into the sterile stock storage area

2.2 Sterile Stock Storage System:
The following are general requirements to be considered when choosing a sterile stock storage system:
• Protects the integrity of the sterile stock packaging system
• Does not facilitate dust collection (see Figure 1 & Figure 2)
• Facilitates inventory management and stock rotation
• Both reprocessed and commercially prepared sterile stock can be stored in the same area
• Shelving systems should be flexible (not fixed) to facilitate product changes – adjustable shelving, not fixed to the wall
• Shelving should take into consideration Occupation Health & Safety issues/concerns such as height of shelving and storage, and accessibility to stock
• Prevents sterile stock from coming in contact with walls
• Sterile stock is to be stored on open shelving must be at least 250mm from the floor & 440mm below ceiling fixtures
• Shelving to be manufactured from non-shedding material, easily cleanable and with smooth surface that will not damage packaging
• Shelving should be constructed of a continuous solid (not hollow) single piece of material (e.g. such as Stainless Steel, not “plated” with another material). Joins and hard to clean corners should be minimised or avoided
• Adjustable to accommodate all common dimensions of sterile stock to prevent damage of the packaging and the item

Solid Plastic container systems (e.g. Figure 1) are prone to collecting dust & contaminants. The use of stainless steel “wire” (e.g. Figure 2) or plastic/polypropylene baskets is recommended as these will still provide the same storage solution & flexibility, but are less prone to dust & contaminant collection & can be put through washer disinfectors & sterilizers.
Figures 3, 4 & 5 demonstrate acceptable storage systems but due to the way in which the system is used (Figures 4 & 5) to store reprocessed sterile stock there is a potential for damaging to the packing system, as well as storing packaging boxes in the sterile store room.

Sterile Wrapped Packs should not be stacked.

Outer packaging boxes should not be stored in the Sterile Store Room.
Figure 6 represents the incorrect way to store sterile consumables. They should be removed from the packaging box (in this instance it would seem old packaging boxes are being re-used) and stored in an acceptable container such as Figure 2.

![Figure 6](image)

Figures 7, 8 & 9 demonstrate consequences of the selection of poor quality sterile stock storage systems includes rust and degradation of shelving and joints.

![Figure 7](image)  ![Figure 8](image)  ![Figure 9](image)

*These examples are chrome plated products and they are prone to easy damage. As soon as the chrome layer is penetrated, it allows rust & corrosion. The chrome layer is generally easy to chip or damage & if the product has not been manufactured correctly, the rust can even form under intact chrome plating.*
2.3 Imprest Systems

Queensland Health has a custom built imprest system that resides as a module within FAMMIS. Imprest refers to the stock held within a ward or department. The generation of the Imprest list is based on material consumption. Each material’s consumption is totalled for the analysis period and divided by seven to calculate the weekly average usage. The weekly consumption value is then proposed as the maximum stock holding for that material. This stock holding can be modified by the appropriate supply staff.

- **Standard Imprest System**
  - Stock replenishment orders are delivered at pre-defined intervals (daily, weekly, every 2nd day etc)
  - Order (Imprest) levels can be changed as and if required given sufficient notice
  - Order delivery can be suspended or frequency changed through quieter service periods
  - When new stock is delivered, ensure old stock is at front of shelf for first use (stock rotation principles must be applied)

- **Roll in / Roll out system (acceptable for non sterile products)**
  - Set order levels are placed on a trolley & delivered to site/local store room
  - Unused items on the existing trolley are returned to inventory when the new trolley is placed (it is not appropriate to send back & reprocess sterile items, which is why this system would only be acceptable for non-sterile).
  - Unused returned items are placed as first available stock on the next trolley to be processed/picked so they will be first used when Trolley is distributed to the next imprest location

2.4 Transportation Systems

When choosing transport systems to deliver sterile stock the following is to be considered:

- Occupational health and safety (OH&S) requirements such as lifting, pushing and height restrictions
- The sterile barrier system (i.e. packaging) integrity is protected
- Transport compartment in vehicles should be clean, dry, & free from surface irregularities, it should protect the sterile stock from ingress of exhaust and other potential contaminates and it is to facilitate the segregation of sterilized product from other items being transported
- Enables reprocessed sterile stock to be transported in closed solid walled containers or in enclosed or covered carts with solid bottom shelves (this also assists in preventing sterile stock from being exposed to environmental contaminants such as dust and water)
- Hoists, trolleys, carts and containers used to transport sterile stock should be dedicated for that purpose (if possible), kept clean and not used for the collection of used items, food or garbage
- Hoist, trolley, carts or containers that are used to deliver sterile stock and pick up used reusable items are to undergo a cleaning process prior to the transport of sterile stock
3.0 Specific Department/Area Requirements

3.1 CSD & Operating Theatre Sterile Store

3.1.1 Function

- CSD – designed for dedicated short-term storage of reprocessed sterile stock
- OT – designed for the dedicated storage of sterile stock to support operating theatres and procedural rooms (where applicable)

3.1.2 Location

- CSD – situated on the sterile side of the department
- CSD – access to dispatch goods to clinical areas
- CSD/OT – secure access to reduce traffic flow
- OT – centrally located
- Designed to minimise the need for multiple handling of sterile stock

3.1.3 Key Requirements

- Dedicated for the intended purpose only, such as:
  - Sterile reprocessed stock; and
  - Sterile consumable/pre-packaged stock
- A dedicated area to remove transportation packaging & boxes of stock (refer to de-box area) prior to entering sterile stock storage area.
- Controlled to prevent contamination of sterile stock
- Free of dust, insects & vermin
- Protected from direct sunlight
- Temperature range between 18 – 22 degrees Celsius
- Relative Humidity range between 35% – 68%

Note: Sterile reprocessed stock and sterile consumable/pre-packaged stock may be stored in the same room but should be separated by shelving.

3.1.4 Mechanical Services

- Air-handling systems within sterile stock storage areas within CSD and OT are to be configured in such a way as to maintain appropriate environmental conditions such as:
  - Appropriate pressure differentials, i.e positive pressure to all surrounding areas; and
  - Air filtration with High Efficiency Particulate Absorbing or Air (HEPA) Filter
- Within CSD cooling area it is essential that because of the discharging vapour from the sterilizers that the sterilizers are connected to a suitable exhaust system in accordance with the Manufacturer’s instructions observing the requirements for air breaks. Some equipment is manufactured to discharge vapour directly into the work space. This vapour discharge can impact on the sterile stock cooling or stage area by increasing the heat load and creating hot or cold zones within the work space
- Natural ventilation such as open windows are not suitable for sterile stock

3.1.5 Debox Area

- This room is required for the removal of commercially prepared stock from their shipping/transportation packaging prior to being placed in dedicated storage area
- This room can be shared between CSD and OT
3.2 Endoscopy Units:

3.2.1 Function
- To ensure the level of reprocessing for the flexible endoscope is maintained

3.2.2 Location
- A dedicated area within the endoscopy unit

3.2.3 Key Requirements
- Flexible endoscopes, where applicable, are to hang vertically in dry & well ventilated storage cupboard or be stored in dedicated specific-to-product storage container (as per manufacturers instructions)

3.2.4 Equipment
- Endoscope Storage Cabinets
  - Dry
  - Well ventilated
  - Protect the flexible endoscope from environmental contamination
  - Secure & accessible to authorised personnel only

3.3 Wards /Clinical areas:
Locations where Sterile & Non-Sterile Stock is required to be stored together

3.3.1 Key Requirements
- Storage of sterile and non sterile stock and consumables in these wards or clinical areas should consider the following:
  - Non Sterile Stock may be stored in the same area as Sterile Stock, but should have clear segregation from the Sterile Stock by barrier, dividers or partition
  - All design & environmental requirements should reflect those of Sterile Stock only storage areas to maintain the integrity of the Sterile Stock
  - Proper hand washing facilities – easily accessible but separated from sterile storage
  - Dividers in “storage containers/receptacles” to ensure no mixing of different stock (esp. same type of item but different size)
  - Be clearly labelled
  - Appropriate space to allow where necessary for:
    - Hanging of sterile stock
    - Sterile stock of varying sizes & shapes
    - Packaging and contents are not compromised
  - Stock to be deboxed external to the storage area
  - Standardised storage systems and location (if possible) throughout all clinical areas
  - Recommend proxy card / security access to restrict unauthorised access to the area
  - General principle that the storage units will be mobile (to allow greater flexibility of the space)
  - Preference not to install fixed shelving in storage areas
3.4 Transportation (external) & Loading Dock:

3.4.1 Function
- To receive or transport sterile stock from external suppliers without compromising the stock

3.4.2 Location
- Loading dock should allow for ease of transfer on & off of vehicles.
- Loading dock area should be easily cleaned
- Separate docks for Clean & Dirty – If not practical, clearly defined clean area & dirty area

3.4.3 Key Requirements
- To maintain sterility of medical devices during external transportation
- Transportation equipment does not contribute to the contamination of the sterile stock
- Provide protection to prevent damage to sterile packaging materials.
- A system in place when unloading to prevent contamination and maintain integrity of the sterile stock

3.4.4 Equipment
- Transportation containers should be closed with solid walls and be washable
- Carts/Trolleys should have solid bottom shelves and be covered & enclosed to protect from exposure to the environment
- Vehicles (for external transportation) should be dedicated to the purpose and provide segregation for sterile & used medical devices

3.4.5 Mechanical
- Automated Trolley lifting device

4.0 Procurement

Procurement of storage solutions can be made via PL003-1 CSD Solution Panel.

The 5 Total Solution Providers are:
- Device technologies - 3263 1400
- Gallay Medical & Scientific - 3245 3388
- Getinge - 3399 3311
- In Vitro Technologies - (03) 9771 3700
- SESS - 3849 1077

Specialty Product Providers that have storage solutions in their scope are:
- Smartline Machinery - 5478 9977

To access the CSD Solution Panel providers & pricing you will need to contact:
Steve Goldsmith, Manager - Clinical Contract Management Purchasing & Logistics
steve_goldsmith@health.qld.gov.au
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