Storage, Handling and Transport Requirements for Sterile Stock Procedure

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1. Guiding Principles

This procedure applies to the storage, handling and transport of reprocessed reusable medical devices (RMDs) or commercially sterile single use consumables and also includes the storage and handling of non-sterile consumables critical to the reprocessing of RMDs in a health service.

A requirement of AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations (HSO) *is "that the state of the required quality"* and integrity of the item is maintained until use, to prevent contamination and ensure patient safety.

Storage areas are to be dedicated for the purpose that they are intended for and are to comply with the requirements of AS/NZS 4187:2014, sections 5, 9, A9.5. Australasian Health Facility Guidelines Part B - Health Facility Briefing and Planning 0190 – Sterilizing Services Unit and manufacturer's instructions for storage and handling.

Compliance with standards and guidelines is required to ensure that the integrity of sterilised items and non-sterile bulk consumables used in the reprocessing of RMDs is maintained.

2. Procedure

The procedure applies to the management and control of storage environments and items stored, and the handling and transportation of RMDs and critical consumables throughout WACHS health services which includes the following:

- sterilisation services and theatre departments
- clinical areas
- external health facilities/clients for whom reprocessing is performed
- community health, mental health and aged care

Note: Whilst the principles of storage, handling and transporting apply to endoscopy departments as well, this specialty has unique requirements that will be addressed in detail in procedures developed for that area.

2.1 Storage Environment

Storage areas in a health facility store a diverse range of items used for a variety of purposes such as medical equipment, administrative supplies, clean and dirty linen, general and clinical waste, and medication. These items require designated areas, and shall not share storage space with reprocessed RMDs, commercially processed sterile stock, or critical bulk consumable supplies for reprocessing.

Ventilation and airflow

The risk of infection transmission can be mitigated by effective heating, ventilation and air conditioning (HVAC) systems.

Sterile storage areas must have restricted access to reduce traffic flow and ensure only appropriate staff have access to the area.

Sterile stock storage areas are to be environmentally controlled as per: AS/NZS 4187:2014, section A9.5 (f), (g) and managed to maintain:

- temperature within the range of 18°C – 25°C
- humidity 35% - 70%.

Monitoring can be achieved by daily recording by staff or back-to-base monitoring systems managed by the engineering department. Staff responsible for monitoring of sterile storage areas must be aware of the environmental parameters and the appropriate response if parameters are exceeded.

Ventilation purification is required in sterile storage areas that store reusable RMDs in the perioperative setting, via HEPA filtration and air changes per hour (ACH) which is comparable to that delivered to the operating room: AusHFG sections B and D. 03.03 *Environmental Considerations* AUSHFG HPU_B.0190_6.2. https://www.healthfacilityguidelines.com.au/

Surfaces - Walls, floors and ceilings

Walls, floors and ceilings are to be continuous, smooth, impervious, and capable of easy and frequent cleaning. Surfaces must be well maintained in a clean, dry and dust free state. Joins and hard to clean corners must be minimised or avoided.

Shelving Requirements

Sterile stock storage shelving should:

- be constructed from robust, non-shedding materials that are easy to clean and maintain in good condition
- where practicable, be flexible to facilitate product changes i.e. adjustable shelving
- be designed and installed to support safe handling practices
- take into consideration Work Health and Safety (WHS) issues / concerns such as height of shelving, storage and accessibility to stock.
- have smooth surfaces that do not damage products, packaging and other materials
- be flush with wall surfaces and ceilings where possible
- avoid sterile stock contacting walls
- be at a height of 250mm off the floor that facilitates cleaning without any risk of contamination to packaging during floor cleaning processes
- prevent contamination of sterile stock from ceiling surfaces by ensuring the highest shelf is approximately 400mm from ceiling height.

The use of stainless steel “wire” or alternative plastic / polypropylene baskets with perforated bases is recommended. Solid based storage containers are prone to dust collection and require significant cleaning resources to maintain in a clean state, which

can also lead to increased sterile stock handling and the potential for increased environmental contamination. Cleaning and disinfection can be performed manually or via washer disinfectors as tolerated / as per manufacturer's instructions for use.

Ward or mobile storage

Where sterilised items are stored in a ward/clinical area or mobile storage container where environmental conditions cannot be monitored and controlled, risk mitigating controls must be employed such as:

- sterile stock produced in/by the HSO must be enclosed in a sealed plastic dust cover prior to leaving the Sterilisation Services Department
- stock must be stored in a cupboard, drawer or rigid container dedicated for that purpose and protected from environmental contaminants such as sunlight, dust, and water
- storage conditions must not exceed the required parameters
- packaging of all sterile stock items must always be inspected for integrity prior to use.

2.2 Management of the stored items

- Hand hygiene must be performed prior to handling released RMDs. Hand hygiene opportunities must be available on the entrance to the storage area and within the storage area.
- Contents of external cardboard boxes must be decanted prior to entering the sterile storage area.
- Rotation of sterile stock ensures optimal stock control.
- Commercially processed items must be segregated from items processed in house – RMDs.
- If constraints of space exist, in-house items must be located on different shelves or protected in sealed plastic dustcovers.

Terminally sterilised RMDs

Terminally sterilised RMDs are packaged and commonly managed and controlled using either event or time related storage principles. Individual facilities must risk assess their storage conditions to determine which method is more applicable.

- **Event related** implies that sterility prevails in ideal conditions until the item is subjected to an event which will compromise that state. *"The contamination of a sterile item is event related, and the probability of its occurrence increases over time and with increased handling."* ANSI:AAMI ST 79. 2017 & 2020 Amendment 11.1.3. Events that could compromise an RMD include:
  - frequent handling of packaging
  - lack of rotation of stored RMDs
  - packaging material torn, opened or damaged
  - packaging is damp, i.e. moisture or condensation is obvious, or RMD has been in contact with a damp surface
  - the processed RMD has been dropped, is dirty or has contacted a dirty surface
  - process indicators such as indicator tape or accompanying documentation do not indicate RMD has been through any process

- illegible labelling of contents
- incorrect temperatures during storage for a period of more than 24 hours
- humidity in excess of 70% for a period of more than 24 hours for sterile RMDs
- for commercially sterilised products, temperature or humidity outside of those specified by the manufacturer
- storage area is not clean
- excessive exposure to sunlight
- presence of vermin or insects in storage area or on packages
- inappropriate handling or rough handling e.g. item is carried under arm
- inappropriate storage e.g. compressed tightly in draws, trays stacked 3-4 high or items bundled together with rubber bands.

- **Time related sterility** must be adopted in situations where less than ideal storage conditions exist and is a risk mitigation strategy to ensure every effort is made to preserve the integrity of the item. Studies performed on shelf life of sterile stock suggest that reprocessing must occur in less than ideal conditions at a minimum of 12 monthly.

Commercially sterilised items

Commercially sterilised items undergo rigorous testing regimes to satisfy TGA requirements of processing conditions and packaging systems. This testing confirms that commercially processed items can withstand more extremes of storage and handling conditions than sterile stock produced in/by the HSO processed however, adequate storage is still required to protect packaging and its contents and manufacturer's instructions for temperature, humidity, and expiry must be consulted.

Management of stock exposed to environmental conditions that exceed recommended parameters

- RMDs exposed to temperatures above 25°C and/or over 70% relative humidity for a period of over 24 hours must be reprocessed
- RMD packaging exposed to humidity greater than 70% for 1hr-24hrs will require inspection of the packaging for moisture or wetness and where this exists the items will require reprocessing

2.3 Bulk critical consumables for reprocessing

Bulk critical consumables for reprocessing require areas which are external to the cleaning and packing areas in the sterilisation services department. This includes sterile barrier systems (SBS) wrap, packaging, chemical and biological indicators; and cleaning equipment such as brushes, wipes, cloths and PPE.

Bulk stores of reprocessing chemicals must be stored in a dedicated chemical storage area, must be a restricted area and chemicals must be stored according to SafeWork Australia*, Managing the risks associated with hazardous chemicals* manufacturer's instructions. Safety data sheets must be available wherever chemicals are used (Safety data sheets | Safe Work Australia).

2.4 Handling

When handling processed RMD's (sterile stock produced in/by the HSO or commercially processed items), every effort must be made to ensure items are not subject to contamination or damage. This includes:

- hand hygiene must be performed prior to handling processed items
- all surfaces where processed RMDs are placed must be clean and free from dust or debris
- RMDs must not be handled before being aerated and cooled following sterilisation
- RMDs must be handled as little as possible
- all sterile items must be inspected for damage prior to use.

Handling of critical consumables requires following manufacturer's instructions, inspecting items for integrity, cleanliness and ensuring items are within manufacturer's use by date.

2.5 Transport

Transportation of items that have undergone a process must be performed in a manner that protects items from being damaged and contaminated until the point of use. Transportation must be performed by personnel who have received training in transporting RMDs and who understand the principles of standard precautions.

Appropriate transportation of processed RMDs includes:

- all processed items are to be fully covered and placed on a trolley for transportation
- transport containers must be:
  - designated for that purpose only and clearly labelled.
  - rigid, robust, and leak-proof.
  - adequate in size to contain items securely and safely, protecting their integrity until point of use.
  - able to be cleaned regularly and disposed of and replaced when no longer serviceable.
  - able to be sealed or locked - tamperproof
- temperature and humidity is to be monitored during transport and maintained within the following parameters: 18°C-25°C and humidity 35%-70% as per: AS/NZS 4187:2014, section A9.5 (f), (g).

3. Definitions

Air changes per hour (ACH)	Air changes per hour, or air change rate is a measure of the air volume added to or removed from a space in one hour, divided by the volume of the space.
Decant / De-box	To unload or remove commercially prepared items from their shipping boxes.
Health Service Organisation (HSO)	Separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body.

HEPA Filter	A high efficiency particulate air (HEPA) filter is a disposable, extended media, dry type filter in a rigid frame, having a minimum filtration efficiency of 99.97% and designed to remove particles greater than 0.3 microns.
Personal protective equipment (PPE)	Personal protective equipment such as gloves, gowns, aprons face masks/shields and eye protection.
Released RMD	Reusable medical device that has been released from a phase of processing after achieving the required parameters of processing.
Reusable medical device (RMD)	A medical device designated or intended by the manufacturer as suitable for processing and reuse. Clarification notes: 1. This is not a medical device that is designated or intended by the manufacturer for single use only. 2. An RMD is presented for use either as an individually packaged RMD or as more than one RMD assembled and packaged together as a group or set. For the purposes of this guideline document, the term RMD includes a loan RMD and a trial RMD and applies to all reusable devices that require reprocessing.
Sterile barrier system (SBS)	Used to sterilise reusable medical devices. This includes Wrap, steripeel and rigid containers. Minimum packaging utilised to reduce the risk of ingress of microorganisms and allow aseptic presentation of the sterile contents at the point of use. Both sterile stock produced in/by the HSO (reprocessed RMDs) and commercially produced sterile stock are packaged in an SBS.
Sterilisation Services Department	Also known as Central Sterilisation Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service organisation that performs cleaning, disinfection and sterilising actions on reusable medical devices and manages storage of sterile stock and consumables.
Sterile Stock	Sterile reprocessed items and purchased sterile consumables (commercially prepared sterile items).

4. Roles and Responsibilities

The **Health Service Organisation** (HSO) must ensure suitable and sufficient storage is provided; and that processes in place comply with the requirements of the standard.

The manager of the sterilisation services department is responsible for the management and control of the storage, handling, and transport of processed items including sterile stock produced in / by the HSO or commercially produced sterile items and the storage and handling of bulk non-sterile consumables critical to processing RMDs.

This includes:
- risk assessing available stock storage areas for compliance
- risk assessing conditions of storage to determine if time or event related storage requirements are appropriate
- assessing that risk mitigating processes are in place for appropriate handling and storage of critical processing consumables
- ensure all HCW handling or transporting sterile stock receive appropriate education and understand the importance of good infection prevention and control practices in maintaining sterility of items until use.

All Health Care Workers (HCWs) are responsible for appropriately handling, transporting, and inspection of sterile stock prior to use.

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS/NZS 4187:2014.

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* and is binding on all WACHS staff which, for this purpose, includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.
WACHS staff are reminded that compliance with all policies is mandatory.

6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System in accordance with the Records Management Policy.

All WACHS clinical records must be managed in accordance with the Health Record Management Policy

7. Evaluation

Monthly auditing of:
- temperature and humidity in storage areas
- housekeeping of storage areas
- RMD handling and storage.

The results of these audits must be reviewed monthly by Department managers. They are to be tabled and discussed at site and with the Regional Infection Prevention and Control Committee meetings, with any issues escalated to the regional Safety and Quality Committee meetings.

Ensure that risk assessments are completed, outcomes evaluated, and action taken as required.

Evaluation gained from regular monitoring will contribute to compliance to Standards, good quality patient outcomes and improved staff satisfaction.

8. Standards

National Safety and Quality Health Service Standards – 3.01, 3.02, 3.08, 3.10, 3.11, 3.12, 3.14, 3.17.

AS/NZS 4187:2014 Reprocessing of Reusable Medical Devices in Health Service Organisations and Amendment 2:2019

AS/NZS 4815:2016 Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment

ISO/TS 17665-3: 2017 Sterilisation of health care products – Moist heat

9. Legislation

Therapeutic Goods Act 1989 (Cwlth)
Health Services Act 2016 (WA)

10. References

1. Australian College of Perioperative Nurses (ACORN) - Standards for perioperative nursing in Australia 16th Edition, May 2020.
2. Australasian Health Infrastructure Alliance Australasian Healthcare Facility Guidelines, Part D: *Infection Prevention and Control,* North Sydney, NSW.
3. Building Guidelines Western Australia Health Facility Guidelines for Engineering Services 2017, Department of Health, Western Australia.
4. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities ANSI:AAMI ST79: 2017 & 2020 Amendments.
5. National Health and Medical Research Council (NHMRC) 2019, Australian Guidelines for the Prevention and Control of Infection in Healthcare, National Health and Medical Research Council, Commonwealth of Australia.
6. Therapeutic Goods (Medical Devices) Regulations 2002 Statutory Rules No. 236, 2002 made under the *Therapeutic Goods Act 1989* (Cwlth) Compilation No. 54 Compilation date: 5 March 2022 Includes amendments up to: F2022L00243. Registered: 22 March 2022.

11. Related Forms

Nil

12. Related Policy Documents

WACHS Environmental Cleaning Policy
WACHS Hand Hygiene Policy
WACHS Infection Prevention and Control Policy
WACHS Reprocessing Reusable Medical Devices Policy

13. Related WA Health System Policies

MP 0172/22 - Identification and Use of Personal Protective Equipment in the Clinical Setting Policy
MP 0134/20 - National Safety and Quality Health Service Standards Accreditation Policy

14. Policy Framework

Clinical Governance, Safety and Quality

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