Australasian Health Facility Guidelines

HPU 190 – Sterilizing Services and Endoscope Reprocessing Unit

Part B – Health Facility Briefing and Planning

May 2025

Revision **8.0. Draft V3.0**

Revision 8.0 of this guideline incorporates updates to align with the Australian Standard AS 5369:2023 “Reprocessing of reusable medical devices and other devices in health and non-health related facilities” and the revised AusHFG HPU format.

A full review of content will be undertaken at a later date in line with the five-year review cycle for AusHFG resources, acknowledging the last full update was completed in 2022.

AHIA australasian health infrastructure alliance

AusHFG Australasian Health Facility Guidelines

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Australasian Health Facility Guidelines

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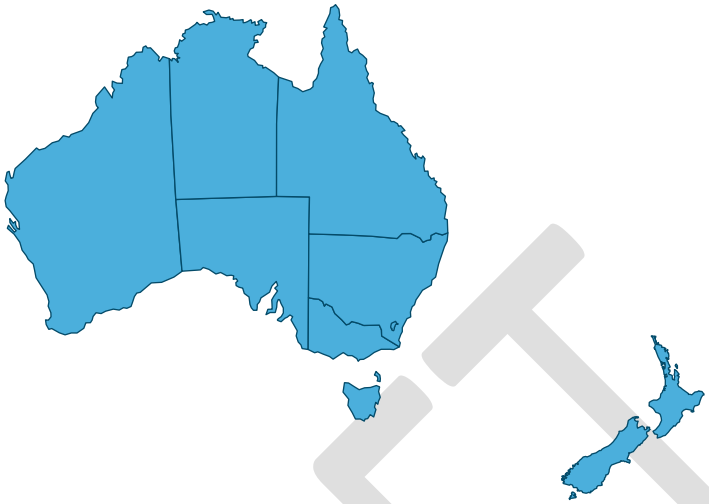
Cultural Acknowledgement and Terminology

The Australasian Health Facility Guidelines (AusHFG) are developed in collaboration with stakeholders across Australia and Aotearoa, New Zealand.



Acknowledgement of Country

We acknowledge the Aboriginal people and Torres Strait Islander People as traditional owners and continuing custodians of the land throughout Australia and the Torres Strait Torres Strait Islands.

We acknowledge their connection to land, sea, sky and community and pay respects to Elders past and present.

Acknowledgement of Te Tiriti o Waitangi

We acknowledge Māori as tāngata whenua in Aotearoa New Zealand.

Te Tiriti o Waitangi obligations have been considered when developing the AusHFG resources.

Terminology and Language in the AusHFG

Throughout the AusHFG resources, the term ‘Indigenous Peoples’ is used to refer to both the Aboriginal and Torres Strait Islander Peoples of Australia and Māori of Aotearoa, New Zealand. Where references to specific cultural requirements or examples are described, the terms ‘Aboriginal and Torres Strait Islander Peoples’ and ‘Māori’ are used specifically. The AusHFG respect the right of Indigenous Peoples to describe their own cultural identities which may include these or other terms, including particular sovereign peoples or traditional place names.

Contents

Acronyms

Acronym	Definition
ACSQHC	Australian Commission on Safety and Quality in Healthcare
AHBR	Alcohol-Based Hand Rub
AFER	Automated Flexible Endoscope Reprocessor
ARTG	Australian Register of Therapeutic Goods
AS	Australian Standard
CEESC	Controlled Environment Endoscope Storage Cabinet
EN	European Norm
ERU	Endoscope Reprocessing Unit
HPU	Health Planning Unit
IAP	Inspection, Assembly and Packaging Room
ICU	Intensive Care Unit
ISO	International Organization for Standardization
NHMRC	National Health and Medical Research Council
NICU	Neonatal Intensive Care Unit
PPE	Personal Protective Equipment
RMD	Reusable Medical Device
RO	Reverse Osmosis
SBS	Sterile Barrier System
SSU	Sterilizing Services Unit
TGA	Therapeutic Goods Administration
UPS	Uninterruptible Power Supply
WD	Washer-disinfector

1 Introduction

1.1 Preamble

The Australasian Health Facility Guidelines (AusHFG) are freely available resources for health services and project teams across Australia and New Zealand to support better planning, design, procurement and management of health facilities.

The AusHFG are an initiative of the Australasian Health Infrastructure Alliance (AHIA), a cross-jurisdictional collaboration of all health authorities across Australia and New Zealand. Part A of the AusHFG provides further information relating to the purpose, structure and use of these resources. It is acknowledged that the application of the AusHFG varies between jurisdictions across Australia and New Zealand.

This Health Planning Unit (HPU) has been developed by AHIA following extensive consultation during 2021/22. Further consultation was undertaken in 2025 to ensure the HPU aligns with the Australian Standard AS 5369:2023 “Reprocessing of reusable medical devices and other devices in health and non-health related facilities”.

This document is intended for new-build projects, however, refurbishment projects should adhere to these guidelines as far as is possible, particularly with respect to achieving segregation of clean and dirty activities. It is acknowledged that meeting the recommended spatial allocation may not be achievable in a refurbishment project.

1.2 Introduction

This HPU outlines the specific requirements for planning and designing a Sterilizing Services Unit (SSU) for reprocessing of reusable medical devices (RMDs). Additional information is included to inform the planning of an Endoscope Reprocessing Unit (ERU). This can be a standalone unit within the Operating Unit or Day Surgery / Procedure Unit or may be integrated into the SSU.

Healthcare facilities should provide adequate facilities to clean, disinfect and sterilize reusable medical devices (RMDs) to optimise the care and safety of patients and staff.

This document does not address procedural practices and does not replace procedure manuals.

This document should be read in conjunction with the Australasian Health Facility Guidelines (AusHFG) generic requirements and Standard Components described in:

- Part A: Introduction and Instructions for Use
- Part B: Section 80: General Requirements
- Part B: Section 90: Standard Components, Room Data and Room Layout Sheets
- Part C: Design for Access, Mobility, Safety and Security, and
- Part D: Infection Prevention and Control.

Planning and design processes will require expert input given the complexity of these units. This includes close consultation with local SSU / ERU staff to understand local service requirements.

1.3 Policy Framework

The overarching standard for SSUs is AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities (Standards Australia). AS 5369:2023 has been adopted by the New Zealand (NZ) Ministry of Health as the standard for use in NZ.

AS5369:2023 requires reprocessing equipment to comply with ISO Standards, European Norms and Australian Standards where these exist.

Other important policy documents related to sterilizing services include:

- National Health and Medical Research Council (NHMRC), Australian Guidelines for the Prevention and Control of Infection in Healthcare

- Australian Commission on Safety and Quality in Healthcare, Preventing and Controlling Healthcare Associated Infections Standard 3, May 2021, and
- Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021.

Before undertaking a project, planners and project personnel are encouraged to familiarise themselves with local jurisdictional requirements. Other jurisdictional specific policy information is included in the Further Reading section of this HPU.

1.4 Description of Unit

1.4.1 Definition of Sterilizing Services Unit (SSU)

Processing or reprocessing of reusable medical devices (RMDs) is a highly specialised and technical activity. Medical devices that undergo cleaning, disinfection or sterilization and where applicable, storage, prior to use in patient care require a processing environment that minimises the risks for contamination of the medical devices throughout each stage of the processing cycle to ensure patient safety.

The SSU is usually a discrete unit that:

- cleans, disinfects and/or sterilizes RMDs for selected clinical services across the health service and selected outlying services / centres in compliance with requirements in AS 5369:2023
- ensures that all processes are validated according to requirements in AS 5369:2023 and the applicable ISO Standards, European Norms or Australian Standards
- assures that the processed RMDs meet the requirements for safety and quality and the needs of the health service organisations.

It is important to note that reprocessing of RMDs can occur in a centralised SSU and also in satellite areas located at the point of use. Refer to Section 2.1.6 for further information on Point of Use Reprocessing.

1.4.2 Definition of Endoscope Reprocessing Unit (ERU)

The Endoscope Reprocessing Unit is usually a discrete unit that:

- cleans, disinfects and stores thermolabile flexible endoscopes for selected clinical services across the health service and selected outlying services / centres in compliance with requirements in AS5369:2023
- ensures that all processes are validated according to requirements in AS5369:2023 and the applicable ISO Standards, European Norms or Australian Standards
- completes routine quality monitoring and testing of reprocessing equipment and flexible endoscopes.

The ERU can be combined with the SSU according to the needs of the health service.

1.4.3 Terminology

The following definitions have been derived from a variety of sources including but not limited to AS 5369:2023 and NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019.

Cleaning

The removal of contamination from an item to the extent necessary for further processing or for intended use.

Critical Medical Device

A medical device intended to come into contact with sterile tissues or the vascular system. Must be sterile at the time of use.

Disinfection

Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

Immediate Use Sterilization

Process in which sterilized RMDs are transferred aseptically to the sterile field in the shortest practicable time after removal from the sterilizer.

Non-critical Medical Device

A medical device intended to only come into contact with intact skin. Must be cleaned after each use.

Reusable Medical Devices (RMDs)

A medical device that is designated or intended by its manufacturer as suitable for reprocessing and reuse. It is not a medical device that is designated or intended by its manufacturer for single use only.

Semi-critical Medical Device

A medical device that is intended to come into contact with non-intact skin or mucous membranes. Must be cleaned and high-level disinfected between uses, or preferably sterilized if compatible with a sterilization process.

Sterile Barrier System (SBS)

Packaging materials applied to RMDs prior to exposure to a sterilization process that are intended to maintain the sterility of the RMD during storage and up until the time the RMDs are used. This may include rigid reusable sterilization containers, sterilization wrappers or paper/laminate combinations commonly referred to as pouches.

Sterilization

Validated process used to render a product free from viable microorganisms.

Terminal sterilization

A sterilization process where RMDs are sterilized within a sterile barrier system.

Traceability

The ability to trace the history, application or location of a product.

2 Planning

2.1 Operational Models

2.1.1 Model of Service Delivery

The complexity of patient care in clinical services such as the Operating Unit and Day Surgery / Day Procedures Unit is increasing the demand for reprocessing services, however, single use products and devices frequently replace the use of RMDs in lower acuity clinical services. This has concentrated the activities of sterilizing services to support:

- surgical services
- procedural services (e.g. endoscopy, transesophageal echocardiogram, etc)
- specialist clinical services (e.g. interventional radiology, radiation oncology, intensive care services, medical imaging), and
- oral health services.

Selected hospital sterilizing services may also support off-site services e.g. oral health services or health services that do not have their own reprocessing capacity. Most health service organisations will centralize sterilizing services rather than have multiple sites for cleaning, disinfection and sterilization. This concentration of reprocessing activities has arisen as:

- the equipment, training and systems needed to ensure the correct, effective and safe reprocessing of RMDs increases the complexity and cost to set up and deliver these services
- the efficiencies and economies of scale that can be generated by centralising reprocessing and using automated and/or semi-automated equipment are realised
- requirements to track all RMDs through the reprocessing cycle and to patient use.

The use of satellite reprocessing units is still an accepted approach for selected services such as endoscopy and point of use reprocessing.

An endoscope reprocessing unit located close to the point of use is often preferred to reduce the number of scopes needed and reduce opportunities for damage. However, centralisation of all RMD reprocessing, including all flexible endoscopes to SSU, is occurring successfully in the UK and Ireland, therefore consideration should be given to this option during the planning stages.

While oral health services located in community health settings have traditionally included reprocessing units, many services choose to undertake reprocessing at a nearby hospital SSU.

SSUs and ERUs should use quality systems approaches to reprocessing of RMDs. These principles will ensure reprocessing practices are clearly defined and controlled and staff have the necessary training to carry-out the work in accordance with these procedures.

There has been significant improvement in equipment associated with cleaning, disinfecting and sterilizing RMDs. Automation of loading and unloading of some reprocessing equipment has improved efficiency and addressed workplace health and safety concerns.

Once the reprocessing is complete, RMDs will usually be dispatched to designated, clean storage rooms in each clinical unit however for SSUs co-located with the Operating Unit, the sterile store could be contiguous with the SSU to reduce unnecessary handling and transport of processed RMDs. Recommended spatial allocations for sterile storage rooms are provided in AusHFG HPU 520 Operating Unit.

2.1.2 Service Capacity

The size and complexity of an SSU and ERU will be dependent on:

- the number of operating rooms and procedure rooms and other clinical services it supports, including any off-site or external clients

- the casemix undertaken (e.g. trauma and joint replacement procedures utilize a large number of RMDs compared with other specialties)
- the current and the projected future workloads, including casemix, surgical specialties, complexity of procedures and staff numbers
- the expected turnaround time between uses of RMDs and the cycle times of the reprocessing equipment
- the extent of services provided to other health related organisations such as community dental practices and other health services
- types, size, number, and complexity of reprocessing equipment required within the SSU
- methods used to transport soiled and processed RMDs internally and externally to the organisation
- whether change rooms, meeting rooms and other amenities are shared with other units
- hours of operation, and
- space to accommodate additional reprocessing equipment for future changes to casemix.

It is essential that a level of redundancy is factored into calculating service capacity. This will accommodate downtime associated with validation, maintenance, repairs and other related activities. This is an important consideration for rural and remote health services where distance impacts access to service technicians and the timeliness of maintenance and repairs. For smaller and rural and remote SSUs, two WDs, two AFERs and two steam sterilizers, and if required the option for one low temperature sterilizer, are the preferred solution, as this allows redundancy for equipment maintenance and breakdown.

The size, capacity and cycle time of the equipment will also influence the quantity required, as will the volume of RMDs requiring reprocessing. This will need to be established with the users during planning stages.

Orthopaedic loan RMDs consume significant WD and sterilizer capacity due to the volume of trays and the multiple trays inside each container used for just one procedure. Similarly oral health RMDs consume large volumes of WD and sterilizer capacity due to the large number of RMDs that are used in this setting on a daily basis. Where the health facility uses rigid reusable sterilization containers as a packaging system for RMDs, additional WD capacity is required to process these.

In general, WD capacity will be greater than SS capacity, since trays are often broken down into multiple wash trays for reprocessing.

For ERUs, a general guide is that one procedure room will require the capacity to process at least two endoscopes at a time and requires storage sufficient to accommodate the number of endoscopes in the fleet. This will vary according to the complexity of endoscopy services undertaken by the health service. Additional storage may be required for endoscopes that have been quarantined on the basis of microbiological testing and results.

It is important to consider the design and layout of both SSU and ERU with respect for future growth in service delivery, facilitating either expansion into adjacent spaces or installation of additional WDs, AFERs and sterilizers. Installation of electrical and data cabling, plumbing and drainage should consider the needs for future expansion.

Section 5.3 provides further information regarding estimating reprocessing equipment capacity requirements.

2.1.3 Technology

Reprocessing equipment and related infrastructure have undergone significant evolution, and utilisation of these technologies can result in improvements to the quality, efficiency and efficacy of the SSU.

Examples can include:

- height adjustable cleaning sinks and packaging workstations
- centralized chemical dosing systems for washer-disinfectors (WDs) and cleaning sinks that are monitored remotely and automatically replenished
- pass-through WDs, automated endoscope reprocessors (AFERs) and steam and low-temperature sterilizers to achieve physical separation of soiled and clean processing activities

- automation systems to load and unload WDs and steam sterilizers
- automated washer rack storage solutions
- utilisation of water treatment systems for the final rinse process in manual and automated cleaning processes and for steam generation to improve the quality and the longevity of this equipment and RMDs
- controlled environment storage cabinets (CESC) for drying and storage of flexible endoscopes (noting the controlled environment may be in the form of a storage bag)
- testing systems for electrosurgical and fibreoptic RMDs
- enhanced visual inspection of RMDs using video microscopes and borescopes
- automated wrapping systems using robotic technology
- heat sealers that verify sealing conditions for each pouched RMD and automated conveyer systems
- electronic instrument traceability systems that can track individual RMDs via data matrix markings and in future, Unique Device Identifiers
- RFID and other emerging technologies that can identify RMDs without a data matrix marking, and
- use of automated guided vehicles or autonomous mobile robots to transport RMDs to and from the SSU.

2.1.4 Summary of process flows

RMDs can be broadly categorised into two types, heat stable RMDs and heat labile (thermolabile) RMDs. Typically, thermolabile RMDs include a variety of flexible endoscopes, transoesophageal echocardiogram probes and ultrasound transducers, however other types of RMDs such as telescopes, cameras and light leads may also be thermolabile.

Whilst both categories of RMDs require cleaning, disinfection and may require sterilization prior to use on a patient, the thermolabile nature of some RMDs requires specialist equipment for low temperature cleaning, disinfection and/or sterilization. This creates a need for a separate reprocessing pathway for thermolabile RMDs, and in particular flexible endoscopes. The reprocessing of both types of RMDs can occur in a combined SSU or can occur in a separate ERU according to the size of the SSU, workflow and the needs of the health service.

Regardless of whether the processing of these RMDs occurs separately or is combined, the process flows are the same, where the user is responsible for pre-cleaning at the point of use prior to return of the RMDs to the SSU or ERU. Within the SSU or ERU, the RMDs may undergo further testing and pre-cleaning steps prior to being loaded into WDs or AFERs for cleaning and disinfection. Pre-cleaning of RMDs may be manual, such as rinsing or processing in an ultrasonic cleaner. Ultrasonic cleaners shall comply with AS2773. WDs for heat stable RMDs shall comply with ISO15883 Part 1 and Part 2 and AFERs shall comply with ISO15883 Part 1 and Part 4.

After removal from the WD or AFER, compatible RMDs can be inspected, packaged and subjected to a terminal sterilization process and then stored, or if the RMDs are semi-critical, they may be removed from the AFER and placed directly into a CESC that complies with EN16442, or equivalent system.

RMDs will require repair or maintenance from time to time. Prior to being sent for maintenance or repair the RMDs needs to be cleaned and disinfected before being sent off-site. Upon return the RMDs shall be exposed to the full reprocessing procedure prior to use on a patient.

Similarly, RMDs on loan (loan RMDs) shall be exposed to the full reprocessing procedure after receipt and prior to use on a patient and after use the RMDs shall be reprocessed as per the instructions from the loan company prior to return to the loaning organisation. These pathways should be considered when designing the SSU.

Figure 1 provides an overview of process flows for RMDs and flexible endoscopes.

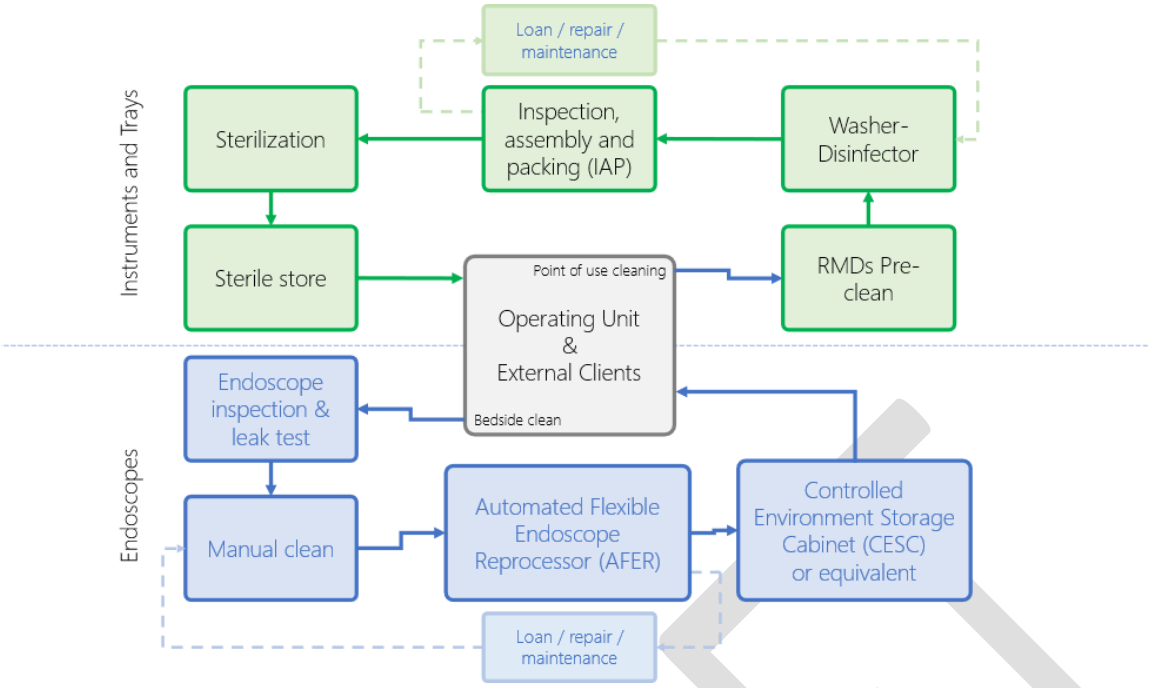


Figure 1 Overview of Reprocessing Flows

2.1.5 Off-site or Outsourcing of Reprocessing

Some health services may elect to use a hub and spoke model and centralize reprocessing to one health facility or utilise a third party to undertake reprocessing of RMDs or endoscopes at a location remote to the health facility.

A dirty dispatch room will be required where the RMDs or endoscopes are held for collection by the courier or off-site reprocessing contractor. A dirty utility may also be needed if a clean-up room is not available in the Operating Unit where the RMDs or endoscopes can have gross soiling removed. The spaces provided will be dictated by the operational model, volume of RMDs or endoscopes being sent off-site and frequency of collections. Specific site requirements shall be confirmed with the users.

The dirty dispatch room shall include or be in the vicinity of a clinical hand basin (Type B) for hand hygiene tasks associated with the risk of handling grossly soiled RMDs and the doffing of personal protective equipment (PPE). Fixtures and finishes are to be easily cleaned, non-porous and of adequate size to safely store contaminated RMDs and transport equipment. Access to the area should be secure and limited to staff only, including protocols for access by external parties such as couriers.

Depending on the operational model, the health facility may require a separate clean receiving room for the contractor to deliver processed RMDs or endoscopes. From this room the RMDs could be retrieved by clinical services or alternatively, the processed RMDs may be delivered directly to the applicable clinical service. The space provided will be dictated by the volume of RMDs or endoscopes being delivered. It should be sufficient to allow for check in / receipt of items and may require provision for a traceability system.

In some cases, RMD inventory may need to be increased to support the turnaround time associated with off-site reprocessing. Additional sterile storage space will be required at the health service supporting off-site services and suitable storage for sterile RMDs will be required at the receiving health service. The location of these rooms will require direct or ready access to the clinical services that utilise the off-site reprocessing contractor and be accessible from an external corridor with good access to the hospital loading dock.

2.1.6 Point of Use Reprocessing

Whilst reprocessing of RMDs usually occurs in a centralised SSU, evolving health technology increasingly utilises non-critical and semi-critical RMDs at the point of use that require processing after each use, such as ultrasound transducers used in Medical Imaging.

In many cases it may not be feasible to send these types of medical devices to a centralised SSU to be processed, therefore, consideration should be given to provision of point of use satellite reprocessing rooms in key locations within the health service to facilitate safe and effective reprocessing of these devices.

If used in Operating Units, equipment for cleaning and high-level disinfection of ultrasound intraoperative transducers should ideally be located in the SSU.

Where decentralised, point of use reprocessing rooms are provided within a health service, it is expected that the environment is consistent with the requirements in AS 5369:2023 in terms of:

- where reprocessing of RMDs occurs at the point of use in new or refurbished facilities, a dedicated area or room for reprocessing of RMDs shall be provided that is separate to the patient/clinical treatment area or room
- the point of use reprocessing area/room shall meet the requirements for environmental control, effective segregation of clean and dirty activities, unidirectional workflows and facility fixtures and finishes (this should be informed by a process map or flow diagram to minimise the risk of cross contamination)
- access to appropriate hand hygiene facilities, including clinical hand basins (Type B)
- sufficient space to store accessories, chemicals and documentation
- surface finishes are smooth, non-porous and easily cleaned
- systems for the identification and traceability of the point of use reprocessing
- storage facilities for reprocessed transducers that protect them from the risk of contamination
- high level disinfection systems used for RMDs should be provided with reference to TGA requirements and included on the Australian Register of Therapeutic Goods (ARTG).

2.2 Operational Policies

2.2.1 General

The following should be considered in developing the operational model for the SSU, ERU and any satellite reprocessing rooms as they will all impact the configuration and overall space requirements.

Operational policies should be developed as part of the project planning process. Refer to Part B Section 80 for further information.

2.2.2 Hours of Operation

The operating hours for SSU will be determined by the size and complexity of the health service.

Some health services may operate 24/7, whilst others have limited staffing on weekends or overnight. Other health services may require SSU staff to be on call after hours.

2.2.3 After Hours Supplies

An after-hours store is not recommended. Clinical services should have the stock levels available to meet requirements.

2.2.4 Staffing

The SSU and ERU staffing may include a manager, team leaders and sterilization technicians. The overall workforce profile will be dependent on the size and complexity of the service.

Additional positions may be needed to support larger services (e.g. clinical educators, Admin, IT support).

Staffing profiles will include consideration of requirements relating to validation, monitoring and testing of equipment. This includes data analysis for monitoring of quality standards.

2.2.5 Staff Education and Training

Access to a tutorial room is needed to support staff meetings and ongoing education. This can be a shared space with other Units.

2.2.6 Pre-treatment at the Point of Use

After use, RMDs shall be wiped or rinsed free from gross soiling by the user before being placed in a designated container or location for transport / transfer to SSU.

In Operating Units, it is customary for the scrub nurse to remove gross soiling continuously throughout the procedure. In areas outside the Operating Unit, pre-cleaning usually occurs in dirty utility rooms.

2.2.7 Transport of Used/Soiled RMDs

The methods used for transportation of used/soiled RMDs shall protect personnel and the environment from contamination or harm. In Operating Units, methods for transportation of soiled RMDs to the SSU may include enclosed case carts, trolleys with lidded containers or the trolleys used during the procedure.

Where the SSU is located remotely from the Operating Unit, a system for moving used/soiled and sterile RMDs will be needed. Systems may include lifts or hoists, where the Operating Unit is located on another level, or automated guided vehicles. Parking space will be needed in both the SSU and Operating Unit to accommodate the numbers of trolleys required to provide the service.

Logistical modelling may be required during the design phase to determine maximum volumes of case carts or trolleys in each functional area. Consideration should be given to the accumulation of transport equipment during hours of low activity.

The most common method for transportation of soiled RMDs from areas outside the Operating Unit is washable, rigid containers with lids and these may be placed on transport trolleys.

The types of collection trolleys and containers may impact on reprocessing equipment needs. For example, the use of case carts will necessitate the installation of a WD that conforms to ISO15883 Part 1 and Part 6. These machines are intended for cleaning and disinfection of case carts, trolleys or larger containers and other non-invasive, non-critical items, such as rigid reusable sterilization containers. These machines are often referred to as Trolley or Cart Washers. Some health service organisations may specify that this large WD also conform to ISO15883 Part 1 and Part 2 so that RMDs may also be processed, particularly in organisations that process large volumes of RMDs for orthopaedic joint replacement.

Whilst provision of an automated method for cleaning of transport trolleys or containers is preferred, smaller health services may rely on processing containers through batch washer-disinfectors and manual cleaning of trolleys in situations where installation of a Trolley/Cart Washer would be cost-prohibitive.

Where RMDs/other devices are transported between sites the procedure shall be subject to a risk assessment in line with AS5369:5369 Section 9.5 and Appendix B.

2.2.8 Cleaning of RMDs

Cleaning RMDs usually involves a combination of steps including pre-treatment involving flushing, brushing, rinsing or exposure of the RMD to an ultrasonic cleaning process; manual cleaning if required and exposure to an automated cleaning and disinfection process. A limited number of RMDs will require manual cleaning only, when no other compatible automated cleaning process can be applied. Recommended cleaning methods will be prescribed by the manufacturer of the RMD in their instructions for use (IFU).

Cleaning Sinks

Cleaning sinks should be height adjustable, supplied with both hot and cold running water or may be temperature controlled with a thermometric mixing valve to a set temperature. Consideration should be given to ‘hands-free’ tap systems. Provision should be made to enable automated dosing of cleaning agents into the designated cleaning [dirty] sink.

The number, shape and dimensions of the basins should be confirmed by the users. Typically, two or even three basin configurations are preferred for manual cleaning workstations, however for pre-rinsing of RMDs prior to loading into WDs, a single sink configuration may be all that is required.

Sinks for general RMD cleaning shall be configured so that a water gun is available on the dirty side of the sink to enable water flushing of cannulated RMDs. Air guns, connected to Medical Air should be located on the clean side of the sink and are used to blow excess water out of the cannulated RMD and check for cleanliness. These will not be required if cannulated RMDs will never be reprocessed in the unit.

For endoscope cleaning sinks, a height adjustable double basin configuration is preferred (GESA 2021) with provision for a leak testing device on the dirty side of the sink. Basins should be large enough and deep enough to enable the endoscopes to be fully immersed, however not so deep that ergonomic injuries can occur. The edges of the sink should be lipped to stop water overflowing.

Shower rose, spray systems should be avoided on cleaning sinks unless systems are installed to limit the dispersal of contaminated aerosols.

Water quality for cleaning and rinsing of RMDs shall be in accordance with requirements in AS 5369:2023. Water treatment systems to improve the quality of water used for all stages of cleaning RMDs may be necessary in some geographical areas.

Consideration can be given to installation of a treated water outlet on the clean rinse sink for the final rinse of manually cleaned RMDs to comply with final rinse water requirements in AS 5369:2023. This should be limited to one designated manual cleaning sink to avoid unnecessary terminal points in the treated water system design.

It is suggested that a magnification lamp be provided to cleaning workstations to enable enhanced visual inspection of RMDs to confirm cleanliness.

Ultrasonic Cleaners

If required in the RMD manufacturer's IFU, exposure to an ultrasonic cleaner should be completed as part of the cleaning process. Typically, RMDs are rinsed free from gross soiling and cannulated RMDs will be brushed and flushed before immersion in the ultrasonic cleaner, noting some machines may have connections for cannulated devices.

Ultrasonic cleaners may become heavily contaminated during use. Smaller ultrasonic cleaners are best located on the dirty side of the cleaning sink or in between the dirty sink and the clean rinse sink. Consideration should be given to lowering the bench or the part of the sink that smaller ultrasonic cleaners sit on for ergonomic reasons.

There are larger ultrasonic cleaners that have hydraulic lifting capacity for large or heavy trays and these should be considered to avoid manual handling issues, where applicable.

It is important that ultrasonic cleaners are not installed separately to the cleaning sinks, as this interferes with unidirectional workflows and can create slip hazards due to dripping water.

Automated Cleaning and Disinfection

It is an expectation that the processes used for cleaning and disinfection will be automated wherever possible and the use of manual cleaning and disinfection procedures will be limited to only those RMDs that are not compatible with any other process. This includes automated cleaning and chemical disinfection of flexible endoscopes that may undergo sterilization in a low temperature sterilizer.

WDs for heat stable RMDs come in a variety of configurations such as:

- batch type
- multi-chamber or index / tunnel washers
- cart or trolley style washer-disinfectors.

To facilitate unidirectional workflows and effectively separate soiled and clean activities, pass-through WDs and AFERs should be installed in SSU and ERU.

2.2.9 RMD Drying

After manual cleaning, heat stable RMDs will need to be dried in a drying cabinet that complies with AS5330. The drying cabinet should be pass-through to facilitate a unidirectional workflow and effectively segregate soiled and clean activities.

After conclusion of a cleaning and disinfection process in a WD, RMDs should be dry. Historically it has been a common practice for the drying stages on the WD process cycle to be abbreviated at user request to improve throughput, resulting in wet RMDs being removed from the WD and placed in drying cabinets. Discussions with the users may be required to assess the size, number or capacity of the WDs required so that RMDs can be subject to a full drying stage in WDs versus relying on drying cabinets for this purpose.

The selection of the type of drying cabinet will be influenced by the need to provide only racks for trays of RMDs or combined with adaptors suitable for drying the internal lumens of cannulated RMDs or tubing.

Where compressed medical air is provided in the Inspection, Assembly and Packaging Room (IAP) area to assist the drying of RMDs or endoscopes following washing or disinfection, an enclosure shall be provided which prevents the dispersion of aerosols.

ISO15883-4 has no mandatory requirement for the AFER to have a drying stage in the process cycle, therefore after removal from the AFER, thermolabile RMDs may need to be placed on a clean surface to be dried using low-linting cloths prior to its next use or being placed into storage.

Flexible endoscopes removed from an AFER and not used immediately should be placed in an EN16442 CESC or equivalent alternate system.

The selection of the CESC can be influenced by the AFER selected and the design of the SSU or ERU. CESCs come in single or double door (pass-through) configurations and endoscopes may be hung vertically or stored horizontally in trays or cassettes. Alternate controlled environment storage systems for endoscopes exist, where the endoscope is dried and stored in a sealed bag that forms the controlled environment. It is important to note that where these alternate systems are used, space will be required to store the bagged endoscopes.

2.2.10 Immediate Use Sterilization

Most health services do not support immediate use sterilization for RMDs that can be terminally sterilized and instead have implemented systems within the SSU to ensure urgent items can be processed in a timely way so that clinical care is not compromised.

2.2.11 Liquid chemical sterilization processes

There are liquid chemical sterilization systems, and some AFERs that offer a ‘sterile’ cycle option, that may be used to sterilize flexible endoscopes, for example bronchoscopes, cystoscopes, duodenoscopes and where required, gastrointestinal endoscopes. After processing these RMDs shall be transferred aseptically to the sterile field immediately after they are removed from the sterilizer.

Where a health service intends to utilise liquid chemical sterilization systems for these purposes, the unloading of the machine shall occur in a designated clean room and consideration shall be given to the pathway for transport of the sterile scope to the point of use, for example not having to transit through a dirty room.

It is the responsibility of the health service to develop and ensure that procedures for the aseptic transfer minimize the exposure to air and other environmental contaminants as required in AS 5369:2023.

2.2.12 Transport of Processed RMDs

Systems used to transport processed RMDs shall protect them from contamination. Containers or trolleys used for this purpose shall be constructed of materials that are free from rough edges, are easily cleaned and ideally can withstand processing through a WD or Trolley/Cart washer.

Whilst some models of service delivery may use dedicated transport systems for processed RMDs, the use of a WD or Trolley/Cart washers for cleaning and disinfection of transport containers and trolleys provides advantages and efficiencies through enabling the same containers and trolleys used for transport of soiled RMDs to transport processed RMDs. Therefore, as part of service planning, the health service organisation needs to determine whether the transport containers or trolleys are going to be dedicated for soiled RMD transportation only or whether these containers or trolleys might be used for both transport of soiled RMDs and processed RMDs. Where the containers and trolleys are going to be used for both purposes, they shall be cleaned and disinfected between uses using a WD or Trolley/Cart washer and this shall be factored into capacity planning.

In smaller health services where containers are used for transportation of both soiled RMDs and processed RMDs, the volume of containers needs to be factored into capacity planning for batch type or multi-chamber WDs, where no Trolley or Cart washer is available.

2.2.13 Loan RMDs

The use of loan RMDs is commonplace in most hospitals. The use of these loan RMDs requires careful coordination between surgical suppliers, transport companies, hospitals and SSU. The process is extremely labour-intensive, requiring repeated manual checking, unpacking and rechecking prior to return. Operational practices regarding the use of loan RMDs should be informed by a risk management plan.

Dedicated space should be provided to receive, manage and dispatch loan RMDs where utilised. This space shall be sufficiently sized to accommodate the volume of loan RMDs used by the health service in consultation with the users.

Consideration for the handling and storage of the empty loan set transport cases needs to be included in the planning. Rural and remote facilities may hold loan sets and transport cases for a longer period of time to allow for courier delivery and dispatch timeframes – additional space should be allowed for this.

Refer to:

- Design and handling of surgical instrument transport cases, A guide on health and safety standards, WorkSafe NSW, May 2011(<https://www.safework.nsw.gov.au/resource-library/health-care-and-social-assistance/design-and-handling-of-surgical-instrument-transport-casesguide-on-health-and-safety-standards>). This document describes processes and facility requirements associated with the management of these sets; and
- Section 4.2.1 Non Standard Components: Loan RMDs – receipt / dispatch for a detailed description of this room.

2.2.14 Traceability of Reusable Medical Devices

AS5369:2023 and Action 3.17 of the ACSQHC's Preventing and Controlling Infections Standard require health services to have a traceability process in place for critical and semi-critical RMDs that is capable of identifying the patient, the procedure and the reusable equipment, RMDs and devices that were used for the procedure.

Whilst traceability systems can be manual or electronic, health services should be working towards implementation of electronic traceability systems as recommended in AS 5369:2023.

Electronic traceability systems enable tracking of all RMDs processed by the SSU and records their journey through the cleaning, disinfection, packing and sterilizing process including dispatch to the clinical unit and to use on each patient. This includes the ability to track loan RMDs.

Electronic traceability systems are preferred as they:

- allow integration with all major reprocessing equipment used within the sterilizing services environment
- allow live data logging and electronic recording of sterilizer, WD and AFER cycles
- provide electronic linking to the patient for each RMD used
- provide a record of the life cycle of the RMD

- have provision for inventory management and reporting functions that assist with production management and quality control, and
- alert the user if a product (RMD) from a failed process is dispatched for use.

Access to a scanner, computer and where applicable, printers, will be provided at each workstation and at each stage of the reprocessing cycle so staff can record the process as it occurs. IT equipment should be able to withstand regular cleaning.

Data, power and related equipment for traceability devices may be required at the loading and unloading areas of reprocessing equipment, including washer-disinfectors and sterilisers.

Existing RMDs may require data matrix marks or bar-codes to be applied to facilitate electronic tracking of individual RMDs. In large facilities consideration needs to be given to the allocation of a dedicated space, referred to as the ID station for installation of the data labelling equipment. The ID Station should be separate to the Cleaning (Decontamination) Room and IAP to ensure new RMDs or newly marked, existing RMDs are only introduced into circulation once the correct processes have been followed.

Capability for the electronic traceability system to track loan RMDs is essential.

2.2.15 Endoscope Reprocessing

In hospitals with a small endoscopy case load, facilities for flexible endoscope processing may be incorporated into the SSU. In this context, it is suggested that there are two distinct processing pathways created with dedicated height adjustable cleaning sinks, one for RMDs and one for endoscopes, unless the service will only be performing surgical procedures or endoscopy procedures on any given day.

Larger services will usually co-locate the ERU with the endoscopy service. This arrangement is generally preferred as endoscopes are delicate, expensive and a time-efficient turn around is needed.

As with the SSU, a dedicated ERU will have:

- a dirty or cleaning room where scopes are received, leak tested and manually pre-cleaned in a height adjustable cleaning sink, prior to loading into a pass-through automated endoscope reprocessor (AFER) (Refer to Section 2.2.8 and Section 4.2.7 for further information on requirements for cleaning workstations and ultrasonic cleaners).
- a clean room where processed scopes are unloaded from the AFER and stored in a CESC or an equivalent system (Refer to Section 2.2.9 and Section 4.2.7 for further information on requirements for drying of endoscopes).

The endoscope CESC or equivalent system should be located in the clean room. They can be single door opening or pass-through, as selected to fit with the design of the facility. Where alternate equivalent systems for endoscope drying and storage are used, for example controlled environment storage bags, consideration shall be given to the location of the storage system for the bagged endoscopes.

Refer to:

- Standards for Endoscopic Facilities and Services, Gastroenterological Society of Australia and Gastroenterological Nurses Society of Australia, 3rd Edition 2006
- Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021, and
- Non Standard Components - Endoscope Reprocessing Unit (Section 4.2.7).

2.2.16 Reprocessing Records

It is essential that records be kept of all RMDs (including endoscopes) reprocessed and all cleaning, disinfection and sterilizing cycles so that a non-conforming RMD may be recalled if necessary and malfunctioning equipment, operator error and/or product and processing defects identified and corrected.

The records kept shall be in accordance with requirements stipulated in AS 5369:2023 and be retained in accordance with local policy with reference to jurisdictional requirements.

Electronic traceability systems will increasingly replace the need to store hard-copy records. Appropriate back-up and storage of these records are also required to meet local policy or jurisdictional requirements.

2.2.17 Storage - Consumables

Bulk storage rooms should be located on the periphery of the SSU so that deliveries can be received and de-boxed before being taken into the clean work spaces.

Storage is required for:

- detergents and disinfectants - where centralised chemical dosing systems have been installed, storage of chemicals and disinfectants may occur in the same room, ensuring chemical safety standards are met. Chemicals with high acidity or alkalinity should be stored in a chemical storage cabinet in accordance with workplace health and safety requirements
- consumables that may be used in the cleaning, assembly and packaging of RMDs for sterilization
- consumables used in tracking, testing and checking of reprocessing equipment
- packaging material (wraps, dust covers etc), and
- spare unsterile RMDs and containment devices.

2.2.18 Storage - Sterile Supplies

Once RMDs have been processed, RMDs may be returned to the point of use. Large sterile storage rooms will not generally be provided within the SSU, unless they are co-located with the Operating Unit.

Refer to Operating Unit HPU for further information.

2.2.19 Waste Disposal

Waste generated within the SSU should be placed in the appropriate containers and options for recycling should be considered. Clinical and general waste receptacles will be required in the Cleaning (Decontamination) Room and general waste receptacles will be sufficient in all other areas.

'Sharps' containers should be provided in the Cleaning (Decontamination) Room for disposal of sharp items inadvertently returned to SSU.

2.3 Planning Models

2.3.1 Location

The SSU should have direct access to the Operating Unit. This may be an adjacent location or accessible by lifts / hoist systems.

Consideration needs to be given to access arrangements for internal or external customers that produce a significant volume of RMDs to be processed.

2.3.2 Connectivity with Operating Theatres

Where the SSU is located on a different floor to the Operating Theatres, a vertical transport system for the movement of RMD will be needed. This may include lifts or hoists.

The number and size of lifts or hoists will be dependent on the volume of clean and used / soiled RMD that need to be moved during peak times. The lifts or hoists should be located so as to maintain the integrity of designated 'clean' and 'dirty' areas at all department levels.

Where lifts or hoists are used for transport of RMDs, the interiors should be fully lined to facilitate cleaning and to protect RMDs from environmental contamination.

A system to notify staff at each end will be needed, such as an audible or light based alarm, so that their lifts or hoist can be emptied.

2.4 Functional Areas

2.4.1 Functional Areas

The SSU comprises the following functional areas according to the service level and size of the health service. They include:

- entry / reception
- loan RMD receipt and dispatch room, often referred to as the Loans Room
- receiving area for used/soiled RMD arriving from the Operating Unit and external customers where applicable. This function is usually integrated into the Cleaning (Decontamination) Room
- cleaning / decontamination / disinfection area, referred to as the Cleaning (Decontamination) Room
- packing and sterilizing area, referred to as the Inspection, Assembly and Packaging (IAP) Room
- cooling and dispatch area
- support areas, including a de-boxing room and storage for consumable products, and
- staff areas including amenities.

2.4.2 Entry / Reception

The entry to the SSU should be secure and controlled to prevent unauthorised access. An external intercom point will allow visitors to communicate with sterilizing services staff. This point may be an office space.

In larger facilities, alternate points for the delivery of bulk clean consumables, loan sets and RMDs from other health facilities or external customers should be provided, ensuring that means for separation of clean and soiled deliveries is considered during the planning stages, in consultation with the user.

2.4.3 Loan RMD Receipt and Dispatch Room (Loan Sets Room)

Loan RMDs in their transport cases will be received and dispatched from this room. Refer to Section 4.2.1 Non Standard Components ‘Loan RMDs – receipt / dispatch’ for a detailed description of this room. This room should be accessible from the main service corridor enabling large volumes of loan RMDs to be delivered to and dispatched from SSU back to the loan company.

In health services performing significant amounts of procedures utilising loan RMDs, consideration needs to be given to the provision of an automated system that reads the RFID tags on implantable items. Refer to Section 2.2.5 in HPU 520 – Operating Unit.

2.4.4 Receiving Area and Cleaning (Decontamination) Room (Dirty Room)

A receiving area is provided within the cleaning (decontamination) room to unload, sort and prepare soiled RMD that are received on trolleys via:

- the main service corridor from clinical units throughout the hospital and outlying services (e.g. oral health, other facilities within the health service without their own reprocessing capacity), and
- an internal route (hoists, lifts or corridor), from the Operating Unit.

Where the SSU provides services to a large number of external clients or outlying health services, consideration shall be given to providing sufficient space in the receiving area to accommodate the transport trolleys and containers used for the delivery of used/soiled RMDs. Consultation with the user will be required.

If lifts or hoists are used, a staging area or lift lobby for holding of trolleys containing soiled RMDs will be required in both the Operating Unit and in the receiving area.

The cleaning (decontamination) room will include stainless steel benches with sinks, preferably height adjustable, for the disassembly of RMD prior to pre-treatment or cleaning (where needed) and segregation into major cleaning pathways that include:

- manual cleaning only, with or without the application of ultrasonic cleaning
- manual and/or ultrasonic pre-treatment prior to cleaning in a WD

- cleaning and disinfection in a pass-through WD or AFER. Sufficient space for loading and unloading systems (either manual, automated or robotic) will be required
- provision of a hatch for return of empty wash racks from the IAP to the Cleaning (Decontamination) Room is recommended
- a pass-through drying cabinet for those RMDs that are manually cleaned, and
- where required a pass-through Trolley/Cart washer-disinfector. This machine may be positioned to unload in the IAP. If also being used to process heat stable RMDs, or alternatively to unload in a dedicated area linked with the sterile store or dispatch area so that the trolleys can be used to transport processed RMDs back to the user.

After pre-treatment or pre-cleaning RMDs will be loaded onto wash-racks. Each WD is usually equipped with a minimum of two wash-racks, therefore provision shall be made for suitable, ergonomic storage of wash-racks when not in use.

Wash-racks are transported to the WD or automated loading system on trolleys that are usually battery operated and will need a space for recharging.

A clinical hand basin (Type B) should be readily accessible to this room.

2.4.5 Inspection, Assembly and Packaging Room (IAP) (Clean Room)

After cleaning and disinfection, heat stable RMDs that undergo terminal steam sterilization and thermolabile RMDs that undergo terminal low temperature sterilization are inspected, tested, maintained, assembled and packaged in preparation for sterilization.

After cleaning and disinfection, thermolabile RMDs, including flexible gastrointestinal endoscopes that do not undergo terminal sterilization will be removed from the AFER, and returned to the user for use, or storage if these are not stored within the SSU.

Trolleys or automated systems may be used to transport the wash racks from the WD to the packaging workstations. These trolleys and systems are usually battery operated and will need a space for recharging.

The number of packaging workstations is determined by the size, casemix and throughput of the service. Packaging workstations shall be height-adjustable with power and data supplied for use with the electronic traceability system. This can include a computer screen and keyboard, bar code scanner and access to a printer for tray lists or tray labels.

Packaging workstations should also include facilities for storage of packaging materials such as wraps or pouches, a tape dispenser for sterilization wrap tape, and other consumable products used in preparation of RMDs for sterilization such as tip protectors and internal chemical indicators. An illuminated magnifier will also be needed at each station and space for trolleys for the RMDs awaiting loading into the sterilizers.

Where possible the volume of single instrument packing should be limited through the use of SBS container systems to minimise labour intensive processes and potential WHS issues.

The layout of the packaging workstations may align with the main inspection, assembly and packaging pathways, for example dedicated workstations for packaging of RMDs in pouches, for testing of electrosurgical RMDs, or for preparing RMDs for terminal low temperature sterilization.

Pass-through sterilizers are best practice and should be provided, however they may not be practical in all circumstances, and it is still accepted practice in small facilities to have single door opening machines. Where pass-through sterilizers are not provided, the design shall ensure effective segregation of cleaning and dirty activities and unidirectional workflows from dirty to clean activities.

There are a number of automated loading and unloading options available depending on space and the throughput of the SSU. Usually, two to three loading racks are provided for each sterilizer loading trolley. The loading trolleys are typically battery operated, and space will need to be allocated for recharging.

Space is required on either side of the packaging workstations for trolleys to be parked for unloading or loading.

Where single door opening machines are used, provision shall be made for the parking of the trolley after unloading from the sterilizer whilst the RMDs cool. This should be separate from the area where trolleys are being loaded with unsterile RMDs to avoid the risk of an unsterile product being mistaken for a processed product. Where a dispatch room is provided, the trolleys with cooling RMDs can be pushed into this room for cooling.

For pass-through sterilizers, cooling of RMDs will occur on the unloading side. This may be a designated section of a larger sterile storage room or included as part of a larger dispatch area, where SSU is remote to the Operating Unit. Sterilizers may have automated loading and unloading systems to improve efficiency and productivity. Where there is automated unloading, the unloading station is utilised as the cooling area.

Where there is no provision for automated loading or unloading, space may be required for the empty trolleys to be parked after the sterilizer has been loaded and typically this may be in front of the machines.

For facilities with pass-through sterilizers, provision of a sterilizer loading rack return system is advised.

2.4.6 Cooling and Dispatch

Pass through sterilizers will be unloaded in the cooling and dispatch room. Steam sterilized loads will be left here to cool prior to RMDs being returned to clinical areas. Sufficient space for cooling sterilizer trolleys is needed to avoid risks of burns to personnel working in this area.

It is important that air conditioning supply grills are not located directly over the area where loads will be cooled, as cool air contacting the hot packaged RMDs upon removal from the sterilizer can cause condensation to form, compromising sterility.

The dispatch room can be used for the temporary storage of reprocessed RMD ready to be returned to the point of use (e.g. operating units or other clinical areas). The dispatch area will be contiguous with the area used for cooling RMDs after they have been removed from the sterilizers.

Where the SSU provides services to a large number of external clients or outlying health services, consideration shall be given to providing sufficient space in the dispatch area to accommodate the transport trolleys and containers used for the delivery of processed RMDs. Consultation with the user will be required.

When the SSU is co-located with the Operating Unit, the Cooling and Dispatch room should be integrated as a dedicated space within a larger Sterile Storage Room.

Hoists or lifts, if used to return RMD to the Operating Unit will be located in this room.

Direct access is required to the external corridor to return reprocessed items to a range of clinical areas.

2.4.7 Support Areas

Some SSUs will require access to a disposal room for soiled linen and waste generated by SSU activities to be held prior to collection. This room should connect with the Cleaning (Decontamination) Room and have external corridor access so waste can be removed without entering SSU.

Best practice is to have two cleaner's cupboards for SSU, one for cleaning the Cleaning (Decontamination) Room and one for the IAP, cooling, dispatch and if applicable sterile storage rooms to avoid risks for cross contamination. Smaller units may have one cleaner's cupboard, ideally with two sets of cleaning equipment to avoid cross contamination risks.

A room for de-boxing and a room for storage of consumable products will be provided. This room will have access to the external corridor and be accessible from the IAP. In smaller facilities this space may be shared with the Operating Unit.

There are often competing demands on space. It is recommended to include sufficient space for:

- consumables such as PPE, SBS wraps and PSBS (pouches and reels), tray liners, tip protectors, biological and chemical indicators, cleaning equipment (brushes and other accessories) and cleaning chemicals where centralised dosing is not provided
- spare RMDs to complete sets that have broken or repaired items and, where rigid sterilization containers are used, spares of these

- equipment / RMDs awaiting repair or requalification to re-enter service
- archived records
- chemical storage, particularly for process chemicals used in AFERs
- water treatment plant, compressors, steam generators, and other equipment (this may be shared with the facility's general plant room, or it may be a dedicated plant room space located in the SSU).

Access (doors, lifts, corridors) should be large enough, with sufficient weight/load capacity to allow passage of the largest piece of equipment. Consideration could also be given to having an access opening for the plant on an external wall.

2.4.8 Staff Areas

Change rooms with lockers, shower and toilets will be provided for staff working in the Unit. These facilities should be collocated but, may be shared where SSU / ERU is adjacent to the Operating Unit.

A staff room may be a shared central facility outside the SSU within the controlled environment of the Operating Unit.

Consideration shall be given to the size of shared facilities to ensure sufficient amenities for Operating Unit and SSU / ERU staff.

2.5 Functional Relationships

2.5.1 External

The SSU / ERU should have direct horizontal or vertical adjacency to the Operating Unit (with dedicated and controlled point of entry).

Ready access is required to:

- day surgery / day procedure and endoscopy procedure rooms if separate to the Operating Unit
- critical care units (ICU, NICU, birthing suite)
- interventional imaging
- emergency unit
- hospital loading dock.

Easy access is required to:

- inpatient units
- oral health unit
- medical imaging
- ambulatory care.

2.5.2 Internal

The SSU / ERU will be arranged to provide physical separation of clean and dirty activities. It will provide an environment that minimises the risk of cross contamination of cleaned, disinfected and sterilized RMD and endoscopes. The workflow will be unidirectional from dirty to clean.

The Unit will be access controlled and restricted to authorised staff.

Refer to the Functional Relationship Diagram included at Section 5.2.

3 Design

3.1 Access

There should be separate and distinct entry to the SSU, separated from other hospital traffic and located to restrict entry by unauthorised staff. The entry points for receiving soiled RMDs shall be separate from entry points for personnel, receipt of loan RMDs, other consumable items and separate from the exit for processed RMDs.

The entry point for soiled RMDs shall be sized to ensure trolley access for returns from clinical services, as well as returns from the Operating Unit.

A controlled exit is required for trolleys returning processed RMD to the Operating Unit and other clinical services. These entry and exit points may be achieved by either controlled doors or vertical transport.

Where required, access is needed for loan RMD deliveries. Loan RMDs are generally received and dispatched from dedicated loan equipment rooms. Consideration needs to be given to the route between the loading dock and the loan equipment room in SSU.

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

3.2 Maintenance

Access to the plant room for maintenance should be such that disruption to the staff and the operation of the unit is minimal. In particular, access to services should be outside ‘clean areas’ wherever practicable and preferably away from staff work areas.

WDs, AFERs and sterilizers will usually have integrated plant that will require access. Ideally maintenance on WDs and AFERS should be carried out in the Cleaning (Decontamination) Room and for sterilizers, in the IAP.

Ongoing requirements for testing and documenting that equipment is operating correctly is detailed in Section 8 and Section 10 in AS 5369:2023.

3.3 Parking

Bulk deliveries and deliveries of loan RMDs to the SSU will routinely be made via the hospital loading dock.

During planning, the path of travel for the receipt and return of loan sets and RMDs from external clients’ needs to be mapped and included in the design.

3.4 Disaster Planning

The impact on the SSU will need to be understood as part of broader disaster planning for the health service and local jurisdictional policies.

Consideration should be given to connecting at least one WD, one sterilizer, the electronic traceability system and the ventilation system for the sterile store to an emergency power supply to ensure continuity of service delivery.

Refer to AusHFG Parts B and C for further information.

3.5 Infection Prevention and Control

Infection prevention and control issues that need to be considered include:

- restricted / controlled access to the Unit
- dirty to clean to sterile (unidirectional) workflows with the use of pass-through equipment

- appropriate air handling systems and heat / moisture management in accordance with AS1668.2 and applicable jurisdictional requirements
- dedicate storage rooms that prevent contamination of consumables used in the preparation of RMDs for use
- access to hand hygiene facilities across all work areas within the Unit.

Hand hygiene basins should not be located in the IAP or in the sterile store room as the sinks pose a hazard for contamination of RMDs. Alcohol based hand-rubs (ABHR) are more suitable for use in these areas. However a clinical hand basin (Type B) should be accessible to the clean areas and may be located at the entry point into the clean areas for use prior to entry and if hands become visibly soiled.

A clinical hand basin (Type B) will be required in the Cleaning (Decontamination) Room.

Consideration shall be given to:

- availability of PPE in all areas of the Unit
- the use of suitable materials and finishes that are easily cleaned
- appropriate facilities for cleaning and management of waste and
- provision of change facilities.

Refer to:

- AusHFG Part D Infection Prevention and Control
- Section 5.6 in AS 5369:2023
- Infection Prevention and Control in Endoscopy, Gastroenterological Society of Australia and Gastroenterological Nurses Society of Australia, 4th Edition 2021
- jurisdictional policies.

3.6 Environmental Considerations

3.6.1 Temperature and Humidity

Consideration needs to be given to the impact reprocessing equipment has on heat and moisture gain in the SSU.

Temperatures within the Unit should be maintained within the ‘comfort’ range for staff. The temperature in the Cleaning (Decontamination) Room may need to be significantly cooler than the IAP, as personnel working in this room will be wearing full PPE.

In storage rooms, temperatures should not exceed 25°C and sterile medical devices, including processed RMDs should be protected from direct sunlight.

Humidity should be maintained at a range between 35 and 70% for processed RMDs, noting that many commercially sterilized medical devices may have requirements for humidity to be maintained under 60%.

In line with AS5369:2023, ventilation of storage areas for reprocessed RMDs shall enable temperature and relative humidity to be controlled with appropriate processes in place to alert and respond to variations.

3.6.2 Lighting

Natural light is highly desirable especially for the IAP. Lighting layout should consider the bench layout and requirements of staff to minimise shadowing. Lighting will enable the visual examination of RMDs for residual contaminants. Selected areas may need additional task lighting and magnification.

Light fittings, including covers, should be fully recessed and selected to prevent dust and insects from entering.

3.7 Space Standards and Components

3.7.1 Ergonomics, Human Engineering and Accessibility

Equipment selection and design can eliminate or reduce many hazards. Examples include:

- height adjustable workstations (cleaning sinks and packing tables) for RMD cleaning and packing
- ultrasonic cleaners with automated lifting capability for ease of loading and unloading large and heavy trays of RMDs
- battery operated carrier and trolley systems that integrate with reprocessing equipment such as WDs and steam sterilizers to reduce manual handling. These reduce pushing and pulling movements
- the use of automated systems for loading and unloading reprocessing equipment
- the use of hoists, height adjustable trolleys and roller systems to manage manual handling of loan RMDs.

Refer to AusHFG Part C for further information.

3.7.2 Building Elements

Doorways should be sized to admit delivery and dispatch trolleys without impediment. On major travel routes, doors will routinely be automated.

Door and corridors shall be wide enough to accommodate large items of equipment.

Eliminate where possible ramps and differences in floor height. This can be an issue where (for example) trolley / cart washer-disinfectors are not installed with a pre-formed pit. Due to the combined weight of the loading trolleys and the load contents, it is a manual handling risk where staff are required to push trolleys up ramps. If ramps are unavoidable, ensure the slope is as shallow as possible.

Building elements are addressed in detail in Part C of these Guidelines.

3.8 Safety and Security

3.8.1 Safety

Automation, through self-loading machines and conveyors can both improve efficiency and reduce manual handling tasks.

The management of loan RMDs poses a major manual handling risk to staff. Refer to:

- Design and handling of surgical instrument transport cases, A guide on health and safety standards, WorkSafe NSW, May 2011
- Section 4.2.1 Non-Standard Components ‘Loan RMDs– Receipt and Dispatch’ for details of space and equipment required to manage loan RMDs.

3.8.2 Security

The periphery of the Unit will be secure and only accessible to authorised staff. Also refer to AusHFG Part C.

3.9 Finishes

3.9.1 Windows

Any windows provided within the Unit should not be able to be opened. Windows should be easy to access for cleaning and ledges should be avoided. Window coverings should be integrated within the window frames to avoid dust accumulation.

3.9.2 Wall Finishes

All walls within the Unit should be washable with adequate protection against damage by trolleys. Full height vinyl or equivalent materials will fulfill this requirement.

Robust wall, door and corner protection should be considered in areas where trolleys are manoeuvred or stored, such as the Loans Set Room, Receiving area or Dispatch Room

3.9.3 Floor Finishes

Slip resistant flooring is essential for all work areas.

The floor surface should be impervious, have adequate drainage and be easy to clean. Welded sheet vinyl, coved up the wall, is recommended.

Floor wastes should not be located in the IAP or in Clean or Sterile Store Rooms. Where floor wastes are required to avoid the risk of flooding from leaking reprocessing equipment, these should be located and enclosed within the plant area.

3.9.4 Ceiling Finishes

Ceilings shall be washable, impermeable, preferably monolithic and sealed against walls. Shadow-line cornice is not to be used.

Access points will be needed to maintain essential equipment such as air handling systems. Location of access points in the clean areas should be avoided wherever possible. If access points need to be located in the IAP or in the Sterile Store Room, these should be pressurised to avoid the ingress of dust into these rooms.

Ceilings should be resistant to humidity in spaces where moisture or condensation may occur.

Refer to AusHFG Part C for further information regarding finishes.

3.10 Fixtures, Fittings & Equipment

3.10.1 General Requirements

All work surfaces, fixtures, fittings and equipment should be constructed from robust materials and be easy to clean. Fittings will be flushed mounted on walls and ceilings where possible. Fittings and fixtures should be selected to avoid opportunities for dust accumulation.

3.10.2 Equipment Standards

Equipment typically used within SSU / ERU are described in the Non-Standard Components section of this HPU.

Equipment used within the SSU / ERU shall comply with the applicable European Norms, ISO or Australian Standards as specified in AS 5369:2023.

When purchasing new reprocessing equipment, RMDs, other devices and related accessories, the TGA requirements shall be reviewed and items included on the Australian Register of Therapeutic Goods (ARTG). For further information refer to:

- AS5369:2023, Clause 2.5.2
- ACSQHC, Australian Guidelines for the Prevention and Control of Infection in Healthcare, Section 3.1.4.

3.11 Building Service Requirements

3.11.1 Air-Handling

Several jurisdictions have published engineering services guidelines for health services. Reference shall be made to the relevant applicable jurisdictional guidelines to confirm specified air-handling requirements are met for SSU and ERU. These guidelines are listed in the Further Reading section.

The general principles is that air movement and ventilation shall achieve a positive airflow from clean to contaminated work rooms.

In line with AS5369 the ventilation of RMD cleaning areas shall align with the requirements of a dirty utility room in AS1668.2. The Cleaning (Decontamination) Room and dirty endoscope cleaning room air-handling system should be designed to be at a negative pressure relative to adjacent areas. The system shall be designed to address heat gain and vapours discharged from washer-disinfectors and to achieve a minimum of 12 air changes per hour. Temperatures should be appropriate to ensure the comfort of staff wearing full PPE.

Endoscope cleaning (dirty) rooms may require a localised exhaust system to capture and remove air that may be contaminated with vapours from the chemical disinfectants.

Air quality delivered to the IAP, cooling area, dispatch and sterile storage rooms for processed RMDs will be equivalent to the air quality delivered to operating rooms and be maintained at a positive pressure relative to the surrounding environment.

Figure 2 shows an example of the pressure gradient and direction of airflows. Each pressure gradient should be designed to 10Pa.

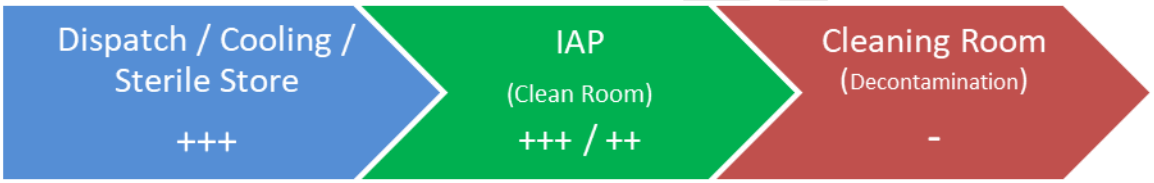


Figure 2 Pressure Differentials within SSU

Plant room areas should be at a negative pressure to the surrounding environments.

Fans serving areas where maintenance of a unidirectional air flow is necessary for contamination control should operate 24 hours a day. In line with AS 5369:2023, ventilation systems for IAP and sterile store rooms shall be continuously operational.

All air handling systems shall be tested when the Unit is commissioned. Refer to:

- Standards Australia 2011, AS 3666: Air-handling and water systems of buildings -Microbial control
- Standards Australia 2024, AS 1668.2: The use of air conditioning and ventilation in buildings
- AS5369 Sections 5.6.15 Ventilation and Appendix A including Figure A.5.6.15 Ventilation design and operation
- ACSQHC, 2022, Optimising ventilation for infection prevention and control in healthcare settings
- Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia, 2021
- Jurisdictional engineering services guidelines for healthcare facilities
- NSW Health Clinical Excellence Commission, 2024, Risk assessment and escalation of temperature or humidity variation in perioperative and sterile stock environments.

3.11.2 Information Technology and Communications

It is essential that planning include consideration of Information Technology requirements related to the electronic traceability system. These systems often require a highly available network and server architecture that allows for redundancy and as protection against critical data loss.

The following will/may be required:

- intercom at the visitor entry to communicate with internal staff
- intercom between Cleaning Room and IAP, if required

- data outlets to cleaning and packaging workstations – may be ceiling-suspended and designed to be easy to clean
- equipment tracking using RFID technology
- networking of all reprocessing equipment, such WDs, AFERs, CESC and sterilizers
- access to networked PCs and Wi-Fi in all areas of the Unit to facilitate traceability
- general phone / data outlets to all workspaces.

3.11.3 Compressed and Medical Grade Air

Compressed air is frequently utilised by reprocessing equipment for opening and closing of automated door systems.

Medical grade air outlets and pressure guns are required on the clean side of cleaning workstations. Discussion with the user is required to identify the number of air guns required, however at least one should be fitted on the designated manual cleaning workstation.

Some health services may require:

- compressed air in the IAP to facilitate the use of automated lubricating systems for dental handpieces
- medical grade air outlets and pressure guns in the IAP to check lumens of RMDs are clean and dry. Where such a request is made, installation of a ductless fume hood should be considered to limit the dispersal of aerosols during use of the air gun.

3.11.4 Hydraulic Services

The trade waste plumbing and drainage system shall be designed to meet the requirements of the relevant authorities.

Information regarding the type and amount of chemicals to be used / discharged shall be provided by the client to the hydraulics engineer.

Most items of reprocessing equipment will be discharging hot water to waste. Consideration is required to ensure drainage is capable of withstanding high temperatures.

Main drains should be protected from potential contaminants.

Systems will be connected to the building maintenance system so that problems arising can be detected and rectified quickly.

3.11.5 Power Supply

At least one WD, one sterilizer and the sterile store should be on emergency power supply to ensure continuity of service delivery. An emergency back-up system for the power supply should also be available for lighting and plant (e.g. chemical dosing, steam generators and reverse osmosis).

Inclusion of the electronic tracking system on the UPS is strongly recommended.

Power and data to workstations can be suspended from the ceiling.

3.11.6 Steam Purity

AS5369:2023 contains specifications for the feedwater used for steam generation in sterilizers. The sterilizers usually require their own steam generators and water treatment system to achieve the specifications in AS5369:2023.

Steam sterilizers can be specified to have their own individual internal steam generators, however in larger facilities, consideration can be given to having a large steam generator to supply steam to multiple sterilizers. In this case it may be useful to consider having two separate steam generators to enable service provision to continue in case of steam generator breakdown and during maintenance activities.

Steam supply pipework should be lagged and correctly installed and trapped to reduce and remove condensate and fitted with appropriate strainers. Where steam is created using RO water, pipework to the sterilizer shall be compatible.

It is important to establish early in the planning process how steam will be delivered, by gas-fired or electric generators, in addition to decisions regarding whether this system needs to operate off the UPS.

3.11.7 Steam Quality

After installation of new steam sterilizers or relocation of existing sterilizers, AS 5369:2023 requires steam quality tests to be completed. In order to complete these tests, special test fittings need to be provided as part of the sterilizer and steam supply pipework installation and manufacturers / suppliers shall be asked to include this in any request for quotation.

The tests for steam quality include (1) dryness fraction, (2) non-condensable gases and (3) superheat.

For further detailed information on water used for steam generation, steam supply systems and steam quality test requirements, refer to EN285.

3.11.8 Water Quality for Manual Cleaning and Supply to WDs and AFERs

The quality of water required for each process stage shall be provided in accordance with AS 5369:2023.

In some geographical areas water treatment systems may be required to improve the quality of water used for all process stages in cleaning, disinfection and sterilisation of RMDs. This will be influenced by the quality of the incoming water supply and in some cases, seasonal variations. The hot and cold tap water supplied to cleaning sinks should have a hardness level of <150mg/L and chlorides <120mg/L. If these levels cannot be achieved from the mains water supply, a water treatment system will need to be installed.

Manufacturers of WDs and AFERs will specify the requirements for water quality for the wash stages of the process cycle. The mains water supply is usually sufficient for this purpose, however some WDs and AFERs may require softened and even heated water for the wash stages. This should be verified with the manufacturer prior to installation.

Specifications for the final rinse water used in WDs and AFERs are very different to each other, and reference should be made to AS 5369:2023. For WDs a Water Treatment System is usually required to achieve the specification. For AFERs, filtration systems are usually sufficient, however the manufacturer should be consulted.

According to AS 5369:2023, the final rinse water for manual cleaning shall meet the same specifications as final rinse water in a WD, therefore consideration can be given to installing a treated water tap on the clean rinse sink of the designated manual cleaning workstation. This option works best where the health service indicates that there is a significant volume of RMDs not compatible with automated cleaning and disinfection in a WD or AFER that require manual cleaning. For health services that undertake limited amounts of manual cleaning, use of commercially produced distilled water may be a more cost effective option.

If a treated water outlet is installed on a cleaning workstation, it shall be plumbed to a sanitary outlet that can be decontaminated on a regular basis to avoid this tap becoming a source of contamination for the water treatment system. Do not plumb treated water to a shower rose fitting, as these cannot be effectively cleaned and can become a source of contamination to the system.

Well designed and maintained water treatments systems are essential to ensure that water will continue to be produced at the specified quality. Water sampling points for regular water quality testing are recommended to be placed as close as possible to plant, in addition to sampling ports located close to the point of entry to the reprocessing equipment.

Water treatment systems can include a water storage system to ensure there is sufficient water to meet or exceed peak demand. It is important to ensure that any water storage tanks do not contaminate the rest of the system through having the tank properly vented with bacterial filters and having a zero-water retention design.

Reverse Osmosis Water Systems

Where used, RO water systems should be designed with a ring main loop and pump systems to ensure a continual flow of water and avoid stagnation. RO systems that have terminal points into WDs or steam generators without a return loop should not be installed. Connections between the ring main and the reprocessing equipment should be as short and as straight as possible to avoid problems with stagnation. Dead-legs shall be avoided.

RO water treatment systems operate best when there is continuous disinfection by heating and circulating the water at >600C, however these systems may be seen to be cost prohibitive or energy consuming. Lower cost options for disinfection such as chlorine dioxide, ozone or regular hyper-chlorination can be considered. Most RO systems also include UV light disinfection and endotoxin filters on the exit loop of the ring main to reduce the risk of system contamination.

Redundancy Considerations

In larger health services, consideration should be given to two smaller water treatment systems to ensure continued operation of the SSU should one system need maintenance, repair or a contamination event occurs. This shall be considered in line with local jurisdictional advice / guidelines.

Redundancy may also be an important consideration for rural and remote health services where delays in servicing and repairs may be experienced.

Verification of Water Quality

AS 5369:2023 requires regular verification and sampling of water quality. The chemical purity of the water is easily verified through installation of conductivity meters. Installation of a conductivity meter in a location that can readily be checked by SSU staff is strongly recommended.

AS 5369:2023 requires monthly tests for the microbiological quality of the final rinse water in WDs and AFERs. For AFERs, final rinse water samples are usually taken from the endoscope basin in accordance with the manufacturer's IFU. If a WD has a rinse water storage/heating tank, the sample should be taken from inside the machine. However, if a WD does not have a rinse water storage / heating tank, provision shall be made for a sampling point as close as possible to the point of entry of the treated water line into the WD, recognising that development of techniques to sample from inside the WD may eliminate the need to have sampling points in this location.

Nonetheless, sampling ports shall be located at key points throughout the system and be a sanitary type to protect the system from contamination. Sampling ports should be located on the exit and return loop on the ring main, near the water storage tank in addition to fitting sampling ports closer to the point of entry into the WDs. Location of multiple sampling ports allows testing to be undertaken to isolate the root of the contamination within a system when required. Advice should be taken from the specialist water treatment system manufacturer.

Refer to:

- AS5369:2023
- ISO 15883 Washer disinfectors, Parts 1 to 6
- Standards Australia 2006, AS 3666: Air-handling and water systems of buildings - Microbial control, SAI Global.

3.11.9 Chemical Management Systems

A dedicated automated dosing chemical management system will ideally be installed to support the chemical requirements for WDs. This system can be located outside of the Unit and in a location that supports refilling by the supplier. Some suppliers may require allocated space within the Cleaning (Decontamination) Room for their centralised chemical dosing systems. The requirements should be confirmed as part of the planning process.

The chemical dosing system will be accessible or preferably provide remote monitoring to SSU so staff can monitor the amount of chemicals being used.

4 Components of the Unit

4.1 Standard Components

Rooms / spaces are defined as:

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

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

The current Standard Components can be found at: AusHFG Standard Components

Non-Standard Components for this HPU are described below.

4.2 Non-Standard Components

4.2.1 Loan RMDs – Receipt / Dispatch (Loan Sets Room)

Description and Function

A designated room provided for the receipt / dispatch of loan RMDs. Delivery crates / transport containers may be numerous, bulky and heavy.

The loan RMDs shall be unpacked from the delivery crates / transport containers, checked, inspected for damage and may be photographed, against the supplier's inventory before being put through routine reprocessing procedures.

After use, reprocessing and prior to returning the loan RMDs to the supplier, the loan RMDs shall again be checked to ensure all have been returned as they are placed back into the delivery crates / transport containers.

These receipt, dispatch and checking processes require an appropriate work room with space to store the crates / transport containers, lifting equipment, height adjustable benches and good lighting for checking the loan RMDs into and out of the facility. The room should include a workstation with computer, printer with access to the traceability system and a photocopier with scanning capability.

Consideration of the pathways for receipt of sterile implants is essential, as the Loan Sets Room is not intended to be a sterile storage room. In some facilities, sterile implants may be delivered to the Loan Set Room for checking prior to delivery to the Operating Unit, whilst in other health services the implants may be delivered directly to the Operating Unit. Where they are delivered to the Loan Sets Room a designated clean zone will be required. Consultation with the users is essential to ensure these pathways are clearly defined.

Location and Relationships

To be located so that loan RMDs can be received, checked, rechecked and dispatched from a single location.

The room should be located adjacent to the Cleaning (Decontamination) Room so that trolleys with checked RMDs can be pushed directly into this room for processing through the WDs. Collocation with the IAP / Cooling Dispatch room should also be provided if practicable so that loan RMDs that are to be sent back to the company can be pushed directly back into the loans room after removal from the WD or where applicable, removal from the sterilizer.

Considerations

Adequate space is needed to pack and unpack loan sets. Transport cases should remain on the wheeled platform at all times to assist with handling and transportation.

The area should be configured to eliminate / minimise risks associated with manual handling. This will include:

- adequate floor space for the systematic packing and unpacking of loan sets, including the manoeuvring of lifters and associated mobile equipment
- designated holding and storage areas for empty transport containers
- level non-slip floor surfaces
- mechanical lifters and height adjustable work benches with fitted rollers
- mobile trolleys, that may be height adjustable to assist with equipment handling and movement
- digital camera with a stand to enable clear images of the RMDs to be captured
- task lighting and magnification.
- telephone, computer linked to electronic traceability system, printer and photocopier with scanning capability.

For health facilities dealing with large volumes of sterile implantable medical devices, consideration of the installation of an RFID reader for checking sterile implants in and out of the facility is recommended.

For further information, refer to Design and handling of surgical instrument transport cases, A guide on health and safety standards, SafeWork NSW, May 2011.

4.2.2 Receiving Area

Description and Function

Area where soiled RMDs are received from clinical services and any residual waste is disposed of. Where volumes of processed RMDs justify, a trolley / cart washer may be installed as per section 2.2.7.

Location and Relationships

The receiving area for soiled RMDs should have direct access from the main services corridor, and direct access from the Operating Unit, either horizontally or vertically via lifts or hoists.

The receiving area should be contiguous with the Cleaning (Decontamination) Room and adjacent to the Loans Room and Disposal Room.

Considerations

FF&E will include:

- computer and scanners associated with the electronic traceability system
- cart / trolley washer-disinfector or a space for manual cleaning of trolleys, noting the cart / trolley WD might be better located in the Cleaning (Decontamination) Room
- trolleys
- clinical and general waste disposal bins
- clinical hand basin (Type B) and PPE and ABHR dispensers.

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

For further information, refer to Design and handling of surgical instrument transport cases, A guide on health and safety standards, SafeWork NSW, May 2011.

4.2.3 Cleaning (Decontamination) Room

Description and Function

Room where soiled RMDs are cleaned and disinfected prior to further processing.

Location and Relationships

The Cleaning (Decontamination) Room is contiguous with the Receiving area and is physically separated from the IAP.

Considerations

FF&E will include:

- stainless steel height-adjustable cleaning workstations for sorting, pre-treatment or manual cleaning of RMDs. Sinks should have a depth not exceeding 200mm to avoid injury and the shape and dimension of the sinks should be confirmed by the users
- a water gun on the dirty side and an air gun on the clean side of the cleaning workstation
- automated chemical dosing, task lighting and magnification on the cleaning workstation
- antifatigue floor mats
- ultrasonic cleaners according to service requirements. This may include provision of an ultrasonic cleaner capable of connection to cannulated RMDs and a hydraulic lift for heavy trays
- pass-through RMD and tubing drying cabinets, according to service requirements
- pass-through WDs for heat stable RMDs
- pass-through AFERs for thermolabile RMDs that undergo terminal sterilization
- WD wash baskets, wash racks and loading trolleys, including provision of a charging area for same
- automatic loading / unloading systems for WDs are recommended
- centralized chemical dosing system for WDs with remote system monitoring in SSU and dedicated storage cabinets for process chemicals used in WDs and AFERs
- reverse osmosis or other suitable water treatment system to ensure compliance with AS5369:2023 for water quality
- rack return for empty wash racks to be returned from IAP to the Cleaning (Decontamination) Room
- storage system for wash racks when not in use
- computer and scanners associated with the electronic traceability system
- PPE and ABHR dispensers and a clinical hand basin (Type B) if not readily accessible in the receiving area
- clinical and general waste disposal bins
- clocks
- telephone
- exhaust air extraction over sinks and equipment doors
- pass-through hatch from the IAP for non-conforming RMDs that require repeat cleaning processes.

Space to park trolleys is required.

If provided, a cart / trolley WD may be located in this room.

Other than pass through equipment and transfer hatch, there should be no direct access to the IAP.

Air-handling system to be negative pressure to adjacent areas, designed to address heat gain and vapours discharged from reprocessing equipment and achieve a minimum of 10 air changes per hour.

All reprocessing equipment discharging vapour should be connected to exhaust systems in accordance with the manufacturer's recommendation.

After installation all equipment should undergo Installation Qualification and Operational Qualification by the manufacturer. Performance qualification will be undertaken by the health service in conjunction with the manufacturer or a third-party validation services provider.

4.2.4 Inspection, Assembly and Packaging Room (IAP)

Description and Function

The IAP is where clean RMDs are sorted, inspected, tested, maintained, assembled and where applicable, packaged for sterilization.

Location and Relationships

Directly adjacent to, but physically separated from, the Cleaning (Decontamination) Room and directly adjacent to the bulk store.

Ideally the IAP is adjacent to the Loans Room, or with easy access between IAP and Loans Room.

Contiguous with the sterilizer loading area.

Considerations

There will be sufficient power and data to support systems of work. The packaging workstations will be height adjustable. The workstation will accommodate packaging materials and other consumable products required for tray assembly.

FF&E should include:

- height adjustable workstations, preferably stainless steel
- computers, scanners, printers, label printers
- task lighting and magnification
- stereo magnifying viewer and / or borescope for enhanced visual inspection
- antifatigue floor mats
- height adjustable stools or chairs
- electrosurgical RMD testing system
- fibreoptic RMD testing system [where available]
- lubrication system for dental handpieces if applicable
- if required by the users, a medical grade air gun and ductless fume cabinet
- mobile trolleys or shelving to accommodate RMDs awaiting further processing
- unloading trolleys for WDs
- heat sealers
- general waste bins
- clocks
- telephone
- ABHR dispensers and ready access to a hand hygiene basin.

The workstations and floorplan should be arranged so that there is adequate space for the movement of staff, trolleys and materials.

4.2.5 Sterilizers Loading Area

Description and Function

Area where sterilizers are loaded. Automated loading systems may be provided.

Ethylene oxide and low temperature hydrogen peroxide sterilizers require separate installation and accommodation according to manufacturer's recommendations.

The size of the area will be dependent on the number and type of sterilizers installed and, importantly, whether the sterilizers are single door or pass-through.

Where single door sterilizers are installed, additional space may be required to house trolleys with cooling loads.

Location and Relationships

The sterilizer loading area is contiguous with the IAP.

Considerations

Special consideration should be given to the location of the sterilizers to support unidirectional workflows and manoeuvrability of sterilizer loading trolleys.

FF&E will include:

- steam and low temperature sterilizers
- sterilizer loading racks and loading trolleys including provision of an area for charging same
- rack return for empty loading racks to be returned from the cooling area to the IAP
- automated loading systems to maximise efficiency, improve workflow and reduce manual handling risks are recommended
- height adjustable workstation for computer and QA activities
- mobile storage shelving for packaged RMDs awaiting sterilization may be required.

After installation all equipment should undergo Installation Qualification and Operational Qualification by the manufacturer. Performance qualification will be undertaken by the health service in conjunction with the manufacturer or a third-party validation services provider.

4.2.6 Sterilizer Unloading and Cooling Area

Description and Function

Area where sterilizers are unloaded at the completion of the process cycle. Automated unloading systems may be provided.

Location and Relationships

The unloading area will be contiguous with the RMD Dispatch areas. This will make the space flexible and it can be used for storing trolleys overnight. Dispatch areas will store reprocessed items prior to transfer. Items will be held in trolleys.

Considerations

FF&E will include:

- sterilizer unloading trolleys including provision of an area for charging same
- automated unloading systems to maximise efficiency, improve workflow and reduce manual handling risks are recommended
- height adjustable workstation for computer and QA activities
- heat sealing device and height adjustable workstation for applying dust covers (optional)
- mobile shelving for cooled, processed RMDs to be transported to dispatch may be required.

4.2.7 Endoscope Reprocessing Unit (ERU) - Standalone

Description and Function

Dedicated environment for processing endoscopes and accessories. The endoscope reprocessing unit should provide physical separation of soiled and clean activities to eliminate the risk for cross-contamination.

ERU's may be required to accommodate reprocessing of ultrasound transducers and thermolabile flexible endoscopes from other units within the health service, for example bronchoscopes from ICU and ED, nasendoscopes from outpatients and TOE probes from cardiac investigation units. As these RMDs may require different types of reprocessing equipment, this should be considered in capacity planning requirements.

A traceability system, preferably electronic, should be provided at each stage in the reprocessing cycle.

- Refer to Section 2.2.15 for further information on processing of endoscopes.

Dirty (Cleaning) Room

A height adjustable cleaning workstation with two sinks is required. Sinks will be large enough to adequately hold a colonoscope. Hot and cold water is needed along with automated chemical dosing, a leakage testing device and optional mechanical flushing unit. Flushing units reduce manual cleaning requirements, although users may not require these where ISO15883 Part 1 and 4 compatible AFERs are in use.

- Refer to Section 2.2.8 for further information on cleaning workstation requirements.

Where reusable buttons and valves are still in use, an ultrasonic cleaner may be required in the cleaning room, however some health services may elect to send these items to the SSU for processing. Most health services are moving toward disposable options, however, may have reusable options available in case of supply chain disruptions.

Pass-through automated flexible endoscope reprocessors (AFER) will be used. At minimum, each AFER will need hot and cold water, power and data and waste. Some AFERs and CESCs may require installation of an air compressor for correct functioning.

A water treatment system will be required, the extent of which will be influenced by the available water quality. The water quality and filtration requirements will be specified by the AFER manufacturer and should be confirmed prior to installation.

For each procedure room a capacity to process at least two endoscopes at a time is required. This may be in the form of two separate AFERs or an AFER with the capacity to process two endoscopes at the same time or asynchronously.

Adequate bench or trolley space will be needed for holding endoscopes waiting for pre-cleaning or to be loaded into the AFERs.

Space for the storage of consumables used in the cleaning process should be provided.

Dedicated storage space for process chemicals and where applicable, suitable storage cabinets for hazardous process chemicals should be provided. This may be in a room separate to the endoscopes cleaning room, however ready access is required.

Clinical and general waste bins are required.

PPE and ABHR dispensers are required.

Access to a clinical hand basin (Type B) is needed.

Staff shall be able to access the cleaning room without the need to enter the procedure room.

Clean Room

Processed endoscopes are unloaded from the clean side AFER in this room.

Endoscopes intended to be used immediately may be unloaded onto clean benches or mobile trolleys.

Endoscopes not required for immediate use will be placed into CESC or other approved equivalent storage system.

Consideration should be given to an allocated space with a trolley or bench to facilitate microbiological sampling activities.

PPE and ABHR dispensers are required.

While electronic tracking systems may be in place, there may still be some paperwork associated with system checks that will need to be accommodated.

Staff shall be able to access the clean room without the need to enter the procedure room.

Endoscope Storage

The storage of endoscopes may occur in EN16442 compliant CESC located in the clean room or in a designated area close to the Endoscopy Procedure Room. These cabinets may be single door or pass-through.

Alternate controlled environment storage systems may be used. These will require bench space for the drying and bagging equipment to be located within the clean room. After drying and bagging, the endoscopes will need a suitable cupboard or trolley system where they can be stored until required for use. Refer to Section 2.2.9 for further information on drying of endoscopes.

Location and Relationships

The Endoscope Reprocessing Unit could be adjacent to the endoscopy procedure rooms.

Alternatively, a dedicated endoscope processing pathway in SSU could be provided, ensuring easy transport of clean and soiled endoscopes between the point of use and the point of reprocessing.

For designs where the ERU is positioned between procedure rooms, separate access is required for staff to move between the dirty, clean and where applicable, endoscope storage rooms without the need to transit through a procedure room.

Where applicable, consideration should also be given to ensuring that there is an appropriate pathway for soiled endoscopes and other thermolabile RMDs used in other clinical units to be delivered to the ERU.

Considerations

Traceability systems will be used throughout the process so space for computers and scanners may be needed in each room. Hardware needs to be fluid resistant and easy to clean.

5 Appendices

5.1 Schedules of Accommodation

Recommended Schedules of Accommodation (SOA) for sterilizing services units and endoscopy reprocessing units are provided in the following tables. These are based on an analysis of recently delivered facilities and include scenarios for SSUs supporting 2, 10 and 20 operating rooms and ERUs supporting 1-2 and 4 procedure rooms.

Area allocations are indicative only and will need to be adjusted given the size and requirements of individual units will vary according to:

- the total number of operating and procedure rooms to be supported
- caseload and casemix
- the number of external clients to be serviced
- the regulatory environment
- location of the unit in relation to the hospital

Special consideration in planning and equipping SSUs and ERUs is required for health services located in rural and remote areas. In most cases it is preferable to supply two of each type of equipment or plant to ensure that the services can continue to be provided in the case of equipment breakdown, delays in planned and unplanned maintenance activities and during process validation activities.

Health services in these areas may also be providing reprocessing services for other smaller affiliated health services, in addition to providing services to a number of other external customers, for example primary health care service providers. This may also influence the spatial requirements needed for receiving and dispatch and sterile storage spaces, in addition to requirements for additional reprocessing equipment capacity.

The recommended schedules of accommodation provided assume the installation of the following pass-through equipment:

- Washer-disinfectors
- Automated flexible endoscope reprocessors
- Trolley / cart washer-disinfectors
- RMD drying cabinets
- Controlled environment endoscope storage cabinets (if applicable according to design of the ERU and endoscopy unit)
- Steam sterilizers
- Low-temperature sterilizers.

A challenge for hospital design is the balance between maximising value for money during the initial development phase and enabling future expansion. The design should incorporate features to enable ready expansion of the SSU.

The ‘Room / Space’ column within the SOA describes each room or space within the Unit. Some rooms are identified as ‘Standard Components’ (SC) or as having a corresponding room which can be derived from a SC (SC-D) by referring to the relevant room code. All other rooms are non-standard and will need to be briefed using relevant functional and operational information provided in this HPU. In some cases, Room / Spaces are described as ‘Optional' or ‘o’. Inclusion of this space will be dependent on a range of factors such as operational policies or clinical services planning.

Reference is made to the room codes included in the Functional Relationship Diagram (FRD) Codes included in Section 5.2.

Note that space allocations may be required in other areas of the facility for reprocessing of items (such as ultrasound transducers) that are reprocessed close to the point of use.

STERILIZING SERVICES UNIT

ENTRY

Room Code	Room / Space	SC / SC-D	FRD Code	2 Operating Rooms		10 Operating Rooms		20 Operating Rooms		Remarks
				Qty	m2	Qty	m2	Qty	m2	
OFF-1P-9	Office - Single Person	Yes	SSU01	1	9 (o)	1	9	1	9	Optional for smaller unit depending on staff profile. Total number of workstations will depend on staff profile and local jurisdictional policies. Larger units may require a dedicated reception area in addition to office spaces.
OFF-WS	Office - Workstation	Yes	SSU01		4.5		4.5		4.5	Number of workstations will be dependent on staff profile and local jurisdictional policies.
	Discounted Circulation				25%		25%		25%	

REPROCESSING AREAS

Room Code	Room / Space	SC / SC-D	FRD Code	2 Operating Rooms		10 Operating Rooms		20 Operating Rooms		Remarks
				Qty	m2	Qty	m2	Qty	m2	
Loan RMD Receipt and Dispatch										
	Loan Sets Room		SSU14	(o)	30	1	50	1	70	Optional for smaller units depending on casemix or whether they operate as a hub and spoke or reprocess for external customers, as this room could be used as a receipt and dispatch area for these circumstances. The actual spatial requirements for a Loan Sets room is dependent on facility casemix. Specific casemix requirements should be taken into account with reference to user requirements.
Receiving / Cleaning / Decontamination										
	Receiving Area		SSU05	1	40	1	130	1	195	Lobby space will be required in the Operating Unit to accomodate trolleys waiting to be loaded into lifts/hoists. Lobby space will also be required in the SSU to accommodate trolleys that have been unloaded from lifts/hoists but have not yet been formally received into SSU.
	Cleaning (Decontamination) Room		SSU06							If automated loading of washer-disinfectors is selected, the space requirements of the particular automation system must be taken into account in allocating floor area. Includes storage for cleaning brushes and consumables.
DISP-8	Disposal room	Yes	SSU07	1	5	1	15	1	20	Access to Cleaning (Decontamination) room and external corridor. This may be a bay for smaller units. Disposal room is for SSU produced waste only.
CLRM-5	Cleaner's Room (soiled side)	Yes	SSU08	1	5	1	5	1	5	Two cleaners rooms are expected for large SSUs. A single room with two separate sets of cleaning equipment is acceptable for small SSUs.
	Washer Disinfectors		SSU10 SSU11	1	10	1	20	1	35	Includes other pass through equipment such as RMD drying cabinets. Check dimensions of preferred supplier's equipment to confirm allowances. Rural and remote health services will require a minimum of 2 WDs.
	Trolley Wash		SSU12			1	15	1	30	Smaller SSUs may manually clean trolleys, check with the user to confirm requirements. Where SSUs service a large volume of external customers, operate as a 'hub and spoke' or handle a large number of loan sets, provision of a trolley washer should be considered.

Room Code	Room / Space	SC / SC-D	FRD Code	2 Operating Rooms		10 Operating Rooms		20 Operating Rooms		Remarks
				Qty	m2	Qty	m2	Qty	m2	
Inspection, Assembly and Packaging										
	Inspection, Assembly and Packaging (IAP)		SSU13	1	45	1	105	1	220	If automated unloading of washer-disinfectors and automated loading of sterilisers is selected, the space requirements of the particular automation system must be taken into account in allocating floor area.
	Sterilizers		SSU18 SSU19	1	8	1	20	1	30	Check dimensions of preferred supplier's sterilizers to confirm allowances. Space allocations will be altered by the selected sterilizer capacity. Rural and remote health services will require a minimum of 2 sterilizers.
	Store - General		SSU15	1	15	1	20	1	40	The Consumables Store may be shared with the Operating Unit in smaller SSUs. Consideration needs to be given to proximity to the SSU in this scenario. Discuss with users during planning stages.
	Cleaner's room (clean side)		SSU17	1	5	1	5	1	5	Two cleaners rooms are expected for large SSUs. A single room with two separate sets of cleaning equipment is acceptable for small SSUs
Cooling and Dispatch										
	Sterilizer Unloading and Cooling Area		SSU20	1	30	1	75	1	190	If automated unloading of sterilisers is selected, the space requirements of the particular automation system must be taken into account in allocating floor area
	Dispatch - operating unit		SSU21							Assumes RMDs are returned and stored in the Operating Unit's Sterile Storage Room. Lobby space will be required to accommodate trolleys prepared and waiting for dispatch to the Operating Unit. Lobby space may also be required in the Operating Unit to accommodate trolleys of processed RMDs not yet formally received into the Operating Unit.
	Dispatch - other units		SSU22							e.g. IPUs, ED and Critical Care Units. Assumes RMD are returned and stored at the point of use. If the facility operates as a hub and spoke or services a large number of external customers, spatial allocations may need to be increased. Confirm with users during planning stages.
	Discounted Circulation				16%		16%		16%	

SUPPORT AREAS

Room Code	Room / Space	SC / SC-D	FRD Code	2 Operating Rooms		10 Operating Rooms		20 Operating Rooms		Remarks
				Qty	m2	Qty	m2	Qty	m2	
	Store - Chemical Dosing		SSU09	1	2	1	5	1	10	Smaller SSUs may use a chemical storage cupboard. Some suppliers require space for chemical dosing within the Cleaning (Decontamination) Room for central chemical dosing. Confirm requirements with the users.
	Store - Deboxing and Consumables		SSU15	1	10	1	20	1	40	May be shared with the Operating Unit if appropriate. Deboxing must be a separate room, with easy access to the consumable store. The proportion of space allocated to deboxing versus storage should be confirmed with the user.
	ID Station		SSU16	1	2	1	4	1	10	An ID Station is required where the hospital is tracking RMDs at the instrument level to accommodate instrument marking equipment and the staff that use it. Smaller SSUs may use a bay rather than a separate room.
	Plant Room - SSU		SSU03	1	5	1	40	1	60	Includes water treatment plant. This area can be combined with general hospital plant if location is suitable.
	Discounted Circulation				16%		16%		16%	

STAFF AREAS

Room Code	Room / Space	SC / SC-D	FRD Code	2 Operating Rooms		10 Operating Rooms		20 Operating Rooms		Remarks
				Qty	m2	Qty	m2	Qty	m2	
CHST-10	Change – Staff	Yes	SSU02	See note		2	10	2	25	Assumed shared amenities with Operating Unit for 2 Operating Room scenario. Additional spatial allocation will be required if SSU is remote from Operating Unit - otherwise use communal staff amenities where possible. Ensure that the sizing of any shared amenities takes into consideration the additional number of SSU staff that will be using the change rooms, staff room and other amenities such as toilets.
SMR-15	Staff Room	Yes	SSU02	See note		1	15	1	20	
MEET-15	Meeting Room	Yes	SSU02	See note		1	15	1	15	
	Discounted Circulation						10%		10%	

ENDOSCOPE REPROCESSING UNIT

The following SOAs are based on scenarios of:

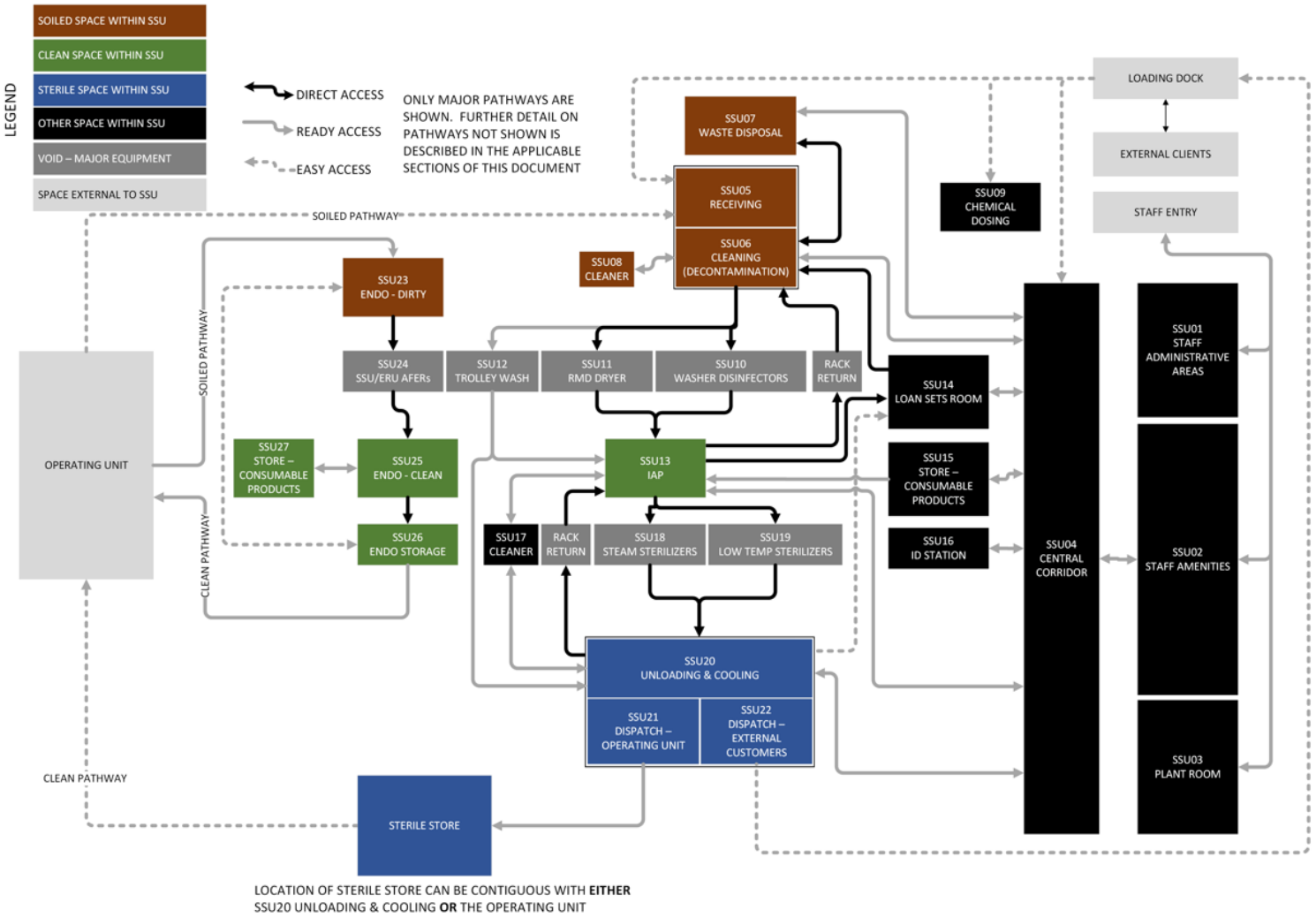
- one to two endoscopy procedure rooms, and
- four endoscopy procedure rooms.

These recommended space allocations are applicable whether the unit is a stand-alone ERU or integrated within the SSU. A small amount of additional storage space for consumables and chemicals has been included as noted, however this may be reduced if storage can be shared across the broader SSU for integrated units.

Room Code	Room / Space	SC / SC-D	FRD Code	1-2 Procedure Rooms		4 Procedure Rooms		Remarks
				Qty	m2	Qty	m2	
	Endoscope Reprocessing - Dirty		SSU23	1	13	1	17	One double basin sink per one-two procedure rooms is assumed. This space may be reduced by 2m2 if consumable or chemical storage can be shared within an integrated SSU.
	Automated Flexible Endoscope Reprocessors (AFERs)		SSU24	1	4	1	8	The number of AFERs should provide capacity to process two endoscopes for each procedure room. Some AFERs are able to process two endoscopes at a time or asynchronously. Rural and remote health services will require a minimum of 2 AFERs. Check dimensions of preferred supplier's AFERs to confirm allowances. Note that the Quantity "1" refers to the number of spaces, not the number of AFERs or other equipment
	Endoscope Reprocessing - Clean		SSU25	1	8	1	14	This space may be reduced by 2m2 if consumable or chemical storage can be shared within an integrated SSU.
	Endoscope Reprocessing - Storage (CESC or equivalent system)		SSU26	1	4	1	8	Fleet size and the number of storage positions required must be confirmed with the user. Note that the Quantity "1" refers to the number of spaces, not the number of storage cabinets or storage positions. Where a storage bag system is used instead of CESCs, space will be required for the storage of the bagged endoscopes.
	Store - Chemicals		SSU27	1	2	1	4	Area allocation will depend on the volume of chemicals required to service the projected workload. Some reprocessing agents used for endoscopy reprocessing are flammable and/or toxic. Storage of these agents will comply with jurisdictional workplace health and safety regulations. This space may need to be ventilated to exhaust air to a safe location outside the building.
	Discounted Circulation				16%		16%	Personnel access should be provided between the clean and dirty sections of the ERU without transit through the procedure room.

5.2 Functional Relationships / Diagrams

A diagram of key functional relationships shown below.



5.3 Capacity Requirements

5.3.1 General

Calculating required capacity is an important part of design. Total capacity is an outcome of:

- the volume of personnel work-hours available – which is a product of work-hours and available staff (FTE), and what times of day staff are available
- the number of workstations in the cleaning area
- major equipment capacity (washer disinfectors, sterilizers, etc) – noting that the number of machines required will be influenced by the physical capacity of the equipment and the equipment cycle times
- the level of automation around this major equipment (for example, automated loading and unloading);
- the number of packaging workstations in the IAP
- the level of automation in quality management and record keeping (for example electronic traceability systems); and
- the expected turnaround time for RMDs, noting this is influenced by available RMD inventory.

In SSUs in regional and remote areas, redundancy in reprocessing equipment is an important factor for consideration, as the location of the health service may influence access to timely maintenance and repairs. As such, provision of 2 smaller items of equipment provides a margin of safety when compared with providing only one larger item of equipment.

Calculating steam sterilizer capacity requirements is more straightforward than capacity calculation for washer-disinfectors. This is due to the need for some trays of RMDs that are usually presented for sterilization as one complete tray of a specific dimension to be dismantled and spread out across several wash baskets for effective processing in a washer-disinfector.

An overestimate of the capacity required leads to increased project costs, in the form of excess floor space and reprocessing equipment. Underestimating required capacity leads to processing inefficiencies, workplace health and safety risks, additional work hours at penalty rates, delays in availability of RMDs for use and in the worst case, overloaded equipment and consequent infection risks from inadequate cleaning, disinfection or sterilization.

Three main options exist for designers in estimating capacity requirements:

- Request assistance from reputable major equipment suppliers
- Use general guides – for example as outlined in Section 2.1.2.
- Perform a detailed analysis of incoming flows of soiled RMDs against equipment capacity

Required capacity is a function of the soiled RMD output of all operating and procedure rooms serviced by the SSU, whether on-site or off-site. Total soiled RMD output is not constant over time. Analysis should focus on the peak volume of soiled RMDs that will arrive at the SSU in the busiest hour of the busiest day, and the time available to process that peak output.

An important factor in calculating required capacity is to establish the user's expectations for turnaround time for RMDs, from time of use until the RMDs are ready for reuse. In general terms, an expedited or 'fast-tracked' turnaround time, where RMDs are processed as a high priority is a minimum of 2.5-3 hours. On average, turnaround times range between 5-12 hours and sometimes longer. Expected turnaround time is often linked to the availability or inventory of RMDs and how the Operating Unit schedules operative lists.

If the SSU is required to be able to process the peak load in a short time (for example, to have the RMDs quickly available for re-use, or to prevent late SSU operating hours), more processing capacity is required. The mathematics of queuing theory can be useful to model the passage of load through the SSU.

5.3.2 Reprocessing Equipment Capacity

There is an industry 'language' used to describe the capacity of reprocessing equipment used in SSU.

Washer-disinfector capacity is usually described according to their DIN capacity (e.g. a 15-DIN capacity). DIN refers to a German Standard and is a term used to describe the size of a basket used within a washer-disinfector. A DIN tray measures 480mm long x 250mm wide and 50mm deep; and a half DIN tray is 240mm long x 250mm wide and 50mm deep.

Steam sterilizer capacity is usually described according to their chamber volume or in sterilization modules or units, referred to as STU. An STU measures 600mm long x 300mm wide and 300mm deep and one STU equates to a volume of 54 litres. In practical terms, 1 STU aligns with the capacity of the sterilizer to accommodate 1 DIN tray as not all the volume in a sterilizer chamber is usable space.

In some cases, sterilizer capacity may also be limited by the total mass of an individual RMD or the total mass of the load that can be accommodated and this should be considered when planning for a service that may need to accommodate significant volumes of RMDs used in joint replacement and other heavier RMDs, for example skin graft meshers.

Large dental hospitals will usually process their dental instruments in instrument management system cassettes. Each of the cassettes will hold between 16 to 20 items. As these cassettes can be loaded into WDs on their side, the throughput can be hugely increased. In practice, a 15 DIN capacity WD could accommodate 30 large instrument management system cassettes.

Relevant data on the number of processed trays and tray sizes may be available from the health service.

It is recommended that experts are consulted to assist with capacity calculations to inform the number and capacity of reprocessing equipment required.

5.4 References

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5.5 Further Reading

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