Australasian Health Facility Guidelines

Part B - Health Facility Briefing and Planning

0560 – Pharmacy Unit

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Australasian Health Facility Guidelines

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Index

01 INTRODUCTION

1.1 PREAMBLE

This Health Planning Unit (HPU) has been developed by the Australasian Health Infrastructure Alliance (AHIA). This revision has been informed by an extensive consultation process that was completed in 2020.

The document is intended to be used by design teams, project managers and end users to facilitate the process of planning and design.

1.2 INTRODUCTION

This HPU outlines the specific requirements for planning and designing a hospital pharmacy.

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.

1.3 POLICY FRAMEWORK

Before undertaking a project, planners and project staff should familiarise themselves with individual jurisdictional plans, policies and service specific guidelines. Key policy documents and related information are listed below:

- Australian Commission on Safety and Quality in Healthcare, National Safety and Quality Health Service Standards – Medication Safety Standard.
- Codes, Guidelines and Policies, Pharmacy Board of Australia.
- SHPA Standards of Practice, The Society of Hospital Pharmacists of Australia.
- Factors to Consider for the Implementation of Automated Pharmacy Distribution Systems in Hospitals and Health Services, SHPA, June 2019.

Other jurisdictional specific policy information is contained in the Further Reading section of this HPU.

1.4 DESCRIPTION

A Hospital Pharmacy Unit provides a facility for a range of services that may include:

- clinical pharmacy service including medication management plan, medication and clinical review, medication reconciliation and therapeutic monitoring;
- inpatient and outpatient dispensing;
- maintenance and monitoring of inpatient medication distribution systems;
- patient education and advisory services including admission and discharge planning, liaison with community providers, counselling and compliance monitoring;

- outreach services including home medication review, remote home monitoring and liaison with patients and their care providers;
- controlled storage, recording and distribution of narcotics and accountable substances;
- compounding and/or the preparation of non-aseptically prepared compounds, known as extemporaneous compounds (lotions, ointments etc.);
- aseptic compounding and IV admixture services, e.g. parenteral nutrition, eye drops, injections and cytotoxic preparations;
- specialised manufacture of biological products, e.g. gene therapy and preparation of live vaccines;
- medication utilisation review and adverse drug reactions reporting;
- medication monitoring, information and advisory services;
- quality programs including antimicrobial stewardship;
- repacking and pre-packing of medications;
- staff education and training;
- management of medications for specialised programs such as clinical trials and S100 medications; and
- undertaking and contributing to hospital-wide governance activities relating to medication safety, procurement, warehousing, distribution, prescribing, dispensing, and administration.

The term ‘medication’ is used throughout the document to describe a drug, medicine, pharmaceutical preparation (including a compounded preparation), therapeutic substance, vaccine, diagnostic agent for patient administration or fluid for intravenous use.

02 PLANNING

2.1 OPERATIONAL MODELS

Pharmacists play an important role as part of the multidisciplinary healthcare team. The delivery of an efficient pharmacy service is critical to ensuring optimal medication management and patient flow. Key project considerations relating to the pharmacy service delivery model are described below.

2.1.1 Automated Pharmacy Distribution Systems

Increasingly medication management is being enhanced through the use of technology including electronic medication management (EMM) systems, bar coding, tele-pharmacy, pharmacy robots, automated dispensing cabinets (ADCs), unit dose packing equipment and controlled substance registers and cabinets. These solutions are important steps towards the development of closed loop medication management systems whereby fully electronic medication management processes are established through the integration of automated systems which also automatically document all relevant information.

As described in The SHPA's 2019 publication 'Factors to Consider for the Implementation of Automated Pharmacy Distribution Systems in Hospitals and Health Services'. there are safety, efficiency and financial benefits associated with automated pharmacy solutions. However, given the significant capital costs associated with the establishment of these systems, they must be considered on a case by case basis through a cost benefit analysis within the context of current and future service requirements.

The proposed approach to pharmacy distribution systems will need to be confirmed early in the project planning process as it will underpin the arrangement and design of the pharmacy and medication storage areas within clinical units.

Pharmacy Robots

Pharmacy robots have been established in several hospitals across Australia to efficiently store, retrieve and label medications for dispensing and imprest management. Benefits include efficiency gains associated with retrieving medications; improved inventory control; reduced inventory holdings; reduced selection errors; and improved after hours dispensing capability. Where pharmacy robots are being proposed, the following should be considered:

- establishing a robot within an existing pharmacy is challenging given the required spatial arrangements, ceiling height and floor load capacity;
- the set up and location of the robot will dictate how other areas in the pharmacy need to be arranged;
- the choice of robot and associated design of the unit will depend on the specific service requirements and will require a coordinated approach between engineering consultants (including a structural engineer), the robot vendor and pharmacy service;
- a modular robot design enables ready expansion in the future;
- a reconfiguration of pharmacy staff will be required to support the new operational model and will need to include specialist pharmacy roles focused on automated systems and informatics;
- the pharmacy robot will not be able to store all medications so other forms of storage will still be required, e.g. for bulky items;
- some robotic systems can accommodate refrigerated, controlled medications or part pack storage however these are not commonly implemented;

- sufficient software capability and IT integration with dispensing and inventory management software, EMM systems and ADCs is essential; and
- contingency plans for machine breakdowns and downtime procedures will need to be in place.

Automated Dispensing Cabinets (ADCs)

Early consideration needs to be given to the use of these systems with regard to:

- the type of system being considered;
- IT integration of vendor and health service pharmacy management systems;
- arrangements for stock ordering and replenishment;
- impact on Pharmacy Unit storage, workflows and staffing relating to stock ordering and replenishment of ADCs and the management of Users;
- the inclusion of an ADC terminal in the pharmacy;
- the impact on layout of clean utility and/or medication rooms in clinical units;
- building service requirements such as power and data outlets;
- storage of refrigerated and controlled medications; and
- security considerations.

The establishment of ADCs requires a comprehensive change management process to be implemented to ensure a smooth transition to the optimal use of these devices. Close consultation with clinical staff that will be using ADCs is essential. It is also recommended that the planning for ADCs considers 'lessons learnt' from other facilities that have recently implemented similar systems.

2.1.2 Logistics

The logistics management of medications is also changing. Many healthcare organisations are implementing vendor managed inventory systems where some medications are delivered from the supplier direct to the point of use, e.g. inpatient unit (known as an imprest box distribution system), rather than the pharmacy department managing the receipt and distribution to units. Key considerations relating to this include the available space within the clinical units to store these items and the volume of stock being delivered. For example, vendor managed solutions work well for IV fluids and bulk medications but are challenging to manage for smaller volumes of medications coming from different suppliers when being used to stock ADCs.

Pneumatic tube systems may be used to transport selected medications to and from the Pharmacy Unit.

2.1.3 Hub and Spoke Models

Pharmacy services may be restricted to a single health care facility, or services may be extended to outlying facilities and the wider community, the latter particularly in remote rural areas. Planning for 'hub' services will need to consider appropriate provisions to support smaller services.

2.1.4 Compounding of Medicines

Some specialist pharmacies will be certified by the Therapeutic Goods Administration (TGA) to 'manufacture' medications. However, most hospital pharmacies will not be TGA licensed and will provide 'compounding' services.

Depending on the scope of pharmacy services to be delivered, the following compounding services may be undertaken:

- non-aseptic preparation of medications to be taken orally or topically (extemporaneous compounding);
- aseptic preparation of:
    - sterile products including parenteral admixtures and parenteral nutrition;
    - cytotoxic medications; and
    - biological products such as monoclonal antibodies and gene therapies.

The production of aseptically prepared products are only provided in selected health services. There are strict standards relating to the design of aseptic compounding suites to ensure product quality, safety and efficacy. Further guidance regarding this is provided at Section 2.4.8 and Appendix 5.5. Each project will need to seek expert input for cleanroom design and certification.

Consideration should be given to the use of technology to support quality assurance processes. Quality control requirements will vary between jurisdictions.

2.1.5 Outreach Services

Outreach services may include home medication review, hospital in the home (HITH) services e.g. for chemotherapy or IV antibiotics, remote home monitoring and liaison with patients and their care providers.

All outpatient pharmacies will require fixed or mobile telehealth units to support these services, as well as appropriate areas to store, pack and dispatch medication deliverables.

2.2 OPERATIONAL POLICIES

2.2.1 General

Operational policies have a major impact upon the planning and design and capital and recurrent costs of health facilities. Project teams should review their design proposals with these in mind and be able to demonstrate that the capital and recurrent cost implications of proposed operational policies have been fully considered. Operational policies may have site-wide application or be unit-specific. A list of general operational policies that may apply can be found in Part B: Section 80 General Requirements.

2.2.2 Hours of Operation

In general, most hospital pharmacies are moving to a 7-day service, however the hours of operation should be confirmed on a case by case basis.

An after-hours on call pharmacist service and/or after-hours medication access systems, e.g. after-hours medication store accessible to authorised staff or access via distribution from the pharmacy robot, is used for emergencies.

2.2.3 Storage of Pharmaceuticals

Pharmaceuticals are generally received on the main loading dock and transferred to a receiving area within the Pharmacy Unit or a bulk store. The bulk store may be located in an alternate location closer to the loading dock.

Where an 'imprest box distribution' system is not in place, the stock is then unpacked, checked and receipted before being decanted to the main store or pharmacy robot where provided. Storage will include open shelving, refrigerators and/or cool rooms and freezers as there is an increasing number of medications that need to be refrigerated. Refrigerated storage will require continuously monitored and alarmed temperature and humidity control.

Schedule 8 (S8) medications will be stored separately in a large safe or strongroom. Refer to Section 2.4.4 for further information.

Cytotoxic medications pose an occupational exposure risk and must be stored separate from other medications. Recent research has found the outer vial surfaces and the inner packages of cytotoxic medications can be contaminated by dried cytotoxic residue during the manufacturing process. Skin contamination by these agents when handled by operators is a significant source of occupational exposure. In addition, surfaces on which vials or vial packaging are stored or handled (i.e. shelves, racks, benchtops) become contaminated, exacerbating skin contact and potential drug absorption. A study by Kiffmeyer et al (2002) identified that solid (dried) cytotoxic medicine residues can sublime at room temperature, producing low level but continuous cytotoxic vapour in the working space. A designated closed cabinet and adjoining refrigerator for storage of cytotoxic medicines is recommended. A ducted exhaust for the storage area should be considered, where practical, to remove continuous cytotoxic vapours and heat generated by the refrigerator condenser.

Pharmacy Units in larger hospitals will usually require additional space to accommodate a range of activities including clinical trials, outpatient services and Medicines Access Programs where access to new medicines is provided prior to the implementation of funding arrangements. Space impacts will include storage of medications (including refrigerated storage) and dispensing areas.

A range of hard copy records will need to be retained by the Pharmacy Unit in line with local jurisdictional requirements. These include clinical trials records, dispensing records and S8 records. Some records can be archived off site, however there will still be the need to store some records within the pharmacy, including separated storage for clinical trials records.

2.2.4 Storage of Intravenous and Dialysis Fluids

A remote bulk store may be suitable for storing these fluids depending on the operational model in place. Vendor managed inventory systems may be implemented whereby fluids, including dialysate, will be delivered directly to the point of use.

For many services, fluids are being increasingly managed by the hospital rather than the pharmacy department. However, pharmacies will continue to manage scheduled fluids such as potassium.

Local drug and therapeutic committees will determine who, other than the pharmacist, may prepare additives to IV fluids, e.g. registered nursing staff and the impact this may have on space within the Pharmacy Unit. Refer to jurisdictional policies to determine local approaches.

2.2.5 Unit Dose Systems

Unit dose is a system of packaging whereby medications are contained in single dose packages and dispensed in a ready to administer form.

If a unit dose system is used, there will need to be additional space (either at the hospital or another offsite location) and equipment for supplies, packaging, labelling and storage, as well as medication carts. Automated unit dose dispensing systems may be considered.

2.2.6 Pharmaceutical Benefits Scheme (PBS)

Reforms to the Pharmaceutical Benefits Scheme (PBS) have been implemented in all states and territories, except NSW and the ACT, and eligible patients can receive a PBS quantity (usually up to a month's supply) of each medication on discharge or when attending a public hospital as an outpatient. Refer to Appendix 5.4 Further Reading regarding discharge medication supply requirements for NSW Health.

The Australian Government also provides funding for certain specialised medications under the Section 100 Highly Specialised Drugs Program. These restricted medications are dispensed to outpatients and those patients attending day services in a public hospital.

These programs have implications for storage, both bulk and in dispensing areas, as well as centralised records storage. Consideration should also be given to outpatient supply for chemotherapy and ambulatory care units. The Highly Specialised Drug Program will also impact on refrigerated storage capacity.

2.2.7 Pneumatic Transport Systems

Should pneumatic transport systems be used to transport medications and prescriptions, the location of stations in both the pharmacy itself and outlying units must be carefully reviewed to consider workflow and security. This includes ensuring that stations in clinical areas can only be accessed by authorised personnel.

Within the Pharmacy Unit, bench space to prepare and sort items will be needed. These systems should not be used for the transport of bulk supplies, accountable medications, glass and cytotoxics.

2.2.8 Patient Self-Medication Programs

These programs are commonly implemented in rehabilitation and sub-acute care services to teach patients to administer their own medications.

A locked drawer in the bedside locker can be used to store medications.

2.2.9 Patient Counselling

Pharmacists will need access to an interview room for selected counselling activities. A dedicated room will usually be provided adjacent to the pharmacy counter. Other information will be provided to patients at the collection counter and it is important that this area provides privacy and confidentiality at adjacent reception / counselling counters e.g. opaque partitions.

Access to bookable rooms in inpatient and outpatient environments may also be needed.

2.2.10 Waste Management

Planning teams need to establish disposal techniques and associated storage requirements for all types of waste. The disposal of medications, particularly accountable medications are subject to specific regulations. Other categories of waste will include sharps, cytotoxic waste, packing waste, general waste, confidential waste, biohazard waste and recyclables including glass and containers.

2.3 PLANNING MODELS

2.3.1 Single Unit

The Pharmacy Unit is usually a single self-contained facility, especially in small health services. The provision of a single unit supports efficient utilisation of technology and staff, however in larger health facilities, an increasing number of 'satellite' pharmacies are being provided as health services seek to bring services closer to the patient.

2.3.2 Satellite Pharmacy Units

A satellite Pharmacy Unit is a room or suite of rooms in a hospital that is located away from the main Pharmacy Unit. Typical examples include:

- a cytotoxic aseptic compounding pharmacy collocated with cancer services;
- an outpatient pharmacy provided to improve access for patients and where a high volume of patient counselling is required. This approach may collocate all outpatient services in one location;
- clinical trials pharmacy / investigational drug units which are frequently provided with oncology and other outpatient services; and.
- satellites supporting other clinical services, e.g. a group of inpatient units, where they are located a significant distance to the central pharmacy and/or where services have expanded and there is insufficient space in the central pharmacy. This is only recommended for very large facilities as there may be disadvantages associated with pharmacy resourcing and duplication of stock and equipment.

Early consideration of the proposed distribution of pharmacy services across the health facility is essential to ensure optimal access for patients and efficient use of resources.

2.4 FUNCTIONAL AREAS

2.4.1 Functional Zones

Functional zones within a Pharmacy Unit include:

- reception, waiting and patient counselling;
- after-hours medication store;
- pharmacy dispensary;
- bulk store, distribution and support;
- pharmacy administration areas including clinical pharmacy review; and
- optional areas – aseptic production suites and clinical trials areas (the inclusion of these will depend on the scope of the service / project).

It is essential that the arrangement of space within a Pharmacy Unit clearly demarcates public and restricted areas and accommodates workflows, to ensure that medication errors are minimised.

2.4.2 Entry, Reception and Waiting

At public outpatient counters, staff should be able to see visitors as they approach. Counters should be located at some distance from the waiting areas to ensure that conversations regarding medications being collected are not easily overheard. Staff will be separated from public waiting areas and the counter should be secured when not in use.

For large and busy units, the design of the pharmacy counter should support separate access for hospital staff and patients with the ability to close off the public access point while allowing continued access by hospital staff. It is also ideal if the process for dropping-off prescriptions is separated from the collection of medications to promote better work flows.

The safety of staff working within the reception area is a high priority and needs to be balanced with the need to ensure optimal communication between staff and patients is achieved. Design solutions may include glazing with speech holes, the use of sound absorbing surfaces in the waiting area to minimise background noise (e.g. carpet), and the provision of a secure pass through drawer for medications. Refer to the AusHFG standard component 'Pharmacy – Counter' for further details.

An interview room will be located within this zone to enable pharmacists to provide counselling regarding a patient's medications. This room should have two entry points, one from within the Pharmacy Unit and one from the waiting area with appropriate arrangement of furniture to support optimal staff safety. A duress alarm should be installed in the interview room. A glazed panel should be provided in the door for visibility to ensure staff safety. This room will need to be secured when not in use to ensure that unauthorised entry to the unit is not possible.

Most pharmacies are moving away from handling cash and patients are directed to the central hospital cashier function. Therefore, the location of the cashier needs to be considered and some pharmacies may need to provide this function if the travel distance to the cashier is too far.

2.4.3 After-Hours Medication Store

An after-hours medication store may be part of the Pharmacy Unit accessible from the outside, however it is more commonly provided closer to the clinical units that require access to the store.

If a pharmacy robot is provided, the robot may be linked to a 'drop box' located on the periphery of the pharmacy for after-hours access by authorised staff.

2.4.4 Dispensary

Dispensing: Medications are 'picked' from store areas and taken to a dispensing station (or delivered to each station via a pharmacy robot). Where this work is undertaken by technicians, a dispensing station for a pharmacist is needed to check each medication. Access to a PC, barcode scanner and label printer will be required at every station to support these activities (refer to AusHFG standard component 'Pharmacy – Dispensing Workstation'). Medications are then collected by a patient or an authorised staff member, sent to a clinical area or stored within the Unit awaiting collection.

Direct access to refrigerated medication storage and trolleys to store items awaiting collection is required.

Storage is also required for consumables such as medication packets and refrigerated cold packs.

A separate dispensing bench and storage area for dispensing hazardous oral medications is required with access to a hand washing basin.

Accountable / controlled medications: Schedule 8 (S8) medications will be stored within a safe or strongroom. Pharmacy staff will respond to prescriptions, imprest restocking orders and requisitions from clinical units and process these requests prior to the medications being securely delivered to the clinical unit or collected by clinical staff. An integrated or collocated workspace is needed, including a PC and storage for a small volume of consumables, for preparation of orders, recording of issues and storage of registers. Most pharmacies are transitioning to the use of an electronic controlled medication (S8) register. A small number of S8s need to be refrigerated, e.g. medicinal cannabis, which will require secure refrigerated storage.

The safe / strongroom must comply with local jurisdictional legislation and public health facility policy and should be designed in collaboration with an expert security consultant with assessment of the risks for the particular site. There are strongroom options for concrete / reinforced steel construction and steel plate modular forms dependent on the location, with a torch and drill resistant door and security monitoring (such as with CCTV and alarm monitoring) and a secure caged area for assembling orders. To assure the safety and security of staff, breather tubes and a telephone should be included.

The approach to the storage of S4 and S4D medications / drugs of dependence will vary between jurisdictions. In some cases, these can be stored in the same S8 medication safe or strongroom, however for other jurisdictions, a separate but collocated locked cabinet may or will be required.

Extemporaneous compounding: a dedicated room is commonly required in medium to large hospital pharmacies to compound non-aseptically prepared products. A dedicated extemporaneous compounding room is not usually provided in small hospitals, however all pharmacies should have access to a sink and bench space where they can produce products which need to be prepared as extemporaneous compounded products.

2.4.5 Bulk Store, Distribution and Support Areas

Newly delivered stock should be received in an easily accessible area with ergonomic bench space to support the efficient processing, checking and unpacking of incoming stock. This area will also require access to a workstation to support procurement activities.

Storage and preparation space is required for items to be transferred to the dispensary and clinical units (imprest medications). Storage will be required for a range of medications including bulky items and refrigerated storage. Bench space, at standing height, will be required to package items for distribution. This area may also be used to prepare specialised packs, e.g. resuscitation trolley supplies. A PC, barcoding scanners and a Portable Data Entry (PDE) device, for stock taking and reordering, will be located at each workstation. Trolleys will be located within this area to transport items from the store to the bench. An area is also required to store imprest stock prior to delivery. The size of this area will depend on whether a pharmacy robot will support imprest management, or an imprest box distribution system is in place.

Work areas are also required to process medications being returned from clinical units prior to the return to stock or disposal. For small pharmacies this may be undertaken at the distribution workstations.

2.4.6 Pharmacy Administration

This area will include staff work areas, a meeting room and staff amenities. In addition, this area will provide space for medication information and auditing activities.

Requirements will be informed by the staff work profile, including consideration of specialised roles.

Separate staff work areas are required for clinical trials where provided.

2.4.7 Optional Areas

Depending on the service level, the pharmacy may also include:

- aseptic compounding, which may include the production of non-cytotoxic, cytotoxic, and/or biological products requiring cleanroom suites;
- facilities for clinical trials including dispensing areas (including refrigerated space), secure storage and staff work areas;
- quality control laboratory;
- quarantine room;

- hazardous substance storage areas including cytotoxic medication storage (note that monoclonal antibodies are not considered hazardous substances, however when they are conjugated with a cytotoxic drug, they must be stored as a cytotoxic); and
- flammable liquids storage.

2.4.8 Aseptic Production Suite

There are three types of aseptic production suites used for the preparation of pharmaceuticals and related treatments, designed to limit the presence of particulates and microorganisms:

- aseptic suites used for the preparation of sterile, non-cytotoxic products (undertaken in a positive pressure environment);
- cytotoxic suites used for the preparation of cytotoxic medications and other hazardous substances (undertaken in a negative pressure environment); and
- other suites used for the preparation of products such as gene therapy, live vaccines and live virus clinical trials, as well as biohazard products which may emerge in the future. These suites will need to comply with Physical Containment Level 2 (PC2) requirements and are highly specialised services that will only be provided in selected facilities.

Dedicated heating, ventilation and cooling (HVAC) systems are essential for aseptic production suites to supply air of specified ISO classes, air change rates and temperature and humidity control according to relevant Australian Standards (AS 2252 Controlled Environments Series 1 to 7). While HVAC systems and other design requirements will vary between the different types of aseptic production suites (refer to Appendix 5.5 for design information), the overall layout and workflow is consistent.

An aseptic production suite consists of the following core zones classified according to the air-quality in operation (A, B, C and D) (refer to Section 5.5.2 for further detail):

- a change room which should be designed as an airlock and used to provide dynamic separation between different stages of change to minimise microbial and particulate contamination of cleanroom garments and the cleanroom into which the operator will enter;
- cleanroom;
- a preparation area including two zones – one zone is for the assembly of raw materials and consumables, and decontamination of them; and the second zone is for the reconciliation of finished goods; and
- labelling and release, documentation, and storage space.

Staff accessing the compounding area must 'change' before they enter. This involves the removal of outer garments and donning cleanroom attire. A hand basin will be located outside of the change room. The cleanroom will be accessed from the change room via interlocking doors.

Staff working in the cleanroom will receive decontaminated equipment and materials from the preparation area via a pass-through hatch. When product is prepared, it is sent via another pass-through hatch to the preparation area for transfer to the labelling and release area.

Preparation and labelling and release rooms require external access as they are not directly accessed via the change room or cleanroom (excluding pass-through hatch arrangements).

Design requirements relating to each zone are outlined in Appendix 5.5.

2.5 FUNCTIONAL RELATIONSHIPS

2.5.1 External

Access to a loading dock and bulk storage area is required if this is not part of the main Pharmacy Unit. Easy access is required to all clinical areas within the health service.

As described under Section 2.3.2, satellite pharmacies may be established in larger health facilities for ease of access by patients and to minimise travel distances.

Access to the main hospital cashier may be required, as noted under Section 2.4.2.

2.5.2 Internal

Refer to the Functional Relationship Diagram.

03 DESIGN

3.1 ACCESSIBILITY

3.1.1 External

The Pharmacy Unit will receive bulk supplies from the main loading dock. Couriers will also arrive from the loading dock and deliver supplies to the Pharmacy Unit or direct to clinical areas (e.g. imprest box distribution system and vendor managed inventory).

3.1.2 Internal

Points of access are required by:

- pharmacy staff;
- visitors;
- other staff collecting prescriptions;
- outpatients delivering and collecting prescriptions and medications;
- supplies delivery and dispatch; and
- maintenance, cleaning and waste removal staff.

3.2 DISASTER PLANNING

Consideration needs to be given to the requirements for storing large volumes of selected medications which might be needed in disasters or large-scale emergencies.

Disaster planning is discussed in more detail in AusHFG Part B: Section 80 General Requirements.

3.3 INFECTION CONTROL

Hand hygiene facilities should be provided in each room or space where medications are handled.

Specific requirements relating to cleanrooms are outlined in Appendix 5.5.

Refer to jurisdictional infection control policies and Part D: Infection Prevention and Control.

Refer to the SHPA COVID-19 Hospital Pharmacy Preparation Checklist to assist in developing an approach to achieving the goals of reducing cross-infection, protecting and sustaining the workforce and maintaining optimal treatment of all patients.

3.4 ENVIRONMENTAL CONSIDERATIONS

3.4.1 General

Controlled temperature and humidity is required for medication storage and internal temperatures should not rise above 25^{o}C.

A dedicated HVAC plant is required for aseptic production suits to ensure cleanrooms are maintained between 17^{o}C to 19^{o}C with a relative humidity between 30% and 60%.

3.4.2 Acoustics

Ambient noise should be minimised to reduce staff distraction which can contribute to the incidence of errors. The introduction of robotic systems may impact on ambient noise levels.

3.4.3 Natural Light

The Pharmacy Unit should have access to natural light and external views where possible. This must be balanced with the potential for solar gain and security considerations with windows located on the perimeter walls being reinforced to prevent entry.

3.4.4 Privacy

Access to interview rooms in all patient locations is required. This can be facilitated in bookable rooms or single bed rooms. Pharmacy counters can also be designed to provide some separation between drop-off and collection. In many cases, this design will facilitate confidential communication.

3.5.4 Energy conservation

Reduced HVAC air flows during non-operational hours may be considered for some areas.

Cleanrooms require uninterrupted (i.e. 24/7) HVAC air flows to maintain the facilities at the required conditions. This includes containment workstations.

3.5 SPACE STANDARDS AND COMPONENTS

3.5.1 Ergonomics

Storage systems should be arranged to ensure that staff do not need to reach stock in high locations. A pallet jack may be located in bulk storage areas.

Equipment may assist staff move large parcels onto preparation benches.

Dispensing workstations should be arranged to support effective workflows, reduce travel time and to avoid the potential for error. These stations should be arranged such that extended reaches are avoided. Task lighting may also be required.

Anti-fatigue matting may be needed in areas where staff stand for long periods.

Refer to AusHFG Part C: Design for Access, Mobility, Safety and Security.

3.5.2 Doors, Windows and Corridors

Doorways should be wide enough to facilitate the delivery of large amounts of stock, including pallets and automated guidance vehicles if used.

The main circulation corridors must have a minimum 1000mm clear width in line with the Building Code of Australia access and egress requirements.

The distance between shelves in medication store areas does not need to meet accessibility requirements (in line with the National Construction Code Clause D3.4), however sufficient width should be provided to meet the functional and Work Health and Safety (WHS) requirements of stocking and picking pharmaceutical supplies.

Where dispensing workstations are arranged adjacent to each other, corridors in between them should be wide enough to provide unobstructed movement for staff and allow for space that may be occupied by furniture (e.g. chairs) and staff stationed at those workstations. Refer to the AusHFG standard components.

Reinforce windows on the perimeter to prevent entry. Refer to AusHFG Part C for information.

3.6 SAFETY AND SECURITY

Pharmacies are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows, walls and ceilings and to meet jurisdictional legislation where applicable.

A two-door entry approach should be provided to the pharmacy, i.e. one door for the public and hospital staff to access the front pharmacy counter and a separate door for the entry of pharmacy staff to the pharmacy. Any service windows must be constructed of safety glass while being designed to support communication. Duress alarms must be provided at the outpatient dispensing counter, reception and interview / counselling areas.

The design should allow areas of the Unit to be locked down when not in use such as in the evenings and on weekends. This will be facilitated by locked doors from public corridors and locked shutters to publicly accessible counters.

Doors into the Pharmacy Unit should be fitted with substantial locks and access control systems for authorised staff. Perimeter doors should be constructed of solid core with heavy gauge metal sheeting. Door hinges on external doors should be housed internally to avoid tampering. These doors should be fitted with a closing device, to ensure that they cannot be left open.

An intruder alarm system should be installed to the pharmacy and drug safes, and must be centrally monitored when the Unit is unoccupied.

CCTV will be used to monitor entry points and drug safes.

External entry points should be well lit.

A risk assessment of the pharmacy design must be undertaken that includes consideration of:

- accessibility via window or door breaches;
- security of the drugs safe and storage;
- ability to detect intrusion – intruder alarms;
- accessibility of the pharmacy from the roof and availability of access to the roof;
- security of staff including duress alarms and duress response and CCTV; and
- ability to control and identify persons accessing pharmacy, e.g. by visual identification or card access.

For further information refer to:

- AusHFG Part C Sections 6 & 7 Safety and Security
- NSW Health, 2018, Protecting People and Property - NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies, Section 18 Security in Pharmacies.
- Victorian Pharmacy Authority, 2019 Victorian Pharmacy Authority Guidelines Section 4 Security and Appendix 1.

3.7 MATERIALS & FINISHES

For general information regarding finishes, refer to AusHFG Part C and the associated AusHFG standard components.

Refer to Appendix 5.5 regarding finishes and materials for aseptic production suites.

3.7.1 Wall Construction and Protection

Walls should be:

- constructed of a solid material with as few windows as possible; and
- extended to the underside of the floor slab above to prevent any intrusion over the wall or from the ceiling cavity.

Wall protection will be required to prevent damage from trolleys.

3.7.2 Floor Finishes

Floors should be constructed of a solid material. Carpet is not suitable in areas where medications are handled.

3.7.3 Ceiling Finishes

Ceilings should be constructed of a solid material.

3.7.4 Window Finishes

Windows should be minimised. Where provided, they should be treated to prevent entry and ideally should not be able to be opened, e.g. security glass. Windows in public reception areas should use safety glass, noting communication still needs to be facilitated.

3.8 FIXTURES, FITTINGS & EQUIPMENT

The Room Data Sheets (RDS) and Room Layout Sheets (RLS) in the AusHFG contain standard rooms as described in this HPU.

Where medications are stored on shelving, the shelving solution should promote uncluttered, well organised approaches. This may be achieved through:

- shelf dividers;
- the use of shelving systems with sloping pull-out draws to improve identification; and
- separating medications, e.g. dispensary storage from medications awaiting collection.

Accountable medications will be stored in safes or strongrooms.

For more detailed information refer to the AusHFG standard components

3.9 BUILDING SERVICE REQUIREMENTS

3.9.1 Information Technology and Communications

The pharmacy environment will require reliable and effective IT and communications systems to support their work. Systems will include:

- networked computers, scanners and printers including either fixed PCs, laptops or 'tablets' to review clinical information and increasingly, review and process electronic medication orders (refer to local jurisdictional requirements);
- scanning systems and/or radio-frequency identification (RFID) or other emerging technology to reduce errors (refer to local jurisdictional requirements);
- Portable Data Entry (PDE) hand held units for stock taking and reordering;
- robotics, supporting dispensing, distribution and manufacturing systems;
- integrated medication management systems that will include electronic ordering;
- security systems such as fixed duress systems; and
- teleconferencing and/or tele-pharmacy facilities.

All refrigerators, freezers and cool rooms used to store medications should be powered by emergency power, to ensure that the environment can be maintained at all times. In addition, these rooms and equipment will need to be linked to the Building Maintenance System and local alarms, to ensure that systems are in place to record variation from required storage temperature ranges and to ensure staff are notified in case of a system failure.

3.9.2 Electronic Medication Management

Electronic medication management (EMM) systems enable prescribing, review and administration of medications to be recorded electronically. EMM systems include prescribing by doctors, review and dispensing of medication orders by pharmacists, and administration of medications by nurses. An EMM system can reduce medication errors through improved prescription legibility and dose calculation and providing clinical decision support. It also improves linkages between clinical information systems.

The impacts to pharmacists may include the need for dual screens when dispensing and a mobile electronic platform such as a 'tablet'. Recharging and storage of these devices needs to be considered.

Refer to Electronic Medication Management Systems — A Guide to Safe Implementation (Australian Commission on Safety and Quality in Health Care, 2019).

3.9.3 Barcode Technology

Barcode technology will be located throughout the pharmacy from initial good receipt through to dispensing. This technology is linked to pharmacy dispensing software.

3.9.4 Alarm Systems

Intruder alarms are required in Pharmacy Units where facilities are unoccupied overnight and/or at weekends.

These alarms will detect intrusion at doors, windows and the drug safe. This system should comply with AS/NZS 2201:2008 (Set) Intruder Alarm Systems (Standards Australia, 2008) and may incorporate a duress alarm to enable staff to activate the alarm in the event of an emergency.

3.9.5 Aseptic Production Suites

Refer to Appendix 5.5 for building services requirements associated with aseptic production suites.

04 COMPONENTS OF THE UNIT

4.1 STANDARD COMPONENTS

Rooms or 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; and
- 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: https://healthfacilityguidelines.com.au/standard-components .

4.2 NON-STANDARD COMPONENTS

Non-Standard Components for a Pharmacy Unit are described below.

Detailed requirements for cleanrooms for sterile and cytotoxic manufacturing are described in Australian Standards.

4.2.1 Bay - Clean-up

Description and Function

- A small area used to clean, dry and store measures and other equipment to prepare medications.

Location and Relationships

- Collocated with the preparation / repacking area.

Considerations

- The area will require storage, a sink and drainer.

4.2.2 Store - Refrigerated

Description and Function

- A discrete area for the refrigerated storage of medications.

Location and Relationships

- Adjacent to dispensing and distribution areas.

Considerations

- The demand for refrigerated storage is growing.
- Each unit will need to be alarmed and connected to the building maintenance system.
- Access to some collocated bench space may be required for assembly.
- Refrigeration systems should support stock rotation.

4.2.3 Dispatch / Collection - Inpatients

Description and Function

- This area is used to hold imprest medications on trolleys prior to delivery to patient care areas.

Location and Relationships

- Adjacent to distribution areas.

Considerations

- While most deliveries are planned and provided by the pharmacy service, hospital staff may collect some items.
- This may require a video intercom system to enable pharmacy staff to identify those collecting medications. A refrigerator will be collocated to store selected items.

4.2.4 Preparation / Repacking Area

Description and Function

- Bench space, at standing height, for packaging of items for distribution. This area may also be used to prepare specialised packs, e.g. resuscitation trolley supplies, anaphylaxis kits.

Location and Relationships

- Proximity to the bay-clean up area is required.

Considerations

- Space allocation and fit out requirements will depend on the items to be packed or repacked.

4.2.5 Goods Receipt – Pharmacy

Description and Function

- Area to receive newly delivered stock. Access to an ergonomic bench is required to support the efficient processing, checking and unpacking of incoming stock.

Location and Relationships

- This area is ideally collocated with the bulk store for ease of transporting unpacking stock.
- Direct external access from the loading dock / bay is required.

Considerations

- Access to a workstation is required to support purchasing activities.
- Dedicated separate area for cytotoxic and other hazardous medication stock, that is appropriately ventilated, will be required for relevant services.

4.2.6 Aseptic Production Suite

Refer to Appendix 5.5.

05 APPENDICES

5.1 SCHEDULE OF ACCOMMODATION

Indicative Schedules of Accommodation for a Pharmacy Unit are provided in the following tables. These are based on three scenarios as described below. Area allocations will need to be adjusted to suit the scope of pharmacy services being delivered, the level of automation being implemented, the provision of satellite pharmacy services, and the required staffing profile.

- Scenario 1: Pharmacy within a Small Hospital – this scenario relates to Australian Hospital Peer Groups D / some Group C hospitals, and Level 3 pharmacy services as per the NSW Health Guide to the Role Delineation of Clinical Services (2019) and Victorian Pharmacy Authority Guidelines (2019). This assumes that at least one full time pharmacist is provided plus support staff. Limited compounding services would be provided.
- Scenario 2: Pharmacy within a Medium Hospital – this scenario relates to Australian Hospital Peer Groups B / some Group C hospitals, and Level 4 pharmacy service as per the NSW Health Guide to the Role Delineation of Clinical Services (2019) and Victorian Pharmacy Authority Guidelines (2019). The provision of compounding services and clinical trials will depend on the service profile.
- Scenario 3: Pharmacy within a Large / Principal Referral Hospitals – this scenario relates to Principal Referral and Group A Hospital Peer Groups and Level 5 or 6 pharmacy services as per the NSW Health Guide to the Role Delineation of Clinical Services (2019) and Victorian Pharmacy Authority Guidelines. A full range of aseptic compounding services is assumed, as well as active involvement in clinical trials and research activities.

The ‘Room / Space’ column 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. These rooms are described as ‘Standard Components –Derived’ (SC-D). The ‘SD / SD-C’ column identifies these rooms and relevant room codes and names are provided.

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, rooms or spaces are described as ‘Optional' or ‘o’. Inclusion of this room or space will be dependent on a range of factors such as operational policies or clinical services planning.

RECEPTION / WAITING / PATIENT COUNSELLING

AusHFG Room Code	Room / Space	SC / SC-D	Small Hospital Pharmacy		Medium Hospital Pharmacy		Large / Principal Referral Hospital		Remarks
			Qty	m^2	Qty	m^2	Qty	m^2	
WAIT-10	Waiting	Yes	1	4	1	8	1	15	Areas are indicative and will depend on the number of people to be accommodated and volume of outpatient and discharge dispensing. Electronic queueing systems should be considered and will impact on waiting area given patients can go elsewhere while awaiting notification that their medications are ready. 1.2m2 recommended per seat, 1.5m2 per wheelchair space.
PHA-CO	Pharmacy - Counter	Yes	1	4	1	9	1	12	May be divided into separate patient and hospital staff access points in larger services.
INTV	Interview Room	Yes	Shared			9		9	Interview / counselling room. Number dependent on anticipated utilisation. Access to telehealth required to support off-site consultation and patient education. Dual access from Waiting and Pharmacy. Recommend use of glazing to support visual access for safety while providing acoustic privacy.
	Discounted Circulation			25%		25%		25%	

AFTER – HOURS DRUG STORE

AusHFG Room Code	Room / Space	SC / SC-D	Small Hospital Pharmacy		Medium Hospital Pharmacy		Large / Principal Referral Hospital		Remarks
			Qty	m^2	Qty	m^2	Qty	m^2	
AHDR	After Hours Drug Store	Yes	1	3	1	4	1	6	May be located close to clinical areas or on the periphery of the pharmacy with internal and external access. Requirement will depend on adoption of automated technology. May be provided as a 'drop box' linked to a pharmacy robot. Size will be dependent on operational practices and volume of medicines to be stored. ADCs will enable recording of access data.
	Discounted Circulation			25%		25%		25%	

PHARMACY DISPENSARY

AusHFG Room Code	Room / Space	SC / SC-D	Small Hospital Pharmacy		Medium Hospital Pharmacy		Large / Principal Referral		Remarks
			Qty	m^2	Qty	m^2	Qty	m^2	
PHA-DS	Pharmacy - Dispensing Workstation	Yes		4		4		4	Number of workstation dependent on service requirements. May include EMM triage stations. VPA Guidelines recommend one station for each 150 prescriptions or part thereof dispensed on a typical day between 9am and 6pm. Inpatient, outpatient, clinical trials and manufacturing dispensing areas may need to be separated in larger services.
	Bay - Multifunction Device / Storage			2		2		2	Assume shared between 4 dispensing workstations.,
	Bay - Trolleys / Shelves		1	2	1	4	1	6	Storage for trolleys with dispensed items awaiting collection. Includes refrigerated items.
	Store - Refrigerated		1	4	1	10	1	16	Refrigerators and freezers. Also requires access for distribution workflows.
STGN-8	Store - General	Yes	1	3	1	6	1	12	Distribution and dispensing consumables such as labels. Also requires access for distribution workflows.
BHWS-B	Bay - Handwashing, Type B	Yes		1		1		1	Number and location dependent on layout.
STAD	Store - Accountable Drugs	Yes	1	2	1	7	1	10	Assume wall-mounted safe for small pharmacy with collocated workstation. Larger services supporting theatres and ICU will require a strongroom or secure cabinet given high volume of accountable drugs. Will also store drugs awaiting collection. May include refrigerated S8s. Refer to local jurisdictional requirements for storage of S4/S4Ds. Direct access to sink required.
	Workstation		1	2.2 (o)					Optional, provided within strong room for larger services depending on local work flows. Will be required for small services with wall mounted drug safe only.
PHA-PR	Pharmacy - Preparation Room, Non-Aseptic	Yes			1	12	1	16	Preparation of extemporaneous compounds. Provision in smaller hospitals will depend on service needs.
BES	Bay - Emergency Shower	Yes			1	2	1	2	Emergency use. Should include eye wash. Accessible from compounding areas.
	Preparation / Repacking Area				1	6	1	10	Space allocation dependent on volume of items to be packed or repacked. May include specialised packs eg resuscitation trolley supplies, anaphylaxis kits.
	Bay - Clean-up		1	3	1	3 (o)	1	4 (o)	Area to store measures etc. for dispensing and wash up / dry after use. Collocate with prep/repacking area. This area may be combined with the Non-Aseptic Preparation Room.
	Discounted Circulation			25%		25%		25%	

BULK STORE, DISTRIBUTION AND SUPPORT

AusHFG Room Code	Room / Space	SC / SC-D	Small Hospital Pharmacy		Medium / Large Hospital Pharmacy		Principal Referral Hospital Pharmacy		Remarks
			Qty	m^2	Qty	m^2	Qty	m^2	
	Goods Receipt - Pharmacy				1	10	1	14	Area requirement will depend on operational arrangements. Combine with bulk store for small hospitals. May be collocated with or remote from the Store - Bulk. Requires ergonomic bench for efficient processing, checking and unpacking of incoming stock and workstation to support purchasing activities.
STBK-40	Store - Bulk	Yes	1	20	1	60	1	130	Requirements will depend on scope of service and provision of vendor managed inventory solutions. Area allocations assume that bulk fluids and dialysis fluids are not stored in the pharmacy. If pharmacy robot is being provided this will also include separate storage for items that cannot be stored within the robot. Requirements to support other services across the network to be considered. Flammable liquids and hazardous substance storage to be determined based on local hospital policies. Disaster management requirements to be considered.
	Workstation		Shared			2.2		2.2	For ADC terminal / other depending on local requirements.
PHA-DB	Pharmacy - Distribution Workstation			6		6		6	Number of workstation dependent on service requirements. Requires bench space, PC, barcoding system, PDE devices and space for trolleys to “pick” and store items for delivery. Will be collocated with Bay - Trolleys
PHA-RE	Pharmacy - Returns Workstation				1	6	2	6	Number of workstations dependent on volume of items to be packed or repacked. Smaller service will combine with distribution workstation.
	Dispatch / Collection			3		8		12	Distribution trollies / carts for delivery of imprest stock to clinical units.
BPTS	Bay - Pneumatic Tube					1		1	
STFS-10	Store - Files	Yes	1	3	1	6	1	10	Old prescriptions, registers. Requirements will depend on digitisation of records, mainly relating to S8 records. Assumes off-site storage of archives.
DISP-8	Disposal Room	Yes	Shared		1	5	1	8	Separate waste streams including recycling and confidential waste.
CLRM-5	Cleaner's Room	Yes	Shared		1	5	1	5	
	Discounted Circulation			25%		25%		25%	

PHARMACY ADMINISTRATION

AusHFG Room Code	Room / Space	SC / SC-D	Small Hospital Pharmacy		Medium Hospital Pharmacy		Large / Principal Referral Hospital		Remarks
			Qty	m^2	Qty	m^2	Qty	m^2	
OFF-S9	Office – Single Person	Yes	1	9	1	9	1	9	Number and area allocation will depend on staff profile and local jurisdictional policies.
	Office - Workstation			4.4		4.4		4.4	Number and area allocation will depend on staff profile and local jurisdictional policies. Consider provision of telehealth pods and work space for students.
STPS-8	Store - Photocopy / Stationery	Yes	1	3	1	5	1	8	Provided as a bay in smaller units.
MEET-L-15	Meeting Room	Yes			1	15	1	40	
PROP-2	Property Bay - Staff	Yes	1	1	2	2	4	2	
BBEV-OP	Bay - Beverage, Open Plan	Yes	1	3				-	
SRM-15	Staff Room	Yes	Shared		1	15	1	20	Requirements will depend on staff profile and opportunity to share with adjacent services.
WCST	Toilet - Staff	Yes	1	3	3	3	4	3	Number in accordance with staff profile. Access to an accessible toilet will be required.
	Discounted Circulation			25%		25%		25%	

ASEPTIC PRODUCTION SUITE – OPTIONAL AREA

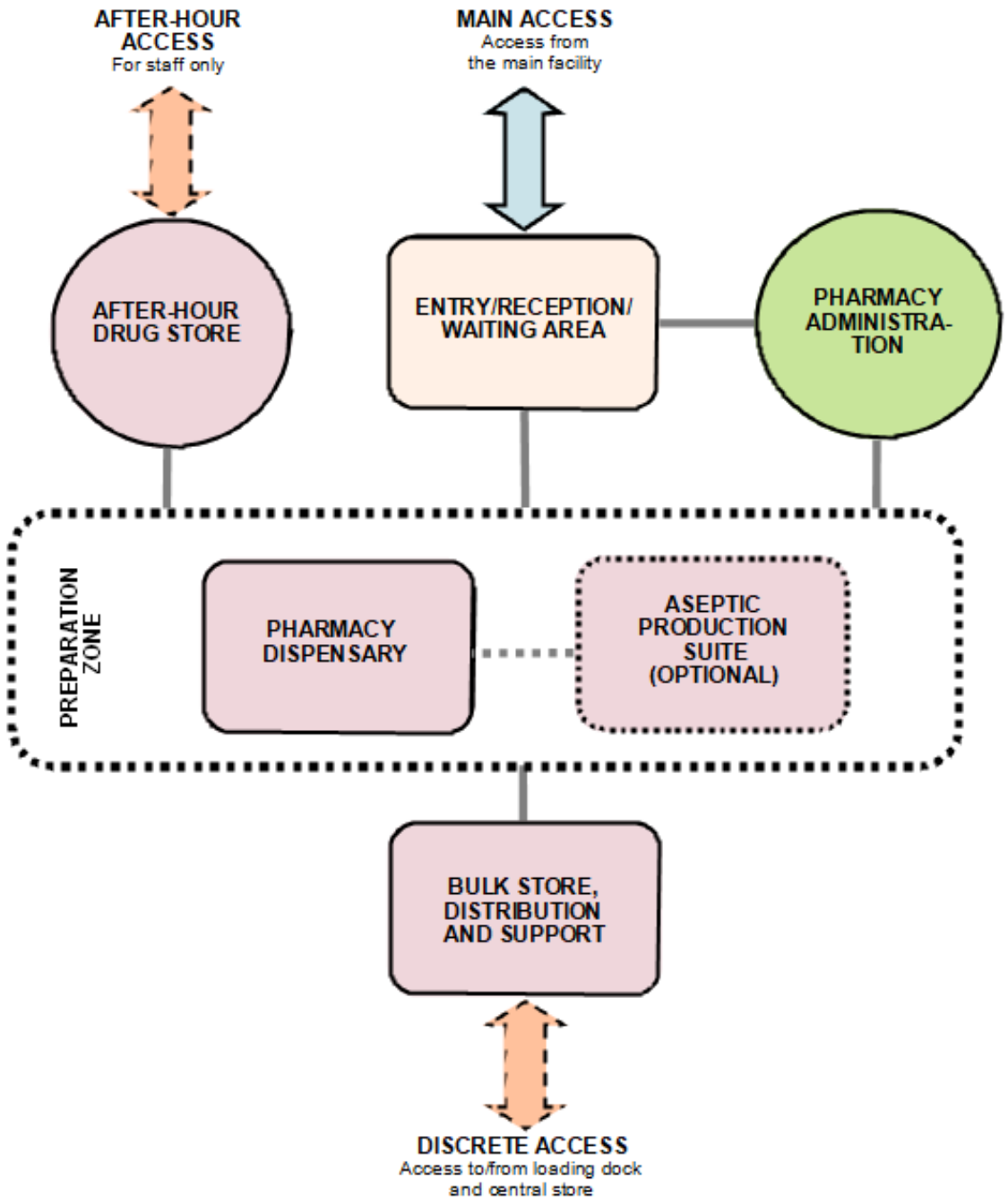
The area requirements for an aseptic production suite will require expert input from a GMP cleanroom consultant and will depend on the types of products being prepared and the number and types of cabinets to be installed. Indicative areas to support an aseptic production suite, including a cleanroom with three clean workstations, are provided below.

AusHFG Room Code	Room / Space	SC / SC-D					Qty	m^2	Remarks
	Change Room						1	10	Size will depend on number of people to be accommodated.
	Cleanroom						1	24	This indicative area allocation assumes the inclusion of 3 clean workstations. Area requirements will depend on the number and type of cabinet to be installed and requires expert input. Isolators will require more room than clean workstations or CDSCs.
	Preparation Room						1	26	Indicative area allocation. Actual area requirements to be confirmed in consultation with GMP cleanroom consultant.
	Documentation, Storage Area						1	12	Indicative area allocation. Actual area requirements to be confirmed in consultation with GMP cleanroom consultant.
BES	Bay - Emergency Shower	Yes					1	2	
	Discounted Circulation							25%	

CLINICAL TRIALS – OPTIONAL AREA

AusHFG Room Code	Room / Space	SC / SC-D					Qty	m^2	Remarks
PHA-DS	Dispensing - Clinical Trials	Yes					4	4	Number of workstations is indicative and will depend on no. of clinical trials.
	Bay - Multifunction Device / Storage						1	2	1 shared between 4 dispensing workstations.,
	Bay - Clean-up						1	2	Area to store measures etc. for dispensing and wash up / dry after use.
	Store - Drugs, Clinical Trials						1	15	Area is indicative and will depend on scope of clinical trials. To be separate from main drug storage. Includes refrigerated storage and may require freezer storage.
STFS-10	Store - Files	Yes					1	10	Area is indicative and will depend on scope of clinical trials. Records to be kept for 25 years.
	Office - Workstation						2	4.4	Pharmacy audit
	Discounted Circulation							25%	

5.2 FUNCTIONAL RELATIONSHIPS



5.3 REFERENCES

- AHIA, 2016, AusHFG Part B: Health Facility Briefing and Planning, Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW
- AHIA, 2018, AusHFG Part C: Design for Access, Mobility, Safety and Security, Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW
- AHIA, 2016, AusHFG Part D: Infection Prevention and Control, Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW
- Australian Commission on Safety and Quality in Healthcare, National Safety and Quality Health Service Standards (NSQHS) – Medication Safety Standard.
- Australian Commission on Safety and Quality in Health Care, 2017, National Safety and Quality Health Service Standards (NSQHS) - Guide for Multi-Purpose Services and Small Hospitals 2017.
- Australian Commission on Safety and Quality in Health Care, 2019, Electronic Medication Management Systems — A Guide to Safe Implementation.
- Australian Government Department of Health, 2013, National Vaccine Storage Guidelines: Strive for 5.
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- Kiffmeyer T, Kube C, Opiolka S, Schmidt K, Schoppe G and Sessink P, 2002, Vapour pressures, evaporation behaviour and airborne concentrations of hazardous drugs: implications for occupational safety, The Pharmaceutical Journal, Vol 268, pp. 331-337.
- Pharmacy Board of Australia, Codes, Guidelines and Policies: https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx.
- SHPA Standards of Practice, The Society of Hospital Pharmacists of Australia: https://www.shpa.org.au/standards-of-practice**.**
- The Society of Hospital Pharmacists of Australia (June 2019) Factors to Consider for the Implementation of Automated Pharmacy Distribution Systems in Hospitals and Health Services.
- Standards Australia, 2008, AS/NZS 2201:2008 (Set) Intruder Alarm Systems (Standards Australia, 2008), Standards Australia, Sydney, NSW.
- Standards Australia, 2002, AS/NZS ISO 14644:2002 Cleanrooms and Associated Controlled Environments (Standards Australia, 2002), Standards Australia, Sydney, NSW.
- Standards Australia, 2017, AS2252.5:2017 Cytotoxic Drug Safety Cabinets – Installation and Use (Standards Australia, 2017), Standards Australia, Sydney, NSW.

5.4 FURTHER READING

- NSW Health Policy Directive, Medication Handling in NSW Public Health Facilities.
- NSW Health Policy Directive, Protecting People and Property - NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies.
- NSW Health Policy Directive, Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services.
- NSW Health, Policy Directive, Outpatient Pharmaceutical Arrangements and Safety Net Arrangements (this includes information relating to discharge medication supply).
- Victorian Pharmacy Authority, Victorian Pharmacy Authority Guidelines.

5.5 ASEPTIC PRODUCTION SUITES

5.5.1 Relevant Standards

Many standards related to Pharmacy Manufacturing Units have been updated in recent years and several are still being finalised. Relevant standards at the time of publication of this HPU include:

- AS 2252-5: 2017 Cytotoxic drug safety cabinets (CDSC) - Design, construction, installation, testing and use
- AS2252-6: 2011 Clean workstations - Design, installation and use
- AS4273-1999 Design, Installation and Use of Pharmaceutical Isolators (Standards Australia, 1999) (due for revision as AS 2252-7 Pharmaceutical Isolators in 2021)
- AS/ISO 14644-1: 2017 Classification of air cleanliness by particle concentration
- AS/ISO 14644-2: 2017 Monitoring to provide evidence of cleanroom performance relating to air cleanliness by particle concentration
- AS/NZS ISO 14644-4:2002 Cleanrooms and Associated Controlled Environments (Standards Australia, 2002) Part 4: Design, Construction and Start-up, is of particular relevance when planning for hospitals. There is a requirement for four controlled zones cascading from 'cleanest' to 'least clean'
- Pharmacy Board of Australia – Guidelines on compounding of medicines, 2017
- PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments PE 010-4 (PIC/S, 2014)
- The Society of Hospital Pharmacists of Australia (SHPA) Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments, Journal of Pharmacy Practice and Research. Current SHPA Standards of Practice are listed here: https://www.shpa.org.au/standards-of-practice
- Position Statement: Safe Handling of Monoclonal Antibodies in Healthcare Settings (Clinical Oncological Society of Australia (COSA), 2013)

5.5.2 Building Services Requirements

The design of aseptic production suites should:

- limit airborne particles as specified by AS/NZS ISO 14644.1:2017 Classification of air cleanliness by particle concentration;
- define and control airflow patterns;
- control temperature and humidity through the provision of a dedicated HVAC plant. Within the cleanroom, a temperature maintained between 17ºC and 19ºC and a relative humidity between 30% and 60% is suitable;
- regulate air pressure;
- define and control volatile and hazardous agents;
- eliminate the use of floor penetrations (sinks, basins and floor waste) in change rooms and cleanroom. A Type B basin should be located in an adjacent location to the change room entry with hands free operation; and
- support a range of operating procedures and processes that can be validated.

Classification of Air Cleanliness

Classification of cleanrooms is normally performed to either EU GMP PIC/S or ISO14644 Part 1. These classifications relate to the number of particles of a certain size per cubic metre. The EU GMP Grades can be related to the ISO Classes.

The EU GMP Grade A to D requirements are noted below. Both viable particle counts (for particles containing one or more living microorganisms) and non-viable particle counts are performed. This is undertaken as part of the certification of a cleanroom and during regular environmental monitoring.

EU GMP Pic/s Requirements:

Grade	Maximum permitted number of particles/m³ equal to or greater than the tabulated size			
	At rest		In operation	
	0.5µm	5.0µm	0.5µm	5.0µm
A	3,520	20	3520	20
B	3,520	29	352,000	2,900
C	352,000	2,900	3,520,000	29,000
D	3,520,000	29,000	not defined	not defined

Air Pressure Requirements

For the majority of aseptic production suites (i.e. with clean workstations or cytotoxic drug safety cabinets), the following four controlled zones are required:

- an airlock designed as a change room with Grade B quality air;
- cleanroom with Grade B quality air;
- a preparation area that accommodates yet provides separation between a decontamination and reconciliation / finished goods area with Grade C quality air; and
- labelling, documentation and storage space with Grade D quality air. A corridor will usually provide connection between this area and the change room. This corridor will be part of the suite and will blend from Grade C to D in operation.

There are different air pressure requirements for aseptic production suites using containment isolators given the isolator itself provides the sterile environment and a complete barrier between the product and the technician. Containment isolators are configured to operate at positive pressure for non-hazardous products or negative pressure for the handling of hazardous products.

5.5.3 Finishes / Materials

Specialised materials and construction methods will be required. The materials used within the suite will be smooth, impervious and resistant to physical abrasion, disinfectants, detergents and particle generation. Ceilings will be constructed of anodized aluminium or polymer sheet or coating. Coving of the floor, wall and ceiling interfaces is required using a finish which does not conceal unknown physical damage (e.g. water leaks). Floor coverings should be non-porous, abrasion and chemical resistant and should support dynamic loads.

The use of glass in aseptic production suites is useful as it allows staff to be supervised. These suites are often isolated or separated from the main department, so staff isolation can occur.

5.5.4 Cleanrooms – General Requirements

The cleanroom should only contain the following:

- Workstations, drug safety cabinets or containment isolators – refer to information below.
- A trolley containing minimum access stock used in the compounding process (needles, syringes, filters, IV 'drip' bags, etc.)
- Large waste bins.
- For preparation of cytotoxic medications or hazardous materials, specialised safety equipment such as a heat sealer for sealing bags of contaminated waste can be present.
- Top loading balances and bar-code readers may also be present.
- Apart from the entry door, the only other penetrations into the room are HEPA filtered double-door (inter-locked) materials transfer hatches between the cleanroom and the preparation room. Ideally, there are two of these hatches – one from the decontamination zone and the other out into the reconciliation zone. Access hatches to the ceiling space are not permitted. Light fittings should be sealed and accessible from the ceiling space.
- To ensure air does not travel from the change room to the cleanroom, a high level HEPA supply for the change room immediately above the door to the cleanroom with a low level return adjacent to the external change room door will create a flushed tunnel.
- Aseptic suites may include a clean workstation or isolator.
    - An open fronted clean workstation, which is classed as a Grade A environment, must be installed into a Grade B environment, complying to AS2252-6, and the relevant gowning requirements must be adhered to.
    - An isolator is considered a 'mini environment', and, although this is also a Grade A environment, the environment it is installed in can be reduced, normally to a Grade C environment.
- Cytotoxic suites may include a drug safety cabinet or containment isolator.
    - An open fronted clean workstation, which is classed as a Grade A environment, must be installed into a Grade B environment that complies with AS2252-5. This includes a requirement for a 100% outside air cleanroom design that does not allow for any exhausted air from the cleanroom being recirculated. The relevant gowning requirements must be adhered to.
    - An isolator is considered a 'mini environment', and, although this is also a Grade A environment, the environment it is installed in can be reduced, normally to a Grade C environment. In addition, the air from the isolator is exhausted either to the outside, or through a carbon filter. There is no requirement for a 100% outside air system.
- In some cases, the use of CCTV will allow a pharmacist to check doses prepared by technicians.

5.5.5 Aseptic Dispensing Cleanroom Containing Clean Workstations

- Aseptic cleanrooms containing clean workstations shall be designed as per AS2252-6: 2011 and tested to the requirements of AS/ISO 14644-3: 2020 (soon to be adopted by AS).
- The main cleanroom, Grade B, shall be at least 10-15Pa above the change room and be designed with not less than 20 air changes per hour. HEPA filter velocities should not exceed 0.6 m/s.
- The change room shall be at least 10Pa greater than the surrounding area.

- The cleanroom shall have high level HEPA supply air with low level return air designed to ensure that the particulate contamination within the room meets the requirements for Grade B.
- Doors between the change room and the outer area shall open into the change room. Doors between the change room and the main compounding room shall open into the main cleanroom. They shall be interlocked so that more than one door cannot be opened at any time.

Clean Workstations

- Aseptic compounding of non-cytotoxic, non-hazardous materials takes place within the confines of horizontal unidirectional Air Flow workstations (CWS), as defined in AS2252-6: 2011, typically 1200mm wide by 760mm height (depending on the products being prepared). PIC/S recommends use of 'single operator' workstations to minimise risk of 'mix ups', and airflow disruption.
- A typical hospital pharmacy aseptic production suite requires more than one workstation. If additional workstations are needed, they should be arranged in a line so that airflow from one cannot interfere with another.
- Clean workstations preserve the sterility of already sterilised objects introduced into them and only offer product protection.
- Clean workstations shall be certified to meet the requirements of AS2252-6: 2011 using test methods contained in AS1807: 2020 (soon to be published).

5.5.6 Cytotoxic Cleanroom with Cytotoxic Drug Safety Cabinets

- Cytotoxic cleanrooms shall be designed as per AS2252-5: 2017 and tested to the requirements of AS/ISO 14644-3: 2020 (soon to be adopted by AS).
- The main cleanroom, Grade B, shall be approximately 10 to 20Pa below the change room, in order to ensure containment, and be designed with 30 to 40 air changes per hour. HEPA filter velocities should not exceed 0.6 m/s.
- The change room shall be at least 30Pa greater than the surrounding area.
- The cleanroom shall have high level HEPA supply air with high and low level return air designed to ensure that the particulate contamination within the room meets the requirements for Grade B.
- The cleanroom shall be designed with no recirculation of the air exhausted from the cleanroom or change room.
- All air exhausted from the cytotoxic drug safety cabinets shall be captured by an HEPA filtered exhaust canopy. Air must be discharged to atmosphere according to AS1668.2.
- Doors between the change room and the outer area shall open into the change room. Doors between the change room and the main cytotoxic room shall open into the change room. They shall be interlocked so that more than one door cannot be opened at any time.
- Used garments shall be stored in an area classified to the same requirements as the main cleanroom.

Cytotoxic Drug Safety Cabinets

- Cytotoxic compounding takes place within the confines of cytotoxic drug safety cabinet (CDSC), as defined in AS2252-5: 2017. PIC/S recommends use of 'single operator' CDSCs to minimise risk of 'mix ups', and airflow disruption.
- A typical hospital pharmacy cytotoxic production suite requires more than one CDSC. If additional CDSCs are needed, they should be arranged in a line so that airflow from one cannot interfere with another.

- CDSCs preserve the sterility of already sterilised objects introduced into them and offer a degree of protection to the operator and the environment.
- CDSCs shall be certified to meet the requirements of AS2252-5: 2017 using test methods contained in AS1807: 2020 (soon to be published).

5.5.7 Cleanrooms with Containment Isolators

- Cleanrooms containing containment isolators should be designed with minimum requirements of a Grade C cleanroom including high level terminal HEPA filters and a low-level return air. In addition, a change room should be adopted.
- Isolators shall have unidirectional Grade A air quality.
- The room shall be tested to the requirements of AS/ISO 14644-3: 2020 (soon to be adopted by AS).
- The main cleanroom, Grade C, shall be at least 10Pa below the change room and be designed with a minimum of 20 to 25 air changes per hour. HEPA filter velocities should not exceed 0.6 m/s.
- The change room shall be at least 10Pa greater than the surrounding area.
- Doors between the change room and the outer area shall open into the change room. Doors between the change room and the main compounding room shall open into the main cleanroom. They shall be interlocked so that more than one door cannot be opened at any time.
- Transfer chambers with electromagnetic timed interlocks and high air change rates for total suppression of airborne contamination during material transfers in and out, and for rapid evaporation of disinfecting agents shall be used.
- It is recommended that an isolator with two transfer hatches, one for goods in and one for goods out, should be used. This enables a good flow for materials through the isolator. Transfer hatch times should be able to be able to be adjusted and set to ensure that hatches cannot be opened until materials are fully ‘flushed’ inside the transfer hatch.
- Pressure decay testing of the isolator shall be performed on a regular basis based on a risk assessment performed by the user. A pressure decay test is an important test to ensure that the operator and/or material being manufactured inside the isolator are not compromised.

Aseptic Containment Isolators

- Aseptic Containment Isolators shall be positive pressure.
- Exhaust air from the isolator can be returned into the cleanroom.

Cytotoxic Drug Containment Isolators

- Cytotoxic Drug Containment Isolators shall be negative pressure.
- Exhaust air from the isolator should not be returned into the cleanroom, but if it is, it must be through a carbon filter fitted on the discharge of the isolator. This carbon filter must be replaced at least annually. Where exhaust air from the isolator is exhausted to outside, this shall be by a thimble connection, or direct coupling of the exhaust ductwork to the isolator, however, an anti-backdraft damper must be fitted into the exhaust ducting to ensure that this isolator cannot be affected by outside air conditions. Exhaust ducting must comply with the requirements of AS1668 Part 2.

5.5.8 Change Room

- In addition to a change room, there may be a requirement for an ante room.

- Floor and wall junctions should be coved.
- No penetrations to be used within this space and a hand basin should be located outside of this room.
- The change room area close to the cleanroom shall be classed as a Grade B area.
- To achieve zoning within the change room, a stainless-steel bench (not fixed) extending two-thirds of the width of the room may be used with staff sitting on the seat to don cleanroom garments. Once boots are on, the booted foot swings across to the clean side. The use of different colour vinyl can demarcate these zones.
- This room should be 'flushed' with HEPA filtered air from the cleanest end (entry into the cleanroom) to the least clean (exit into the outer zone).
- Doors between the change room and the outer area shall open into the change room.
- The door swing will vary depending on the type of aseptic production as noted above.

5.5.9 Preparation Room

- The workflow should support a continuous forward pathway from assembly to decontamination to processing to reconciliation to checking and product release in a circular fashion. The floor space for these areas is significantly greater than is required for the cleanroom.
- This room will include two distinct zones - one zone is for the assembly of raw materials and consumables, and decontamination of them; and the second zone is for the reconciliation of finished goods. The area must be designed with adequate bench space to ensure separation is achieved being raw materials being processed and finished products.
- A hand basin should be provided outside the entry to the Preparation Room. No floor penetrations are permitted in this room.
- A safety shower and eye wash station are required adjacent to the entry of containment cleanroom suites.
- A single entry for staff into this room is possible with staff not having to travel through one zone to reach the other. However, separate preparation rooms are required for sterile and containment suites to avoid cross contamination.
- Double door pass-through hatches with interlocking doors are installed in walls between clean zones to permit passage of materials and finished products from one classified zone to a zone of greater or lesser classification. The doors are typically mechanically or electrically interlocked so that while one door is open, the other is locked closed.

Pass through hatches between a cytotoxic cleanroom and preparation room shall be HEPA filtered.

Preparation Room – Decontamination Zone

- This space is located within the Preparation Room but in a separate zone.
- Activities carried out in this room include the assembly of raw materials and sterile-wrapped consumable items (needles, syringes, etc.) into prescription orders, checking consistency with process documentation and surface decontamination with suitable disinfectants and in a suitable manner, before placing each 'prescription' in an individual sanitised 'tote' bin.
- The prescription components, consumables and any specialised equipment is then organised into segregated lots prior to introduction to the cleanroom via a pass-through hatch. A significant amount of bench space is needed so that opportunities for 'mix ups' are minimised. Uncluttered benches are needed.

Preparation room – Reconciliation / Finished Good Zone

- This space is located within the Preparation Room but is in a separate zone. Activities carried out in this room include reconciliation of components, assuring concurrence with process documentation.
- A significant amount of amount of bench space is needed. Opportunities for 'mix ups' must be minimised, so uncluttered benches are needed.

5.5.10 Labelling, Documentation, Storage Area

- Used for a range of functions, including documentation, using computers and printing information such as labels. Some storage for associated documentation will be needed.
- Storage of some medications, including some refrigerated items, will be required.
- Storage of consumables on shelving may be required. Items should be removed from boxes to minimise particles.
- A wet area for cleaning items such as 'tote' bins and equipment may be required and may also house an autoclave.

5.5.11 Other Considerations

Testing and Certification

Testing and certification of Grade A and Grade B areas shall be performed at least 6 monthly by a NATA accredited testing laboratory.

Testing and certification of Grade C and Grade D shall be performed at least annually by an accredited testing laboratory.

Accredited testing laboratories shall be accredited to ISO17025.

Testing and certification of cleanrooms shall be tested as per the requirements of AS/ISO14644-3: 2020 (soon to be adopted as an AS)

Testing and accreditation of Clean Workstations, Cytotoxic Drug Safety Cabinets and Containment Isolators shall be tested as per the requirements of AS1807: 2020 (soon to be published).

Cleanroom Consumables

Garments to be reused shall be stored in an area classified to the same requirements as the main cleanroom.

When considering the consumable needs for the cleanroom (garments, gloves, wipers, face masks, disinfectants) the following factors should be considered;

- Grade A and B areas require sterile products.
- Non-sterile consumables can be used in Grade C and D and unclassified areas.
- Should disposable or reusable consumables be used?

It is important that users ensure that the consumables used are compatible for the requirements they are to be used for and that they are certified and validated, to ensure that the cleanroom can maintain the cleanliness required.

Ideally, all cleanroom consumable products should be manufactured, washed and packed in cleanrooms ranging from ISO Class 4 – ISO Class 5 with carton packaging and manufacturing in a minimum ISO Class 7.