

Australasian Health Facility Guidelines

Part B - Health Facility Briefing and Planning 0560 - Pharmacy Unit

Uncontrolled when printed

COPYRIGHT AND DISCLAIMER

Copyright

© 2015 Australasian Health Infrastructure Alliance

The Australasian Health Facility Guidelines (AusHFG) and the information in them are the copyright of the Australasian Health Infrastructure Alliance (AHIA). The information in the AusHFG is made freely available.

Australasian Health Facility Guidelines

Address: PO Box 1060, North Sydney NSW 2059
Website: <http://www.healthfacilityguidelines.com.au>
Email: webmaster@healthfacilityguidelines.com.au

The AusHFGs are an initiative of the Australasian Health Infrastructure Alliance (AHIA). AHIA membership is comprised of representatives from government health infrastructure planning and delivery entities in all jurisdictions in Australia and New Zealand.

Disclaimer

AHIA gives no warranty or guarantee that the information in the AusHFG is correct, complete or otherwise suitable for use. AHIA shall not be liable for any loss howsoever caused whether due to negligence or otherwise arising from the use of or reliance on this information.

AHIA recommends that those seeking to rely on the information in the AusHFG obtain their own independent expert advice.

Index

01 INTRODUCTION	4
01.01 Preamble	4
01.02 Introduction	4
01.03 Policy Framework	4
01.04 Description	4
02 PLANNING	6
02.01 Operational Models	6
02.02 Operational Policies	7
02.03 Planning Models	9
02.04 Functional Areas	9
02.05 Functional Relationships	11
03 DESIGN	12
03.01 Accessibility	12
03.02 Parking	12
03.03 Disaster Planning	12
03.04 Infection Control	12
03.05 Environmental Considerations	12
03.06 Space Standards and Components	13
03.07 Safety and Security	14
03.08 Finishes	14
03.09 Fixtures, Fittings & Equipment	15
03.10 Building Service Requirements	15
04 COMPONENTS OF THE UNIT	19
04.01 Standard Components	19
04.02 Non-Standard Components	19
AX APPENDICES	24
AX.01 Schedule of Accommodation	24
AX.02 Functional Relationships / Diagrams	26
AX.03 Checklists	26
AX.04 References	27
AX.06 Cleanroom Layouts	29
AX.07 Further Reading	30
ATTACHMENTS	32
Attachments	32

01 INTRODUCTION

01.01 Preamble

This Health Planning Unit (HPU) has been developed by the Australasian Health Infrastructure Alliance (AHIA) following extensive consultation during 2014. This HPU is intended to assist in the planning and design process for the design team, project managers and end users.

01.02 Introduction

This HPU outlines the specific requirements for planning and designing a Pharmacy Unit.

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 and Section 90, Standard Components, Room Data Sheets and Room Layout Sheets;
- Part C: Design for Access, Mobility, OHS and Security;
- Part D: Infection Prevention and Control; and
- Part E: Building Services and Environmental Design.

01.03 Policy Framework

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

- Guiding Principles to Achieve Continuity in Medication Management (Australian Pharmaceutical Advisory Council (APAC), 2005);
- Australian Commission on Safety and Quality in Healthcare Standards (Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2012);
- National Vaccine Storage Guidelines: Strive for 5 (Australian Government Department of Health and Ageing, 2013);
- Codes, Guidelines and Policies (Website) (Pharmacy Board of Australia, 2015); and
- SHPA Practice Standards (Website) (The Society of Hospital Pharmacists of Australia (SHPA), 2015).

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

01.04 Description

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

- inpatient and outpatient dispensing;

- maintenance and monitoring of inpatient drug distribution systems;
- patient advisory services including admission and discharge planning, liaison with community providers, counselling and compliance monitoring;
- controlled storage, recording and distribution of narcotics and accountable substances;
- manufacture / preparation of non-sterile compounds, known as extemporaneous compounds (lotions, ointments etc.);
- sterile manufacturing and IV admixture services (e.g. parenteral nutrition and cytotoxic preparations);
- utilisation review and adverse drug reactions reporting;
- drug monitoring, information and advisory services;
- quality programs including antimicrobial stewardship;
- staff education and training; and
- management of drugs for specialised programs such as clinical trials and S100 medications.

02 PLANNING

02.01 Operational Models

MODEL OF SERVICE DELIVERY

Pharmacists play an important role as part of the multidisciplinary healthcare team.

Increasingly medication management is being enhanced through the use of technology including e-medication systems, bar coding, tele-pharmacy, robotics and automated dispensing systems. Many of these systems have been reported to:

- reduce the space required to store medicines (Evaluation of an Automated Dispensing System in a Hospital Pharmacy Dispensary, *The Pharmaceutical Journal*, Vol 274, pp763-765 (R. Fitzpatrick, P. Cooke, C. Southall, 2005));
- improve service quality (Evaluation of an Automated Dispensing System in a Hospital Pharmacy Dispensary, *The Pharmaceutical Journal*, Vol 274, pp763-765 (R. Fitzpatrick, P. Cooke, C. Southall, 2005), Case study: Novel Ways Automation Enhances Medication Safety , *American Journal of Health-System Pharmacy*, Vol 64, Issue 14, pp521-523 (Witkowski, Paul, 2007));
- improve medication safety through reduced errors (A Report Assessing the Impact of an Automated Dispensing System at Kings College Hospital (Brinklow, N, 2006); Witkowski, 2007);
- reduce recurrent costs (Impact of Pharmacy Automation on Patient Waiting Time: An Application of Computer Simulation, *Annals of the Academy of Medicine*, Vol 38, Issue 6, pp501-507 (Tan, Woan Shin. Et al, 2009));
- allow pharmacists to be reallocated for clinical pharmacy (A Report Assessing the Impact of an Automated Dispensing System at Kings College Hospital (Brinklow, N, 2006)); and
- efficiency (An Evaluation of Two Automated Dispensing Machines in UK Hospital Pharmacy, *International Journal of Pharmacy Practice*, Vol 16, pp47-53 (Franklin, B. et al, 2010)).

As pharmacists move between the Pharmacy Unit and clinical units, alternate work practices (such as the use of computer 'tablets') are being implemented to promote the interface with other electronic systems.

Drug information services are now delivered electronically with minimal use of hand-copy reference books.

The logistics management of medicines is also changing. Many health care organisations are implementing vendor managed inventory systems where medicines are delivered from the supplier direct to the point of use (e.g. inpatient unit). Pneumatic tube systems may also be used to transport selected medicine to and from the Pharmacy Unit.

As the role of pharmacists becomes more clinically focused, pharmacy technicians are increasingly being used.

Pharmacy services are ideally organised as a single Pharmacy Unit. This can maximise the utility of expensive technology and staff. This arrangement of service cannot always be achieved as health services seek to bring services closer to the patient. Examples include:

- an pharmacy collocated outpatient services; and
- chemotherapy pharmacy collocated with cancer services.

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. This will create specific requirements for storage, packing and dispatch of goods. In addition, alternate delivery systems such as tele-pharmacy may be needed.

02.02 Operational Policies

GENERAL

Operational policies impact on the capital and recurrent costs of a facility. The cost implications of proposed policies should be fully evaluated to ensure the most cost-effective and efficient solutions are provided.

Refer to Part B: Section 80 General Requirements for further information.

HOURS OF OPERATION

In general, the Pharmacy Unit will operate during weekday business hours with a limited service on Saturdays. An after-hours on call pharmacist service and/or after-hours drug cupboard, accessible to authorised staff, is used for emergencies

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.

The stock is then unpacked and decanted to the main store (for imprest medications) to support dispensing for inpatient and outpatient services. Storage will include open shelving, refrigerators and / or cool rooms and freezers (both general and specialised as used for selected clinical trial preparations) as there is an increasing number of medications that need to be refrigerated. Robotics storage systems are now available with units providing storage for stock including refrigerated products.

Schedule 8 medications will be stored separately in a large safe or strongroom. The safe will be large enough to store both stock on-hand and medications awaiting delivery to clinical areas. Adjacent to lockable storage, additional space will be needed for checking, registers and barcode equipment.

Alternatively, health services may utilise vendor managed inventory systems for imprest stock which are delivered from the dock to the point of use (e.g. inpatient unit).

Pharmacy Units in larger hospitals will usually require additional space to accommodate a range of activities including clinical trials, highly specialised drugs programs (Section 100) and medical access programs where access to new medicines is provided prior to the implementation of funding arrangements. Space impacts will include storage of medicines (including refrigerated storage) and protocols and dispensing.

A range of records will also need to be retained by the Pharmacy Unit.

STORAGE OF INTRAVENOUS AND DIALYSIS FLUIDS

A remote Bulk Store may be suitable for storing these fluids. In some cases, vendor managed inventory systems will be used and fluids, including dialysate will be delivered from the dock to the point of use.

The Pharmacy Unit will need to store limited supplies of intravenous fluids to reconstitute medicines and as a back-up supply.

ASEPTIC PRODUCTION SUITE

Selected health services, usually tertiary referral hospitals, will manufacture sterile products including intravenous admixtures, parental nutrition, cytotoxic drugs, antibiotics and monoclonal antibodies. These products are manufactured in an aseptic production suite which is a specially constructed and enclosed area. There are two types of aseptic production suites used to manufacture pharmaceuticals and related treatments:

- conventional suites used to manufacture sterile products such as parental nutrition; and
- containment suites used to manufacture cytotoxic drugs and other hazardous substances. These environments are capable of containing vapours and reduce opportunities for contamination of operators and the working environment.

Information related to relevant standards and design requirements are contained in the Design section of this HPU.

INTRAVENOUS ADMIXTURE

Local drug committees will determine who, other than the pharmacist, may prepare 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.

UNIT DOSE SYSTEMS

If a unit dose system is used, there will need to be additional space and equipment for supplies, packaging, labelling and storage, as well as medication carts.

AUTOMATED DISPENSING CABINETS

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 replenishment;
- impact on Pharmacy Unit storage;
- the impact on layout of clean utility / medication rooms in clinical units;
- building service requirements such as power and data outlets; and
- security considerations.

PHARMACEUTICAL BENEFITS SCHEME (PBS)

Reforms to the Pharmaceutical Benefits Scheme (PBS) have been implemented in all states except NSW and eligible patients can receive up to a month's supply of each medicine on discharge or when attending a public hospital as an outpatient. The Australian Government also provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions. These restricted medicines are dispensed to outpatients and those patients attending day services in a public hospital.

This may have implications for storage both bulk and in dispensing areas.

PNEUMATIC TRANSPORT SYSTEMS

Should pneumatic transport systems be used to transport medications and scripts, the location of the station within the Pharmacy Unit location of stations in both the Pharmacy itself and outlying units must be carefully reviewed to consider workflow and security. 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 drugs, glass and cytotoxic drugs.

ROBOTIC STORAGE AND DISPENSING

The use of robotic systems within Pharmacy Units may be considered to store medicines and automate inventory systems. Adoption of this technology is usually evaluated through a business case. These systems can also be used to:

- store a range of medicines including accountable drugs and items that require refrigeration;
- 'pick' medicines for imprest stock; and
- medication dispensing, including unit dosing.

The workflow and design considerations will need to be considered during design. In addition, IT integration of vendor and health service pharmacy management systems needs to be considered early in the project.

PATIENT SELF-MEDICATION PROGRAMS

These programs are usually not suitable in acute healthcare environments but may be considered for non-acute care services. A locked drawer in the bedside locker can be used to store medications.

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. Access to bookable rooms in inpatient and outpatient environments may also be needed. Other information will be provided to patients at the collection counter. This space will need to provide some level of privacy.

DISPENSING WORKFLOW

The use of technicians in Pharmacy Units is common. Dedicated dispensing stations will be needed that can accommodate stock and some consumables, a PC (one or two screens), a bar-coder, printers and space to store medications waiting to be checked by the pharmacist. This workflow will need to be redesigned if robotics systems are used.

WASTE MANAGEMENT

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

02.03 Planning Models

SINGLE UNIT

The Pharmacy Unit is usually a single self-contained facility, especially in small health services.

DEDICATED OUTPATIENT PHARMACY

In large facilities it may be necessary to establish a separate Outpatient Pharmacy if it is not possible to locate the main Pharmacy Unit in close proximity. This approach also collocates outpatient services in one easy to access location.

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 Pharmacy collocated with cancer services; and
- satellites supporting clinical services (e.g. a group of inpatient units). Many health services do not support this model as it duplicates stock and equipment and makes the use of technical staff problematic.

02.04 Functional Areas

FUNCTIONAL ZONES

Functional zones within a Pharmacy Unit include:

- entry / reception / waiting;
- after hours drug store;
- preparation areas including dispensing and sterile manufacture (where provided)
- goods receipt / bulk store / drug store area; and
- staff areas.

It is essential the arrangement of space within a Pharmacy Unit clearly demarcates public and restricted areas and accommodates workflows so medication errors are eliminated.

ENTRY / RECEPTION / 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 so 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.

An interview room will be located within this zone so pharmacists can provide counselling regarding a patient's medicines. This room will ideally have two entry points, one from within the Pharmacy Unit and one from the waiting area. This room will need to be secured when not in use so unauthorised entry to the Unit is not possible.

In large and busy Units, it is ideal if the process for dropping-off scripts is separated from the collection of medicines to promote better work flows. The location of a cashier needs to be considered as many transactions require payments.

AFTER HOURS DRUG STORE

An after-hours drug store may be part of the Pharmacy Unit accessible from the outside or located in a 24 hour zone of the health service.

MEDICATION PREPARATION AREAS

Major areas include:

- **imprest:** Storage and preparation space is required for items to be transferred to clinical units. Storage will be required for a range of medicines including bulky items, medication packets 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). Barcoding scanners 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;
- **dispensing:** Storage is required for a range of medicines such as medication packets and refrigerated storage. Medications are 'picked' and taken to a dispensing station. Where this work is undertaken by technicians, a dispensing station for a Pharmacist is needed to check each medication. Medications are then collected by a patient, sent to a clinical area or stored within the Unit awaiting collection;
- **accountable drugs:** Pharmacists prepare imprest stock for clinical units adjacent to the safe / strongroom. A workspace is needed for preparation, administration and storage of registers. The medications may be collected by clinical staff so access needs to be considered; and
- **extemporaneous manufacture:** An area is usually provided to manufacture selected non-sterile preparation such as creams.

GOODS RECEIPT / BULK STORE / DRUG STORE

Newly delivered stock should be received in a good receipt area of the Unit so the newly arrived stock can be processed, checked and unpacked at a bench. This area will also require access to a workstation to support purchasing activities.

The storage of expired and returned stock should be in a separate area so it is not confused with current stock.

The requirements for storage of old accountable drugs registers have recently increased from two years to seven years and some pharmacies also store completed registers. This may be transferred to an off-site location after a few months.

STAFF AREAS

This area will include a visitor reception, office space, a meeting room and staff amenities. In addition, this area will provide space for drug information staff and auditing activities.

OPTIONAL AREAS

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

- sterile manufacturing, which may include sterile and cytotoxic manufacturing cleanroom suites; and
- facilities for clinical trials including dispensing areas (including refrigerated space), secure storage and office space.

ASEPTIC PRODUCTION SUITE

While air conditioning and other design requirements will vary between conventional and containment aseptic production suites, the overall layout and workflow is consistent.

The aseptic production suite consists of four zones:

- an airlock designed as a change room;
- cleanroom;
- a preparation area that accommodates yet provides separation between a decontamination and reconciliation / finished goods area; and
- documentation, bulk assembly and storage space.

Staff accessing the suite must 'change' before they enter. This involves 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. Staff working in the cleanroom will receive decontaminated equipment and materials from the decontamination zone via a pass-through hatch. When product is manufactured, it is sent via another pass-through hatch to the reconciliation zone.

It is possible for the decontamination and reconciliation zones to be located within one room (to be referred to as a preparation room) where the functions are separated and each has a dedicated pass-through hatch into the cleanroom. External access to these rooms will be needed as these spaces will not be directly accessed via the change room or cleanroom (excluding pass-through hatch arrangements).

02.05 Functional Relationships

EXTERNAL

Access to a loading dock and bulk storage if this is not part of main Pharmacy Unit. Easy access is required to all clinical areas within the health service. Where patients pay for medicines, access to the main cashier may be required.

INTERNAL

Refer to the Functional Relationship Diagram.

03 DESIGN

03.01 Accessibility

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 (i.e. Vendor Managed Inventory).

INTERNAL

Points of access are required by:

- pharmacy staff;
- visitors;
- other staff collecting scripts;
- outpatients delivering and collecting scripts and medications; and
- supplies delivery.

03.02 Parking

This clause is not applicable, but has been included for consistent HPU clause numbering.

03.03 Disaster Planning

Consideration needs to be given to requirements for storage of large volumes of selected medications such as antibiotics and Tamiflu.

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

03.04 Infection Control

Hand hygiene facilities should be provided in each room / space where medicines are handled.

Specific requirements relating to clean rooms are outlined in the Non-Standard Components of this HPU.

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

03.05 Environmental Considerations

GENERAL

Controlled temperature and humidity is required for drug storage and internal temperatures should not rise above 25oC.

ACOUSTICS

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

NATURAL LIGHT

The Pharmacy Unit should have access to natural light and external views where possible. Good lighting within a Pharmacy Unit is associated with a significantly lower rate of dispensing errors. 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.

For further information refer to Illumination and Errors in Dispensing, American Journal of Hospital Pharmacy, Vol 48, Issue 10, pp2137-2145 (Buchanan, T.L et al, 1991).

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 as shown in the picture below.



03.06 Space Standards and Components

ERGONOMICS

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

Equipment, such as spring-loaded trolleys, may assist staff move large parcels onto preparation benches.

Dispensing workstations should be arranged so workflows are accommodated and the potential for error reduced. These stations should be arranged so 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 Part C: Section 790, Safety and Security Precautions for information.

HUMAN ENGINEERING

Refer to Part C: Section 730, Human Engineering for information.

ACCESS AND MOBILITY

Refer to Part C: Section 730, Human Engineering for information.

DOORS, WINDOWS AND CORRIDORS

Doorways should be wide enough to facilitate the delivery of large amounts of stock, including pallets. Where shelving is used to store medications, corridors should be a minimum of 750mm wide to provide access to staff and trolleys.

Reinforce windows on the perimeter walls to prevent entry. Refer to Part C: Section 710, Space Standards and Dimensions for information.

03.07 Safety and Security

Duress alarms should be located at the outpatient dispensing counter.

Staff accessing the Pharmacy Unit should be restricted. Staff entries will be separated from public / general staff entry points.

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

CCTVs will be used to monitor entry points and drug safe. All external doors will be operated with access control with only authorised staff permitted access. 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 so they cannot be left open.

An intruder alarm system should be installed and centrally monitored when the Unit is unoccupied. External entry points should be well lit.

Also refer to Part C: Section 790, Safety and Security Precautions for additional information.

03.08 Finishes

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 to prevent any intrusion over the wall or from the ceiling cavity.

Wall protection will be required to prevent damage from trolleys. Also refer to Part C: Design for Access, Mobility, OHS and Security, Space Standards and Dimensions.

FLOOR FINISHES

Floors should be constructed of a solid material. Carpet is not suitable in areas where medicines are handled. For further information refer to Part C: Design for Access, Mobility, OHS and Security, Space Standards and Dimensions.

CEILING FINISHES

Ceilings should be constructed of a solid material. For further information refer to Part C: Design for Access, Mobility, OHS and Security, Space Standards and Dimensions.

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 shopfront areas should use shatterproof glazing, noting communication still needs to be facilitated.

03.09 Fixtures, Fittings & Equipment

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

The colour of dispensing benches should provide a contrast so packaging and medicines can be easily identified.

Where medicines 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. This improves identification; and
- separating medicines (e.g. dispensary storage from medications awaiting collection).

Accountable drugs will be stored in safes or strongrooms that comply with AS/NZS 3809:1998 Safes and Strongrooms (Standards Australia, 1998). Very large safes may require the floor to be strengthened.

For more detailed information refer to the RDS and RLS and to:

- Part C: Section 710, Space Standards and Dimensions; and
- Part F: Section 680 Furniture Fittings and Equipment.

03.10 Building Service Requirements

INFORMATION TECHNOLOGY / COMMUNICATIONS

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

- networked computers, either fixed PCs or 'tablets' to review clinical information and increasingly, review and process electronic medication orders;
- barcoding systems to reduce errors;
- robotics, both dispensing and manufacturing systems;
- integrated medication management systems that will include electronic ordering;
- security systems such as fixed duress; and
- teleconferencing / tele-pharmacy facilities.

All refrigerators, freezers and cool rooms used to store medications should be powered by emergency power so 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, so staff are notified in case of a system failure.

ELECTRONIC MEDICATIONS MANAGEMENT

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

The impacts to Pharmacists may include the need for dual screen 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, 2012).

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.

ROBOTICS

Robots are being increasing use to store and dispense medications. These units will require power and data. These units will range in size from approximately two metres through to much larger units and will usually replace space previously allocated to medication shelving.

Larger services may in future consider robotic systems to manufacture chemotherapy products. Floor loads will need to be considered where large robotic systems are installed.

ALARM SYSTEMS

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

ASEPTIC PRODUCTION SUITE

As the aseptic compounding of medicines is a three-stage process, it is a common mistake to allocate the most space within the cleanroom and not enough within preparation areas. The schedule of accommodation is indicative of space requirements.

Aseptic production suite design elements have been summarised by the Guidelines for Design and Construction of Hospital and Health Care Facilities (ASHRAE, 2006). The design should:

- limit airborne particles as specified by AS/NZS ISO 14644.1:2002 Cleanrooms and Associated Controlled Environments (Standards Australia, 2002);
- define and control airflow patterns;
- control temperature and humidity through the provision of dedicated HVAC plant. Within the cleanroom, a temperature maintained between 17 and 19°C is suitable;
- regulate air pressure. In conventional suites, the highest air pressure is in the cleanroom;
- employ the use of specialised materials and construction methods. The materials used within the suite will be smooth and resistant to physical abrasion, cleaning fluids and particle generation. Any use of wood should be sealed. Ceilings will be constructed fixed plaster board. The selected use of glass walls and doors allow staff good vision to and from rooms within the suite and reduces the feeling of isolation. Vinyl with coved skirtings should be used on the floors;
- define and control volatile agents. Containment suites will require the air supply to be 100% exhausted with air changes per hour not less than 40; and
- support a range of operating procedures and processes that can be validated.

- Additional measure will include:
- eliminating 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; and
- coving of the wall and ceiling using a finish which does not conceal unknown physical damage (e.g. water leaks).
- In conventional suites, air pressure is controlled and cascades from highest (cleanest) to lowest (ambient, uncontrolled air). Four controlled zones are defined including:
 - 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 is provided; and
 - documentation, bulk assembly and storage space with Grade D quality air is provided.

A corridor will usually provide connection between the documentation / storage area and change room. This corridor will be part of the suite and will blend from Grade C to D.

To ensure air does not travel from the change room to the cleanroom, a high level HEPA supply for the changing room immediately above the door into the cleanroom with a low level return adjacent to the change room door will create a flushed tunnel.

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. In cases where glass is not an option, CCTV may be used. In some cases, the use of CCTV will allow a pharmacist to check doses prepared by technicians.

Many standards related to Pharmacy Manufacturing Units have been updated in recent years and several are still being finalised. Refer to:

- ASHRAE Applications Handbook (ASHRAE, 2002);
- AS1386-1989 Cleanrooms and Clean Workstations (Standards Australia, 1989), noting parts 5 and 7 were superseded by ISO 14644 in 2002;
- AS 2567-2002 Laminar Flow Cytotoxic Drug Safety Cabinets (Standards Australia, 2002). This is likely to be superseded by AS2252, Part 5 (refer below);
- AS2639-1994 Laminar Flow Cytotoxic Drug Safety Cabinets – Installation and Use (Standards Australia, 1994) This is likely to be superseded by AS2252, Part 5 (refer below);
- AS4273-1999 Design, Installation and Use of Pharmaceutical Isolators (Standards Australia, 1999);
- AS/NZS ISO 14644:2002 Cleanrooms and Associated Controlled Environments (Standards Australia, 2002) Part 4 Design, construction and start-up is of particular relevant when planning for hospitals. There is a requirement for four controlled zones cascading from 'cleanest' to 'least clean';
- PIC/S Guide to Good Manufacturing Practice for Medicinal Products, PE 009-8 (PIC/S, 2009). The requirements outlined in this guide are aligned with AS/NZS ISO 14644;
- PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments PE 010-4 (PIC/S, 2014);
- AS2522-2011 Controlled Environments (Standards Australia, 2011), Parts 1-7 (Part 5 and 7 are currently being revised);
- The Society of Hospital Pharmacists of Australia (SHPA) Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments, Journal of Pharmacy Practice and Research (SHPA, 2006); and

- Position Statement: Safe Handling of Monoclonal Antibodies in Healthcare Settings (Clinical Oncological Society of Australia (COSA) , 2003).

It is anticipated that revised Standards will require negative pressure isolators being operated in Grade C cleanrooms. In that case, wearing of some types of cleanroom garments will be required.

Some conceptual layouts for aseptic production suites are shown in Appendices.

04 COMPONENTS OF THE UNIT

04.01 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: www.healthfacilityguidelines.com.au/standard-components

04.02 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.

ASSEMBLY - IMPREST

Description and Function

An area where technicians will assemble imprest supplies for inpatient units and other clinical areas of the health service.

Location and Relationships

Adjacent to the store – assembly / dispensing.

Collocated with dispatch / collection.

Considerations

Large volume of trolley and tote movements will need to be accommodated.

Depending of service volumes, each assembly bench will need to accommodate a PC, barcoding system and space for a trolley.

REPACKING AREA

Description and Function

This area is used by technicians and pharmacists to assemble and prepare items such as resuscitation kits, bowel preps, pre-packed medicines for imprest or emergency starter packs etc.

Location and Relationships

Adjacent to the store – assembly / dispensing.

Collocated with dispatch / collection.

Considerations

Sufficient bench space will be provided so that separation between batch numbers can be achieved.

Access to a PC, and label printer will be needed.

A discrete quarantine zone will be required so that checks by the pharmacist can be safely facilitated.

DISPENSING STATION

Description and Function

The areas where prescription drugs are assembled packaged and labelled and associated quality control procedures completed. Much of the dispensing will be undertaken by technicians and overseen and checked by pharmacists. Workflows should accommodate this practice. The outpatient and inpatient workstations will usually be separately defined and in large units may be two distinct but adjoining areas. A location for a pneumatic tube system station will be needed if installed.

Each workstation will provide a minimum of 0.6m² clear bench space and accommodate computers and label printers.

Location and Relationships

Adjacent to the store – assembly / dispensing and public counter (if collocated).

Considerations

Accessible storage space will be required for labels drug information sheets etc.

STORE – ASSEMBLY / IMPREST

Description and Function

A store located adjacent to both assembly and dispensing areas which stores medications and related materials that are routinely accessed.

Location and Relationships

Adjacent to assembly and dispensing areas. Also ideally located near the bulk store (if collocated with the Pharmacy Unit).

Considerations

Medications will mostly be stored on mobile pharmacy shelving (with the exception of bulky items) so that stock is easy to identify, access and rotate. Isles will be wide enough to accommodate trolleys as technicians will 'pick' stock and take to assembly or dispensing areas.

STORE / 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 (Non Sterile) area used for extemporaneous preparation.

Considerations

The area will require storage, a sink and drainer.

STORE - REFRIGERATED

Description and Function

A discrete area for the refrigerated storage of medicines.

Location and Relationships

Adjacent to assembly and dispensing 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.

DISPATCH / COLLECTION - INPATIENTS

Description and Function

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

Location and Relationships

Adjacent to assembly, repacking and dispensing areas.

Considerations

While most deliveries are planned and provided by the Pharmacy Service, staff may collect some items. This may require a video intercom system so pharmacy staff can identify those collecting medications.

A refrigerator will be collocated to store selected items

DISPENSING – CLINICAL TRIALS

Description and Function

A dedicated area where pharmacists store, prepare, assemble and label clinical trial medications. Comprehensive records are maintained and stored for extended periods.

Location and Relationships

Proximity to inpatient and outpatient dispensaries, cleanrooms.

Considerations

Stations for dispensing will be in line with other dispensing stations. Storage may be required for items waiting to be collected by patients or staff.

May be collocated in a specialist oncology treatment facility if predominantly clinical trials for cancer treatments.

Tertiary hospitals: Requirement for long term storage of clinical trial documentation requires special consideration for space allocation in accordance with the number of trials expected.

ASEPTIC PRODUCTION – CLEANROOM SUITE

Description and Function

An aseptic production suite, both conventional and containment, is made up of four zones configured into four separate rooms / spaces including:

- 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. 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). This is one room only; both a change room and an airlock are not required. Staff are not required to change their inner clothing or shower. Work clothes should be removed prior to entering the changing room. Cleanroom garments are donned within this Grade B controlled space;
- cleanroom;
- preparation area including two zones. One is for the assembly of raw materials and consumables, and decontamination of them. The second is for reconciliation, labelling and release of finished goods; and
- documentation, bulk assembly and storage space. This is where staff will work on computers etc.

Location and Relationships

As an aseptic production suite is a specially constructed and enclosed area, it may be located within a Pharmacy Unit or in the case of a chemotherapy production, collocated with cancer services.

Considerations

Change 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;
- 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;
- the door swing will vary depending on the type of aseptic production. The door will swing into the cleanroom in a conventional suite and into the change room in containment suites; and
- in the area outside this room, hooks will be needed for hanging outer garments and a mobile shelving unit will be needed to store cleanroom garments. An 'air blade' style hand dryer is provided instead of paper towels so that particulate matter arising from paper is eliminated.

Preparation Room - General:

- the workflow should support a continuous forward pathway from assembly to decontamination to processing to reconciliation to checking and product release. The floor space for these areas is significantly greater than is required for the cleanroom;
- a hand basin should be provided outside the entry to the Preparation Room. No floor penetrations are permitted in this room;
- a single entry for staff into this room is possible with staff not having to travel through one zone to reach the other;
- 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; and
- hatches ventilated by HEPA filtered air are preferred. For containment suites such as required for preparation of cytotoxic drugs and antibiotics, air for the filtered pass-through hatches will be sourced from, and returned to, the Cleanroom.

Preparation Room – Decontamination Zone:

- this space is located within the preparation room but in a separate zone;
- activities carried out in this room include assembly of raw materials and sterile-wrapped consumable items (needles, syringes, etc.) into prescription order, checking consistency with process documentation and surface decontamination with sterile alcohol before placing each 'prescription' in an individual sanitised 'tote' bin; and
- 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 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, labelling of product, checking and releasing finished goods; and
- a significant amount of amount of bench space is needed. Opportunities for 'mix ups' must be minimised, so uncluttered benches are needed.

Cleanroom:

- aseptic compounding of non-cytotoxic, non-hazardous materials takes place within the confines of horizontal laminar Air Flow workstations (LAF), typically 1300mm wide by 800mm deep. 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;
- isolators and workstations preserve the sterility of already sterilised objects introduced into them. The type chosen depends on the type of suite – conventional or containment. Isolators and Cytotoxic Drug Safety Cabinets (CDSCs) have vertical air flow, away from the operator. These are containment devices intended for handling cytotoxic drugs or other hazardous materials;
- a cleanroom is characterised by absence of fixtures or fittings. The equipment permitted within this space include workstations, (usually free-standing) and stainless steel trolleys used to assemble pre-processed materials and hold finished preparations (usually two for each workstation);
- a larger trolley contains the stock used in the process (needles, syringes, filters, spare masks, IV 'drip' bags, etc.) and large waste bins. For preparation of cytotoxic drugs 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 used, usually on dedicated stainless steel trolleys; and
- apart from the entry door, the only other physical objects are double-door 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.

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, may be required;
- storage of consumables on shelving may be required. Items should be removed from boxes to minimise particles; and
- a wet area for cleaning items such as tote bins and equipment may be required.

AX APPENDICES

AX.01 Schedule of Accommodation

A Generic Schedule of Accommodation for a Pharmacy Unit at Levels 3, 4, 5, and 6 follows.

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, Room/ Spaces are described as 'Optional' or 'o'. Inclusion of this Room/ Space will be dependent on a range of factors such as operational policies or clinical services planning.

ENTRY / RECEPTION / WAITING

AusHFG Room Code	Room / Space	SC / SC-D	Qty x m2 Level 3	Qty x m2 Level 4	Qty x m2 Level 5	Qty x m2 Level 6	Remarks
WAIT-10	Waiting	Yes	1 x 5	1 x 5	1 x 8	1 x 8	Discrete. 4 - 6 seats, some standing room
PHA-CO	Pharmacy Counter	Yes	1 x 9	1 x 9	1 x 9	1 x 9	Includes shelving for scripts.
MEET-9	Meeting Room, 9m2	Yes	1 x 9	1 x 9	1 x 9	1 x 9	Interview / counselling. Dual access from Waiting and Pharmacy.

AFTER - HOURS DRUG STORE

AusHFG Room Code	Room / Space	SC / SC-D	Qty x m2 Level 3	Qty x m2 Level 4	Qty x m2 Level 5	Qty x m2 Level 6	Remarks
AHDR	After Hours Drug Store	Yes	-	1 x 3	1 x 4	1 x 10	May be remote or may be at the Pharmacy perimeter with inside / outside access. Size will be dependent on operational practices and volume of medicines to be stored.

ASSEMBLY / DISPENSING AND PREPARATION

AusHFG Room Code	Room / Space	SC / SC-D	Qty x m2 Level 3	Qty x m2 Level 4	Qty x m2 Level 5	Qty x m2 Level 6	Remarks
	Assembly - Imprest		1 x 6	1 x 6	1 x 8	1 x 12	Requires bench space, PC, barcoding system and space for trolleys to "pick" and store items for delivery. Will be collocated with Dispatch / Collection.
	Repacking		-	-	1 x 6	1 x 10	Space allocation dependent on volume of items to be packed or repacked. Smaller service may use Assembly area when volumes are low.
	Dispensing Station		4 x 2.2	2.2	2.2	2.2	Base on 2.2m2 per pharmacist station. Inpatient and outpatient may need to be separate areas. Adjust for staffing.
	Assembly / Dispensing		1 x 9	1 x 9	1 x 24	1 x 36	Includes IPU stock. Dispensing supplies such as labels
STGN-8	Store - General, 8m2	Yes	-	1 x 4	1 x 6	1 x 8	Dispensing supplies such as labels.
	Store / Clean-up		-	1 x 3	1 x 4	1 x 4	Area to store measures etc. for dispensing and wash up / dry after use.
	Store - Accountable Drugs		1 x 4	1 x 6	1 x 8	1 x 8	May be a wall-mounted safe or a strongroom, depending on volumes. Near Assembly and Office for observation. Will also store drugs awaiting collection.
BHWS-B	Bay - Handwashing, Type B	Yes	1	1	1	1	Number dependent on layout.
	Office - Workstation, 4.4m2		-	-	1 x 4.4	1 x 4.4	Located adjacent to Store – Accountable Drugs.
	Store - Refrigerated		1 x 6	1 x 6	1 x 12	1 x 12	Refrigerators and freezers.
	Dispatch / Collection (Inpatients)		-	-	1 x 12(o)	1 x 20	Imprest trolleys.
PREP	Preparation Room - Non-sterile	Yes	1 x 10(o)	1 x 12	1 x 16	1 x 20	Preparation of extemporaneous compounds.
	Dispensing - Clinical Trials		-	-	1 x 12(o)	1 x 20	Includes space for storage and dispensing but excludes associated office space.
	Discounted Circulation		20%	25%	25%	25%	

ASEPTIC MANUFACTURING

AusHFG Room Code	Room / Space	SC / SC-D	Qty x m2 Level 3	Qty x m2 Level 4	Qty x m2 Level 5	Qty x m2 Level 6	Remarks
	Change Room		-	-	-	1 x 5	Used to don cleanroom garments.
	Cleanroom		-	-	-	1 x 18	Assumes a three station design.
	Preparation Room		-	-	-	1 x 20	
	Documentation, Storage Area		-	-	-	1 x 18	
	Discounted Circulation					25%	

Sizes based on a three station design within the cleanroom for either a sterile or containment suite but not a combined unit.

GOODS RECEIPT / BULK STORE / DRUG STORE AREA

AusHFG Room Code	Room / Space	SC / SC-D	Qty x m2 Level 3	Qty x m2 Level 4	Qty x m2 Level 5	Qty x m2 Level 6	Remarks
GRE	Goods Receipt - Pharmacy	Yes	1 x 5	1 x 5	1 x 14	1 x 18	Direct and / or from remote Bulk Store.
STBK-40	Store - Bulk	Yes	1 x 30	1 x 40	1 x 110	1 x 130	May include pallets. <i>Confirm size?</i> In Pharmacy or Stores.
	Office - Workstation, 5.5m2	Yes	-	-	1 x 5.5	1 x 5.5	Manager - stores, for ordering, receipting etc.
DISP-8	Disposal Room, 8m2	Yes	Shared	1 x 8	1 x 8	1 x 8	
CLRM-5	Cleaner's Room, 5m2	Yes	Shared	1 x 5	1 x 5	1 x 5	
STFS-10	Store - Files, 10m2	Yes	1 x 6	1 x 6	1 x 8	1 x 12	Old prescriptions, registers. Assumes off-site storage of archives.
STGN-9	Store - General, 9m2	Yes	-	-	1 x 20	1 x 20	May be part of bulk store. Access from sterile manufacturing suite.
	Discounted Circulation		20%	25%	25%	25%	

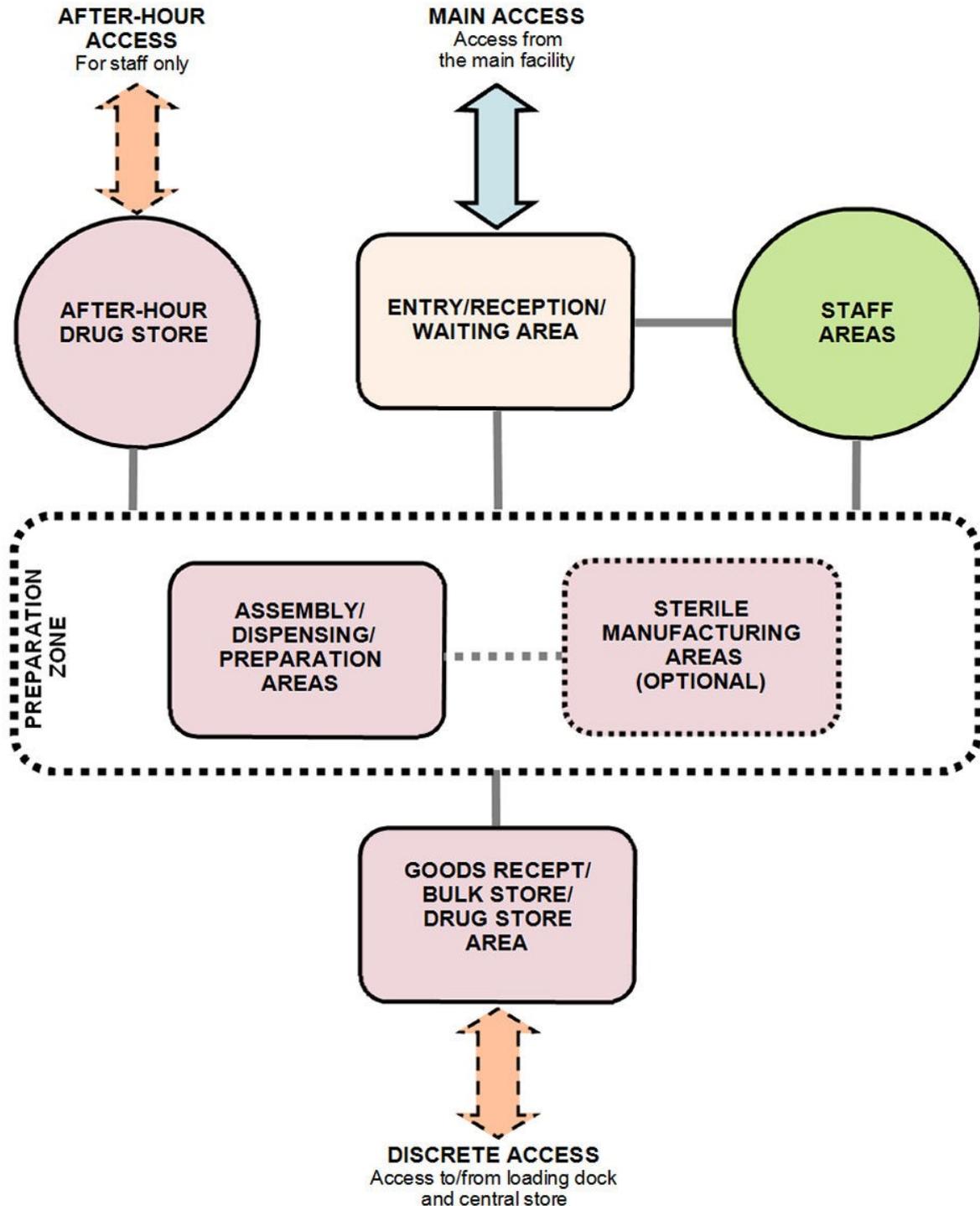
STAFF AREAS

AusHFG Room Code	Room / Space	SC / SC-D	Qty x m2 Level 3	Qty x m2 Level 4	Qty x m2 Level 5	Qty x m2 Level 6	Remarks
OFF-S9	Office – Single Person, 9m2	Yes	1 x 9	1 x 9	1 x 9	1 x 9	Drug information.
OFF-S12	Office – Single Person, 12m2	Yes	1 x 9	1 x 9	1 x 9	1 x 12	For Director.
	Office - Workstation, 4.4m2		-	4.4	4.4	4.4	As per Pharmacist / senior technician staff establishment.
STPS-8	Store - Photocopy / Stationery, 8m2	Yes	-	1 x 8 (o)	1 x 8	1 x 8	
MEET-12	Meeting Room, 12m2	Yes	-	1 x 12	-	-	
MEET-L-15	Meeting Room, 15m2	Yes	-	-	1 x 15	-	
MEET-L-20	Meeting Room, 20m2	Yes	-	-	-	1 x 20	
PROP-2	Property Bay - Staff	Yes	1 x 2	1 x 2	1 x 2	1 x 2	
BES	Bay - Emergency Shower	Yes	-	-	1 x 2	1 x 2	Emergency use. Should include eye wash.
BBEV-OP	Bay - Beverage, Open Plan, 4m2	Yes	1 x 3	1 x 3	-	-	For use by staff. Part of Meeting Room for Level 5 and Level 6.
SRM-15	Staff Room, 15m2	Yes	-	-	1 x 15	1 x 15	Includes Beverage Bay for Level 5 and Level 6.
WCST	Toilet - Staff, 3m2	Yes	1 x 3	1 x 3	3	3	Level 5 and Level 6 number dependent on staff establishment.
	Discounted Circulation		20%	25%	25%	25%	

Will depend on staff establishment.

AX.02 Functional Relationships / Diagrams

A diagram of key functional relationships is shown below. Please provide a higher resolution version.



AX.03 Checklists

A Security Checklist is attached in the "Security" Section. Refer also to Part C: Section 790, Safety and Security Precautions, Australasian Health Facility Guidelines (AHIA, 2015) for general requirements.

AX.04 References

- AHIA, 2010, Part C: Design for Access, Mobility, OHS and Security, Australasian Health Facility Guidelines (AHIA, 2010), Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- AHIA, 2010, AusHFG Part B: Section 90, Standard Components, Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- AHIA, 2010, Part B: Section 80 General Requirements, Australasian Health Facility Guidelines (AHIA, 2010), Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- AHIA, 2015, Part D: Infection Prevention and Control, Australasian Health Facility Guidelines (AHIA, 2015), Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- AHIA, 2010, Part C: Section 730, Human Engineering, Australasian Health Facility Guidelines (AHIA, 2010), Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- AHIA, 2010, Part C: Section 710, Space Standards and Dimensions, Australasian Health Facility Guidelines (AHIA, 2010), Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- AHIA, 2015, Part C: Section 790, Safety and Security Precautions, Australasian Health Facility Guidelines (AHIA, 2015), Australasian Health Facility Guidelines, AHIA, Sydney, NSW.
- AHIA, 2010, Part F: Section 680 Furniture Fittings and Equipment, Australasian Health Facility Guidelines (AHIA, 2010), Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance (AHIA), Sydney, NSW.
- Alexander, M et al, 2014, Australian Consensus Guidelines for the Safe Handling of Monoclonal Antibodies for Cancer Treatment by Healthcare Personnel, Issue 1.0 (Alexander, M et al, 2014), no. 1.0, Western and Central Melbourne Integrated Cancer Service, Melbourne, VIC.
- ASHRAE, 2006, Guidelines for Design and Construction of Hospital and Health Care Facilities (ASHRAE, 2006), American Society of Heating, Refrigerating and Air-Conditioning Engineers, Atlanta, GA.
- Australian Commission on Safety and Quality in Health Care, 2012, Electronic Medication Management Systems — A Guide to Safe Implementation (Australian Commission on Safety and Quality in Health Care, 2012), ACSQHC, Sydney, NSW.
- Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2012, Australian Commission on Safety and Quality in Healthcare Standards (Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2012), Commonwealth of Australia, Sydney, NSW.
- Australian Government Department of Health and Ageing, 2013, National Vaccine Storage Guidelines: Strive for 5 (Australian Government Department of Health and Ageing, 2013), Commonwealth of Australia, Canberra, ACT.
- Australian Pharmaceutical Advisory Council (APAC), 2005, Guiding Principles to Achieve Continuity in Medication Management (Australian Pharmaceutical Advisory Council (APAC), 2005), Commonwealth of Australia, Canberra, ACT.
- Brinklow, N, 2006, A Report Assessing the Impact of an Automated Dispensing System at Kings College Hospital (Brinklow, N, 2006), NHS Trust, London.
- Buchanan, T.L et al, 1991, Illumination and Errors in Dispensing, American Journal of Hospital Pharmacy, Vol 48, Issue 10, pp2137-2145 (Buchanan, T.L et al, 1991), American Journal

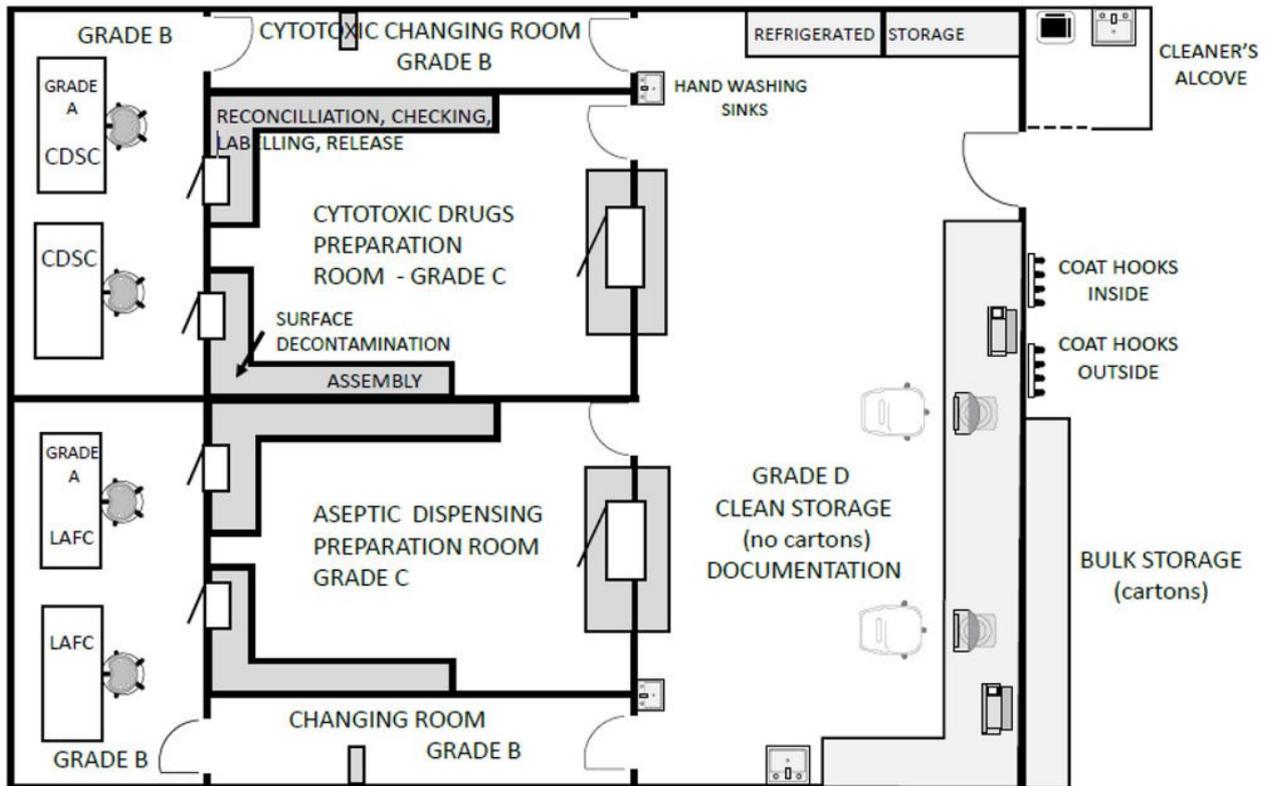
of Hospital Pharmacy, vol. 48, no. 10, pp. 2137 - 2145, American Society of Health-System Pharmacists (ASHP), Bethesda, MD.

- Clinical Oncological Society of Australia (COSA), 2003, Position Statement: Safe Handling of Monoclonal Antibodies in Healthcare Settings (Clinical Oncological Society of Australia (COSA), 2003), Clinical Oncological Society of Australia (COSA), Parramatta, NSW.
- Franklin, B. et al, 2010, An Evaluation of Two Automated Dispensing Machines in UK Hospital Pharmacy, International Journal of Pharmacy Practice, Vol 16, pp47-53 (Franklin, B. et al, 2010), International Journal of Pharmacy Practice, vol. 16, pp. 47 - 53, Royal Pharmaceutical Society of Great Britain, London.
- NSW Health, 2003, Medication Handling in NSW Public Health Facilities (PD2013_043) (NSW Health, 2003), NSW Government, North Sydney, NSW.
- NSW Health, 2015, Protecting People and Property - NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies (NSW Health, 2015), NSW Government, North Sydney, NSW.
- NSW Health, 2015, Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services (PD2015_007) (NSW Health, 2015), NSW Government, North Sydney.
- Pharmaceutical Society of Australia, 2015, Support Practice Guidelines (Website) (Pharmaceutical Society of Australia, 2015), Pharmaceutical Society of Australia, Deakin, ACT.
- Pharmacy Board of Australia, 2015, Codes, Guidelines and Policies (Website) (Pharmacy Board of Australia, 2015), Pharmacy Board of Australia, Canberra, ACT.
- R. Fitzpatrick, P. Cooke, C. Southall, 2005, Evaluation of an Automated Dispensing System in a Hospital Pharmacy Dispensary, The Pharmaceutical Journal, Vol 274, pp763-765 (R. Fitzpatrick, P. Cooke, C. Southall, 2005), The Pharmaceutical Journal, vol. 274, pp. 763 - 765, Royal Pharmaceutical Society, London.
- 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, 1994, AS2639-1994 Laminar Flow Cytotoxic Drug Safety Cabinets – Installation and Use (Standards Australia, 1994), Standards Australia, Sydney, NSW.
- Standards Australia, 1998, AS/NZS 3809:1998 Safes and Strongrooms (Standards Australia, 1998), Standards Australia, Sydney, Australia.
- Tan, Woan Shin. Et al, 2009, Impact of Pharmacy Automation on Patient Waiting Time: An Application of Computer Simulation, Annals of the Academy of Medicine, Vol 38, Issue 6, pp501-507 (Tan, Woan Shin. Et al, 2009), Annals of the Academy of Medicine, vol. 38, no. 6, pp. 501 - 507, Academy of Medicine, Singapore.
- The Society of Hospital Pharmacists of Australia (SHPA), 2015, SHPA Practice Standards (Website) (The Society of Hospital Pharmacists of Australia (SHPA), 2015), The Society of Hospital Pharmacists of Australia (SHPA), Collingwood, VIC.
- Victorian Pharmacy Authority, 2013, Victorian Pharmacy Authority, Victorian Pharmacy Authority Guidelines 2013 (Victorian Pharmacy Authority, 2013), State Government of Victoria, Parkville, VIC.
- Witkowski, Paul, 2007, Case study: Novel Ways Automation Enhances Medication Safety , American Journal of Health-System Pharmacy, Vol 64, Issue 14, pp521-523 (Witkowski, Paul, 2007), American Journal of Health-System Pharmacy, vol. 64, no. 14, pp. 521 - 523, American Society of Health System Pharmacists, Bethesda, MD.

AX.06 Cleanroom Layouts

ASEPTIC PRODUCTION SUITE COMBINING CONVENTIONAL AND CONTAINMENT

This is a conceptual representation only and rooms and components are not drawn to scale.

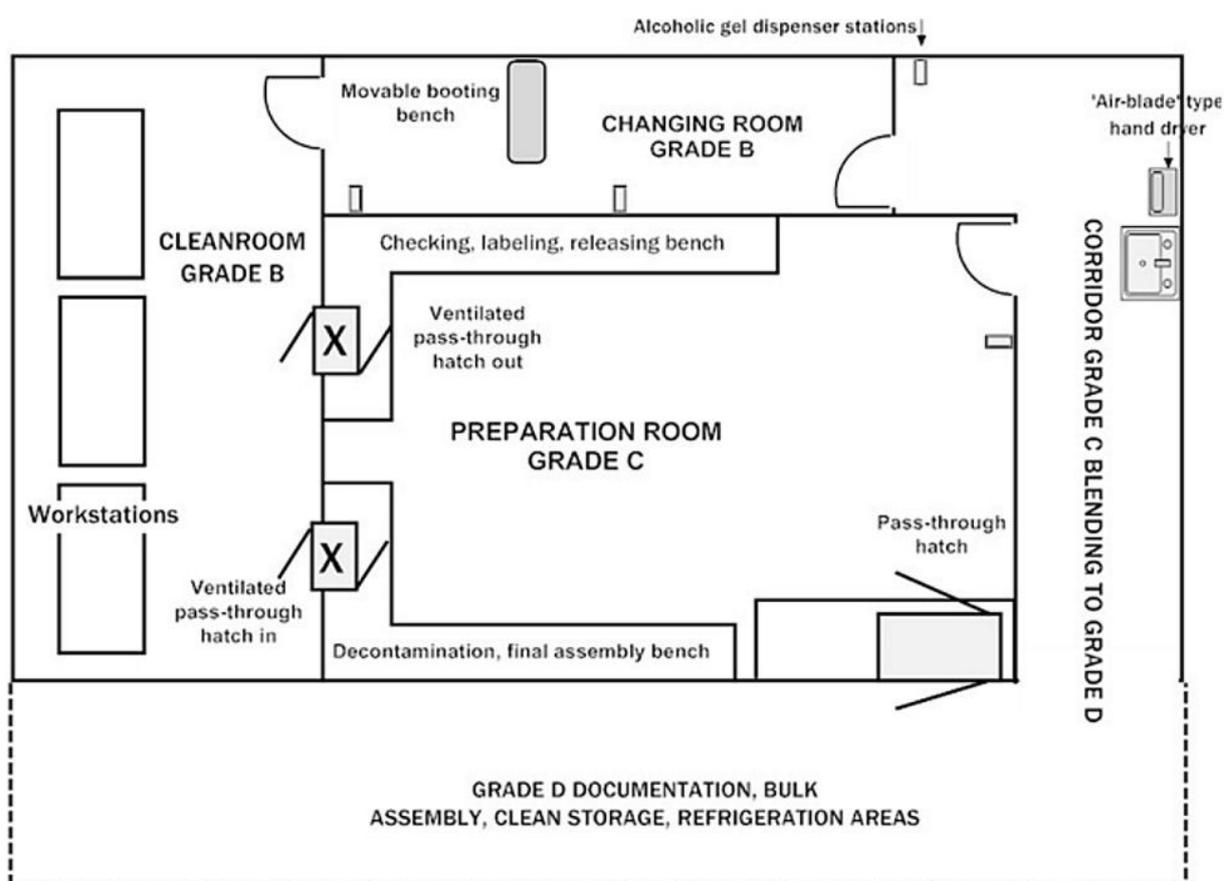


ASEPTIC PRODUCTION SUITE

This is a conceptual representation only and rooms and components are not drawn to scale.

The direction of swing of the door from the Changing Room to the Cleanroom is for conventional positive pressure cleanroom. For a negative pressure containment cleanroom, that direction is reversed.

Note that the workstations are drawn to scale; in this concept illustration, a six metre long cleanroom can accommodate three single operator laminar flow workstations, cytotoxic drug safety cabinets or two single operator cytotoxic drug isolators.



AX.07 Further Reading

- Position Statement: Safe Handling of Monoclonal Antibodies in Healthcare Settings (Clinical Oncological Society of Australia (COSA) , 2003)
- Medication Handling in NSW Public Health Facilities (PD2013_043) (NSW Health, 2003)
- Protecting People and Property - NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies (NSW Health, 2015) (particular reference to Chapter 18 - Security in Pharmacies)
- Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services (PD2015_007) (NSW Health, 2015)

- Support Practice Guidelines (Website) (Pharmaceutical Society of Australia, 2015)
- Victorian Pharmacy Authority, Victorian Pharmacy Authority Guidelines 2013 (Victorian Pharmacy Authority, 2013)
- Australian Consensus Guidelines for the Safe Handling of Monoclonal Antibodies for Cancer Treatment by Healthcare Personnel, Issue 1.0 (Alexander, M et al, 2014)

ATTACHMENTS

Attachments

SECURITY ISSUES FOR PHARMACY UNIT

GENERIC SAFETY AND / OR SECURITY RISKS	POTENTIAL SOLUTIONS
1. Entry for personnel visiting or working within the clinic.	<ol style="list-style-type: none"> 1. CCTV monitoring of entry and exit doorways. 2. Intercom on entry doors. 3. Use of reed switches on all external doors and swipe card entry to staff areas.

SPECIFIC SAFETY AND / OR SECURITY RISKS	POTENTIAL SOLUTIONS
1. Client / Visitor access	1. Client access to secure dispensing counter but not to 'secure' areas utilised to store and dispense drugs.
2. Furniture fittings and equipment including Computers, Office and Medical Equipment	<ol style="list-style-type: none"> 1. Non-removable 'Asset No.' on all equipment above a predetermined value. 2. Keep equipment in lockable area.
3. Hospital personnel safety	<ol style="list-style-type: none"> 1. Staff working in this area to have knowledge of where the fixed duress system is located and / or use a mobile duress pendant. 2. Locked doors between dispensing areas and clients. 3. Dispensing Counter to be constructed to prevent unauthorised client entry / access. 4. Determine risk of hold-up / break-in and design facility to meet risk.
4. Staff personal effects	1. Provision for lockers in staff areas and lockable desk drawer to keep small personal effects.
5. Drugs storage	<ol style="list-style-type: none"> 1. Drugs safe to be located in area that can be monitored by staff. 2. Safes to comply with the Poisons Act in respect of secure storage provisions.

SECURITY CHECKLIST FOR PHARMACY UNIT

FACILITY	DEPARTMENT: Pharmacy Unit
RISK ISSUE	DESIGN RESPONSE
1. Has a secure "barrier" been installed between staff and the dispensing area to: (a) Monitor the dispensing area; and (b) Provide staff contact with patients.	
2. Do staffs have access to both fixed and mobile duress systems?	
3. Is access to patient records restricted to staff entitled to that access?	
4. Is a system implemented to prevent theft of equipment, files, personal possessions, etc.?	
5. Are drug safes installed in accordance with current regulations and the Poisons Act?	
6. Is the dispensing area furniture incapable of being utilized as a "weapon"?	
7. How is after- hours access provided for staff?	
8. How is this area secured during and after hours?	
9. Are there lockable storage areas available for specialised equipment?	
10. Is lockable furniture provided for storage of staff personal effects?	
11. Has the potential risk of hold-up and / or break-in been addressed in the design?	
DESIGN COMMENTARY / NOTES	DESIGN SIGN-OFF
	Name:..... Position: Signature: Date:
	Name: Position: Signature: Date:
	Name: Position: Signature: Date: