NT Pharmacy Premises Committee

PS10 Premises Standard for Pharmacy Departments

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| Acronyms | Full form |
| NT | Northern Territory |
| the Committee | Pharmacy Premises Committee for the Northern Territory |
| CMI | Consumer Medicines Information |
| PN | Parenteral Nutrition |
| cRABS | closed Restricted Access Barrier Systems |
| OPP | Opioid Pharmacotherapy Program |
| PBS | Pharmaceutical Benefits Scheme |
| DUE | Drug Utilisation Evaluation |
| ICU | Intensive Care Unit |
| NSQHS | National Safety and Quality Service |

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# General Information

Pursuant to the *Health Practitioners Act 2004 (HPA),* Schedule 7, Clause 4the Pharmacy Premises Committee (the Committee) prescribes that all pharmacy departments in the Northern Territory (NT) must comply with the following premises standard.

## Definition of a pharmacy department

The *Health Practitioners Act 2004* defines a pharmacy department as a premise or part of a premise which provides a pharmacy service. A pharmacy service means a service that includes the custody of medicines, the dispensing of medicines on prescription and the supply of scheduled medicines to patients and consumers.

## Compliance of this standard

Pharmacy Departments are deemed to be in compliance of the following standard - will be issued a Certificate of Compliance with the following conditions:

* Valid only for the listed address;
* Effective for two years; and
* Not applicable if the premises undergoes major retrofitting.

# Overview

The premises must consist of an enclosed area with sufficient space for the safe provision of therapeutic products and pharmacy services. The premises must:

* Provide adequate security for the storage of scheduled medicines;
* Provide the necessary lighting, temperature and humidity control to ensure the integrity of medicines;
* Allow an appropriate level of public access; and
* Protect consumer privacy.

# Service Level

The level of service provided by a pharmacy department is defined in Appendix A.

# Pharmacy Department Signage

The pharmacy department must have appropriate signage to inform the public of relevant details. Details on the requirement for signage can be found in **PS11 Display of Names Standard for Pharmacy Departments**.

Upon closure or relocation of a pharmacy, all signage indicating that the premise was a pharmacy department must be immediately removed.

# Security

## Physical Security

The pharmacy department must be constructed to prevent unauthorised access through walls, doors, windows and ceilings.

External walls of the pharmacy department should be of solid construction to ensure they cannot be breached. Stand-alone pharmacy departments and pharmacy departments located with outside walls to buildings must be constructed to avoid intentional breaches.

It is recommended that the ceiling spaces above pharmacies are secured to ensure the crawl spaces cannot be accessed from adjoining areas and that walls are continued to the roof line/next floor level or security grills are installed to cordon off the ceiling space.

External doors should be constructed of a solid core. Where this is not possible heavy gauge roller door or security grill may be used in addition to a lockable door.

All other external entry points, including windows and skylights, must be lockable with additional security grills or roller doors. High security glass providing an equivalent level of security as a security grill or roller door will be accepted.

It is recommended that external bollards are considered if the pharmacy is at high risk of ram raid.

## Alarm Systems

Pharmacies must be protected by a back to base electronic alarm which meets Australian Standards. Alarm detectors should cover the entire pharmacy department space. Where this is not possible, priority should be given to areas that store scheduled medicines. The alarm system must undergo regular testing and be monitored by appropriate personnel on a 24 hour basis.

The ability to arm/disarm the pharmacy department alarm must only be known by the pharmacist.

Duress alarms are also recommended.

# Pharmacy Access

The pharmacy department must allow public access through at least one doorway or servery window.

In addition:

* The pharmacy department must be under the direct supervision of a pharmacist at all times while it is open to the public.
* The principal key holder must either be the Director of Pharmacy, Pharmacy Manager or pharmacist-in-charge of a pharmacy department who can then nominate other key holders.
* The principal key holder must keep a register or have access to a register of all keys.
* The premises must be designed in such a manner as to only allow 24 hour access to the pharmacy department by pharmacists.

Note: Codes or swipe cards used to access pharmacy departments are considered keys.

# Lighting

All working areas used for the selection, preparation and supply of medicines must have adequate lighting in the range of 320 to 400 Lux.

Undue exposure of medicines to direct sunlight, or ultraviolet light, must be prevented.

# Temperature Control

The pharmacy department must have the facility to ensure that recommended storage conditions for medicines are maintained at all times. For room temperature stable medicines, temperatures must not exceed 25°C. Where 24 hour temperature control is not possible, the pharmacy must have a documented process to monitor and evaluate temperatures to ensure stock viability. The use of data loggers or minimum/maximum recording thermometers with appropriate documentation, are considered acceptable methods of monitoring temperatures.

The pharmacy must also have the facilities to ensure that temperature conditions are maintained during periods of power outages. A backup generator allowing uninterrupted power supply to critical items is recommended. Alternatively facilities that allow temperature monitoring and recording can be used to inform evaluation of stock viability after a power interruption.

It is recommended temperature control systems undergo regular testing and maintenance by a licensed contractor.

Humidity control may be a consideration to ensure medicines integrity if required.

# Pharmacy Department

The area of the pharmacy department needs to be appropriate for the service delivery requirements. The minimum area of the pharmacy department must be as follows:

* Level 1 & 2: n/a
* Level 3: 45m2
* Level 4: 85m2
* Level 5 & 6: 180m2

Smaller areas may be considered by individual application to the Committee.

## Dispensary

The dispensary is an area dedicated to the storage/dispensing of medicines and the secure storage of patient records. It should be located in an area of the pharmacy department which allows minimal throughway of personnel not associated with the dispensing process. Lighting, ventilation, temperature and humidity control are essential to maintain the integrity of medicines.

### Dispending Station(s)

The dispensary in a pharmacy department must include at least one dispensing station for each 150 to 200 dispensing events or part thereof dispensed on a typical day.

Each dispensing station is to include a dispensing bench area of at least 0.6m2 and be equipped with:

* Screen;
* Keyboard and mouse;
* Computer processor;
* Dedicated scanner; and
* Dedicated printer for medicine labels.

Access to a printer for the printing of Consumer Medicines Information (CMI) may be located at or away from the dispensing station and may service a network of dispensing stations.

### Dose Administration Aids

The pharmacy department must allow sufficient space for the preparation of dose administration aids. Consideration must also be given to:

* Lighting;
* Access to hand hygiene;
* A location free from interruption; and
* Meet applicable health and safety requirements.

## Client Waiting Area

The pharmacy department must provide at least one client waiting area. The area is to be utilised by clients who are waiting to collect their dispensed medicines. Its use should be encouraged to minimise overcrowding in the counselling area so that patient privacy is not compromised.

## Counselling Area

The pharmacy department must have access to an area for the provision of counselling in relation to dispensed or other medicines. This area must be separated from other areas of the department to minimise interruption to client interactions and protect client confidentiality. The design of the counselling area must minimise the risk of conversations being overheard and ensure that medicines and documents cannot be seen by other persons.

At the servery counter, privacy screens must be fitted that rise at least 0.6m above the bench to provide confidentiality. An arrangement that provides an equivalent level of privacy may be considered by the Committee.

A separate room should be considered for more in-depth counselling for professional service interactions.

## Non-sterile Medicines Production

Non-sterile medicines production includes all activities associated with extemporaneous preparation and prepacking of non-sterile pharmaceuticals. Sufficient space, equipment and access to dedicated sinks are all requirements if the service is undertaken by the pharmacy department. Activities include the following.

### Pre-packaging

Prepacking of pharmaceuticals includes the following activities:

* Maintain a batch1 record.
* Enter information on prepacking record.
* Preparation and labelling.

### Extemporaneous Compounding

Extemporaneous compounding is the preparation of a product which is not commercially available and must be compounded from raw or intermediary products and includes the following activities:

* Maintain a batch1 record.
* Complete a batch1 record sheet.
* Obtain supplies.
* Prepare equipment and containers.
* Compound the pharmaceutical.
* Label appropriately.

## Sterile Medicines Production

Medicines production of sterile pharmaceutical products includes aseptic preparation and end stage sterilisation of formulations. Sufficient space, equipment and access to dedicated sinks are all requirements if the service is undertaken by the pharmacy department. All equipment used in the process must be maintained and inspected with accurate records of service and maintenance history kept. Activities include:

### Aseptic

Preparation of a pharmaceutical product utilising appropriate aseptic technique. Products may include:

* Aseptic Admixture.
* Parenteral Nutrition (PN).
* Eye Drops.

### Terminally Sterilised

Preparation of a product which requires a terminal sterilisation process for example autoclaving

## Radiopharmaceuticals

Production of radiopharmaceuticals in the pharmacy department must be licensed under the *Radiation Protection Act* and a current compliance certificate must be displayed near the site.

Persons authorised to use the equipment must also be licensed under the *Radiation Protection Act 2004.*

## Cytotoxic Medicines Production

Cytotoxic medicines production or assembly requires the use of barrier isolated systems or closed restricted access barrier systems (cRABS). Evidence of ongoing maintenance and records of certification must be readily available for auditing and compliance.

The air within these systems must be HEPA-filtered before being exhausted out of the system. Dedicated ducts must be used to remove the air from the building.

Lypolisation of cytotoxic agents requires additional handling and containment. Separate ingress and egress points with de-gowning areas must be in place to ensure cytotoxic agents are not carried in to ‘clean’ areas.

1. *Note: For the purposes of this document, the term ‘batch’ means a unique identifier of the end product that has not been manufactured.*

## Medicines Information

Pharmacy departments play an important role in the dissemination of medicine information to health professionals and patients. Pharmacy departments providing a medicine information service should have a separate area set aside for the provision of this service. The area should be of a sufficient size, be designed to minimise distraction and include access to appropriate, up-to-date information resources.

## Staff Rooms, Toilets and Change Rooms

If staff convenience facilities are located within the pharmacy department they should be located in an area which minimises the interaction and distraction of staff not accessing these facilities.

The staff room must have a dedicated sink for the preparation of foodstuffs. Toilets and change rooms must also have dedicated access to hygiene facilities.

# Schedule 8 Safe

The pharmacy department must have a minimum of one safe for the storage of Schedule 8 substances. The pharmacy department should have a suitable size and number of Schedule 8 safes to ensure storage in a neat orderly manner. All safes used for storing S8 substances must comply with the **Code of Practice for the Transport and Storage of Schedule 8 Substances.**

# Medication Refrigerator / Cold Room and Freezer (Cold Chain Management)

## Medication Refrigerator / Cold Room

The pharmacy department must have a minimum of one pharmacy grade refrigerator or cold room for the storage of temperature sensitive medicines. All refrigerators or cold rooms used for the storage of medicines must comply with the current version of **National Vaccine Storage Guidelines (*Strive for 5*)** and must be dedicated to the storage of pharmaceutical products.

The pharmacy department must have a suitable size and number of refrigerators or cold rooms to ensure temperature sensitive medicines are stored in a neat and orderly manner.

Appropriate measures should be in place to ensure power to refrigerator or cold room is maintained at all times, including the provision of back-up power generation devices.

## Medication Freezer

If a pharmacy department is required to store medications in a freezer, an appropriate medication freezer must be kept. The size must be adequate for the needs of the pharmacy department.

Medicines must be stored in accordance with manufacturers’ requirements and be monitored appropriately.

Applicable measures should be in place to ensure power is maintained at all times, including the provision of back-up power generation devices.

# Sinks

The pharmacy department must have at least one sink with running hot and cold water dedicated to support hand hygiene practices.

*Note: hand hygiene sinks must be separate, with dedicated water source and drainage, to sinks used for other purposes.*

If the pharmacy department has an area for staff breaks and meal preparation, this area must have a sink with hot and cold running water that is separate to the sink for hand hygiene practices.

Where the pharmacy produces medicines onsite, including the preparation of extemporaneous products, it must have a separate sink for the cleaning of medicines preparation equipment.

*Note: A double bowl sink, with one bowl restricted for cleaning of meal preparation equipment and the other for cleaning of medicines preparation equipment is considered acceptable providing the two bowls have separate draining areas, separate water sources and separate drainage points (including s-bends).*

Pharmacy departments must have access (within the building) to a cleaner’s sink, floor waste or other similar facility connected to drainage to dispose of mop water and other liquid waste. Sinks used for the maintenance of floor cleaning equipment must be separate from those used for hand washing, food and medicines preparation. Facilities and chemicals for cleaning must be kept separate from pharmaceuticals.

# Hygiene and Pest Control

The building must be constructed in a manner to minimise the ingress of debris. Buildings and fixtures must be kept clean, tidy and well maintained.

All cleaning equipment must be maintained to support hygiene and infection control.

The building must be constructed and maintained to minimise entry of rodents, vermin, birds and pests. Animals including pets are not permitted in the pharmacy, with the exception of guide dogs and other assistance animals.

# Medicines Storage

All scheduled medicines must be stored according to the manufacturers’ guidelines.

Bulk storage of scheduled medicines, kept outside of the pharmacy department must meet the same security, access, supervision and temperature control standards as the pharmacy department.

Storerooms containing scheduled medicines in a location separate to the pharmacy department must be approved by the Committee.

# Opioid Pharmacotherapy Program (OPP)

Where a pharmacy department provides treatment to more than 20 clients per day it must have a designated area exclusively to dose clients. This area must:

* Meet requirements for security, lighting and temperature control;
* Protect the privacy of OPP clients;
* Be fitted with a safe for the storage of OPP medicines;
* Have lockable storage for client records; and
* Contain suitable storage and equipment necessary for the provision of this service.

Where the pharmacy department provides treatment for less than 20 clients per day, the same requirements must be met, but the counselling area may be used for the dosing of patients.

*Note: Dedicated clinics providing opiate pharmacotherapy services on hospital grounds are outside the scope of this standard.*

# Acknowledgements

This standard was developed with reference to:

* Victorian Pharmacy Authority Guidelines, The Victorian Pharmacy Authority, 2021.
* NT DoH, Hospital Services Capability Framework, 5 February 2014.
* Pharmacy Guidelines, Pharmacy Regulation Authority of South Australia.
* Australian Code of Good Wholesaling Practice of Medicines in Schedules 2, 3, 4 and 8, The Therapeutic Goods Administration 2011.
* PSA Guidelines and standards for pharmacists, dose administration aids service.
* SHPA Case-mix Working Party, Definitions 1996, Definitions for Hospital Pharmacy Services.
* National Vaccine Storage Guidelines (Strive for 5); The Australia Government, Department of Health and Aging – online version.
* Code of Practice for the Storage and Transport of Schedule 8 Substances, Northern Territory Department of Health – online edition.
* SHPA Managing Risk in the Manufacture of Oncology Drugs.
* *Radiation Protection Act 2012*.
* NT Worksafe: Managing the work environment and facilities, 2020.

# Disclaimer

In case of any conflict or discrepancy between this document and legislation – the legislation prevails.

# Appendix A: Service Level for Pharmacy Departments

The level of service provided by a pharmacy department is defined below in accordance with the NT Hospital Services Capability Framework.

**Level 1:**

A level 1 service provides services to an ambulatory population (eg: as part of a remote health centre that accesses a community pharmacy or other health centre to provide services to a local population).

* Medications are supplied on individual prescription from community pharmacy, primary health care clinic or higher level of service.
* Where there is no pharmacist employed, on-site medication service oversight is provided by a pharmacist located elsewhere from a higher level service via tele-health where available or through a documented process with a community pharmacist.

**Level 2:**

A level 2 service provides services at level 1 plus it provides a limited ambulatory service and in-patient clinical pharmacy service, and complies with relevant statutory regulations regarding the provision and quality use of medications. The service is able to provide a medication service to adult and paediatric patients including:

* Medications for in-patients (supplied on the basis of a legal and safe written order) are sourced from the hub hospital within the network.
* Medications for ambulatory and in-patients on discharge supplied on an individual prescription from either a community pharmacy, appropriate hospital within a network, or a higher level service with documented processes in place for the provision of medications that require compounding.
* Staff education program in place.
* Patient education provided for inpatients from nursing or visiting pharmacy staff.
* Pharmacist support from a hub facility within the network, provided by a visiting pharmacist.

**Level 3:**

A level 3 service provides a level 2 service plus it provides a clinical pharmacy service on weekdays through an on-site pharmacy or a contracted service, and includes an out of hours medication mechanism and ideally has access to a pharmacist for emergency advice 24 hours a day. The service is provided to in-patients as well as rural and remote areas, including a service to dispense medications to ambulatory patients, and provides medications to out-patients not on the Pharmaceutical Benefits Scheme (PBS), as well as providing service to regional and remote health centres within the network.

* Medications and clinical services for in-patients, day patients and, where applicable, ambulatory patients in specialty clinics.
* Provides support to outreach and specialty services.
* Access to basic, non-sterile extemporaneous compounding.
* Clinical services includes drug information, drug monitoring, drug utilisation evaluation (DUE), adverse drug reaction reporting, patient education and support, and membership on hospital based network systems.
* Timely access to clinical information, including medical records and pathology results, reliable access to a dedicated desktop and/or laptop in the ward clinical area.
* Have responsibilities across a defined area within the network, providing support and medication service oversight to lower level services through intermittent visits, via outreach pharmacy or tele-pharmacy services if available, or other means.
* May have a pharmacy undergraduate and postgraduate teaching role.
* Appropriate networking with higher level service.
* Must comply with relevant legislation regarding storage and security requirements.
* Service provided by a pharmacy team which includes a pharmacist, pharmacy assistant and pharmacy technician.

**Level 4:**

A level 4 service provides services at level 3 plus it provides a medication service that is available 24 hours. The service is able to provide care for a full range of patient risk levels, and has the capacity and capability care for patients that are likely to have complex and competing therapeutic needs, and multiple comorbidities that the service must consider when optimising therapy.

* Provides network consultation and accepts referrals from lower level services within the network.
* Services provided to in-patients and may be provided to ambulatory patients as part of specialty clinics.
* Medications distributed and stored by the facility and, as required, to any lower level service that is safe, meets legislative requirements and assures the quality of medicinal products (eg: meets cold chain requirements).
* Provides support for a range of specialty services (eg: chemotherapy).
* Provides support for clinical trial medication distribution as part of a limited clinical trial management service where other clinical services sponsor or participate in clinical medication trials.
* Provides visiting services to lower level services within the network.
* Access to an after-hours, on-call service for medication supply and clinical services, including medicines information, available 24 hours.
* General or junior-level pharmacy staff mentored or clinically supervised by a specialist or advanced-level practitioners where applicable.

**Level 5:**

A level 5 service provides services at level 4 plus it has the capacity to act as a referral service for very high-risk patients except those who need high level specialist clinical services, such as a transplant, or the most complex patients

* Basic, non-sterile, extemporaneous compounding possibly with limited small batch manufacturing for local hospital use, and sterile, individually compounded products (eg: chemotherapy including parenteral, targeted and oral chemotherapy) if the use and manufacture of these products falls within the scope of practice for the pharmacist or trained support staff providing supporting medication services.
* The capacity to respond to requested for medicines information related to direct patient care in a timely manner.
* The service may actively participate in multidisciplinary research.
* Undergraduate and postgraduate teaching role.
* Pre- and postgraduate pharmacy training.
* An extended hours service with a pharmacist available 24 hours a day.
* A pharmacy team structured to deliver services at multiple levels throughout the organisation.
* Specialist pharmacist positions which reflect the range of services provided (eg: ICU, haematology, and medical oncology).

**Level 6:**

A level 6 service provides services at level 5 plus it acts as a referral service for all lower level services across the NT accepting referrals including interstate, where applicable. The service has the capacity and capability to provide care for patients who have the most complex of needs. A team of pharmacists, including specialist advanced level pharmacist aligned with clinical specialist services and provides medication services.

* A full range of specialist pharmacist services which reflect the range of specialist services provided (eg: ICU, haematology, medical oncology, paediatrics, geriatrics, psychiatry, and drug information).

# Appendix B: Determination of risk for pharmacy departments

All pharmacy premises in the Northern Territory are administered by the Pharmacy Premises Committee which must ensure compliance with the *Health Practitioners Act 2004*. The Committee has determined all pharmacy departments to be categorised in to three risk categories. These are normal, high risk and pharmacy departments undergoing desktop or remote assessment.

1. **Normal Risk** pharmacy departments which fit into the following criteria:
	1. attained accreditation in association with the hospital’s National Safety and Quality Service (NSQHS) Standards; and
	2. undertake a normal range of pharmacy services as stated in under Appendix A; or
	3. as determined by the Pharmacy Premises Committee.
2. **High Risk** pharmacies and professional services premises which fit in to the following criteria:
	1. not accredited / reaccredited under the hospital’s NSQHS; and/or
	2. undertake activities which the Pharmacy Premises Committee determines to be high risk; and/or
	3. have been the subject of a substantiated complaint; and/or
	4. found to have significant non-compliance during a routine inspection.
3. **Pharmacy departments undergoing desktop / remote assessment:**
	1. **For existing premises** – the pharmacy’s certificate of compliance may be extended for up to six (6) months.
	2. **For new, relocated and / or refurbished premises** - a new certificate of compliance may be issued for up to six (6) months.
	3. Any extension beyond six (6) months will be at the discretion of the Pharmacy Premises Committee.

**For Items one and two - Inspection and issuing of a Certificate of Compliance:**

**Normal Risk** – pharmacies will be inspected every two (2) years and once deemed compliant, issued with a Certificate of Compliance valid for two years.

**High Risk** – pharmacies will be assessed once a year and if deemed compliant, issued with a Certificate of Compliance valid for one year.