**PHARMACY PREMISES COMMITTEE**

**OF THE**

**NORTHERN TERRITORY**

**PS4**

**PREMISES STANDARD**

**FOR NORTHERN TERRITORY PROFESSIONAL SERVICES PREMISES**

**Version 2.1**

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# GENERAL INFORMATION

1. Pursuant to the *Health Practitioners Act (HPA),* Schedule 7 the Pharmacy Premises Committee (Committee) prescribes that all Professional Services Premises must comply with the following premises standard.

**1.2** Professional Services Premises found to be in compliance with the standard will be issued a Certificate of Compliance under the following conditions:

* effective for two years unless deemed to be of high risk at which a Certificate of Compliance will be issued for one year (see Appendix A);
* valid only for the address listed
* not transferrable from the current ownership structure; and
* not valid if the premises undergo major retrofitting
1. **CONSIDERATION**

The Committee will only consider applications for Professional Services Premises if there is an unmet public need and must also meet the objects of the *HPA.*

These objects are to:

* protect and promote the health and safety of the people in the Northern Territory; and
* promote the highest standard of healthcare services in the Northern Territory.

In addition, the business conducted in the Professional Services Premises must form part of and be owned by a compliant pharmacy business, physically located in the Northern Territory as defined in the *HPA,* Schedule 7, Clause 1.

All applications will be considered on a case by case basis.

1. **OVERVIEW**

The professional services premises must consist of an enclosed area with sufficient space for the safe provision of therapeutic products and pharmacy services and by the nature of the activities undertaken, will not be open to the public. 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; and
* protect consumer privacy.
1. **SECURITY**

**4.1 PHYSICAL SECURITY**

Professional services premises must be constructed to prevent unauthorised access through walls, doors windows and ceilings.

External walls should be of solid construction to ensure they cannot be breached.

Measures are also required to prevent entry through the ceiling. It is recommended that the ceiling spaces are secured to ensure the crawl spaces cannot be accessed from adjoining areas. It is recommended that walls are continued to the roof line or security grills are installed to cordon off the ceiling space.

External doors are to 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 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 or security fencing be considered.

* 1. **ALARM SYSTEMS**

Professional services premises must be protected by a back to base electronic alarm which meets Australian Standards. Alarm detectors must cover the entire internal tenancy. The alarm system must undergo regular testing and be monitored by a licensed security firm on a 24 hour basis.

A register of alarm code holders must be kept by pharmacist-in-charge or a pharmacist nominated by the pharmacist-in-charge.

1. **ACCESS**

The professional services premises is subject to the provisions of the *Health Practitioners Act*, Schedule 7, Clauses 6, 7 and 9 that:

* non-pharmacists must not enter or remain in a professional services premises unless under the direct supervision of a pharmacist; and
* a professional services premises key holder must be the pharmacist-in-charge or a pharmacist nominated by the pharmacist-in-charge. Codes or swipe cards used to access the premises are considered keys.
* a register of key holders must be kept by the pharmacist-in-charge or a pharmacist nominated by the pharmacist-in-charge.

The premises must be constructed in such a manner as to allow 24 hour access by the pharmacist-in-charge.

1. **LIGHTING**

All working areas used for the selection, production and distribution of medicinal preparations 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.

1. **TEMPERATURE CONTROL**

The professional services premises 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.

The premises 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.

Consideration should also be given to control of humidity to ensure medicines integrity.

1. **DISPENSARY/DAA/COMPOUNDING PREPARATION AREA**

The preparation area must consist of an area of at least 8m2,or lesser may be considered by individual application to the Committee.

The preparation area must contain at least one dispense station. For further detail on the requirements for a dispense station see the *Mandatory Equipment List*.

The preparation area must contain at least 1m2 of free bench space for the preparation of dispensed medicines. This bench space does not include the tops of machinery, sinks or fixtures and must not be designated for any other activity. It is strongly recommended that the bench space be immediately adjacent to the dispense station.

The preparation must have access to a sink for the preparation of medicines and maintenance of medicine preparation equipment.

1. **SCHEDULE 8 SAFE**

The professional services premises may have a requirement for a safe for the storage of Schedule 8 substances. If installed, the safe(s) used for storing S8 substances must comply with the Code of Practice for the Transport and Storage of Schedule 8 Substances. If a safe is not installed, the professional services premises must have a policy on the storage of S8 substances, should the need arise.

1. **REFRIGERATOR**

The professional services premises may have a requirement for a refrigerator for the storage of temperature sensitive medicines. If utilised, the refrigerator(s) used for the storage of medicines must comply with National Vaccine Storage Guidelines (*Strive for 5*) and must be dedicated to the storage of pharmaceutical products. If a refrigerator is not available, the professional services premises must have a policy on the safe storage of temperature sensitive medicines, should the need arise.

1. **SINKS**

The professional services premises must have a sink with running hot and cold water dedicated to support hand hygiene practices.

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

If the premises 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 premises compounds medicines onsite, 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).*

Professional services premises must have access 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.

1. **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.

1. **STOREROOMS**

All storerooms must meet the same security, access, supervision and temperature control standards as the professional services premises.

Storerooms containing scheduled medicines in a location separate to the premises must be approved by the Committee and will only be considered in exceptional circumstances.

1. **REFERENCES**

The professional services premises must have access to all references described in the Mandatory References Standard.

1. **ACKNOWLEDGEMENTS**

This standard was developed with reference to:

* The Guide, Pharmacy Council of New South Wales

[Pharmacy Board of New South Wales The Guide (nsw.gov.au)](https://downloads.pharmacycouncil.nsw.gov.au/s3fs-public/the_guide_-_annual_declaration_fee_may_2021.pdf)

* Health Practitioner (New South Wales) Regulation 2016 – Regulation 13

[Health Practitioner Regulation (New South Wales) Regulation 2016 - NSW Legislation](https://legislation.nsw.gov.au/view/html/inforce/current/sl-2016-0543#sec.13)

* Australian Code of Good Wholesaling Practice of Medicines in Schedules 2, 3, 4 and 8, The Therapeutic Goods Administration

[Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8 | Therapeutic Goods Administration (TGA)](https://www.tga.gov.au/resources/publication/publications/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8)

* Pharmacy Board of Australia, Guidelines for Dispensing

[Pharmacy Board of Australia - Codes, Guidelines and Policies](https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx)

* National Vaccine Storage Guidelines (Strive for 5); The Australia Government, Department of Health and Aging.

[National Vaccine Storage Guidelines ‘Strive for 5’ | Australian Government Department of Health and Aged Care](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5)

* Code of Practice for the Storage and Transport of Schedule 8 Substances, Northern Territory Department of Health.

[DoH Digital Library: Code of Practice Schedule 8 Substances - Medicines & Poisons Control](https://digitallibrary.health.nt.gov.au/prodjspui/handle/10137/897)

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| 1. **Disclaimer**
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| In case of any conflict or discrepancy between this document and legislation, the legislation prevails. |

**APPENDIX A: DETERMINATION OF RISK FOR PHARMACY PREMISES.**

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 pharmacies are to be categorised in to three distinct risk categories. These are normal, high risk and pharmacy premises and professional services premises undergoing desktop or remote assessment.

* + - 1. **Normal Risk** pharmacies and professional services premises and pharmacies which fit into the following criteria:
				1. attained a QCPP Certificate (or for the accompanying pharmacy); and
				2. undertake a normal range of pharmacy products and services as deemed by the Pharmacy Premises Committee.
			2. **High Risk** pharmacies and professional services premises which fit in to the following criteria:
				1. not assessed by QCPP; and/or
				2. compounding utilising a Compounding Laboratory; and/or
				3. undertake activities which the Pharmacy Premises Committee determines to be high risk; and/or
				4. have been the subject of a substantiated complaint; and/or
				5. found to have significant non-compliance during a routine inspection.
			3. **Pharmacy premises 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 years and once deemed compliant, issued with a Certificate of Compliance valid for two (2) years.

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