CODE OF PRACTICE

SCHEDULE 8 SUBSTANCES

VOLUME 2 – STORAGE & TRANSPORTATION

2014

NORTHERN TERRITORY GOVERNMENT

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Definitions

Throughout the Code, definitions used are consistent with the *Medicines, Poisons and Therapeutic Goods Act 2012* (MPTGA).

The following definitions are used throughout this Code of Practice:

Act refers to the *Medicines, Poisons and Therapeutic Goods Act 2012* (MPTGA). The Act is administered by the Medicines & Poisons Control section of the Environmental Health Branch of the DoH, on behalf of the Chief Health Officer. Please note that reference to sections in legislation may be abbreviated to 's' e.g. s3 – section 3.

authority holder under the Act includes a manufacturer, wholesaler, the holder of a research authorisation for S8 substances, the holder of a medical kit authorisation who is authorised to possess S8 substances.

common carrier means a company that provides transport services to the general public, without discrimination, and that is generally obliged to take consignments that do not conflict with the carrier's policies and underpinning-regulations;

contract carrier means a company that provides transport services as part of individual private contractual arrangements, without obligation to take any specific consignment. These carriers may limit their operations to a discrete number of clients only.

dose means

For divided preparations (e.g. tablets, capsules, patches, ampoules etc.) one individual dose for therapeutic use;

For undivided preparations (e.g. bulk powders, mixtures etc.) the normal amount administered as a single adult human therapeutic dose, or in the case of veterinary practice a single adult animal therapeutic dose relevant to the animal under treatment;

Schedule 8 substance means a substance or class of substances to which Schedule 8 applies in the 'Standard for the Uniform Scheduling of Medicines and Poisons'- it may be abbreviated as 'S8' substance;

health service facility includes hospitals, nursing homes and declared places e.g. health clinics, day surgery units;

key means any method for unlocking a drug storage cabinet, safe, or strongroom and includes a combination, personal identification number (PIN), password, electronic card, or other electronic proximity device;

health practitioner means a person registered under the *Health Practitioner Regulation National Law* to practise a health profession (other than as a student);

supervised means that a health practitioner is physically on the premises where S8 substances are stored, is aware of activities on the premises in the vicinity of the storage area and is able to intervene in activities as required.

veterinarian has the same meaning as in the *Veterinarians Act (NT)*.

ward means a ward, operating theatre, clinic, day surgery unit, section or department of a health service facility in which patients are treated.

Volume 1 Issuing Prescriptions

Scope

This Code describes:

1. The level of security required for the storage of drugs of dependence by manufacturers, wholesale dealers, pharmacists, dentists, veterinarians, health service facilities, and other persons who manufacture, possess, sell, supply or administer Schedule 8 substances in the Northern Territory; and
2. How to pack, dispatch, and transport drugs of dependence within or from the Northern Territory for manufacturers, wholesale dealers, pharmacists, veterinarians, common or contract carriers, and other persons involved in the transportation of these drugs.

Application

The principles and requirements in this Code apply to the storage and transport of all Schedule 8 (S8) substances, other than drugs stored or transported by patients, or their agents, pursuant to lawful prescription or supply.

Part 1 Storage

In determining which of the following storage area categories applies, organisations are encouraged to consider the specific activities undertaken at the premises or area of premises. If doubt remains, advice may be sought from Medicines & Poisons Control.

1.1 Restricted Access to Drug Cabinets, Safes and Strongrooms

1. No person is permitted access to a drug cabinet, safe, or strongroom key other than a health practitioner, veterinary surgeon, permit holder, or a licence holder who is permitted under the Act to possess S8 substances, and is working at the premises on which a drug cabinet, safe, or strongroom is located.[1]
2. At all times, while on duty, the designated health practitioner for the time being responsible for the ward, medical, dental or veterinary surgery, pharmacy, day surgery unit or health service facility, or the permit or licence holder, must keep the key to the drug cabinet, safe, or strongroom in his or her possession.[2]
3. No person other than those specified in (1) may:
   3.1. Lock or unlock a drug cabinet, safe, or strongroom; or
   3.2. Add to, or in any other way interfere with, drugs stored in the cabinet, safe, or strongroom.
4. A drug cabinet, safe, or strongroom must only be unlocked and accessed for the following purposes and be re-locked immediately after use:
   4.1. Storage of drugs;
   4.2. Supply, administration, destruction of drugs; or
   4.3. Examination and counting of drugs for audit and record-keeping purposes.
5. In the event that an a designated health practitioner is unable to physically handover the drug cabinet, safe, or strongroom key to another designated health practitioner, must ensure that the key is stored in a secure key safe.[3]

[1] To avoid doubt, nothing in this clause prevents a health service facility further restricting the category of health practitioner working at the facility who is permitted access to a key for a drug cabinet, safe, or strongroom in certain circumstances.
[2] It is sufficient compliance with this clause that a health practitioner retains legal possession of the key when a ward is closed by storing the key in a suitable locked location within the health service facility.
[3] A key safe that relies on the use of a physical key is not acceptable.

1.2 Health Service Facility and Surgery

All S8 substances stored in a health service facility, ward, day surgery unit, or medical, dental or veterinary surgery must be placed in a securely locked storage cabinet that meets or exceeds the following requirements:

1. Where the quantity of drugs stored is not more than 15 doses —
    1.1. Made of 15mm thick hardwood;
    1.2. Fitted with a 5 lever key lock, or equivalent locking mechanism; and
    1.3. Securely fixed to the wall or floor.
2. Where the quantity of drugs stored is more than 15 doses and the immediate area in which the cabinet is situated is supervised at all times, the requirements specified above in [1].
3. Where the quantity of drugs stored is more than 15 doses and the immediate area in which the cabinet is situated is not supervised at all times[1] the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade 1; or
4. As approved in writing by the Manager, Medicines & Poisons Control[2].

1.3 Pharmacy

1. All S8 substances stored in a pharmacy must be placed in a securely locked drug safe that meets or exceeds the following requirements:
    1.1. Where the quantity of drugs held at any time is equivalent to 500 doses or less, and the area in which the drug safe is located is supervised 24 hours per day, the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade 0;
    1.2. Where the quantity of drugs held at any time is equivalent to 500 doses or less, and the area in which the drug safe is unsupervised for periods of time, requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade I;
    1.3. Where the quantity of drugs held at any time is equivalent to more than 500, but less than 1000, doses, the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade II;
    1.4. Where the quantity of drugs held at any time is equivalent to more than 1000 doses, the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade III; or
2. Where the pharmacy is fitted with an alarm system monitored by a security company, or the premises are supervised 24 hours a day, or the premises are patrolled by a security

[1] For example, overnight; when a theatre is temporarily closed.
[2] Applies to new facilities or services after 1st May 2014.

guard when not supervised, the Resistance Grade specified at [1.2], [1.3], or [1.4] may be reduced by one Resistance Grade, respectively.

3. For the purposes of this Code, a drug safe having the following specifications is deemed to be equivalent to Resistance Grade I —

   3.1. Constructed of steel plate built not less than 10mm thick;

   3.2. Continuous welding of all edges;

   3.3. Fitted with a flush-fitting door constructed of mild steel plate not less than 10mm thick, with a clearance around the door of not more than 1.6mm;

   3.4. Fitted with a fixed locking bar welded to the inside face of the door near the hinged-edge which engages in a rebate in the safe body when the door is closed;

   3.5. Fitted with a five-lever key lock, or locking mechanism providing equivalent security, securely affixed to the rear face of the door;

   3.6. Attached to a wall or floor of the pharmacy premises away from external walls where it is not visible from outside the room in which it is situated and:

      3.6.1. Where mounted on a brick or concrete wall or floor, be attached to such wall or floor by means of suitably sized expanding bolts through 9.5mm diameter holes drilled in the rear or bottom of the safe; or

      3.6.2. Where mounted on a timber-frame wall or floor, be attached to such wall or floor frame by means of suitably sized coach screws through 9.5mm diameter holes drilled in the rear or bottom of the safe;

      3.6.3. Where the wall or floor is constructed of material other than brick or concrete, or with a frame other than timber, be attached to such wall, floor, or frame in such manner as to provide equivalent security to a mounting made pursuant to [3.6.1] or [3.6.2].

1.4 Analysis, Research, Instruction or Training Authority Holders

All S8 substances stored by the holder of an analysis, research, instruction, or training permit must:

1. Be placed and securely locked in a drug safe that meets or exceeds the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade I; and
2. Be stored in premises fitted with an alarm system monitored by a security company or patrolled by a security guard; or
3. Be stored as approved in writing by the Manager, Medicines & Poisons Control.

1.5 Manufacturer and Wholesaler

1. All S8 substances stored by a manufacturer or wholesaler must be placed in a securely locked safe or strongroom that meets or exceeds the requirements of Australia / New

Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade VII;

2. The safe or strongroom must be situated away from the external walls of the premises; and
3. The premises and the area in which the safe or strongroom is situated must be fitted with an alarm system monitored by a security company; or
4. As approved in writing by the Manager, Medicines & Poisons Control.[1]

1.6 Other Places of Storage

Subject to the above requirements, where drugs are temporarily or permanently stored in any other place[2], any such place of storage must be so constructed, secured, and used as to prevent the unauthorised removal of, or interference with, the S8 substances.

1.7 Quick Reference to Storage Requirements

Storage place	Doses stored	Hours per day supervised	Security level
Health Service Facilities, Medical, Dental, Veterinary Surgeries	≤ 15	–	Locked hardwood cabinet
	> 15	24	
	> 15	< 24	AS/NZS 3809:1998 Resistance Grade I
			As approved by the Manager Medicines Poisons Control
Pharmacies	≤ 500	24	AS/NZS 3809:1998 Resistance Grade 0
	≤ 500	< 24 - Monitored alarm system	AS/NZS 3809:1998 Resistance Grade I
		24	AS/NZS 3809:1998 Resistance Grade 0
	501 – 999	< 24 - Monitored alarm system	AS/NZS 3809:1998 Resistance Grade II
		24	AS/NZS 3809:1998 Resistance Grade I
	≥ 1000	< 24 - Monitored alarm system	AS/NZS 3809:1998 Resistance Grade III
		24	AS/NZS 3809:1998 Resistance Grade II
Manufacturers and Wholesalers	Any quantity	Monitored alarm system required	AS/NZS 3809:1998 Resistance Grade VII
Authority Holders	Any quantity	–	AS/NZS 3809:1998 Resistance Grade III
			As approved by the Manager Medicines Poisons Control

[1] The Manager, Medicines & Poisons Control must have regard to the quantity of S8 substances stored at the manufacturer or wholesale dealer premises at any instant when determining applicable storage requirements.

[2] For example, in a vehicle or aeroplane, in a doctor's or veterinarian's bag.

Part 2 Transport

2.1 Packaging for Transport

The following requirements apply when packaging S8 substances for delivery or transport:

1.1 S8 substances must be enclosed in a package that does not contain any other goods and which is labelled with the following statement:

SCHEDULE 8 – PLEASE CHECK CAREFULLY

1.2 A multi-part document (packing-slip) stating the contents of the package must be enclosed within or securely attached to the package.

1.3 The package in [1.1] must itself then be enclosed in a carton, or other opaque container, addressed to the purchaser or consignee. This carton or container must give no indication that it contains a S8 substance.

1.4 Where possible, parcels containing S8 substances should be consigned to a particular person.

2.2 Road Transport

The following requirements apply when delivering S8 substances by road:

1. S8 substances are to be packaged in accordance with [**Error! Reference source not found. Error! Reference source not found.**];
2. The contents of parcels containing S8 substances *must not* be disclosed to common or contract carrier employees.
3. Vehicles must not be marked so as to identify their carriage of S8 substances.
4. Vehicles must be kept locked at all times and keys not left in the vehicle.
5. All reasonable precautions must be taken to ensure that the time between collection and delivery of consigned S8 substances is minimised.
6. Large-scale deliveries of S8 substances must be consigned with a contract carrier:
    6.1. Who uses standard cargo containers or fully enclosed trucks on which the enclosure is metal or other substantial material sufficient to retard unauthorised access to the cargo. The containers or enclosures must be fitted with high standard security locks that are kept locked at all times en route;
    6.2. Uses vehicles fitted with automatic logs;
    6.3. Who operates a service where no avoidable stops are made, and if scheduled stops are made, the vehicle is not left unattended unless parked in a secure area; and
    6.4. Who provides a terminal where cargo being loaded or unloaded is not easily accessible to unauthorised personnel and is under CCTV surveillance;
7. The consignor of S8 substances *must notify* the consignee that the consignment has been dispatched and provide the expected time and place of delivery; and

8. A signature must be obtained from the consignment-recipient each time the consignment changes hands, with receipts exchanged.

2.3 Postal Transport

S8 substances must only be sent via Australia Post if they meet the following requirements:

1. S8 substances are to be packaged in accordance with [**Error! Reference source not found. Error! Reference source not found.**]; and
2. The sender of S8 substances must notify the receiver that the consignment has been dispatched and provide the expected time and place of delivery.

For additional information please see *D.14.2 Therapeutic Drugs and Medicines Lodged in the Post in the Post Guide, Dangerous and Prohibited Goods and Packaging, September 2009*. A copy can be accessed at:

http://auspost.com.au/parcels-mail/dangerous-and-prohibited-items.html

2.4 Rail Transport

The following requirements apply when delivering S8 substances by rail:

1. Bulk consignments of S8 substances must not be sent by rail;
2. S8 substances are to be packaged in accordance with [**Error! Reference source not found. Error! Reference source not found.**];
3. Where small quantities of S8 substances are sent by rail, they should be included in a larger consignment of other cargo;
4. Where large quantities of S8 substances are sent by rail, the parcel must be insured with the railway or be consigned in such manner that the consignment will be specially handled;
5. A signature must be obtained from the consignment-recipient each time the consignment changes hands, with receipts exchanged; and
6. The sender of S8 substances must notify the receiver that the consignment has been dispatched and provide the expected time and place of delivery.

2.5 Air Transport

The following requirements apply when delivering S8 substances by air freight:

1. S8 substances are to be packaged in accordance with [**Error! Reference source not found. Error! Reference source not found.**];
2. The contents of parcels must not be revealed unnecessarily to airline employees;
3. S8 substances consigned by air freight must be classified as “vulnerable”, unless the consignment is part of normal delivery between a wholesaler to a pharmacy;
4. Care must be taken to ensure that cargo handling, storage, loading, and unloading at either end of the consignment’s journey is inaccessible to unauthorised persons;
5. Consignors must ascertain the flight number on which S8 substances will be carried and insist on notification of any change before flight commencement;

6. Parcels must not be delivered to a city terminal for transport to the airport in airline-operated vehicles. Parcels must be taken to the cargo establishment at the airport in a transport company or contract carrier's vehicle;
7. Delivery to and collection from the carrier's premises must be timed with the object of the S8 substances spending the minimum practicable time at those premises[1];
8. A signature must be obtained from the consignment-recipient each time the consignment changes hands, with receipts exchanged; and
9. The consignor must notify the consignee that the consignment has been dispatched and provide the expected time and place of delivery.

2.6 Health Service Facility Drug Transport Systems

The following requirements apply for all drug transport systems (DTS):

1. All DTS installed in health service facilities must be constructed and operated in a way that ensures the secure delivery of drugs of dependence to intended recipients.
2. All DTS must be approved in writing by the Manager, Medicines & Poisons Control.

2.7 Receiving S8 substances

The following requirements when receiving S8 substances:

1. The consignee must ensure that he or she, or a health practitioner, veterinarian, an authority holder or a person authorised under a licence will be on hand to receive the consignment of S8 substances.
2. A signed receipt must be given for the consignment.[2]
3. The receiver must immediately check the contents of the parcel.
4. In the event a discrepancy is identified the receiver must immediately notify the consignor and consignee (if the receiver is not the consignee). If the consignment remains irreconcilable, then the consignor must within 24 hours notify the Northern Territory Police and the Manager, Medicines & Poisons Control.

[1] For example, all reasonable steps must be taken not to store consignments at a depot over a weekend or public holiday.
[2] It is sufficient compliance with this clause that a signature is endorsed on a carrier's delivery schedule.