

PCP Sample Answers

Poisons Control Plan for a **Licence**: To Sell or Supply by Wholesale **OR** to Manufacture and Sell or Supply by Wholesale **Part Two – Sample Answers**

9. Storage / Security

Schedule 8 or Schedule 9 poisons [if any]

9.1 Indicate how Schedule 8 or 9 poisons are to be stored;

- Free standing safe, weighing approx. 350 kilograms, with twin combination locks
- Reinforced concrete vault with combination and key operated locks

9.2 Indicate the specific security provisions that are to apply;

- The vault has seismic detectors connected to a monitored alarm system at all times.
- The vault door is fitted with a monitored alarm that may only be deactivated by designated persons entering a personal identification number.
- The alarm system has a concealed duress alarm facility.
- The vault door is fitted with a time delay lock / smart lock.
- The vault door is monitored by a closed circuit TV camera with attached recording device.
- The vault is fitted with an internal emergency duress alarm.

Access to Schedule 8 or 9 poisons

9.3 Indicate how unauthorised or unsupervised access to the locked facility is to be prevented;

- The alarm may only be deactivated by entering a Personal Identification Code, which is to be issued only to designated Experienced or Qualified Persons.
- The key(s) to the vault door are to be held only by Qualified Persons.
- The two combinations, required to open the vault, are to be known to two distinct groups of designated persons so that the vault may only be opened in the presence of designated persons from both groups.
- All codes and combinations are to be changed annually and immediately following the departure of a designated Experienced or Qualified Person.

9.4 Indicate how unauthorised or unsupervised access is to be prevented when the storage facility is open;

- The entrance to the vault is to be secured with a locked steel grill when there are personnel within the vault and when the vault door is open.
- Access to the room, in which the entrance to the vault is located, is to be restricted to personnel issued with the necessary electronic access card and Personal Identification Number (PIN).

9.5 Indicate the manner in which details, including name, address and evidence of the National Police Record Check are to be maintained;

- All relevant documents are to be retained in a secure, designated file in the office of the Operations Manager.

9.6 Indicate what criteria are to be used to authorise personnel who may have unsupervised access to the facilities in which Schedule 8 poisons are to be stored and the form of training to be given to other employees who are to work in the facility;

- Documentation, which demonstrates that a person is an Experienced or Qualified Person, is to be verified at the source.
- A National Police Record Check is to be conducted before an employee may be authorised to have access to the vault.
- New personnel will receive personal instruction from an Experienced or Qualified Person and will be required to review this document (PCP) to familiarise themselves with relevant requirements.

Schedule 4 poisons

9.7 Indicate how Schedule 4 poisons are to be stored;

- Schedule 4 poisons are to be stored in a lockable storeroom, separate from other goods.
- Schedule 4 poisons are to be stored within an inner, restricted access section of the warehouse.
- Schedule 4 poisons are to be stored in a lockable metal cabinet.

9.8 Indicate how unauthorised or unsupervised access is to be prevented;

- The key to the storeroom/cabinet is to be held on the person of the warehouse manager.
- Access to the storage area is to be restricted to employees who have been issued with a personalised electronic access card.

Drugs of dependence [other than Schedule 8 or 9 poisons]

9.9 Indicate which drugs of dependence are to be stored on the premises;

- Benzodiazepines
- Pseudoephedrine
- Preparations containing pseudoephedrine
- Anabolic steroids

9.10 Indicate how drugs of dependence are to be stored;

- Drugs of dependence are to be stored in a separate locked cabinet with the key(s) held only by an Experienced or Qualified Person.
- Pseudoephedrine is to be stored in the vault with Schedule 8 poisons.
- Anabolic steroids are to be stored in the lockable area that surrounds the door to the vault in which Schedule 8 poisons are stored.
- Drugs of dependence are to be stored with other Schedule 4 poisons but are to be subject to stringent, periodic stock check procedures – see Item 9.13

9.11 Indicate the manner in which details, including name, address and evidence of the National Police Record Check are to be maintained;

- All relevant documents are to be retained in a secure, designated file in the office of the Operations Manager.

9.12 Indicate what criteria are to be used to authorise personnel who may have unsupervised access to the facilities in which drugs of dependence are to be stored and the form of training to be given to other employees who are to work in the facility;

- Documentation, which demonstrates that a person is an Experienced or Qualified Person, is to be verified at the source.
- A National Police Record Check is to be conducted before an employee may be authorised to have access to the storage facility.
- New personnel will receive personal instruction from another Experienced or Qualified Person and will be required to review this document (PCP) to familiarise themselves with relevant requirements.

9.13 Indicate what security measures, additional to those for similarly scheduled drugs, are to apply to the storage of drugs of dependence;

- Periodic physical stock checks are to be carried out on all DD's. Please indicate the proposed frequency and include a brief summary of action to be taken in the case of a discrepancy.
- Only very small quantities of two products are to be held. These are to be stored in a locked metal cabinet, with the key held only by the Responsible Person.
- Anabolic steroid preparations are stored within the limited access, lockable area that surrounds the vault entrance.

Schedule 2 and 3 poisons [other than drugs of dependence]

9.14 Indicate how Schedule 2 and/or Schedule 3 poisons are to be stored;

- Stored with other therapeutic goods, including Schedule 4 poisons
- Stored in the general warehouse in a designated area
- Stored in the warehouse, with Schedule 4 poisons that are not drugs of dependence

Storage / Stability of Therapeutic Goods

9.15 Indicate how the storage requirements of finished goods are to be determined;

- Relevant data, for all therapeutic goods, is to be contained in computerised records to enable storage locations to be designated
- Items requiring refrigeration are to be identified and listed for relevant storage. All other therapeutic goods are to be stored below 25°C

Temperature control and monitoring

9.16 Indicate how temperature is to be controlled and monitored within storage area(s);

- The storage area has a thermostatically controlled air-conditioning system which is to be active at all times
- Therapeutic goods are to be stored in a small air-conditioned storeroom.
- Storage temperature is to be monitored using a thermograph / computerised temperature monitor.
- Storage temperature is to be monitored with a number of minimum/maximum thermometers. Temperature ranges are to be manually recorded each week.

Refrigerated storage facilities [if any];

9.17 Indicate how adequate refrigerated storage temperatures are to be achieved;

- Thermostatically controlled refrigeration unit, with a temperature-monitoring device, connected to the monitored alarm system plus a visual/audible signal to indicate that refrigeration has failed.
- Minimum/maximum thermometer, located within the refrigerator, is to be checked each day to confirm that the specified temperature range has been maintained.

9.18 Indicate what action is to be taken when refrigeration has failed or has been shown to have failed;

- When the alarm is activated, the rostered manager is to be contacted to arrange for the system to be repaired and/or for short-term intervention to occur (please specify).
- When stock is found to have been stored outside the designated temperature range, it is to be quarantined until stability can be confirmed with the relevant manufacturer(s).
- Stock that cannot be confirmed as stable is to be put aside for disposal.

10. Sale / Supply

10.1 Indicate how orders for substances in Schedules 2, 3, 4, 8 and 9 are to be handled to ensure that the purchaser has the necessary authorisation;

- The computer system enables all account customers to be flagged with the poison schedules that they are authorised to obtain and all poisons to be identified by the relevant poison schedules. Orders may not be generated for clients who lack the necessary authorisation.
- Orders for such substances are expected to be limited, in number, and stock is to be stored in an area with restricted access. All orders are to be manually checked to ensure a current permit is held.
- Before accepting an order for a poison that is not usually requested (eg. indent sale of an imported chemical), the SUSDP is to be consulted to determine the schedule (if any) of the poison requested.
- The authorisation of all new clients is to be checked, with the relevant professional registration board (eg. Medical Practitioners Board), before an account is initiated.
- All new clients are to be required to produce a copy of their current licence/permit before an account is initiated.
- All clients are to be required to provide a current copy of their licence/permit on an annual basis.
- All orders for such substances are to be personally screened by a designated manager.

10.2 Indicate what despatch and delivery procedures are to be used to ensure that consigned orders are delivered to the correct client;

- Dedicated delivery vehicles are to be used and a signed receipt is to be required for all deliveries.
- All deliveries are to be carried out by staff members.
- All deliveries are to be carried out by agents/representatives.
- Contract couriers are to be used with a signed receipt required for all deliveries.
- Stock delivered by couriers is sealed in a container with a tamper-evident seal.
- Only specifically authorised drivers are to be used for the delivery of drugs of dependence.

Calling Orders [i.e. to be collected by the client]

10.3 Indicate the manner in which the identity and authorisation of a person collecting an order are to be verified;

- Requests for all "calling orders" are to be confirmed by a phone call to the client to confirm the identity of the person, who is to collect the order.
- The person's identity and authorisation are to be personally confirmed, by the Warehouse Manager, when the person attends to collect the order.
- No "calling orders" are to be accepted.

Temperature control during delivery [if required]

10.4 Indicate how stringent temperature control, during transportation, is to be achieved;

- Items, which must remain frozen, are to be transported in insulated containers under dry ice.
- Items requiring storage below 8°C are to be transported in insulated containers with ice bricks.
- Items, which are subject to temperature control, are to be only despatched when same day delivery can be guaranteed.
- Temperature monitoring devices are to be used, in insulated containers, to demonstrate that adequate storage temperatures have been maintained.
- Representatives will be required to use insulated containers to prevent professional samples, which they are delivering, being exposed to high temperatures in vehicles.

Exceptional Orders

10.5 Indicate how exceptional requests may be identified and what action is to be taken;

- The computer system enables the detection of atypical purchasing patterns and the supply of drugs of dependence is to be reviewed on a periodic (please specify) basis.
- If/when an exceptional situation is identified, the Responsible Person will be required to advise the Department.
- Staff will be periodically (at least annually) reminded to advise the Manager of any exceptional orders which may be received. Such orders are to be reviewed by the Manager, before supply occurs, and the Department is to be notified of the circumstances.
- Staff involved in picking and packing drugs of dependence will be periodically (at least quarterly) reminded to advise the Manager of any exceptional orders which may be received. Such orders are to be reviewed by the Manager, before supply occurs, and the Department is to be notified of the circumstances.

11. Records of Transactions

Schedule 4, 8 and 9 poisons

11.1 Indicate how records of transactions may be retrieved;

- All records are to be computerised with reporting programs to enable records to be retrieved in relation to a number of parameters, including specific drug names.

11.2 Indicate how records for Schedule 8 or 9 poisons are to be secured and validated;

- In addition to computerised records, manual records are to be maintained in the form of a bound book with consecutively numbered pages, i.e. a Drug of Addiction register.
- The computer system will not permit the amendment of any records for Schedule 8 poisons and incorrect entries must be corrected by another entry.
- Access to computerised records is to be restricted by unique passwords, known only by designated Qualified and/or Experienced Persons.
- Physical stock checks are to be performed periodically (specify).

12. Returned Goods

12.1 Indicate how the integrity of therapeutic goods is to be assessed for possible resupply;

- Orders for temperature sensitive goods are to be verified before despatch as such items are not accepted as returnable items.
- Returned goods, which require storage below 8°C, are to be set aside for disposal as verification of the product integrity is impractical.
- Returned goods, which require storage below 8°C, are to be only considered suitable for resupply if the temperature sensitive device, attached to the container, demonstrates that adequate storage temperatures have been maintained.
- Therapeutic goods are to be only considered suitable for resupply if the integrity of the container can be confirmed, if tamper-evident seals (if any) are intact and if appropriate storage requirements have been met.

13. Disposal of Expired & Unwanted Poisons

Disposal of Schedule 2, 3 & 4 poisons

13.1 Indicate how Schedule 2, 3 and 4 poisons requiring disposal are to be handled;

- Expired stock is to be sent, for high temperature incineration, to a company that holds a permit authorising the possession of such substances.
- Relevant managers have been informed that it must not be supplied to persons who might claim to be seeking expired medications for provision to a humanitarian operation.

Destruction of Schedule 8 & 9 poisons

13.2 Indicate where the documented Operating Procedure, for the destruction of Schedule 8 or 9 poisons, is to be located;

- The pharmacist, who manages the vault, is to maintain the relevant Operating Procedure.