Poisons Control Plan (PCP) for a Permit to Purchase or Obtain and Use Poisons or Controlled Substances for Industrial, Educational, Advisory or Research Purposes - Part One

Note: This section is for the Department of Health, Drugs and Poisons Regulation use ONLY

Details of the permit to which this Poisons Control Plan relates:

Permit Holder:
Permit Number(s):

The registered version of the Poisons Control Plan contains _______ pages, each of which has been stamped by the Department of Health, Drugs and Poisons Regulation.

Poisons Control Plan

A Poisons Control Plan (also abbreviated in this document to PCP) must be submitted for registration in relation to all permits to indicate how the permit holder proposes to comply with the Drugs, Poisons and Controlled Substances Act 1981 (The Act), the Drugs, Poisons and Controlled Substances Regulations 2006 (The Regulations), the conditions of the permit plus relevant codes and standards.

The Act and The Regulations are administered by the Department of Health, Drugs and Poisons Regulation.

It is the responsibility of the permit holder to ensure compliance with The Act and the Regulations.

Important Information

References in this PCP made to a permit or permit holder should equally be read as referencing a permit application or permit applicant.

Notes:

- The electronic version of this PCP is accessible, in Word® format, from the Department of Health, Drugs and Poisons Regulation website at www.health.vic.gov.au/dpu
- The PCP is an integral part of permits to purchase or obtain and use substances in any combination of Schedules 2, 3, 4, 7, 8 and/or 9.
- A version of this PCP is available for manual completion and submission, for use when a permit holder or permit applicant is unable to prepare the PCP by or on computer. Contact the Department of Health, Drugs and Poisons Regulation to obtain this version.
Instructions

- Download the PCP and save it (as a Word® document) to your computer.
- Questions are asked seeking true and accurate responses. The questions are in green font.
- Sample responses have been included, in blue font, to provide examples of responses that may be acceptable to the Department of Health, Drugs and Poisons Regulation, and to indicate the expected length and detail of the responses. One or more of the sample responses may be retained, with or without amendment, but only if they are true and accurate. Additional or alternative responses should be made, where required, to reflect accurately specific circumstances that apply to the permit holder.
- Some items or sections of the PCP may not be relevant to all permits. Where this is the case, delete the sample responses and respond with 'Not Applicable', so that the completed PCP will not be confusing and will serve as a meaningful reference document to relevant personnel. Do NOT leave any question with a response that is blank.
- Save the completed PCP on your computer, to facilitate any necessary and/or future amendments.
- Transmit the completed PCP (as a Word® document) as an email attachment to the Department of Health, Drugs and Poisons Regulation email address at dpu@health.vic.gov.au or alternatively, if it forms part of a permit application, forward it together with the remaining required documentation.
- Other relevant documentation may also be transmitted electronically, other than application forms or documents that require original signatures.
- If a PCP has been completed manually, it will need to be posted to the Department of Health, Drugs and Poisons Regulation, GPO Box 4541, Melbourne 3001 or delivered to 50 Lonsdale Street, Melbourne.

Notes:

- The PCP must be completed and submitted in the format provided. A document comprised only of a list of responses to the PCP questions will NOT be accepted because, after being assessed and registered by the Department of Health, Drugs and Poisons Regulation, the PCP will be returned to the permit holder for use as a reference document, showing how the permit holder proposes to comply with the legislation and related standards.
- The permit holder will be required to review the PCP periodically, including at the time of annual permit renewal.
- Avoid providing too much detail and do NOT include the names of personnel or other information, which may result in additional paperwork to amend the PCP in the future. When required to identify key personnel, use position titles or a description of the role, as these are less likely to change.
- Where a reference is made to external auditors, other licences, standards or forms of accreditation (e.g. NATA, ISO 9002, TGA Licence), ensure that you clearly and unambiguously identify the reference.
- Do not use abbreviations unless these are clearly defined in the document.

Permitted Activities

Notes:

- Poisons schedules should not be confused with similar numbering of classes of poisons in Dangerous Goods legislation.
- A permit is required in relation to each location at which purchasing or obtaining of permitted poisons occurs. All premises at which substances in Schedules 4, 8 and/or 9 plus Listed Regulated Poisons in Schedule 7 are stored must be covered by a permit.
- A permit is required to possess substances in Schedules 4, 8 and 9 plus Listed Regulated Poisons in Schedule 7 (e.g. arsenic, benzene, cyanides).
- When a permit expires or is cancelled, any remaining substances in Schedules 4, 8 and/or 9 plus Listed...
Regulated Poisons in Schedule 7 must be disposed of, in an appropriate manner.

- A permit holder is **not authorised to supply** scheduled poisons.
- The permit document specifies which poisons may be purchased or obtained and contains a number of conditions that must be observed by the permit holder.

**Responsible Person(s)**

The permit document will identify one or more Responsible Persons, who have been **nominated by the permit holder** (and approved by the Department of Health, Drugs and Poisons Regulation) to fulfil the following tasks:

- Ensure maintenance of the accuracy and currency of the registered PCP,
- Provide annual confirmation (as required by the Department of Health, Drugs and Poisons Regulation) that the permit holder is operating in a manner consistent with the registered PCP,
- Ensure that there is a periodic review (at least annually, e.g. at the time of licence renewal) of the permit and the registered PCP to confirm that the permit holder continues to comply with the conditions of the permit, the legislation, relevant codes and required standards and to retain documentary records of such reviews,
- Notify the Department of Health, Drugs and Poisons Regulation of any amendments, which may be required to the permit or to the conditions of the permit (e.g. change of company name, change of address, change of Responsible Person), and
- Submit for assessment to the Department of Health, Drugs and Poisons Regulation any proposed amendments to the registered PCP.

**Sections of the Poisons Control Plan**

**Part One (relates to all permits)**

1. **Documentation**

2. **Purchasing or Obtaining Permitted Poisons**

3. **Security and Storage**

4. **Records of Transactions**

5. **Staff Training**

6. **Waste Disposal**

**Part Two (relates to permits with Schedule 8 and/or Schedule 9 poisons only)**

7. **Storage and Access**

8. **Records of Transactions**

9. **Disposal/Destruction of Schedule 8 and/or Schedule 9 Poisons**

**Part Three (relates to permits with additional campuses)**

10. **Multiple Campuses**
1. Documentation

References

Current versions of the following source material may be accessed on the indicated websites:

- The Department of Health, Drugs and Poisons Regulation website contains application forms and information relating to licence and permit requirements in Victoria and may be accessed at http://www.health.vic.gov.au/dpu
- The current edition and amendments of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which is the source document for poisons schedules plus labelling and packaging requirements, may be accessed at http://www.tga.gov.au/industry/scheduling-poisons-standard.htm

Notes:

- Key aspects of the preceding reference documents are addressed in this PCP but reference must be made to the source material for full details of requirements.

<table>
<thead>
<tr>
<th>Location of the Permit and Poisons Control Plan documents</th>
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<tr>
<td>The registered PCP, which will be stamped and returned by the Department of Health, Drugs and Poisons Regulation, must be maintained by a Responsible Person (who will be named in a condition on the permit). The current permit and registered PCP documents must be readily available and able to be located for reference and review.</td>
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1.01 Indicate the intended or actual locations of the current permit and registered version of the PCP:

The Registered version of the Permit and PCP are to be filed in the office of the Materials Science and Engineering (MSE) Department Manager

Copies of the PCP are to be displayed in each designated lockable storage room within the New Horizons Research Facility and the Engineering Precinct Store

The Responsible Person must ensure that there is a periodic review (at least annually, such as at the time of permit renewal) of the permit and the registered PCP to confirm that the permit holder continues to comply with the conditions of the permit, the legislation, relevant codes and required standards. Proposed or required amendments to the PCP must be submitted to the Department of Health, Drugs and Poisons Regulation for assessment.

Confirmation that each review has occurred is to be recorded in a document and is to be signed and dated by the person who conducted the review. It is to be retained for the life of the PCP (and not less than three years) and is to be provided to the Department of Health, Drugs and Poisons Regulation, upon request.

1.02 Indicate the position or role of the person(s) to be responsible for the periodic review of the registered PCP and the frequency with which the review is to occur:

The MSE Department Manager is required to review the PCP at least annually and to submit any proposed amendments to the Department of Health Drugs and Poisons Regulation, for assessment

1.03 Indicate the manner in which the review of the PCP is to be documented and where the corresponding records are to be retained:

The registered copy of the PCP is to be retained in the MSE Department Manager's Office in a clearly marked folder with the date of review and the name and signature of the reviewer to be recorded on each occasion
Purpose for which poisons are required

1.04 Indicate the type(s) of activities for which the permitted poison(s) may be required:
A range of S4 & S7 poisons are used in various ever-changing research projects by University Academia housed within the New Horizons Research Facility

2. Purchasing or Obtaining Permitted Poisons

The acquisition of scheduled poisons, to which the permit relates, must only occur in accordance with a documented procedure or at the direction of the Responsible Person(s).

2.01 Indicate the position or role of the person(s) to be responsible for ordering scheduled poisons from suppliers:
All purchases must be requested by the Academic Fund Holder and then approved by a Responsible Person and ordered by the MSE Department Manager

2.02 Indicate what records are to be retained in relation to the acquisition of scheduled poisons:
Copies of all invoices are to be retained for a period of 3 Years

3. Security and Storage

Scheduled poisons must be stored securely in order to prevent unauthorised access and illegal diversion.
More stringent security provisions are required for Schedule 8 and 9 poisons, details of which are to be provided in Part Two of this document (if applicable).

3.01 Indicate what security measures are applicable to the premises:
Upon initial delivery to the University all scheduled poisons will be secured in the Engineering Precinct Store dedicated safe and collected as soon as possible by a Responsible Person when notified of its arrival, who will then transport them to one of the designated lockable storerooms within the New Horizons Research Facility
Swipe card access by authorized users of the laboratory envelope at all times
Restricted Access to the building (New Horizons Research Facility) outside of business hours
After hours patrols by University Security Staff
24 Hour video surveillance of ALL entrances into the Laboratory areas
Schedule 4 poisons

The Regulations require a lockable facility for the storage of Schedule 4 poisons.

3.02 Indicate how Schedule 4 poisons are to be stored:

Upon initial delivery to the University all scheduled poisons will be secured in Engineering Precinct Store dedicated safe and collected as soon as possible by Responsible Person when notified of its arrival, who will then transport them to one of the designated lockable storerooms within the New Horizons Research Facility. Swipe card access by authorized users of the laboratory envelope at all times.

After collection Schedule 4 poisons are to be stored in a lockable storeroom within a swipe card protected laboratory envelope.

The storage facility, for Schedule 4 poisons, must remain locked and secured to prevent access by any unauthorised person at all times, except when it is necessary to open it to carry out essential operations.

3.03 Indicate how unauthorised or unsupervised access to Schedule 4 poisons is to be prevented:

The keys to the lockable storerooms are to be issued only to the registered Responsible Persons.

Listed Regulated Poisons in Schedule 7

Schedule 7 poisons (also referred to as Dangerous Poisons) fall into two categories - Listed Regulated Poisons and Schedule 7 poisons (other than Listed Regulated Poisons).

Listed Regulated Poisons are those Schedule 7 poisons that are more strictly controlled and are the Schedule 7 poisons that are listed in Chapter 1, Part 2 of the Victorian Poisons Code, which may be accessed at: http://www.health.vic.gov.au/dpu/poicde.htm

Listed Regulated Poisons in Schedule 7 must be stored in a lockable facility that must remain locked and secured to prevent access by any unauthorised person at all times, except when it is necessary to open it to carry out essential operations.

3.04 Indicate how Listed Regulated Poisons in Schedule 7 are to be stored:

- Upon initial delivery to the University, all scheduled poisons will be secured in Engineering Precinct Store dedicated safe and collected as soon as possible by Responsible Person when notified of its arrival, who will then transport them to one of the designated storerooms within the New Horizons Research Facility. Swipe card access by authorized users of the laboratory envelope at all times.

After collection, Schedule 7 poisons are to be stored in lockable storerooms within a swipe card protected laboratory envelope.

3.05 Indicate how unauthorised or unsupervised access to Listed Regulated Poisons in Schedule 7 is to be prevented:

The keys to the lockable storerooms are to be issued only to registered Responsible Persons.
Special storage facilities

3.06 Indicate what special storage facilities (if any) are to be used for specific poisons:
Locked refrigerators within the lockable storerooms will be used for poisons requiring refrigeration

Loss or Theft of Permitted Poisons

The loss or theft of all permitted poisons must be promptly reported to Victoria Police and, in writing, to the Department of Health, Drugs and Poisons Regulation.

4. Records of Transactions

The definition of a "transaction" includes the preparation, use, transfer within and between premises, administration, disposal or destruction of a substance.

Details of all transactions, relating to substances in Schedule 4 (e.g. antibiotic substances) and Listed Regulated Poisons in Schedule 7 (e.g. arsenic, benzene, cyanide) must be kept for a minimum of 3 years and produced on demand to an Authorised Officer of the Department of Health, Drugs and Poisons Regulation.

4.01 Indicate how records of transactions are to be retained:
Separate logbooks kept in each storeroom for S4 & S7 poisons are to be used to record all transactions

5. Staff Training

Relevant personnel should be trained in all procedures, which relate to their roles and responsibilities for the storage, handling and use of scheduled poisons.

5.01 Indicate how staff training and information relating to permitted poisons are to be provided to employees:
Staff members using a scheduled poison are to hold current University qualifications in the following:
Dangerous Goods
Essential OHS
All laboratories requiring the use of scheduled poisons will prominently display copies of the University Poster "Purchase and Storage of Scheduled Poisons"

6. Waste Disposal

Waste material, which might contain poisons in Schedules 2, 3, 4 and/or 7, must be disposed of in an appropriate manner and must not be disposed of via normal waste collection agencies (e.g. garbage collection). Where permitted poisons are to be provided to another agency specifically for the purposes of destruction, that agency must hold the relevant licence or permit to lawfully possess those poisons.

6.01 Indicate the means of disposal of waste material containing scheduled poisons:
All scheduled poisons requiring disposal are to be collected by the current (at the time) University approved
Note: Parts Two and Three of the PCP are applicable only to permits that relate to those specific activities of the permit holder (or applicant) and may otherwise be discarded.

Authorised by the Victorian Government, Melbourne. To receive this publication in an accessible format phone 1300 364 545 Drugs and Poisons Regulation.