

Guide to completing a PCP



Guide to completing a Poisons Control Plan for a Licence To Manufacture and Sell or Supply by Wholesale

Introduction

A satisfactory **Poisons Control Plan (PCP)** must be developed and maintained by a licence holder and by an applicant for a licence.

The licence will identify one or more **Responsible Person(s)** to ensure compliance with the conditions of the licence and the contents of the Poisons Control Plan.

The Poisons Control Plan is intended to enable the Responsible Person(s) to understand what standards are required and to enable the Department to understand how those standards are to be achieved.

Licence holders will periodically be required to confirm compliance with the Poisons Control Plan and to submit, for approval, any proposed amendments to the Poisons Control Plan.

Sample Answers

To assist in the preparation of a Poisons Control Plan, the Department of Human Services has prepared **Sample Answers** to demonstrate how specified standards may be achieved.

Notes:

- The sample answers are listed beneath item numbers that correspond to the information required to be inserted in the relevant Part of the Poisons Control Plan.
- The sample answers are intended to provide guidance in relation to the volume and type of response that is acceptable.
- The sample answers do not represent the only acceptable methods of achieving the specified standards and, in some cases, more than one sample answer might be applicable.
- The sample answers must **NOT** be used as a substitute for information that is specific to the actual circumstances and should **NOT** be simply copied – unless they accurately describe the procedures and facilities at the establishment.

Directions for preparing a PCP from the Department's Website

All Parts of the Poisons Control Plan plus Sample Answers, to assist in completing a Poisons Control Plan, may be obtained at www.health.vic.gov.au/dpu in Word® format.

The PCP may then be completed and submitted as follows:

1. Print the required Parts of the PCP.
2. Complete the PCP by manually entering information into the spaces provided.
3. Forward the completed PCP, for approval, with other relevant documentation to the Drugs and Poisons Regulation Group, GPO Box 4057, Melbourne 3001.

However, the **recommended** alternative is as follows:

1. Open or copy the required Parts of the PCP to your computer.
2. Complete the PCP by entering information into the spaces provided.
3. **Save** the completed PCP, to facilitate necessary or future amendments.
4. Print the completed PCP and forward it, with other relevant documentation, to the address shown above, **OR** transmit the completed PCP as an Email attachment, if requested to do so.

Suggestions for preparing YOUR Poisons Control Plan

- The PCP **must** be submitted in the form provided.
- A list of answers will **NOT** be accepted because, when approved by the Department, the PCP will be returned to you (the licence holder) for use as **your reference document**, showing how and why you propose to comply with the legislation and related standards.
- You will also be required to periodically review your PCP and, with this in mind, you are **strongly advised** to complete the PCP using terminology that is meaningful to you and your staff – rather than simply copying the Sample Answers.
- Refer to the **Sample Answers** to determine the nature and amount of information that is required.
- **Avoid** providing too much detail, especially the names of staff members or other specific information, as this may result in additional paperwork to amend the PCP in the future.
- Where reference is made to external auditors, other licences, standards or forms of accreditation (eg. NATA, ISO 9002, TGA Licence, Standard Operating Procedures) please ensure that you clearly and unambiguously identify the reference.
- Insert "not applicable" or "**N/A**" in any sections that do not apply to a your licence.

Which Parts must be completed in preparing a Poisons Control Plan for a Licence To Manufacture and Sell or Supply by Wholesale?

- PART ONE, of the Poisons Control Plan, is to be completed by **ALL** applicants for a licence.
- PART TWO is applicable **only** to licences that authorise the sale or supply of Schedule 2, 3, 4, 8 or 9 poisons and may be discarded for licences relating only to Schedule 7 poisons.
- PART THREE is to be completed **only** in relation to a manufacturing licence **or** by those who store Schedule 4, 8 or 9 poisons or Schedule 7 Listed Regulated Poisons in laboratory areas **AND** who have not completed a Poisons Control Plan in relation to a corresponding permit.
- Where a licence holder holds another licence, which relates to the same premises (eg. wholesale licence and manufacturing licence), a single Poisons Control Plan may be prepared in relation to both licences.

Nominating a Responsible Person

Licence holders and applicants should nominate the **minimum number** of persons, to be named on the licence, to be responsible for the tasks outlined in the PCP. Nominating additional persons may make it necessary for the licence to be amended too frequently.