Queensland Health Departmental Standard

Substance management plans for regulated poisons – version 1

27 September 2021

Queensland Government

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Disclaimer:

Version control

Version	Replaces version	Date approved	Commencement date
1	NA	12 August 2021	27 September 2021

Contents

Preface

The Departmental Standard – *Substance management plans for regulated poisons* (this Standard) has been made pursuant to section 233 of the *Medicines and Poisons Act 2019* (the Act) by the Chief Executive of Queensland Health, and outlines the matters that must be addressed in substance management plans relating to regulated poisons.

Maintaining the health and wellbeing of users of regulated substances, as well as the general public who may be exposed to these substances, is the primary focus of the medicines and poisons regulatory framework. By achieving the main purposes of the Act, Queensland Health is confident that this outcome will be attained. Compliance with this Standard will assist in ensuring regulated poisons are made, sold, used and disposed of in an appropriate, effective and safe way.

This Standard must be followed where it is referenced by the Act or Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (the Poisons Regulation) or when it is required as a condition of an authority.

The Standard provides minimum criteria and acceptable actions to achieve the required outcomes. Where more than one course of action is acceptable to achieve the outcomes required, the authorised person may choose the option that is practicable to their needs.

The words ‘must’ or ‘shall’ used in this Standard mean the requirement is mandatory.

The words ‘should’ or ‘may’ recommends a discretionary course of action.

Object of this Standard

The object of this Standard is to ensure that regulated substances are managed in a way that is protective of public health. Compliance with this Standard will ensure risks associated with regulated substances are identified and managed by all persons to prevent harm to public health by prescribing the matters that must be addressed in a substance management plan (SMP).

An SMP is intended to assist in identifying and managing known and foreseeable risks associated with any dealing with a regulated substance. The SMP will provide the overarching risk management framework that is dynamic and proportionate to the risk associated with regulated activities.

A 'responsible person', described in Schedule 5 of the Poisons Regulation, is required under section 93 of the Act to make an SMP, must make the SMP before commencing any regulated activity with a regulated substance, unless the transitional provisions in section 280 of the Act apply. A 'responsible person' is a holder of a substance authority described in section 61 of the Act.

Scope

This Standard prescribes the requirements regarding the matters described in this Standard that must be included in an SMP made by a 'responsible person'.

This Standard specifies requirements for risk management across the lifespan of the poison (as defined in section 12 of the Act) or prohibited substance (as defined in section 13 of the Act), from manufacture to disposal, and should be read in conjunction with the Act and the Poisons Regulation to ensure all requirements are complied with.

This Standard applies to persons carrying out regulated activities where the responsible person for a regulated place is required under section 93 of the Act to make an SMP. The responsible person must have an SMP in place before any dealing happens at a regulated place to manage known and foreseeable risks associated with the activity.

The following authority holders who are 'responsible persons for a regulated place' are required to make an SMP under the Poisons Regulation and will be required to comply with the requirements described in Part 1 – General and Part 2 – Regulated Activities of this Standard:

Responsible person required to make an SMP	Regulated activity described in Part 2 that may be included in an SMP
The holder of the manufacturing licence	Dealings authorised by the manufacturing licence for example, manufacture, buy, possess, supply, and dispose
The holder of the wholesale licence	Dealings authorised by the wholesaling licence for example, buy, possess, supply, and dispose
The holder of a general approval for a high-risk poison	Dealings authorised by the general approval for example, manufacture, buy, possess, supply, and dispose
The holder of the substance authority if an SMP is required as a condition of the authority	Dealings authorised by the substance authority for example, manufacture, buy, possess, supply, and dispose

Part 1 – General

Criterion		Compliance measure
1.1.	Governance and operational arrangements	A. The SMP must state the governance arrangements that ensure accountability for compliance with the SMP. Governance arrangements must include details relating to: • roles and responsibilities • delegations for the SMP. B. The SMP must include the following operational details: • the date of commencement of the SMP as required under section 93(2)(a)(i) of the Act • who (staff) the SMP applies to; and how those staff will understand their role and obligations under the SMP • how compliance with the SMP will be monitored, reviewed and updated • documents that form part of the SMP and their availability to staff, for example the existing work health and safety management system or chemical management system. C. The SMP must be reviewed in accordance with section 68 of the Poisons Regulation. For section 68, a review incident, means any of the following: • there is a substantial change to the internal or external operations related to the dealings, or in connection with, the place • a non-compliant audit outcome results in new risks being identified or recommendations to modify how known and foreseeable risks related to dealing with regulated poisons are managed • a systematic issue is identified • internal checks identify that an amount of a restricted S7 poison or high-risk poison possessed under the substance authority is not accounted for • release of a restricted S7 poison or high-risk poison possessed under a substance authority causes, or is likely to cause, someone to require medical treatment. • the holder of the substance authority is issued a compliance notice, or subject to administrative action or prosecuted for an offence under the Act.
1.2.	Regulated place	A. The SMP must state the: • location where the substance is to be stored and/or used as required under section 93(2)(a)(ii) of the Act • details of how the substance will be stored at the location.
1.3.	Dealings with regulated substances	A. The SMP must state: • all regulated activities with regulated substances to which the plan applies, as required under section 93(2)(a)(iii) of the Act

Criterion		Compliance measure
		• details of compliance with the general requirements under the Poisons Regulation in relation to record keeping, storage, transport and disposal of regulated poisons to which the plan applies.
1.4.	Training and competency	A. The SMP must state the minimum training and/or competency level of all staff undertaking regulated activities, including ongoing training to maintain skills and knowledge.

Part 2 – Regulated activities

Manufacture

Criterion		Compliance measure
1.5.	Regulated substance must be fit for purpose	A. The SMP must include a description or reference to quality assurance program/s, which will be used to verify that the manufactured regulated substances will be fit for purpose.
1.6.	Apply poisons by authorised persons	A. The SMP must describe procedures for ensuring that only appropriately authorised persons apply poisons.
1.7.	Poisons must be applied correctly	A. The SMP must describe: • training and competency requirements for persons applying the poison • supervision of persons applying the poison • process control measures related to regulated activities.

Buy

Criterion		Compliance measure
1.8.	Prevention of unauthorised purchase	A. The SMP must describe procedures for ensuring that only appropriately authorised persons buy regulated substances.

Possess

Criterion		Compliance measure
1.9.	Prevention of contamination	A. In addition to the general requirements in Part 1.3 of this Standard, the SMP must include a description of how regulated substances will be stored to prevent contamination. Such descriptions should consider: • segregation of substances to prevent cross-contamination • design and construction of storage areas to prevent contamination of products.
1.10.	Prevention of spillage or exposure	A. The SMP must include a description of: • access controls to regulated substances • measures to prevent the spread of contamination and clean-up of contamination • first aid for exposed persons.
1.11.	Prevention of diversion and theft	A. In addition to the general requirements in Part 1.3 of this Standard, the SMP must include a description of: • security measures to prevent unauthorised access to regulated substances • security measures must consider the type of regulated substance as listed in the Poisons Standard • record-keeping methods used to identify diversion or theft • the persons (staff) authorised under the SMP to purchase regulated substances. B. The SMP must address internal distribution of regulated substances.
1.12.	Regulated substance must be fit for purpose	A. The SMP must include a description of how the regulated substances will be stored to prevent damage and/or deterioration.

Supply

Criterion		Compliance measure	
1.13.	Prevention of supply to unauthorised persons	A.	The SMP must include a description of procedures to prevent supply of regulated substances to unauthorised persons.
1.14.	Security arrangements for regulated substances must prevent diversion and theft	A.	In addition to the general requirements in Part 1.3 of this Standard, the SMP must include a description of: • measures to ensure regulated substances are transported securely to prevent unauthorised access - security measures must consider the type of regulated substance as listed in the Poisons Standard being transported • record-keeping procedures to identify diversion or theft of regulated substances.
1.15.	Regulated substance must be fit for purpose	A.	The SMP must include a description of measures to prevent cross contamination and interaction of regulated substances during transport.

Apply

Criterion		Compliance measure	
1.16.	Apply poisons by authorised persons	A.	The SMP must describe procedures for ensuring that only appropriately authorised persons apply poisons.
1.17.	Poisons must be applied correctly	A.	The SMP must describe: • training and competency requirements for persons applying poisons • supervision of persons applying poisons • process control measures related to regulated activities.

Disposal

Criterion		Compliance measure
1.18.	Disposal arrangements to prevent diversion and theft	A. In addition to the general requirements in Part 1.3 of this Standard, the SMP must describe procedures to ensure: • only authorised persons dispose of regulated substance waste; or witness disposal of regulated substances by another authorised person, giving consideration to: - the type of regulated substance as listed in the Poisons Standard; and - the risk to public health • accurate record-keeping, including reporting the loss of regulated substances.
1.19.	Exposure or environmental contamination	A. The SMP must describe procedures to prevent: • exposure of regulated substances to persons and • environmental contamination.

A term used in this Standard that is defined in the *Medicines and Poisons Act 2019* or the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 has the meaning stated in the Act or Regulation.