

Queensland Health Departmental Standard

Secure storage of S8 medicines – version 1

27 September 2021



Queensland
Government

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Version control

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1	NA	12 August 2021	27 September 2021

Preface

The *Medicines and Poisons Act 2019* (the Act) establishes a contemporary framework for the regulation of medicines, poisons, pesticides and other prohibited substances in Queensland. This framework will impact a broad range of persons.

This framework includes three regulations (the Regulations):

- Medicines and Poisons (Medicines) Regulation 2021;
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021; and
- Medicines and Poisons (Pest Management Activities) Regulation 2021.

The Act authorises the Chief Executive of Queensland Health to make departmental standards in relation to matters regulated under the Act (section 233, Part 4, Chapter 7 of the Act).

A departmental standard outlines the mandatory expectations and specific requirements needed to ensure regulatory compliance with the Act and Regulations.

This standard (Secure storage of S8 medicines) has been made by the Director General, Queensland Health in accordance with section 233 of the Act.

Introduction

Object

This Standard describes the requirements for an S8 safe for the purposes of section 197 of the Medicines and Poisons (Medicines) Regulation 2021 (the Medicines Regulation).

An S8 safe that complies with this standard will prevent the unauthorised removal of, or interference with, S8 medicines being stored at the place and minimise the risk that these medicines will be misused, abused or diverted.

Application

This standard applies to an S8 safe at any place where stock of S8 medicines is stored. This standard does not apply in relation to the possession of S8 medicines by consumers, or their agents, pursuant to lawful prescription or supply.

Compliance with this Standard

Table 1. General requirements for an S8 safe specifies the outcomes that an S8 safe must achieve and the minimum requirements that must be met or exceeded to demonstrate achievement of that outcome.

In certain limited circumstances, outlined below, an S8 safe that meets or exceeds alternative minimum requirements will be acceptable.

Electronic storage and supply units

At a hospital or another place approved by the chief executive¹, an S8 safe can be an electronic storage and supply unit. **Table 2. Electronic storage and supply units at hospitals or another approved place** specifies the minimum requirements that must be met or exceeded for this type of S8 safe. A person may apply to store S8 medicines in an electronic storage and supply unit at a place other than a hospital. The application must be in the approved form. In considering whether to grant an approval, the chief executive may consider:

- i. the type and quantity of the medicines being stored;
- ii. the location and layout of the S8 safe and premises;

¹ The Director General, as chief executive of Queensland Health (section 10, *Public Service Act 2008*), is the 'responsible head' under the [Administrative Arrangements Order No. 2](#) (2020) to administer the legislation portfolio set out for the Minister for Health and Ambulance Services.

- iii. the warning devices and detectors with which the S8 safe and premises are equipped;
- iv. the number and frequency of transactions;
- v. the number of persons who will have or require access to the s8 safe; and/or
- vi. the structural integrity of the building envelope.

Other acceptable S8 safes

If a medicine is of a type and/or quantity described in column 1 of **Table 3. Other acceptable S8 safes**, and the storage conditions in column 2 are met, then the minimum requirements for an S8 safe outlined in Column 3 are acceptable.

Secure place under the Health (Drugs and Poisons) Regulation 1996

If an inspector has inspected a place for keeping S8 medicines and, in accordance with sections 118 and 119 of the (repealed) Health (Drugs and Poisons) Regulation 1996 (HDPR), was reasonably satisfied that the place was as secure as a receptacle that complies with Appendix 6 of the HDPR, the place is taken to be an S8 safe that complies with this standard.

Note 1. If in doubt about which storage option applies, organisations should contact their local Public Health Unit for advice.

Note 2. To apply to keep S8 medicines in an electronic storage and supply unit, contact the Healthcare Approvals and Regulation Unit at HARU@health.qld.gov.au

Note 3. The holder of a substance authority may have additional requirements for storing medicines imposed as a condition on their license or approval.

Table 1: General requirements for an S8 safe

Outcome	Minimum requirements
<p>1. The S8 safe restricts unauthorised access to the content of the safe.</p>	<p>The S8 safe has the following body, door and lock properties:</p> <ul style="list-style-type: none"> i. constructed of mild steel plate of not less than 10 mm thickness; and ii. constructed with continuous welding of all joints; and iii. fitted with a door constructed of mild steel plate of not less than 10 mm thickness, swung on hinges that do not allow the door to be opened if the hinge is removed, the door being flush fitting with a clearance around the door of not more than 1.5 mm; and iv. fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed; and v. fitted with a 6-lever lock securely fixed to the rear face of the door.
<p>2. It is not possible to easily remove the S8 safe from the premises in which it is located.</p>	<p>The S8 safe:</p> <ul style="list-style-type: none"> i. weighs more than 350kg; or ii. is securely attached to the premises. <p>Note. See the glossary for a definition of securely attached to the premises.</p>

Table 2: Electronic storage and supply units at hospitals or another approved place

Outcomes	Minimum requirements
<p>1. The S8 safe restricts unauthorised access to the content of the safe.</p>	<p>The S8 safe:</p> <ul style="list-style-type: none"> i. restricts access to the stored S8 medicines to those persons who are authorised to possess the S8 medicines and who must use their own unique access code and password or biometric identifier to access the safe; and ii. has in-built features that record and report access, attempted access and discrepancies which are turned on; and iii. gives visual, electronic or audible alerts if it is left open, damaged or disconnected from the power supply; and iv. automatically locks if the power is disconnected; and v. can generate reports or notices of security breaches including attempts at unauthorised physical access or interference with pre-programmed settings.
<p>2. It is not be possible to easily remove an S8 safe from the premises in which it is located.</p>	<p>The S8 safe meets one or more of the following criteria:</p> <ul style="list-style-type: none"> i. weighs more than 350kg; ii. is securely attached to the premises; iii. is secured to the floor with a 4mm hardened steel chain attached to two 10mm sleeve anchors or similar fasteners; iv. has electronic tethering that is continuously monitored; v. is always personally supervised by an approved person.
<p>3. Unauthorised access, or attempted access, to the S8 safe is readily detectable.</p>	<p>The S8 safe is:</p> <ul style="list-style-type: none"> i. always personally supervised by an approved person; or ii. covered by movement detectors that are continuously monitored; or iii. covered by closed circuit television that has vision of the front and sides of the S8 safe and recordings are retained for at least 35 days.

Table 3: Other acceptable S8 safes

If a medicine is of a type and/or quantity described in column 1, and the place where an S8 medicine is being kept accords with column 2, then the minimum requirements for an S8 safe specified in column 3 are acceptable.

Column 1 - Type and quantity of S8 medicine	Column 2 - Place where S8 medicine is being kept	Column 3 - Minimum requirements
S8 medicines that require refrigerated storage	The S8 medicine is kept at a place where a health practitioner or veterinary surgeon usually practices their profession (including a pharmacy or hospital).	<p>The S8 safe is a:</p> <ul style="list-style-type: none"> i. refrigerator that is lockable and securely attached to the premises; or ii. refrigerator in a lockable room, cupboard or other hardwood or metal enclosure that is attached to the premises. <p>The S8 safe is not used to store any other item that is not a medicine.</p>
Less than 6 doses, in total, of S8 medicines for use in an emergency	<p>The S8 medicine is:</p> <ul style="list-style-type: none"> i. kept at the place where a health practitioner or veterinary surgeon usually practices their profession; or ii. kept in a RFDS medicine chest at a place for the Royal Flying Doctor Service of Australia (RFDS). 	<p>The S8 safe is a:</p> <ul style="list-style-type: none"> I. lockable hardwood or metal cupboard or drawer; or II. chest or bag supplied by the RFDS.
S8 medicines that are approved opioids	The S8 medicine is kept at a pharmacy, or other place, where an approved opioid treatment program is conducted, and the pharmacist or other person authorised to administer approved opioids, is responsible for supervising the S8 medicines.	<p>The S8 safe is a lockable hardwood or metal cupboard or drawer.</p> <p>The S8 safe is under the personal supervision of a pharmacist or other person authorised to administer approved opioids.</p> <p>Note. Outside of operating hours, or if the pharmacist or other authorised person, is not present at the place, this alternative storage arrangement ceases to be acceptable and the approved opioids must be returned to a safe that meets the requirements in Table 1 or Table 2.</p>

Column 1 - Type and quantity of S8 medicine	Column 2 - Place where medicine is being kept	Column 3 - Minimum requirements
<p>S8 medicines that are being carried for the purpose of attending patients (or animals) by:</p> <ul style="list-style-type: none"> i. a medical practitioner, nurse practitioner, ambulance officer, midwife, dentist or veterinary surgeon; or ii. a registered nurse authorised to administer or give a treatment dose of the S8 medicine under an extended practice authority; or iii. a person authorised to administer the S8 medicine under a general approval. 	<p>A place the person is attending to treat patients or animals that is not the person's usual place of practice.</p>	<p>The S8 safe is a bag, box or similar container that is kept in the person's personal custody.</p> <p>Note. S8 medicines may not be left in vehicles overnight or when the vehicle is unattended.</p>
<p>S8 medicines that are dispensed into a dose administration aid.</p>	<p>A pharmacy or relevant institution.</p>	<p>The S8 safe is a lockable room, hardwood or metal cupboard or drawer.</p>
<p>S8 medicines that are dispensed or supplied for a child attending the school or child-care facility.</p>	<p>A school or childcare facility.</p>	<p>The S8 safe is a lockable room, hardwood or metal cupboard or drawer.</p>

Glossary

The following definitions apply for this standard

Term	Definition
ambulance officer	As defined in Schedule 22 of the Medicines Regulation
approved opioids	Medicines approved for administration to patients under an opioid treatment program.
Child-care facility	As defined in Schedule 22 of the Medicines Regulation.
dentist	As defined in Schedule 22 of the Medicines Regulation
dose	For divided preparation (for example, tablets, capsules patches, ampoules) one discrete dose unit. For undivided preparations (for example, liquids, powders) the normal amount administered as a single human therapeutic dose, or in the case of a medicine for animal use, a single adult therapeutic dose relevant to the animal being treated.
dose administration aid	A tamper-evident container or packaging used to separate doses of a medicine for administration at particular times.
electronic storage and supply unit	A computerised device or cabinet used to store medicines, such as a robotic device in a pharmacy, an automated medicines unit such as Pyxis® or Omnicell® or an anaesthetic workstation.
health practitioner	As defined in Schedule 1 of the <i>Medicines and Poisons Act 2019</i> .
hospital	As defined in Schedule 22 of the Medicines Regulation
medical practitioner	As defined in Schedule 22 of the Medicines Regulation
midwife	As defined in Schedule 22 of the Medicines Regulation
nurse practitioner	As defined in Schedule 22 of the Medicines Regulation
opioid treatment program	As defined in Schedule 22 of the Medicines Regulation
personally supervising	Physically present, near where the medicines are being stored.

Term	Definition
pharmacist	As defined in Schedule 22 of the Medicines Regulation.
pharmacy	As defined in Schedule 22 of the Medicines Regulation.
Poisons Standard	As defined in Schedule 1 of the <i>Medicines and Poisons Act 2019</i> .
relevant institution	As defined in Schedule 22 of the Medicines Regulation.
RFDS medicine chest	As defined in Schedule 5 Part 3 of the Medicines Regulation.
school	As defined in Schedule 22 of the Medicines Regulation.
securely attached to the premises	Attached to a concrete floor, a brick or concrete wall, or, for a timber wall, through studs or noggins, with at least 4 bolts of at least 12mm in diameter that are fastened inside the rear of the medicine store.
S8 safe	As defined in section 195 of the Medicines Regulation
S8 medicine	A medicine in Schedule 8 of the Poisons Standard as defined in section 11 of the <i>Medicines and Poisons Act 2019</i>
veterinary surgeon	As defined in <i>Veterinary Surgeons Act 1936</i> .

A term used in this Standard that is defined in the Act or the Medicines Regulation, and is not referred to in this glossary, has the meaning stated in the Act or Medicines Regulation.