

Queensland



Subordinate Legislation 1993 No. 509

Health Act 1937

HEALTH (DISPENSARY) REGULATION 1993

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PART 1—PRELIMINARY

Short title

1. This regulation may be cited as the *Health (Dispensary) Regulation 1993*.

Commencement

2. This regulation commences on 1 January 1994.

Definitions

3. In this regulation—

“**AS 1386**” means Australian Standard 1386—Cleanrooms and Clean Work Stations;

“**AS 2639**” means Australian Standard 2639—Cytotoxic Drug Safety Cabinets—Installation and Use;

“**Australian Standard**” means a standard published by Standards Australia;

“**dispensary**” means a place used by a pharmacist to dispense a drug or poison;

“**dispense**” includes compound;

“**equipment**” includes apparatus and utensils;

“**extemporaneous preparation**” means a medicine made from 2 or more weighed or measured ingredients (other than a medicine obtained by merely reconstituting an existing medicine);

“**inspector**” means an inspector appointed under section 27 of the Act;

“**Standard for the Uniform Scheduling of Drugs and Poisons**” has the meaning given by the *Poisons Regulation 1973*;

“**therapeutic use**” means use for or in—

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or

- (b) influencing, inhibiting or modifying a physiological process; or
- (c) testing the susceptibility of a person or animal to a disease or ailment.

PART 2—GENERAL REQUIREMENTS

Restriction on use of place as dispensary

4.(1) The occupier of a dispensary must ensure the dispensary—

- (a) is adequately enclosed, ventilated, painted and lit; and
- (b) has lined walls and ceilings; and
- (c) has a floor covering that may be easily cleaned; and
- (d) has a stainless steel sink supplied with—
 - (i) cold running water; and
 - (ii) hot running water of at least 60° C; and
- (e) has a separate dispensing bench with a smooth, impervious surface.

(2) The occupier of a dispensary must ensure the dispensary is only used for a purpose associated with dispensing a drug or poison.

Maximum penalty—20 penalty units.

Standards to be maintained

5. The occupier of a dispensary must ensure—

- (a) the dispensary is kept clean, and free from anything able to contaminate a drug or poison; and
- (b) benches, shelves, drawers, and other places used in association with the dispensary, where drugs or poisons are placed or stored, are kept clean, and free from anything able to contaminate a drug or poison; and

- (c) equipment used to dispense a drug or poison is—
 - (i) free from cracks and chips; and
 - (ii) regularly serviced, kept in an efficient state of operation, and repaired as necessary; and
 - (iii) kept clean, and free from anything able to contaminate a drug or poison; and
- (d) containers used to hold drugs and poisons are always kept clean, and free from—
 - (i) cracks and chips; and
 - (ii) anything able to contaminate a drug or poison; and
- (e) drugs and poisons are stored at appropriate temperatures.

Maximum penalty—20 penalty units.

Items to be available at dispensary

6.(1) The occupier of a dispensary must ensure the items in Schedule 1 are available at the dispensary.

Maximum penalty—20 penalty units.

(2) If a dispensary is used to dispense an extemporaneous preparation, the occupier of the dispensary must ensure the additional items in Schedule 2 are available at the dispensary.

Maximum penalty—20 penalty units.

(3) If an item mentioned in Schedule 1 or 2 is a document, the document may be a printed, microfiche or electronic copy of the document.

PART 3—STERILE DISPENSING

Application of Part

7.(1) This Part applies to the dispensing of drugs or poisons for therapeutic use, using—

- (a) an aseptic technique; or
 - (b) a process in which sterilisation happens as the last stage of dispensing the drugs or poisons.
- (2) However, this Part does not apply to the dispensing of—
- (a) proprietary eye drops that are merely reconstituted; or
 - (b) antineoplastic drugs.

General requirements

8. The occupier of a dispensary used for drug or poison dispensing to which this Part applies must ensure the dispensing happens—

- (a) in a separate part of the dispensary; and
- (b) under a system that controls particulate and microbial contaminants in a way appropriate to the class of drugs or poisons being dispensed; and
- (c) under a high standard of hygiene; and
- (d) with special care and attention to detail; and
- (e) in the way specified under procedures established and validated by the pharmacist managing or supervising the dispensary; and
- (f) using a properly maintained laminar flow cabinet in an area complying with Parts 1 to 6 of AS 1386.

Maximum penalty—20 penalty units.

Standard operating procedures to be applied

9.(1) An occupier mentioned in section 8 must ensure—

- (a) written policies and standard operating procedures are prepared—
 - (i) for the drug or poison dispensing; and
 - (ii) complying with subsection (2); and
- (b) the policies and procedures are available in the dispensary; and
- (c) the drug or poison dispensing complies with the policies and procedures; and

- (d) the policies and procedures are reviewed at intervals of not more than 1 year.

Maximum penalty—20 penalty units.

(2) The policies and procedures mentioned in subsection (1) must provide for—

- (a) the training and monitoring of staff involved in a technique or process mentioned in section 7(1); and
- (b) the operation and cleaning of the part of the dispensary mentioned in section 8(a); and
- (c) spillage, storage and disposal of waste; and
- (d) servicing of equipment used in drug or poison dispensing; and
- (e) quality assurance; and
- (f) packing, labelling, handling and storage of drugs and poisons.

Maintenance

10.(1) An occupier mentioned in section 8 must ensure equipment used for sterile drug or poison dispensing, and air handling facilities for the part of the dispensary mentioned in section 8(a), are regularly maintained under a planned maintenance schedule.

(2) The occupier must also ensure the equipment and facilities mentioned in subsection (1) are maintained and tested in a way complying with AS 1386.

Maximum penalty—20 penalty units.

PART 4—DISPENSING OF ANTINEOPLASTIC DRUGS

Application of Part

11. This Part applies to the dispensing of antineoplastic drugs.

General requirements

12.(1) The occupier of a dispensary used for dispensing to which this Part applies must ensure the dispensing happens—

- (a) in a separate part of the dispensary; and
- (b) under a system that controls particulate and microbial contaminants in a way appropriate to the class of drugs being dispensed; and
- (c) under a high standard of hygiene; and
- (d) with special care and attention to detail; and
- (e) in the way specified under procedures established and validated by the pharmacist managing or supervising the dispensary.

(2) If it is necessary to store an antineoplastic agent within a particular temperature range to ensure that the agent will be effective when it is used, an occupier mentioned in subsection (1) who has any of the agent must ensure it is stored—

- (a) in a refrigerator at the appropriate temperature; and
- (b) in an enclosed container preventing the agent from contaminating other items in the refrigerator.

Maximum penalty—20 penalty units.

Dispensing

13.(1) An occupier mentioned in section 12(1) must ensure, for the purpose of the dispensing, that—

- (a) AS 2639 is complied with; and
- (b) vertical laminar flow cabinets complying with AS 2639 are used; and
- (c) persons directly involved in the dispensing wear impervious clothing and gloves; and
- (d) the compounding room and an adjoining anteroom have an air supply and extraction system separate from the air supply and extraction for any other part of the premises in which the rooms are situated; and

- (e) air exhausts are sited so as not to cause pollution or toxicity outside the area where the dispensing happens.

Maximum penalty—20 penalty units.

(2) This section does not apply to the dispensing of an antineoplastic drug if it is a pre-packed product not needing further preparation.

Standard operating procedures to be applied

14.(1) An occupier mentioned in section 12(1) must ensure—

- (a) written policies and standard operating procedures are prepared—
 - (i) for the dispensing; and
 - (ii) complying with subsection (2); and
- (b) the policies and procedures are available in the dispensary; and
- (c) the way the drugs are dispensed complies with the policies and procedures; and
- (d) the policies and procedures are reviewed at intervals of not more than 1 year.

Maximum penalty—20 penalty units.

(2) The policies and procedures mentioned in subsection (1) must provide for—

- (a) the training and monitoring of staff involved in the dispensing; and
- (b) the operation and cleaning of the part of the dispensary mentioned in section 12(1)(a); and
- (c) spillage, storage and disposal of waste; and
- (d) servicing of equipment used in the dispensing; and
- (e) quality assurance; and
- (f) packing, labelling, handling and storage of antineoplastic drugs.

Maintenance

15. An occupier mentioned in section 12(1) must ensure equipment used to dispense antineoplastic drugs, and air handling facilities for the part of the dispensary mentioned in section 12(1)(a), are regularly maintained under a planned maintenance schedule.

Maximum penalty—20 penalty units.

PART 5—GENERAL**Inspector may serve notice to comply**

16.(1) If an inspector believes, on reasonable grounds, that a person is contravening a provision of this regulation, the inspector may give the person a written notice (“**notice to comply**”) under this section.

(2) A notice to comply must state—

- (a) the act or omission comprising the alleged contravention; and
- (b) the action the person must take to rectify the alleged contravention; and
- (c) the day by which the person must take the action (the “**due date**”).

(3) The period to elapse between the day the notice is given to the person and the due date must be reasonable, having regard to the action the person has to take.

Prosecution of offences

17.(1) If an inspector gives a notice to comply to a person for an act or omission by the person, the person may not be prosecuted for an offence comprised by the act or omission unless the person does not comply with the notice by the due date.

(2) It is not a requirement of this regulation that a person must be given a notice to comply before the person may be prosecuted for an offence under this regulation.

Repeal

- 18.** The *Dispensary Regulation 1973* is repealed.

SCHEDULE 1**ITEMS TO BE PROVIDED**

section 6(1)

1. A refrigerator, fitted with a device capable of registering the minimum and maximum temperature, for use for storing therapeutic products at appropriate temperatures.
2. Three metric certified dispensing measures.
3. A funnel.
4. Two spatulas.
5. A tablet counting tray.
6. A current copy of each of the following—
 - (a) the *Poisons Regulation 1973*;
 - (b) the Standard for the Uniform Scheduling of Drugs and Poisons;
 - (c) the Register of Medical Practitioners, Queensland;
 - (d) the Register of Dentists Queensland
 - (e) the Roll of Veterinary Surgeons of Queensland.
7. Each document specified in a code of conduct prepared under section 27 of the *Pharmacy Act 1976*.

SCHEDULE 2**ADDITIONAL ITEMS**

section 6(2)

1. A set of mechanical or electronic counter scales, capable of weighing up to 1 kg with an appropriate set of metric weights (if necessary).
2. A dispensing balance capable of weighing up to 50 g that is either—
 - (a) an electronic balance; or
 - (b) a mechanical balance with an appropriate set of metric weights (if necessary).
3. A certified 10 ml, 20 ml, 50 ml, 100 ml, 200 ml and 1 L dispensing measure.
4. A mortar and pestle.
5. A stirring rod.
6. An ointment slab.
7. An electric or gas heating appliance for use in dispensing a drug or poison.

ENDNOTES

1. Made by the Governor in Council on 16 December 1993.
2. Notified in the Gazette on 17 December 1993.
3. Laid before the Legislative Assembly on . . .
4. The administering agency is the Department of Health.